



Safetab Life Science,  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|                |             |              |             |
|----------------|-------------|--------------|-------------|
| Product Name : | GRIPEX      | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322 | Mfg.Date :   | Sep-22      |
| Parameter :    | ROBUSTNESS  | Exp.Date :   | To be fixed |

Each 4500 mg of Sachet Contains:

Paracetamol BP ----- 650mg

Chlorphenamine Maleate BP ----- 20mg

Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE

|                |              |              |                  |         |              |                |       |
|----------------|--------------|--------------|------------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041&030 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|                |              |              |                  | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9  |
|                |              |              |                  | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7  |

|                             |       |            |     |            |   |            |    |
|-----------------------------|-------|------------|-----|------------|---|------------|----|
| Paracetamol Std. Dilution.: | 65.30 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std. conc (in ppm)-65.3     | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                          |       |            |     |            |   |            |    |
|--------------------------|-------|------------|-----|------------|---|------------|----|
| Phenylephrine std. Dil.: | 40.16 | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| Std. conc (in ppm)-20.08 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                           |       |            |     |            |   |            |    |
|---------------------------|-------|------------|-----|------------|---|------------|----|
| Chlorphenamine std. Dil.: | 40.11 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std. conc (in ppm)-40.11  | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                 |         |            |     |            |   |            |     |
|-----------------|---------|------------|-----|------------|---|------------|-----|
| Test dilution.: | 4501.10 | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
|                 | 1       | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

| Chromatographic variation's   | Paracetamol assay in % | Mean assay value of method precision | % Difference | Phenylephrine assay in % | Mean assay value of method precision | % Difference | Chlorphenamine assay in % | Mean assay value of method precision | % Difference |
|-------------------------------|------------------------|--------------------------------------|--------------|--------------------------|--------------------------------------|--------------|---------------------------|--------------------------------------|--------------|
| Low wavelength (217nm)        | 97.4                   | 99.1                                 | 1.70         | 98.8                     | 97.3                                 | -1.50        | 101.0                     | 101.1                                | 0.10         |
| High wavelength (223nm)       | 97.5                   |                                      | 1.60         | 98.8                     |                                      | -1.50        | 99.9                      |                                      | 1.20         |
| Low flow rate (1.1ml/minute)  | 97.9                   |                                      | 1.20         | 97.4                     |                                      | -0.10        | 99.8                      |                                      | 1.30         |
| High flow rate (1.3ml/minute) | 97.2                   |                                      | 1.90         | 98.7                     |                                      | -1.40        | 100.1                     |                                      | 1.00         |
| Low Oven Temperature 25°C     | 97.4                   |                                      | 1.70         | 98.5                     |                                      | -1.20        | 100.6                     |                                      | 0.50         |
| High Oven Temperature 35°C    | 97.3                   |                                      | 1.80         | 99.2                     |                                      | -1.90        | 99.4                      |                                      | 1.70         |

Results:

- 1) Each chromatographic variation System suitability parameters are within limits.
- 2) % Difference of assay within limits at each variation.

Acceptance criteria:

- 1) System suitability should comply for each variable.
- 2) % of drug not differ  $\pm 2\%$  from mean assay value of method precision.

Analysed by :

C. ALBIN JOSE

Date :

02-11-2022

Checked by :

Date :





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                             |            |             |
|--------------|---------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                      | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                 | Mfg.Date   | Sep-22      |
| Stage        | WAVELENGTH CHANGE (LOW WAVELENGTH AT 217NM) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet Contains;  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |              |            |             |                  |         |            |              |                |       |
|----------------------------|--------------|------------|-------------|------------------|---------|------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/039 |            | Balance ID: | ST/QC/EQ/041&030 |         | WS No.:    | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.30        | mg to ---> | 100         | ml to --->       | 5       | ml to ---> | 50           |                |       |
| Std.conc (in ppm)-65.3     | 1            | ml to ---> | 1           | ml to --->       | 1       | ml to ---> | 1            |                |       |
| Test dilution .:           | Granule/Pow. | mg to ---> | 500         | ml to --->       | 5       | ml to ---> | 100          |                |       |
| Test conc(in ppm)-65.01588 | 1            | ml to ---> | 1           | ml to --->       | 1       | ml to ---> | 1            |                |       |
| Conversion factor :        | 1.0000       | mg         |             |                  |         |            |              |                |       |
| Labeled claim :            | 650          |            |             |                  |         |            |              |                |       |
| Average weight :           | 4500         |            |             |                  |         |            |              |                |       |
| System suitability         | 1            | 2          | 3           | 4                | 5       | MEAN       | S.D          | RSD in %       |       |
| Paracetamol                | 5099857      | 5114908    | 5107087     | 5108024          | 5130176 | 5112010    | 11470        | 0.224          |       |
| With Bracketing std.       | 5093045      |            |             |                  |         | 5108850    | 12853        | 0.252          |       |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.10                   | 4957357     | 633.09               | 97.4         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                             |              |            |         |            |         |              |                |          |
|-----------------------------|--------------|------------|---------|------------|---------|--------------|----------------|----------|
|                             |              |            |         |            | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9     |
| Standard dilution.:         | 40.16        | mg to ---> | 200     | ml to ---> | 5       | ml to --->   | 50             |          |
| Std.conc (in ppm)-20.08     | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to --->   | 1              |          |
| Test dilution.:             | Granule/Pow. | mg to ---> | 500     | ml to ---> | 1       | ml to --->   | 1              |          |
| Test conc (in ppm)-20.00488 | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to --->   | 1              |          |
| Conversion factor :         | 1.0000       |            |         |            |         |              |                |          |
| Labeled claim :             | 10           | mg         |         |            |         |              |                |          |
| System suitability          | 1            | 2          | 3       | 4          | 5       | MEAN         | S.D            | RSD in % |
| Phenylephrine HCL           | 1391256      | 1393350    | 1392342 | 1391862    | 1396974 | 1393157      | 2267           | 0.163    |
| With Bracketing std.        | 1398435      |            |         |            |         | 1394037      | 2959.0         | 0.212    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.10                   | 1386086     | 9.88                 | 98.8         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|                            |              |            |         |            |         |              |                |          |
|----------------------------|--------------|------------|---------|------------|---------|--------------|----------------|----------|
|                            |              |            |         |            | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7     |
| Standard dilution.:        | 40.11        | mg to ---> | 100     | ml to ---> | 5       | ml to --->   | 50             |          |
| Std.conc (in ppm)-40.11    | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to --->   | 1              |          |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500     | ml to ---> | 1       | ml to --->   | 1              |          |
| Test conc(in ppm)-40.00977 | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to --->   | 1              |          |
| Conversion factor :        | 1.0000       |            |         |            |         |              |                |          |
| Labeled claim :            | 20           | mg         |         |            |         |              |                |          |
| System suitability         | 1            | 2          | 3       | 4          | 5       | MEAN         | S.D            | RSD in % |
| Chlorphenamine maleate     | 2645968      | 2642063    | 2649597 | 2650824    | 2649120 | 2647514      | 3535           | 0.134    |
| With Bracketing std.       | 2653733      |            |         |            |         | 2648551      | 4055           | 0.153    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.10                   | 2675346     | 20.20                | 101.0        |

Assay limit :90.0% to 110.0%

Calculation formula :

|                     |                                                                          |
|---------------------|--------------------------------------------------------------------------|
| Assay in mg /Sachet | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt |
|                     | Standard area x sample dilution x 100                                    |

Assay in %

|                          |
|--------------------------|
| Assay in mg/Sachet x 100 |
| Labeled claim            |

Analysed by :

C.ALBIN JOSE

Date :

02-11-2022

Checked by :

Date:

*[Signature]*  
02/11/2022





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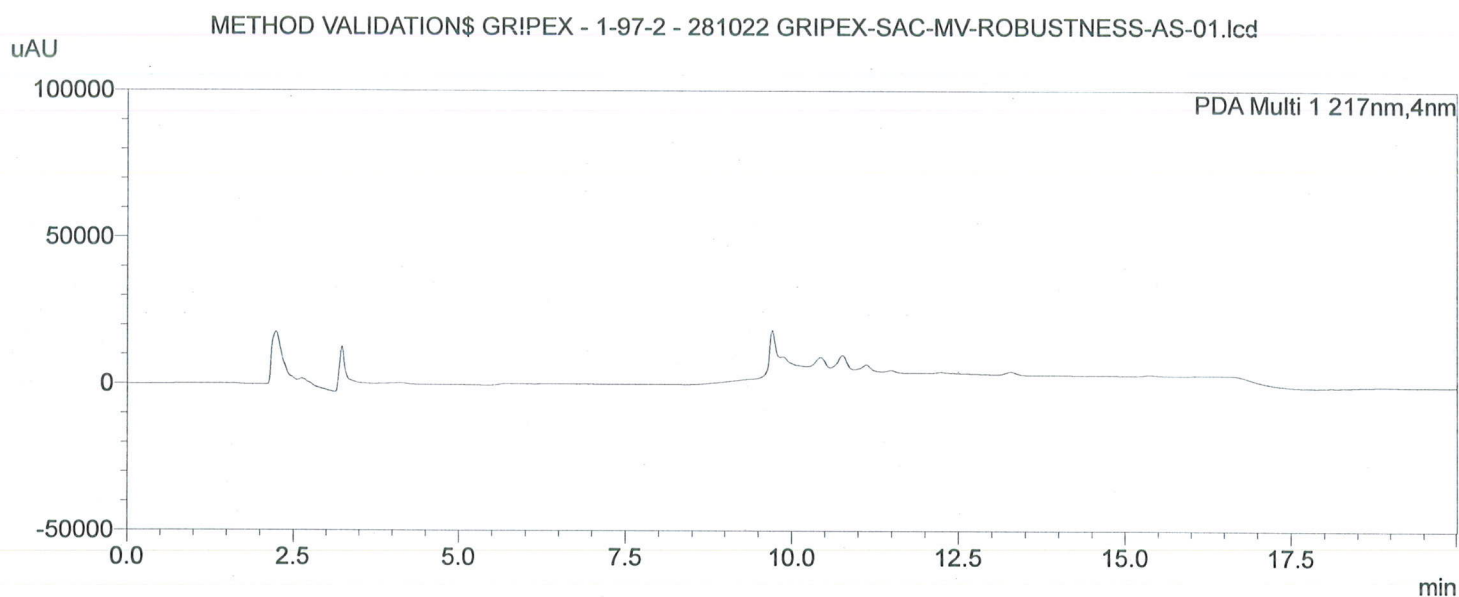
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : BLANK-AS-LWL  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-01.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-1  
Injection Volume : 50 uL  
Date Acquired : 10/28/2022 3:17:05 PM  
Date Processed : 10/31/2022 9:52:06 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 217nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :





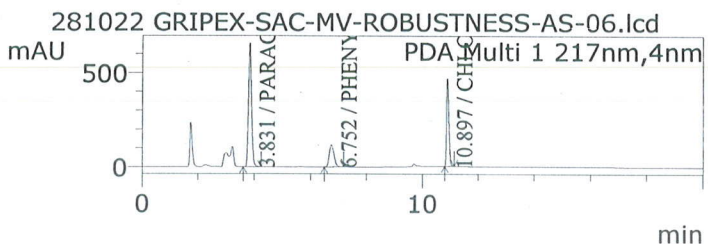
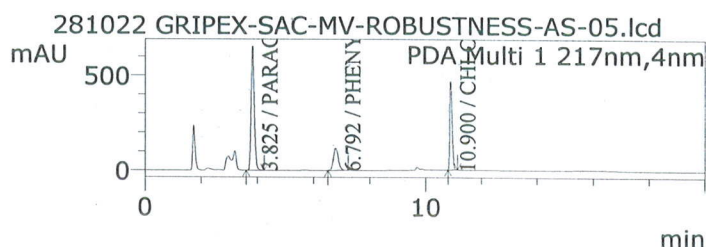
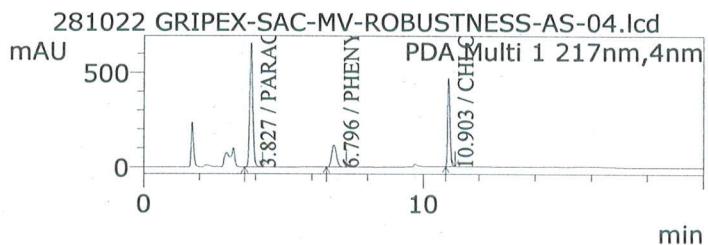
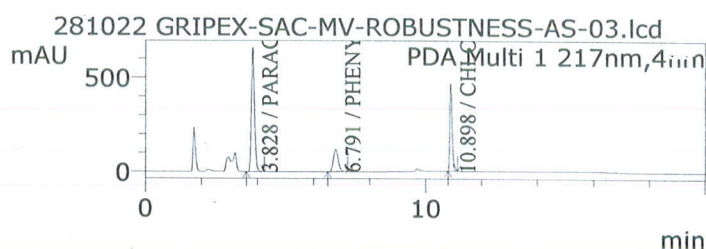
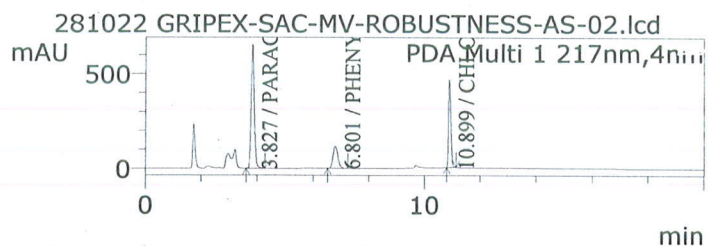
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Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-LWL-AS-STD-01  
Tray# : 2  
Vial# : 2  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-02.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/28/2022 3:37:50 PM  
Date Processed : 10/31/2022 9:52:12 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 2     | ESS-AS-02.lcd | PARA+PHENYL+CPM-LWL-AS-STD-01 | 3.827  | 5099857 | 4849     | 1.256    |
| 2     | ESS-AS-03.lcd | PARA+PHENYL+CPM-LWL-AS-STD-02 | 3.828  | 5114908 | 4819     | 1.253    |
| 2     | ESS-AS-04.lcd | PARA+PHENYL+CPM-LWL-AS-STD-03 | 3.827  | 5107087 | 4846     | 1.254    |
| 2     | ESS-AS-05.lcd | PARA+PHENYL+CPM-LWL-AS-STD-04 | 3.825  | 5108024 | 4850     | 1.253    |
| 2     | ESS-AS-06.lcd | PARA+PHENYL+CPM-LWL-AS-STD-05 | 3.831  | 5130176 | 4834     | 1.248    |
|       | Average       |                               | 3.827  | 5112011 | 4840     | 1.253    |
|       | %RSD          |                               | 0.064  | 0.224   | 0.271    | 0.217    |



## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 2     | ESS-AS-02.lcd | PARA+PHENYL+CPM-LWL-AS-STD-01 | 6.801  | 1391256 | 6935     | 1.173    |
| 2     | ESS-AS-03.lcd | PARA+PHENYL+CPM-LWL-AS-STD-02 | 6.791  | 1393350 | 6918     | 1.173    |
| 2     | ESS-AS-04.lcd | PARA+PHENYL+CPM-LWL-AS-STD-03 | 6.796  | 1392342 | 6926     | 1.171    |
| 2     | ESS-AS-05.lcd | PARA+PHENYL+CPM-LWL-AS-STD-04 | 6.792  | 1391862 | 6918     | 1.173    |
| 2     | ESS-AS-06.lcd | PARA+PHENYL+CPM-LWL-AS-STD-05 | 6.752  | 1396974 | 6949     | 1.173    |
|       | Average       |                               | 6.786  | 1393157 | 6929     | 1.173    |
|       | %RSD          |                               | 0.287  | 0.163   | 0.191    | 0.097    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 2     | ESS-AS-02.lcd | PARA+PHENYL+CPM-LWL-AS-STD-01 | 10.899 | 2645968 | 65110    | 1.378    |
| 2     | ESS-AS-03.lcd | PARA+PHENYL+CPM-LWL-AS-STD-02 | 10.898 | 2642063 | 64918    | 1.381    |
| 2     | ESS-AS-04.lcd | PARA+PHENYL+CPM-LWL-AS-STD-03 | 10.903 | 2649597 | 67107    | 1.385    |
| 2     | ESS-AS-05.lcd | PARA+PHENYL+CPM-LWL-AS-STD-04 | 10.900 | 2650824 | 65919    | 1.377    |
| 2     | ESS-AS-06.lcd | PARA+PHENYL+CPM-LWL-AS-STD-05 | 10.897 | 2645120 | 64775    | 1.385    |
|       | Average       |                               | 10.899 | 2647514 | 65566    | 1.381    |
|       | %RSD          |                               | 0.020  | 0.134   | 1.477    | 0.273    |

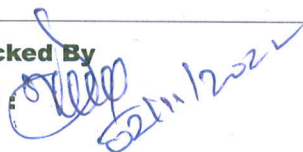
Analysed By

Date :


  
02/11/22

Checked By

Date :


  
02/11/2022



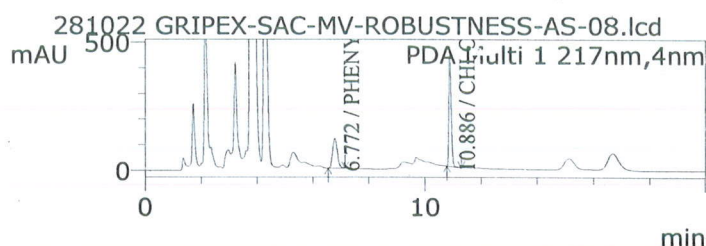
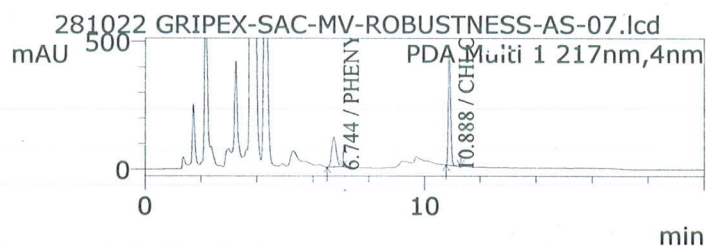
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## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-LWL-AS-SOL-A-01  
Tray# : 2  
Vial# : 3  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-07.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/28/2022 5:20:50 PM  
Date Processed : 11/2/2022 10:58:22 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 3     | ESS-AS-07.lcd | GRIPEX-SAC-MV-LWL-AS-SOL-A-01 | 6.744  | 1385921 | 7008     | 1.175    |
| 3     | ESS-AS-08.lcd | GRIPEX-SAC-MV-LWL-AS-SOL-A-02 | 6.772  | 1386251 | 6994     | 1.170    |
|       | Average       |                               | 6.758  | 1386086 | 7001     | 1.172    |
|       | %RSD          |                               | 0.302  | 0.017   | 0.140    | 0.342    |

ID#2 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 3     | ESS-AS-07.lcd | GRIPEX-SAC-MV-LWL-AS-SOL-A-01 | 10.888 | 2680101 | 64784    | 1.383    |
| 3     | ESS-AS-08.lcd | GRIPEX-SAC-MV-LWL-AS-SOL-A-02 | 10.886 | 2670591 | 64528    | 1.393    |
|       | Average       |                               | 10.887 | 2675346 | 64656    | 1.388    |
|       | %RSD          |                               | 0.016  | 0.251   | 0.280    | 0.496    |

Analysed By

Date :

Checked By

Date :





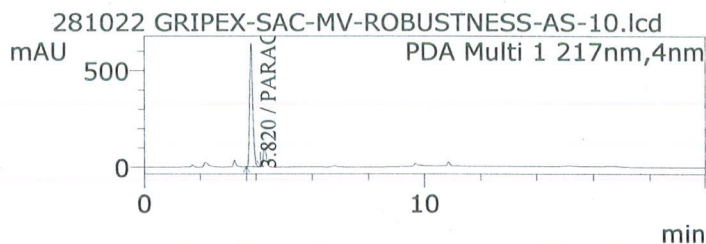
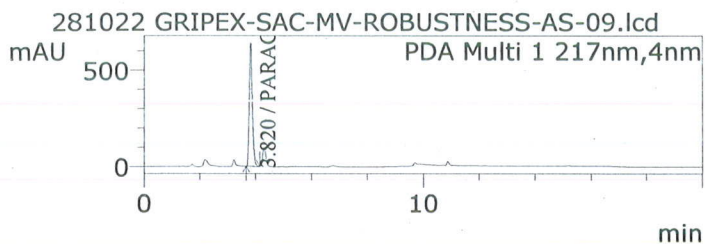
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## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-LWL-AS-SOL-B-01  
Tray# : 2  
Vial# : 4  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-09.lcd  
Method File : GRIPEX-AS.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/31/2022 11:36:02 AM  
Date Processed : 10/31/2022 1:21:00 PM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 4     | ESS-AS-09.lcd | GRIPEX-SAC-MV-LWL-AS-SOL-B-01 | 3.820  | 4957912 | 4831     | 1.262    |
| 4     | ESS-AS-10.lcd | GRIPEX-SAC-MV-LWL-AS-SOL-B-02 | 3.820  | 4956802 | 4819     | 1.262    |
|       | Average       |                               | 3.820  | 4957357 | 4825     | 1.262    |
|       | %RSD          |                               | 0.012  | 0.016   | 0.174    | 0.041    |

Analysed By

Date :

Checked By

Date :



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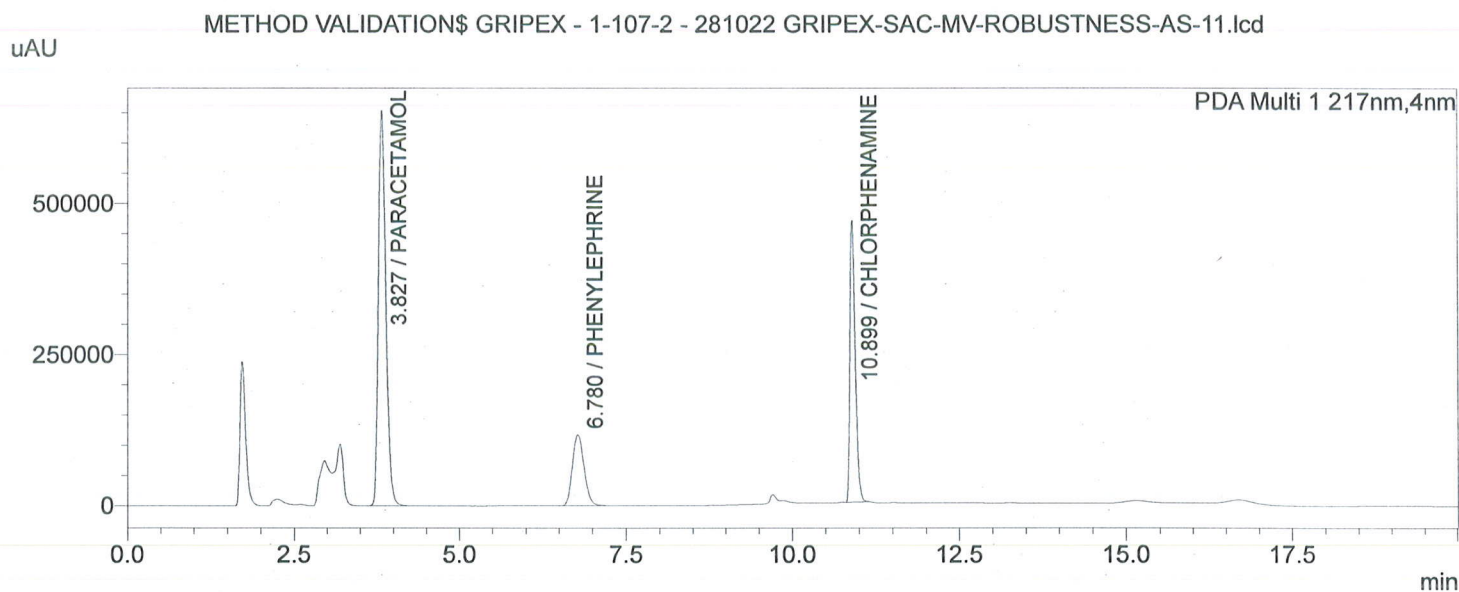
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-LWL-AS-BKT-STD  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-11.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-2  
Injection Volume : 50 uL  
Date Acquired : 10/28/2022 6:43:16 PM  
Date Processed : 10/31/2022 9:52:26 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 217nm

| Peak# | Ret. Time | Area    | Area%   | T.Plale | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.827     | 5093045 | 55.691  | 4842    | 1.255    | --         | --       | PARACETAMOL    |
| 2     | 6.780     | 1398435 | 15.291  | 6936    | 1.177    | 10.82      | --       | PHENYLEPHRINE  |
| 3     | 10.899    | 2653733 | 29.018  | 64716   | 1.385    | 16.58      | --       | CHLORPHENAMINE |
| Total |           | 9145213 | 100.000 |         |          |            |          |                |

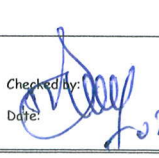
Analysed By

Date :

Checked By

Date :



|                                                                     |                                                                                                                                                                                                           | <b>Safetab Life Science</b><br><b>Puducherry - 605 107</b> |                      |                  |         |            |              |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|----------------------|------------------|---------|------------|--------------|------------------------------|
| <b>QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET</b>                                                                               |                                                                                                                                                                                                           |                                                            |                      |                  |         |            |              |                              |
| <b>ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS</b>                                                         |                                                                                                                                                                                                           |                                                            |                      |                  |         |            |              |                              |
| Product Name                                                                                                                                        | GRIPEX                                                                                                                                                                                                    |                                                            |                      |                  |         | Batch size | 500 SACHETS  |                              |
| Batch Number                                                                                                                                        | ST/T/S-1322                                                                                                                                                                                               |                                                            |                      |                  |         | Mfg. Date  | Sep-22       |                              |
| Stage                                                                                                                                               | WAVELENGTH CHANGE (HIGH WAVELENGTH AT 223NM)                                                                                                                                                              |                                                            |                      |                  |         | Exp. Date  | To be fixed  |                              |
| Each 4500 mg of Sachet Contains:<br>Paracetamol BP ----- 650mg<br>Chlorphenamine Maleate BP ----- 20mg<br>Phenylephrine Hydrochloride BP ----- 10mg |                                                                                                                                                                                                           |                                                            |                      |                  |         |            |              |                              |
| <b>ASSAY OF PARACETAMOL</b>                                                                                                                         |                                                                                                                                                                                                           |                                                            |                      |                  |         |            |              |                              |
| Instrument ID:                                                                                                                                      | ST/QC/EQ/039                                                                                                                                                                                              |                                                            | Balance ID:          | ST/QC/EQ/041&030 |         | WS No.:    | ST/WS/22/011 |                              |
| % Purity (aib)                                                                                                                                      | 100.0                                                                                                                                                                                                     |                                                            |                      |                  |         |            |              |                              |
| Standard dilution.:                                                                                                                                 | 65.30                                                                                                                                                                                                     | mg to --->                                                 | 100                  | ml to --->       | 5       | ml to ---> | 50           |                              |
| Std. conc (in ppm)-65.3                                                                                                                             | 1                                                                                                                                                                                                         | ml to --->                                                 | 1                    | ml to --->       | 1       | ml to ---> | 1            |                              |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                 | 500                  | ml to --->       | 5       | ml to ---> | 100          |                              |
| Test conc (in ppm)-65.01588                                                                                                                         | 1                                                                                                                                                                                                         | ml to --->                                                 | 1                    | ml to --->       | 1       | ml to ---> | 1            |                              |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                            |                      |                  |         |            |              |                              |
| Labeled claim :                                                                                                                                     | 650 mg                                                                                                                                                                                                    |                                                            |                      |                  |         |            |              |                              |
| Average weight :                                                                                                                                    | 4500 mg                                                                                                                                                                                                   |                                                            |                      |                  |         |            |              |                              |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                          | 3                    | 4                | 5       | MEAN       | S.D          |                              |
| Paracetamol                                                                                                                                         | 5728817                                                                                                                                                                                                   | 5719868                                                    | 5722613              | 5709269          | 5689932 | 5714100    | 15246        |                              |
| With Bracketing std.                                                                                                                                | 5721139                                                                                                                                                                                                   |                                                            |                      |                  |         | 5715273    | 13936        |                              |
| RSD in %                                                                                                                                            | 0.267                                                                                                                                                                                                     |                                                            |                      |                  |         |            |              |                              |
|                                                                                                                                                     | 0.244                                                                                                                                                                                                     |                                                            |                      |                  |         |            |              |                              |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                                                                                                                                                 | Sample Area                                                | Content in mg/Sachet | Content in %     |         |            |              |                              |
| 1                                                                                                                                                   | 4501.10                                                                                                                                                                                                   | 5548751                                                    | 633.95               | 97.5             |         |            |              | Assay limit :90.0% to 110.0% |
| <b>ASSAY OF PHENYLEPHRINE HYDROCHLORIDE</b>                                                                                                         |                                                                                                                                                                                                           |                                                            |                      |                  |         |            |              |                              |
| WS No.:                                                                                                                                             | IAARI/WS/344                                                                                                                                                                                              |                                                            | % Purity (aib)       | 98.9             |         |            |              |                              |
| Standard dilution.:                                                                                                                                 | 40.16                                                                                                                                                                                                     | mg to --->                                                 | 200                  | ml to --->       | 5       | ml to ---> | 50           |                              |
| Std. conc (in ppm)-20.08                                                                                                                            | 1                                                                                                                                                                                                         | ml to --->                                                 | 1                    | ml to --->       | 1       | ml to ---> | 1            |                              |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                 | 500                  | ml to --->       | 1       | ml to ---> | 1            |                              |
| Test conc (in ppm)-20.0048                                                                                                                          | 1                                                                                                                                                                                                         | ml to --->                                                 | 1                    | ml to --->       | 1       | ml to ---> | 1            |                              |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                            |                      |                  |         |            |              |                              |
| Labeled claim :                                                                                                                                     | 10 mg                                                                                                                                                                                                     |                                                            |                      |                  |         |            |              |                              |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                          | 3                    | 4                | 5       | MEAN       | S.D          |                              |
| Phenylephrine HCL                                                                                                                                   | 1020534                                                                                                                                                                                                   | 1019951                                                    | 1019652              | 1015133          | 1015548 | 1018164    | 2601         |                              |
| With Bracketing std.                                                                                                                                | 1020239                                                                                                                                                                                                   |                                                            |                      |                  |         | 1018510    | 2475.7       |                              |
| RSD in %                                                                                                                                            | 0.255                                                                                                                                                                                                     |                                                            |                      |                  |         |            |              |                              |
|                                                                                                                                                     | 0.243                                                                                                                                                                                                     |                                                            |                      |                  |         |            |              |                              |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                                                                                                                                                 | Sample Area                                                | Content in mg/Sachet | Content in %     |         |            |              |                              |
| 1                                                                                                                                                   | 4501.10                                                                                                                                                                                                   | 1013596                                                    | 9.88                 | 98.8             |         |            |              | Assay limit :90.0% to 110.0% |
| <b>ASSAY OF CHLORPHENAMINE MALEATE</b>                                                                                                              |                                                                                                                                                                                                           |                                                            |                      |                  |         |            |              |                              |
| WS No.:                                                                                                                                             | ST/WS/22/039                                                                                                                                                                                              |                                                            | % Purity (aib)       | 99.7             |         |            |              |                              |
| Standard dilution.:                                                                                                                                 | 40.11                                                                                                                                                                                                     | mg to --->                                                 | 100                  | ml to --->       | 5       | ml to ---> | 50           |                              |
| Std. conc (in ppm)-40.11                                                                                                                            | 1                                                                                                                                                                                                         | ml to --->                                                 | 1                    | ml to --->       | 1       | ml to ---> | 1            |                              |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                 | 500                  | ml to --->       | 1       | ml to ---> | 1            |                              |
| Test conc (in ppm)-40.00977                                                                                                                         | 1                                                                                                                                                                                                         | ml to --->                                                 | 1                    | ml to --->       | 1       | ml to ---> | 1            |                              |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                            |                      |                  |         |            |              |                              |
| Labeled claim :                                                                                                                                     | 20 mg                                                                                                                                                                                                     |                                                            |                      |                  |         |            |              |                              |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                          | 3                    | 4                | 5       | MEAN       | S.D          |                              |
| Chlorphenamine maleate                                                                                                                              | 2779374                                                                                                                                                                                                   | 2779453                                                    | 2779398              | 2762501          | 2769035 | 2773952    | 7820         |                              |
| With Bracketing std.                                                                                                                                | 2759639                                                                                                                                                                                                   |                                                            |                      |                  |         | 2771567    | 9114         |                              |
| RSD in %                                                                                                                                            | 0.282                                                                                                                                                                                                     |                                                            |                      |                  |         |            |              |                              |
|                                                                                                                                                     | 0.329                                                                                                                                                                                                     |                                                            |                      |                  |         |            |              |                              |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                                                                                                                                                 | Sample Area                                                | Content in mg/Sachet | Content in %     |         |            |              |                              |
| 1                                                                                                                                                   | 4501.10                                                                                                                                                                                                   | 2773371                                                    | 19.99                | 99.9             |         |            |              | Assay limit :90.0% to 110.0% |
| <b>Calculation formula :</b>                                                                                                                        |                                                                                                                                                                                                           |                                                            |                      |                  |         |            |              |                              |
| Assay in mg /Sachet                                                                                                                                 | $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$ |                                                            |                      |                  |         |            |              |                              |
| Assay in %                                                                                                                                          | $\frac{\text{Assay in mg/Sachet} \times 100}{\text{Labeled claim}}$                                                                                                                                       |                                                            |                      |                  |         |            |              |                              |
| Analysed by :                                                                                                                                       | C.ALBIN ROSE                                                                                                                                                                                              |                                                            |                      |                  |         |            |              |                              |
| Date :                                                                                                                                              | 02-11-2022                                                                                                                                                                                                |                                                            |                      |                  |         |            |              |                              |
| Checked by:                                                                                                                                         |                                                                                                                      |                                                            |                      |                  |         |            |              |                              |
| Date:                                                                                                                                               | 02-11-2022                                                                                                                                                                                                |                                                            |                      |                  |         |            |              |                              |



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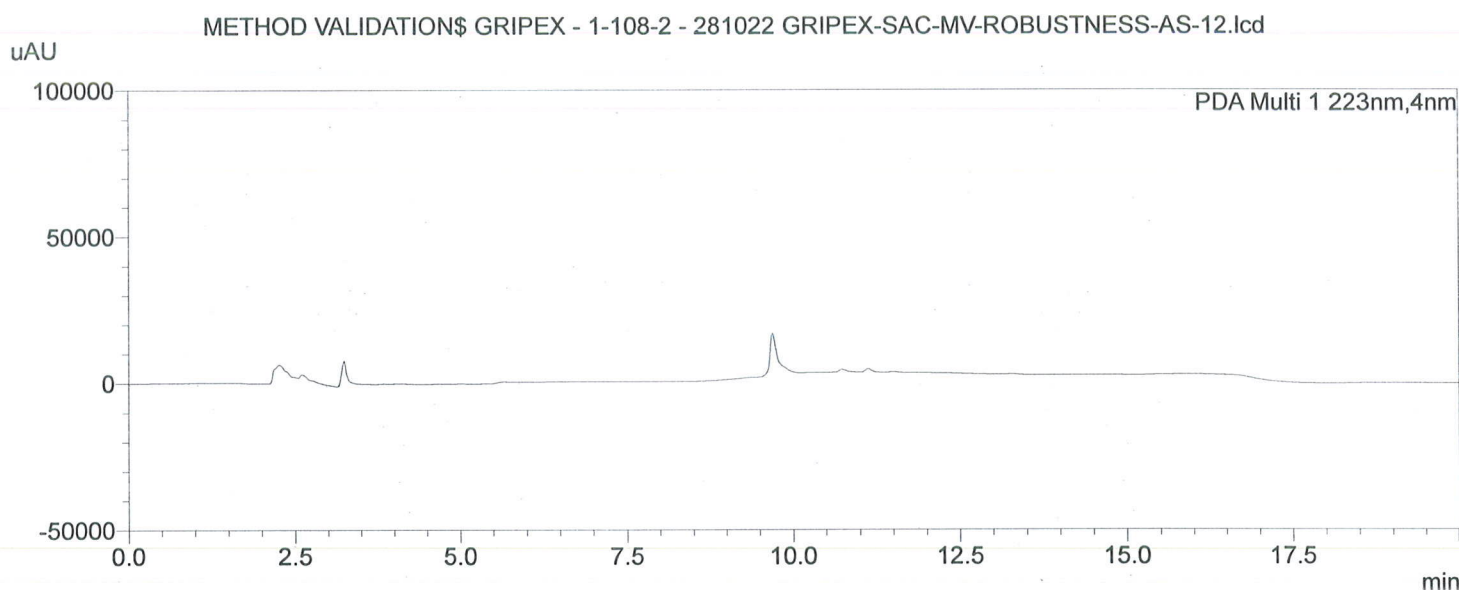
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : BLANK-AS-HWL  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-12.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-5  
Injection Volume : 50 uL  
Date Acquired : 10/28/2022 7:03:53 PM  
Date Processed : 10/31/2022 9:55:02 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 223nm

| Peak# | Ret. Time | Area | Area% | T.Plake | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

*[Signature]*  
02/11/22

Checked By

Date :

*[Signature]*  
02/11/2022





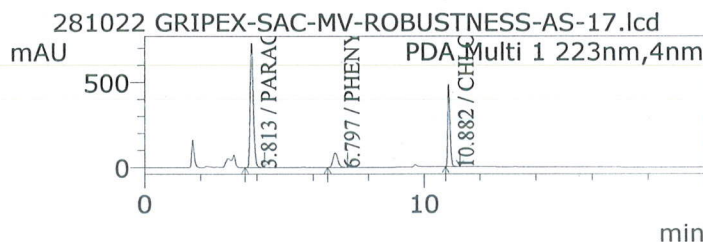
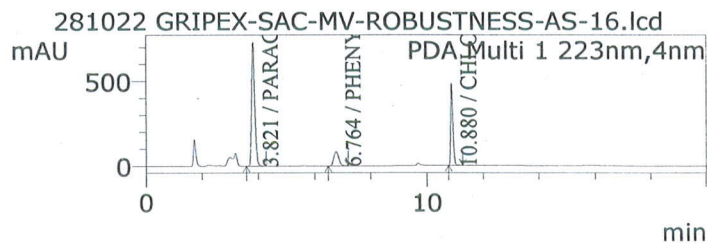
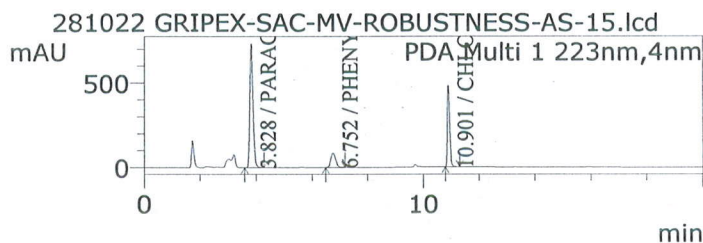
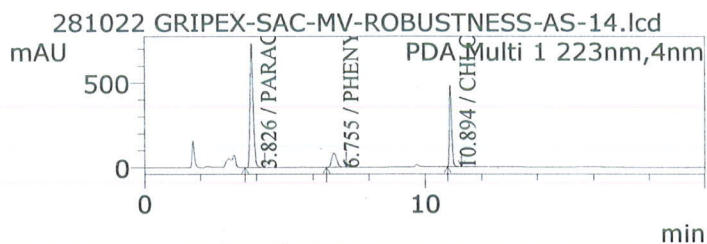
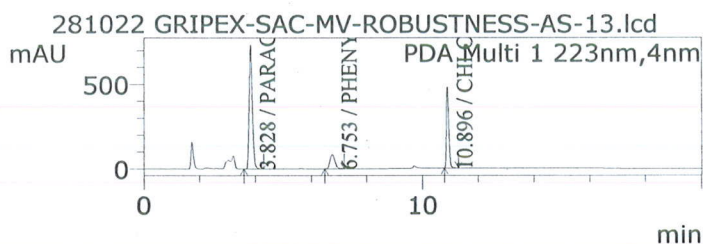
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-HWL-AS-STD-01  
Tray# : 2  
Vial# : 6  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-13.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/28/2022 7:24:30 PM  
Date Processed : 10/31/2022 9:55:04 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 6     | ESS-AS-13.lcd | PARA+PHENYL+CPM-HWL-AS-STD-01 | 3.828  | 5728817 | 4772     | 1.255    |
| 6     | ESS-AS-14.lcd | PARA+PHENYL+CPM-HWL-AS-STD-02 | 3.826  | 5719868 | 4837     | 1.258    |
| 6     | ESS-AS-15.lcd | PARA+PHENYL+CPM-HWL-AS-STD-03 | 3.828  | 5722613 | 4775     | 1.254    |
| 6     | ESS-AS-16.lcd | PARA+PHENYL+CPM-HWL-AS-STD-04 | 3.821  | 5709269 | 4808     | 1.250    |
| 6     | ESS-AS-17.lcd | PARA+PHENYL+CPM-HWL-AS-STD-05 | 3.813  | 5689932 | 4815     | 1.252    |
|       | Average       |                               | 3.823  | 5714100 | 4801     | 1.254    |
|       | %RSD          |                               | 0.165  | 0.267   | 0.574    | 0.242    |

## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 6     | ESS-AS-13.lcd | PARA+PHENYL+CPM-HWL-AS-STD-01 | 6.753  | 1020534 | 6859     | 1.174    |
| 6     | ESS-AS-14.lcd | PARA+PHENYL+CPM-HWL-AS-STD-02 | 6.755  | 1019951 | 6808     | 1.177    |
| 6     | ESS-AS-15.lcd | PARA+PHENYL+CPM-HWL-AS-STD-03 | 6.752  | 1019652 | 6848     | 1.175    |
| 6     | ESS-AS-16.lcd | PARA+PHENYL+CPM-HWL-AS-STD-04 | 6.764  | 1015133 | 6904     | 1.175    |
| 6     | ESS-AS-17.lcd | PARA+PHENYL+CPM-HWL-AS-STD-05 | 6.797  | 1015548 | 6839     | 1.174    |
|       | Average       |                               | 6.764  | 1018164 | 6852     | 1.175    |
|       | %RSD          |                               | 0.278  | 0.255   | 0.512    | 0.079    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 6     | ESS-AS-13.lcd | PARA+PHENYL+CPM-HWL-AS-STD-01 | 10.896 | 2779374 | 67582    | 1.410    |
| 6     | ESS-AS-14.lcd | PARA+PHENYL+CPM-HWL-AS-STD-02 | 10.894 | 2779453 | 66389    | 1.413    |
| 6     | ESS-AS-15.lcd | PARA+PHENYL+CPM-HWL-AS-STD-03 | 10.901 | 2779398 | 65418    | 1.396    |
| 6     | ESS-AS-16.lcd | PARA+PHENYL+CPM-HWL-AS-STD-04 | 10.880 | 2762501 | 65962    | 1.398    |
| 6     | ESS-AS-17.lcd | PARA+PHENYL+CPM-HWL-AS-STD-05 | 10.882 | 2769035 | 66474    | 1.410    |
|       | Average       |                               | 10.891 | 2773952 | 66365    | 1.405    |
|       | %RSD          |                               | 0.083  | 0.282   | 1.204    | 0.545    |

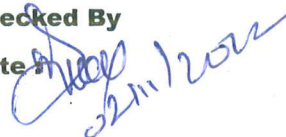
Analysed By

Date :



Checked By

Date :







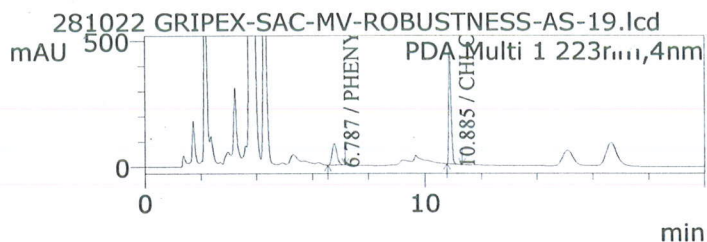
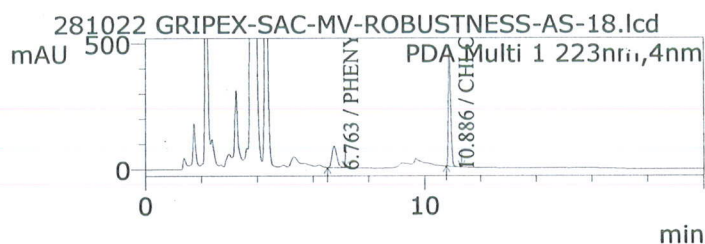
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-HWL-AS-SOL-A-01  
Tray# : 2  
Vial# : 7  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-18.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/28/2022 9:07:55 PM  
Date Processed : 11/2/2022 11:01:09 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 7     | ESS-AS-18.lcd | GRIPEX-SAC-MV-HWL-AS-SOL-A-01 | 6.763  | 1019859 | 6989     | 1.191    |
| 7     | ESS-AS-19.lcd | GRIPEX-SAC-MV-HWL-AS-SOL-A-02 | 6.787  | 1007333 | 6955     | 1.165    |
|       | Average       |                               | 6.775  | 1013596 | 6972     | 1.178    |
|       | %RSD          |                               | 0.248  | 0.874   | 0.346    | 1.562    |

ID#2 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 7     | ESS-AS-18.lcd | GRIPEX-SAC-MV-HWL-AS-SOL-A-01 | 10.886 | 2777815 | 63857    | 1.398    |
| 7     | ESS-AS-19.lcd | GRIPEX-SAC-MV-HWL-AS-SOL-A-02 | 10.885 | 2768927 | 67916    | 1.403    |
|       | Average       |                               | 10.885 | 2773371 | 65887    | 1.400    |
|       | %RSD          |                               | 0.009  | 0.227   | 4.357    | 0.270    |

Analysed By

Date :

Checked By

Date :



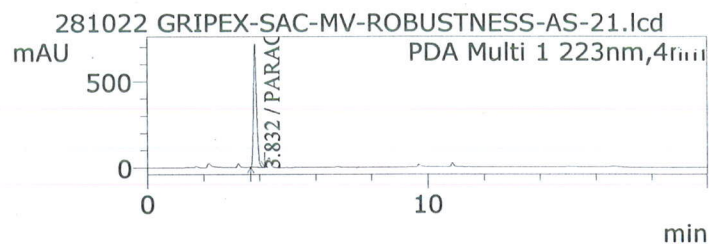
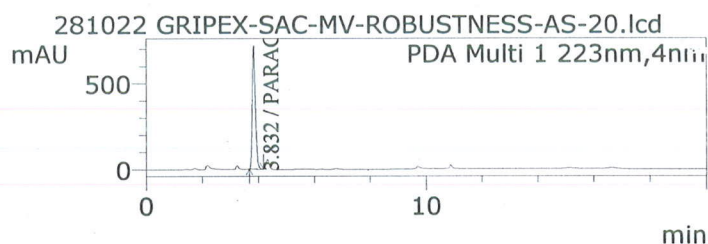
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-HWL-AS-SOL-B-01  
Tray# : 2  
Vial# : 8  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-20.lcd  
Method File : GRIPEX-AS.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/31/2022 12:17:16 PM  
Date Processed : 10/31/2022 1:23:54 PM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 8     | ESS-AS-20.lcd | GRIPEX-SAC-MV-HWL-AS-SOL-B-01 | 3.832  | 5551103 | 4902     | 1.263    |
| 8     | ESS-AS-21.lcd | GRIPEX-SAC-MV-HWL-AS-SOL-B-02 | 3.832  | 5546398 | 4895     | 1.261    |
|       | Average       |                               | 3.832  | 5548751 | 4898     | 1.262    |
|       | %RSD          |                               | 0.004  | 0.060   | 0.104    | 0.125    |

Analysed By

Date :

Checked By

Date :





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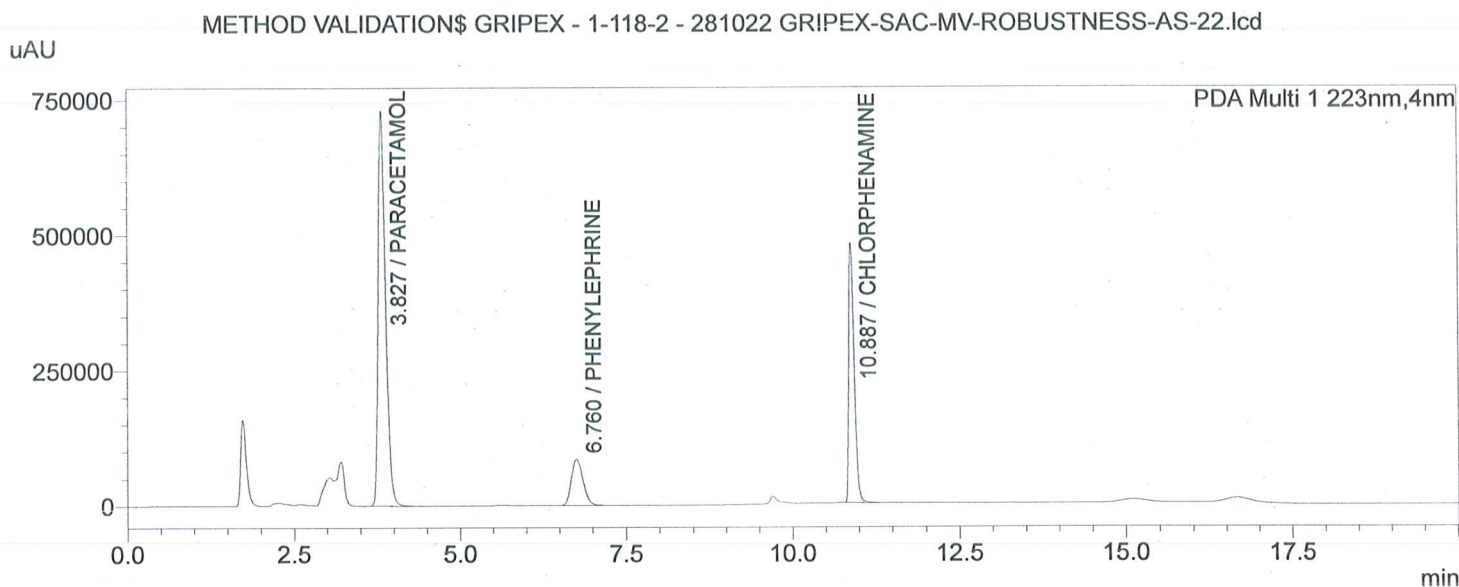
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-HWL-AS-BKT-STD  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-22.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-6  
Injection Volume : 50 uL  
Date Acquired : 10/28/2022 10:30:32 PM  
Date Processed : 10/31/2022 9:55:17 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 223nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.827     | 5721139 | 60.216  | 4799    | 1.254    | --         | --       | PARACETAMOL    |
| 2     | 6.760     | 1020239 | 10.738  | 6849    | 1.176    | 10.71      | --       | PHENYLEPHRINE  |
| 3     | 10.887    | 2759639 | 29.046  | 64450   | 1.402    | 16.56      | --       | CHLORPHENAMINE |
| Total |           | 9501018 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

| Title                                                                                                                                               |                                                                                                                                                                                                           | ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS |             |                      |              |                              |              |                |                |       |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-------------|----------------------|--------------|------------------------------|--------------|----------------|----------------|-------|--|
| Product Name                                                                                                                                        | GRIPEX                                                                                                                                                                                                    |                                                                                      |             |                      |              | Batch size                   | 500 SACHETS  |                |                |       |  |
| Batch Number                                                                                                                                        | ST/T/S-1322                                                                                                                                                                                               |                                                                                      |             |                      |              | Mfg. Date                    | Sep-22       |                |                |       |  |
| Stage                                                                                                                                               | FLOW RATE CHANGE (LOW FLOW RATE 1.1ML/MINUTE)                                                                                                                                                             |                                                                                      |             |                      |              | Exp. Date                    | To be fixed  |                |                |       |  |
| Each 4500 mg of Sachet Contains:<br>Paracetamol BP ----- 650mg<br>Chlorphenamine Maleate BP ----- 20mg<br>Phenylephrine Hydrochloride BP ----- 10mg |                                                                                                                                                                                                           |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| ASSAY OF PARACETAMOL                                                                                                                                |                                                                                                                                                                                                           |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| Instrument ID:                                                                                                                                      | ST/QC/EQ/039                                                                                                                                                                                              |                                                                                      | Balance ID: | ST/QC/EQ/041&030     |              | WS No.:                      | ST/WS/22/011 |                | % Purity (aib) | 100.0 |  |
| Standard dilution.:                                                                                                                                 | 65.30                                                                                                                                                                                                     | mg to --->                                                                           | 100         | ml to --->           | 5            | ml to --->                   | 50           |                |                |       |  |
| Std. conc (in ppm)-65.3                                                                                                                             | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1           | ml to --->           | 1            | ml to --->                   | 1            |                |                |       |  |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                                           | 500         | ml to --->           | 5            | ml to --->                   | 100          |                |                |       |  |
| Test conc (in ppm)-65.01588                                                                                                                         | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1           | ml to --->           | 1            | ml to --->                   | 1            |                |                |       |  |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| Labeled claim :                                                                                                                                     | 650                                                                                                                                                                                                       | mg                                                                                   |             |                      |              |                              |              |                |                |       |  |
| Average weight :                                                                                                                                    | 4500                                                                                                                                                                                                      | mg                                                                                   |             |                      |              |                              |              |                |                |       |  |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                                                    | 3           | 4                    | 5            | MEAN                         | S.D          | RSD in %       |                |       |  |
| Paracetamol                                                                                                                                         | 5602731                                                                                                                                                                                                   | 5623254                                                                              | 5615149     | 5651261              | 5607811      | 5620041                      | 19093        | 0.340          |                |       |  |
| With Bracketing std.                                                                                                                                | 5602865                                                                                                                                                                                                   |                                                                                      |             |                      |              | 5617179                      | 18461        | 0.329          |                |       |  |
| Sample preparation                                                                                                                                  |                                                                                                                                                                                                           | Sample Weight taken in mg                                                            | Sample Area | Content in mg/Sachet | Content in % |                              |              |                |                |       |  |
| 1                                                                                                                                                   |                                                                                                                                                                                                           | 4501.10                                                                              | 5479994     | 636.57               | 97.9         | Assay limit :90.0% to 110.0% |              |                |                |       |  |
| ASSAY OF PHENYLEPHRINE HYDROCHLORIDE                                                                                                                |                                                                                                                                                                                                           |                                                                                      |             |                      |              |                              |              |                |                |       |  |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |             |                      |              | WS No.:                      | IAARI/WS/344 | % Purity (aib) | 98.9           |       |  |
| Standard dilution.:                                                                                                                                 | 40.16                                                                                                                                                                                                     | mg to --->                                                                           | 200         | ml to --->           | 5            | ml to --->                   | 50           |                |                |       |  |
| Std. conc (in ppm)-20.08                                                                                                                            | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1           | ml to --->           | 1            | ml to --->                   | 1            |                |                |       |  |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                                           | 500         | ml to --->           | 1            | ml to --->                   | 1            |                |                |       |  |
| Test conc (in ppm)-20.00488                                                                                                                         | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1           | ml to --->           | 1            | ml to --->                   | 1            |                |                |       |  |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| Labeled claim :                                                                                                                                     | 10                                                                                                                                                                                                        | mg                                                                                   |             |                      |              |                              |              |                |                |       |  |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                                                    | 3           | 4                    | 5            | MEAN                         | S.D          | RSD in %       |                |       |  |
| Phenylephrine HCL                                                                                                                                   | 1343271                                                                                                                                                                                                   | 1346568                                                                              | 1343507     | 1346939              | 1344675      | 1344992                      | 1699         | 0.126          |                |       |  |
| With Bracketing std.                                                                                                                                | 1342280                                                                                                                                                                                                   |                                                                                      |             |                      |              | 1344540                      | 1880.0       | 0.140          |                |       |  |
| Sample preparation                                                                                                                                  |                                                                                                                                                                                                           | Sample Weight taken in mg                                                            | Sample Area | Content in mg/Sachet | Content in % |                              |              |                |                |       |  |
| 1                                                                                                                                                   |                                                                                                                                                                                                           | 4501.10                                                                              | 1319162     | 9.74                 | 97.4         | Assay limit :90.0% to 110.0% |              |                |                |       |  |
| ASSAY OF CHLORPHENAMINE MALEATE                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |             |                      |              |                              |              |                |                |       |  |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |             |                      |              | WS No.:                      | ST/WS/22/039 | % Purity (aib) | 99.7           |       |  |
| Standard dilution.:                                                                                                                                 | 40.11                                                                                                                                                                                                     | mg to --->                                                                           | 100         | ml to --->           | 5            | ml to --->                   | 50           |                |                |       |  |
| Std. conc (in ppm)-40.11                                                                                                                            | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1           | ml to --->           | 1            | ml to --->                   | 1            |                |                |       |  |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                                           | 500         | ml to --->           | 1            | ml to --->                   | 1            |                |                |       |  |
| Test conc (in ppm)-40.00977                                                                                                                         | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1           | ml to --->           | 1            | ml to --->                   | 1            |                |                |       |  |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| Labeled claim :                                                                                                                                     | 20                                                                                                                                                                                                        | mg                                                                                   |             |                      |              |                              |              |                |                |       |  |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                                                    | 3           | 4                    | 5            | MEAN                         | S.D          | RSD in %       |                |       |  |
| Chlorphenamine maleate                                                                                                                              | 2993172                                                                                                                                                                                                   | 2993391                                                                              | 2984657     | 2986478              | 2986505      | 2988841                      | 4123         | 0.138          |                |       |  |
| With Bracketing std.                                                                                                                                | 2982702                                                                                                                                                                                                   |                                                                                      |             |                      |              | 2987818                      | 4459         | 0.149          |                |       |  |
| Sample preparation                                                                                                                                  |                                                                                                                                                                                                           | Sample Weight taken in mg                                                            | Sample Area | Content in mg/Sachet | Content in % |                              |              |                |                |       |  |
| 1                                                                                                                                                   |                                                                                                                                                                                                           | 4501.10                                                                              | 2983279     | 19.95                | 99.8         | Assay limit :90.0% to 110.0% |              |                |                |       |  |
| Calculation formula :                                                                                                                               |                                                                                                                                                                                                           |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| Assay in mg /Sachet                                                                                                                                 | $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$ |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| Assay in %                                                                                                                                          | $\frac{\text{Assay in mg/Sachet} \times 100}{\text{Labeled claim}}$                                                                                                                                       |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| Analysed by :                                                                                                                                       | C. ALBIN JOSE                                                                                                                                                                                             |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| Date :                                                                                                                                              | 02-11-2022                                                                                                                                                                                                |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| Checked by :                                                                                                                                        | [Signature]                                                                                                                                                                                               |                                                                                      |             |                      |              |                              |              |                |                |       |  |
| Date :                                                                                                                                              | 22/11/2022                                                                                                                                                                                                |                                                                                      |             |                      |              |                              |              |                |                |       |  |





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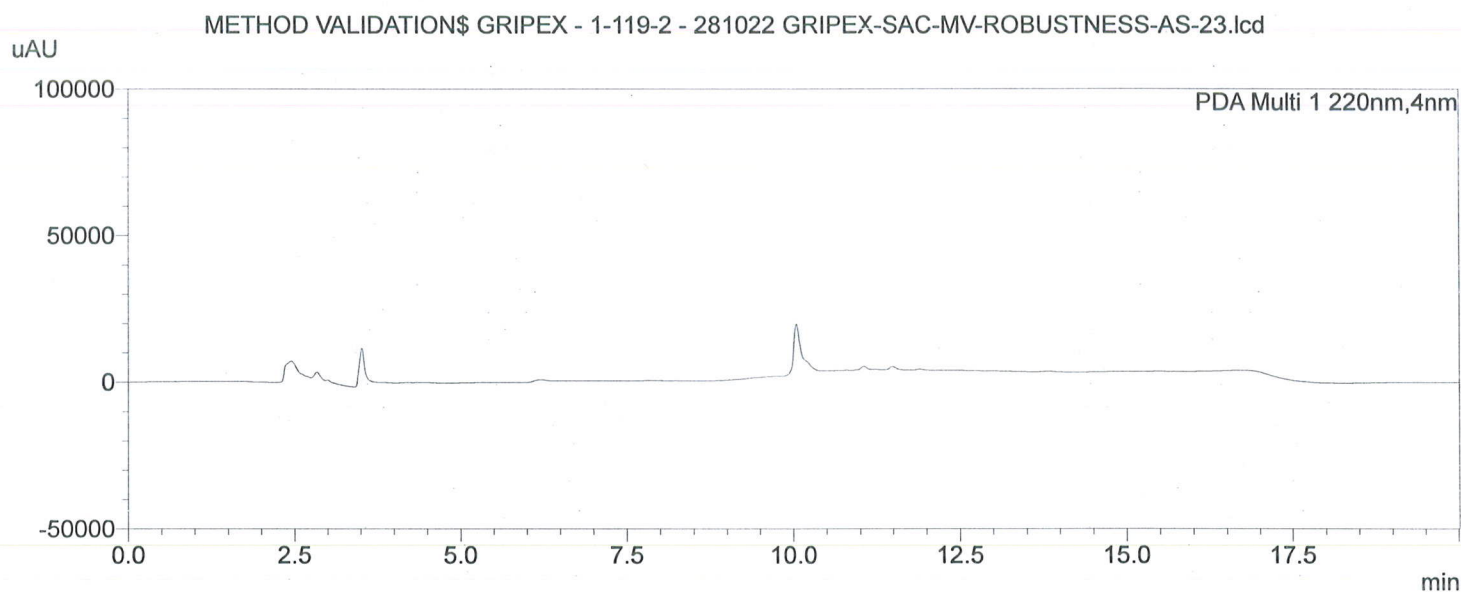
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : BLANK-AS-Low Flow  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-23.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-9  
Injection Volume : 50 uL  
Date Acquired : 10/28/2022 10:51:09 PM  
Date Processed : 10/31/2022 10:32:36 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

*[Signature]*  
02/11/22

Checked By

Date :

*[Signature]*  
02/11/2022



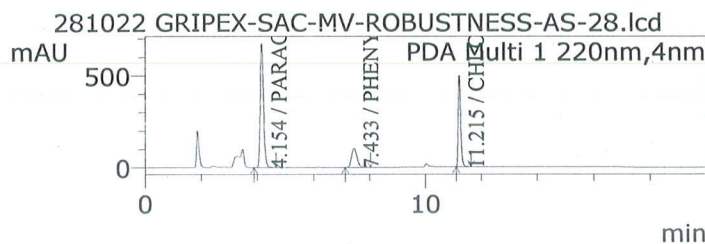
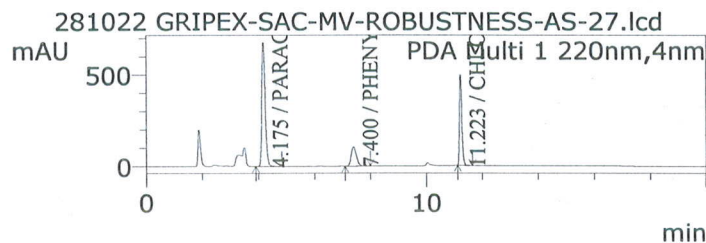
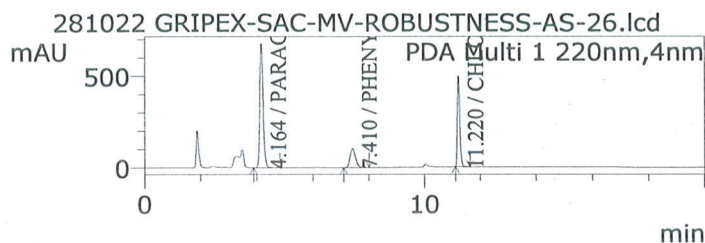
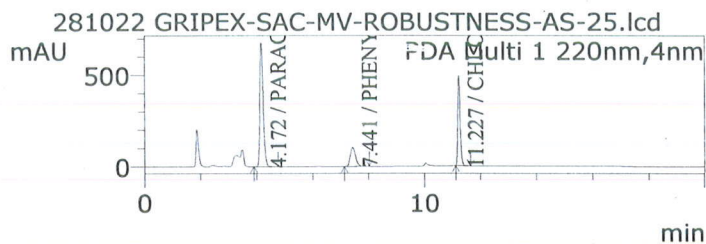
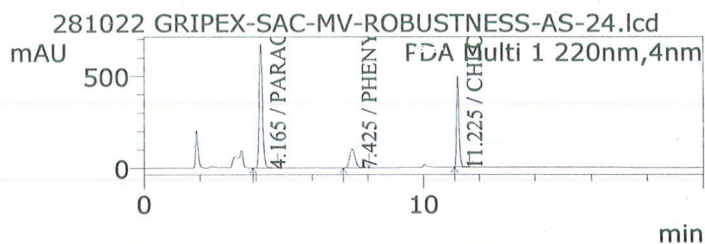
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-LFlow-AS-STD-01  
Tray# : 2  
Vial# : 10  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-24.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/28/2022 11:11:48 PM  
Date Processed : 10/31/2022 10:32:39 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 10    | ESS-AS-24.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-01 | 4.165  | 5602731 | 5154     | 1.260    |
| 10    | ESS-AS-25.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-02 | 4.172  | 5623254 | 5135     | 1.257    |
| 10    | ESS-AS-26.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-03 | 4.164  | 5615149 | 5159     | 1.262    |
| 10    | ESS-AS-27.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-04 | 4.175  | 5651261 | 5148     | 1.263    |
| 10    | ESS-AS-28.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-05 | 4.154  | 5607811 | 5102     | 1.260    |
|       | Average       |                                 | 4.166  | 5620041 | 5140     | 1.260    |
|       | %RSD          |                                 | 0.200  | 0.340   | 0.449    | 0.183    |



## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 10    | ESS-AS-24.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-01 | 7.425  | 1343271 | 7156     | 1.184    |
| 10    | ESS-AS-25.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-02 | 7.441  | 1346568 | 7229     | 1.187    |
| 10    | ESS-AS-26.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-03 | 7.410  | 1343507 | 7131     | 1.186    |
| 10    | ESS-AS-27.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-04 | 7.400  | 1346939 | 7226     | 1.186    |
| 10    | ESS-AS-28.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-05 | 7.433  | 1344675 | 7148     | 1.186    |
|       | Average       |                                 | 7.422  | 1344992 | 7178     | 1.186    |
|       | %RSD          |                                 | 0.226  | 0.126   | 0.645    | 0.089    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 10    | ESS-AS-24.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-01 | 11.225 | 2993172 | 64682    | 1.411    |
| 10    | ESS-AS-25.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-02 | 11.227 | 2993391 | 64908    | 1.424    |
| 10    | ESS-AS-26.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-03 | 11.220 | 2984657 | 63737    | 1.408    |
| 10    | ESS-AS-27.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-04 | 11.223 | 2986478 | 64842    | 1.407    |
| 10    | ESS-AS-28.lcd | PARA+PHENYL+CPM-LFlow-AS-STD-05 | 11.215 | 2986505 | 65131    | 1.420    |
|       | Average       |                                 | 11.222 | 2988841 | 64660    | 1.414    |
|       | %RSD          |                                 | 0.041  | 0.138   | 0.836    | 0.519    |

Analysed By

Date :


  
02/11/2024

Checked By

Date :


  
21/11/2024



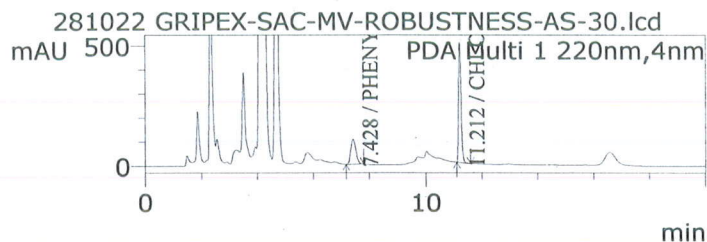
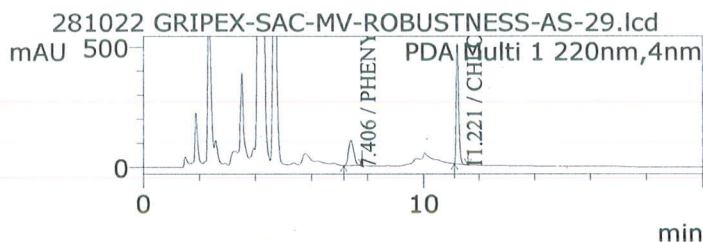
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-LFlow-AS-SOL-A-01  
Tray# : 2  
Vial# : 11  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-29.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 12:54:59 AM  
Date Processed : 10/31/2022 10:43:22 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 11    | ESS-AS-29.lcd | GRIPEX-SAC-MV-LFlow-AS-SOL-A-01 | 7.406  | 1323176 | 7283     | 1.162    |
| 11    | ESS-AS-30.lcd | GRIPEX-SAC-MV-LFlow-AS-SOL-A-02 | 7.428  | 1315148 | 7359     | 1.156    |
|       | Average       |                                 | 7.417  | 1319162 | 7321     | 1.159    |
|       | %RSD          |                                 | 0.211  | 0.430   | 0.735    | 0.350    |

ID#2 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 11    | ESS-AS-29.lcd | GRIPEX-SAC-MV-LFlow-AS-SOL-A-01 | 11.221 | 2986972 | 64527    | 1.396    |
| 11    | ESS-AS-30.lcd | GRIPEX-SAC-MV-LFlow-AS-SOL-A-02 | 11.212 | 2979587 | 64958    | 1.396    |
|       | Average       |                                 | 11.217 | 2983279 | 64742    | 1.396    |
|       | %RSD          |                                 | 0.059  | 0.175   | 0.471    | 0.021    |

Analysed By

Date :

*[Signature]*  
02/11/22

Checked By

Date :

*[Signature]*  
02/11/22





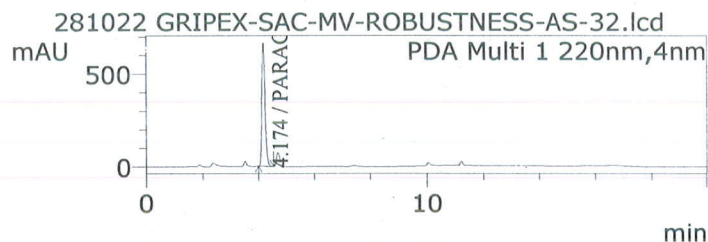
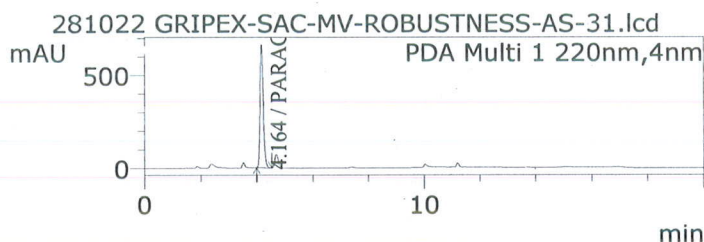
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-LFlow-AS-SOL-B-01  
Tray# : 2  
Vial# : 12  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-31.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/31/2022 1:12:07 PM  
Date Processed : 11/1/2022 7:26:21 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 12    | ESS-AS-31.lcd | GRIPEX-SAC-MV-LFlow-AS-SOL-B-01 | 4.164  | 5472739 | 5176     | 1.268    |
| 12    | ESS-AS-32.lcd | GRIPEX-SAC-MV-LFlow-AS-SOL-B-02 | 4.174  | 5487250 | 5201     | 1.268    |
|       | Average       |                                 | 4.169  | 5479994 | 5189     | 1.268    |
|       | %RSD          |                                 | 0.183  | 0.187   | 0.335    | 0.045    |

Analysed By

Date :

Checked By

Date :



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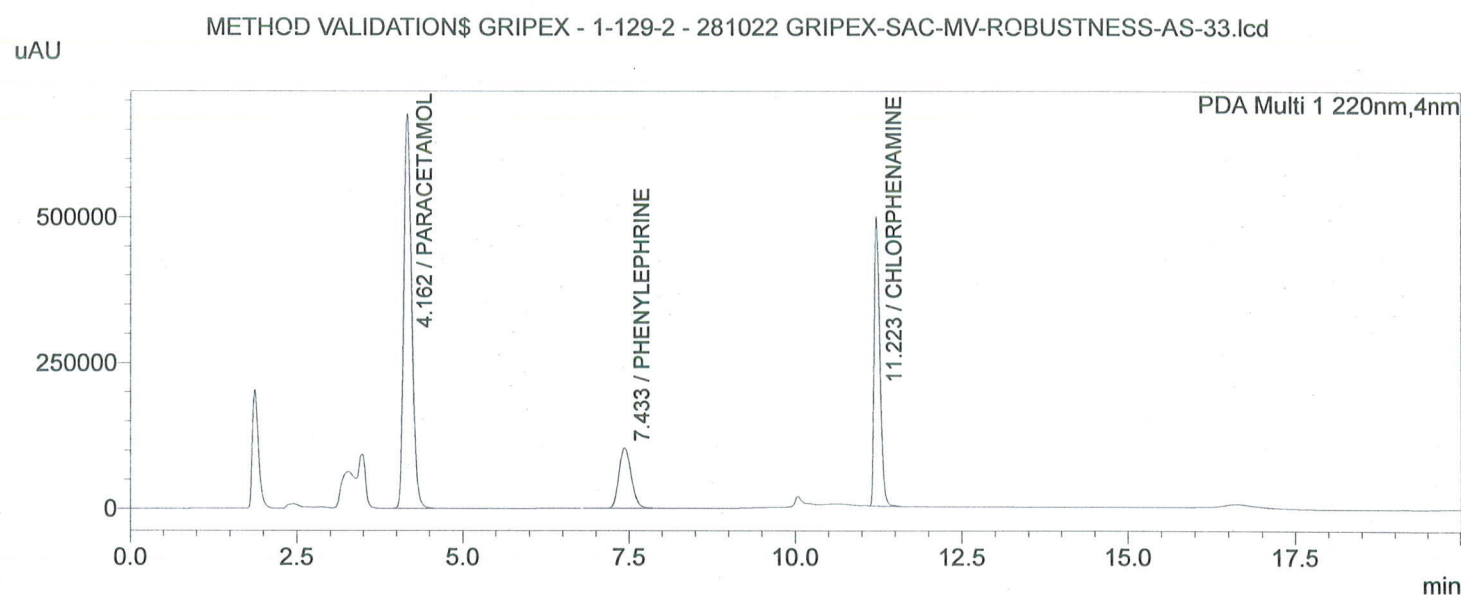
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-LFlo-AS-BKT-STD  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-33.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-10  
Injection Volume : 50 uL  
Date Acquired : 10/29/2022 2:17:23 AM  
Date Processed : 10/31/2022 10:32:51 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 4.162     | 5602865 | 56.436  | 5151    | 1.257    | --         | --       | PARACETAMOL    |
| 2     | 7.433     | 1342280 | 13.520  | 7179    | 1.184    | 11.22      | --       | PHENYLEPHRINE  |
| 3     | 11.223    | 2982702 | 30.044  | 64794   | 1.401    | 14.38      | --       | CHLORPHENAMINE |
| Total |           | 9927847 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                                |  |  |  |            |             |  |
|--------------|------------------------------------------------|--|--|--|------------|-------------|--|
| Title        |                                                |  |  |  |            |             |  |
| Product Name | GRIPEX                                         |  |  |  | Batch size | 500 SACHETS |  |
| Batch Number | ST/T/S-1322                                    |  |  |  | Mfg. Date  | Sep-22      |  |
| Stage        | FLOW RATE CHANGE (HIGH FLOW RATE 1.3ML/MINUTE) |  |  |  | Exp. Date  | To be fixed |  |

Each 4500 mg of Sachet Contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |              |            |             |                  |   |            |              |                |       |
|----------------------------|--------------|------------|-------------|------------------|---|------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/039 |            | Balance ID: | ST/QC/EQ/041&030 |   | WS No.:    | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.30        | mg to ---> | 100         | ml to --->       | 5 | ml to ---> | 50           |                |       |
| Std.conc (in ppm)-65.3     | 1            | ml to ---> | 1           | ml to --->       | 1 | ml to ---> | 1            |                |       |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500         | ml to --->       | 5 | ml to ---> | 100          |                |       |
| Test conc(in ppm)-65.01588 | 1            | ml to ---> | 1           | ml to --->       | 1 | ml to ---> | 1            |                |       |

Conversion factor : 1.0000

Labeled claim : 650 mg

Average weight : 4500 mg

|                      |         |         |         |         |         |         |       |          |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Paracetamol          | 4752119 | 4754500 | 4753685 | 4759695 | 4778631 | 4759726 | 10944 | 0.230    |
| With Bracketing std. | 4794882 |         |         |         |         | 4765585 | 17373 | 0.365    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.10                   | 4606894     | 631.88               | 97.2         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                            |              |            |     |            |   |            |              |                |      |
|----------------------------|--------------|------------|-----|------------|---|------------|--------------|----------------|------|
|                            |              |            |     |            |   | WS No.:    | IAARI/WS/344 | % Purity (aib) | 98.9 |
| Standard dilution.:        | 40.16        | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-20.08    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test conc (in ppm)-20.0048 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |

Conversion factor : 1.0000

Labeled claim : 10 mg

|                      |         |         |         |         |         |         |        |          |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
| Phenylephrine HCL    | 1138804 | 1139126 | 1141459 | 1139243 | 1145911 | 1140909 | 2988   | 0.262    |
| With Bracketing std. | 1150788 |         |         |         |         | 1142555 | 4838.3 | 0.423    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.10                   | 1133793     | 9.87                 | 98.7         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|                            |              |            |     |            |   |            |              |                |      |
|----------------------------|--------------|------------|-----|------------|---|------------|--------------|----------------|------|
|                            |              |            |     |            |   | WS No.:    | ST/WS/22/039 | % Purity (aib) | 99.7 |
| Standard dilution.:        | 40.11        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-40.11    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test conc(in ppm)-40.00977 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |

Conversion factor : 1.0000

Labeled claim : 20 mg

|                        |         |         |         |         |         |         |      |          |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
| Chlorphenamine maleate | 2517667 | 2517700 | 2520742 | 2519611 | 2530300 | 2521204 | 5251 | 0.208    |
| With Bracketing std.   | 2521232 |         |         |         |         | 2521209 | 4696 | 0.186    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.10                   | 2524832     | 20.02                | 100.1        |

Assay limit :90.0% to 110.0%

Calculation formula :

|                     |                                                                                                                   |
|---------------------|-------------------------------------------------------------------------------------------------------------------|
| Assay in mg /Sachet | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt<br>Standard area x sample dilution x 100 |
|---------------------|-------------------------------------------------------------------------------------------------------------------|

|            |                                           |
|------------|-------------------------------------------|
| Assay in % | Assay in mg/Sachet x 100<br>Labeled claim |
|------------|-------------------------------------------|

Analysed by :

C.ALBIN JOSE

Date :

02-11-2022

Checked by :

Date :

02/11/2022



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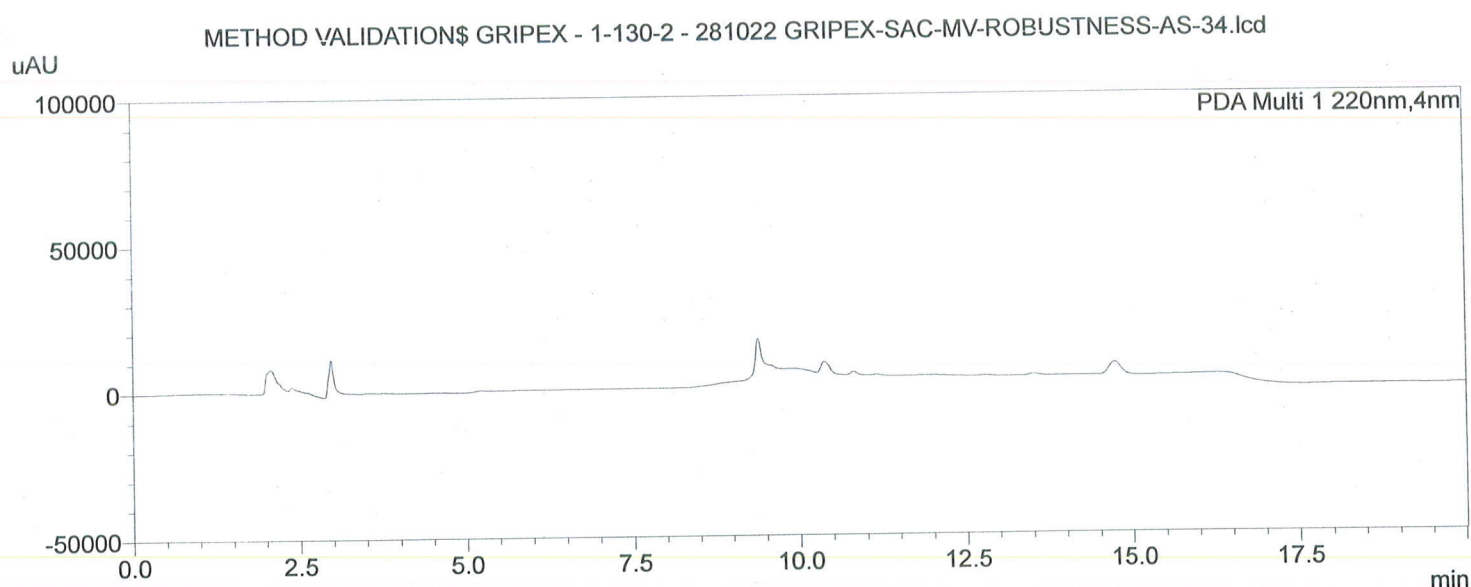
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : BLANK-AS-High Flow  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-34.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-13  
Injection Volume : 50 uL  
Date Acquired : 10/29/2022 2:38:01 AM  
Date Processed : 10/31/2022 10:35:55 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

*[Signature]*  
10/31/22

Checked By

Date :

*[Signature]*  
02/11/2022





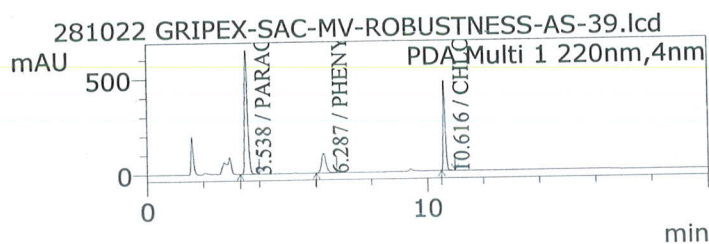
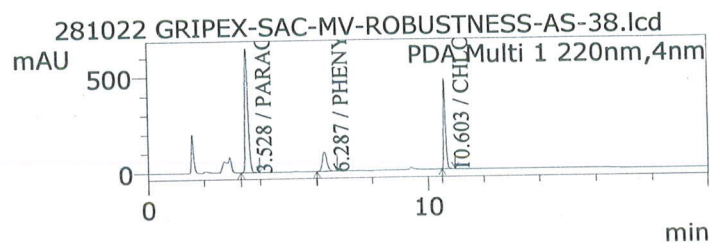
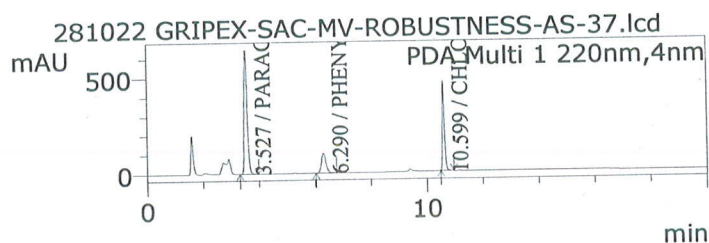
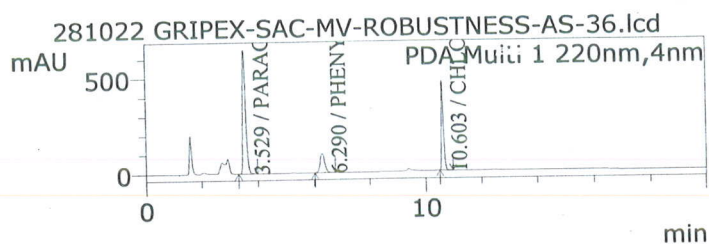
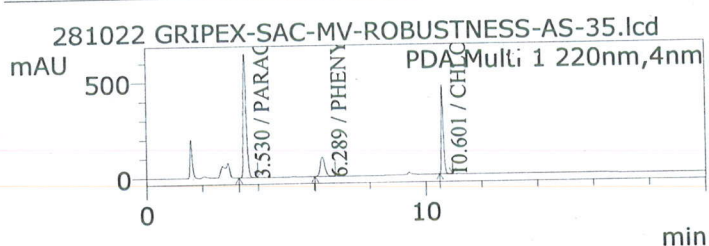
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-HFlow-AS-STD-01  
Tray# : 2  
Vial# : 14  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-35.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 2:58:38 AM  
Date Processed : 10/31/2022 10:35:58 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 14    | ESS-AS-35.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-01 | 3.530  | 4752119 | 4561     | 1.247    |
| 14    | ESS-AS-36.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-02 | 3.529  | 4754500 | 4560     | 1.246    |
| 14    | ESS-AS-37.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-03 | 3.527  | 4753685 | 4531     | 1.249    |
| 14    | ESS-AS-38.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-04 | 3.528  | 4759695 | 4552     | 1.248    |
| 14    | ESS-AS-39.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-05 | 3.538  | 4778631 | 4553     | 1.249    |
|       | Average       |                                 | 3.530  | 4759726 | 4552     | 1.248    |
|       | %RSD          |                                 | 0.125  | 0.230   | 0.267    | 0.110    |

## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 14    | ESS-AS-35.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-01 | 6.289  | 1138804 | 6673     | 1.174    |
| 14    | ESS-AS-36.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-02 | 6.290  | 1139126 | 6635     | 1.173    |
| 14    | ESS-AS-37.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-03 | 6.290  | 1141459 | 6672     | 1.176    |
| 14    | ESS-AS-38.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-04 | 6.287  | 1139243 | 6660     | 1.172    |
| 14    | ESS-AS-39.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-05 | 6.287  | 1145911 | 6660     | 1.176    |
|       | Average       |                                 | 6.289  | 1140909 | 6660     | 1.174    |
|       | %RSD          |                                 | 0.023  | 0.262   | 0.226    | 0.128    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 14    | ESS-AS-35.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-01 | 10.601 | 2517667 | 69081    | 1.399    |
| 14    | ESS-AS-36.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-02 | 10.603 | 2517700 | 69491    | 1.404    |
| 14    | ESS-AS-37.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-03 | 10.599 | 2520742 | 69072    | 1.396    |
| 14    | ESS-AS-38.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-04 | 10.603 | 2519611 | 69985    | 1.403    |
| 14    | ESS-AS-39.lcd | PARA+PHENYL+CPM-HFlow-AS-STD-05 | 10.616 | 2530300 | 72360    | 1.393    |
|       | Average       |                                 | 10.604 | 2521204 | 69998    | 1.399    |
|       | %RSD          |                                 | 0.065  | 0.208   | 1.961    | 0.326    |

Analysed By

Date :

02/11/2022

Checked By

Date :

02/11/2022





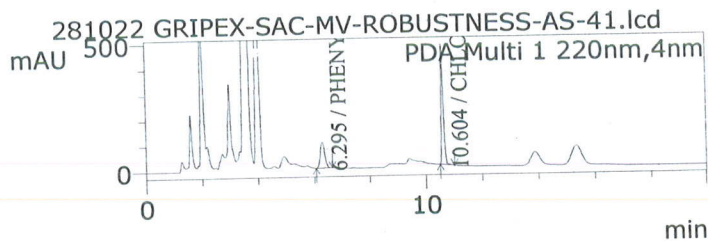
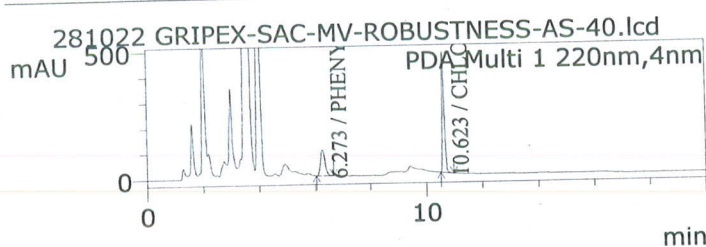
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-HFlow-AS-SOL-A-01  
Tray# : 2  
Vial# : 15  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-40.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 4:41:43 AM  
Date Processed : 11/2/2022 11:11:27 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 15    | ESS-AS-40.lcd | GRIPEX-SAC-MV-HFlow-AS-SOL-A-01 | 6.273  | 1142097 | 6717     | 1.173    |
| 15    | ESS-AS-41.lcd | GRIPEX-SAC-MV-HFlow-AS-SOL-A-02 | 6.295  | 1125489 | 6833     | 1.154    |
|       | Average       |                                 | 6.284  | 1133793 | 6775     | 1.163    |
|       | %RSD          |                                 | 0.248  | 1.036   | 1.214    | 1.149    |

ID#2 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 15    | ESS-AS-40.lcd | GRIPEX-SAC-MV-HFlow-AS-SOL-A-01 | 10.623 | 2524152 | 70742    | 1.402    |
| 15    | ESS-AS-41.lcd | GRIPEX-SAC-MV-HFlow-AS-SOL-A-02 | 10.604 | 2525512 | 72039    | 1.396    |
|       | Average       |                                 | 10.614 | 2524832 | 71391    | 1.399    |
|       | %RSD          |                                 | 0.129  | 0.038   | 1.284    | 0.321    |

Analysed By

Date :

Checked By

Date :



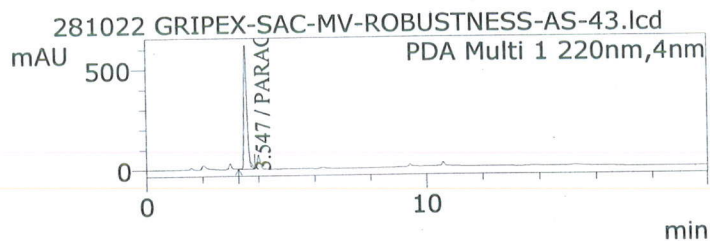
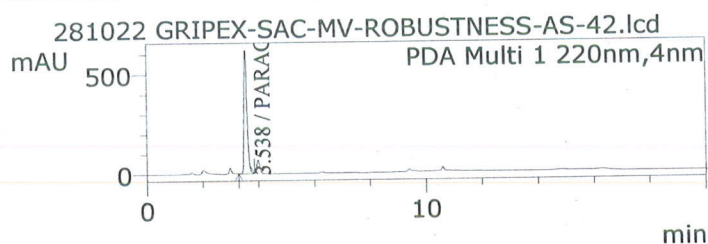
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-HFlow-AS-SOL-B-01  
Tray# : 2  
Vial# : 16  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-42.lcd  
Method File : GRIPEX-AS-High flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/31/2022 1:57:18 PM  
Date Processed : 11/2/2022 10:38:12 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 16    | ESS-AS-42.lcd | GRIPEX-SAC-MV-HFlow-AS-SOL-B-01 | 3.538  | 4598716 | 4527     | 1.264    |
| 16    | ESS-AS-43.lcd | GRIPEX-SAC-MV-HFlow-AS-SOL-B-02 | 3.547  | 4615071 | 4557     | 1.266    |
|       | Average       |                                 | 3.542  | 4606894 | 4542     | 1.265    |
|       | %RSD          |                                 | 0.183  | 0.251   | 0.455    | 0.139    |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

Puducherry- 605 107

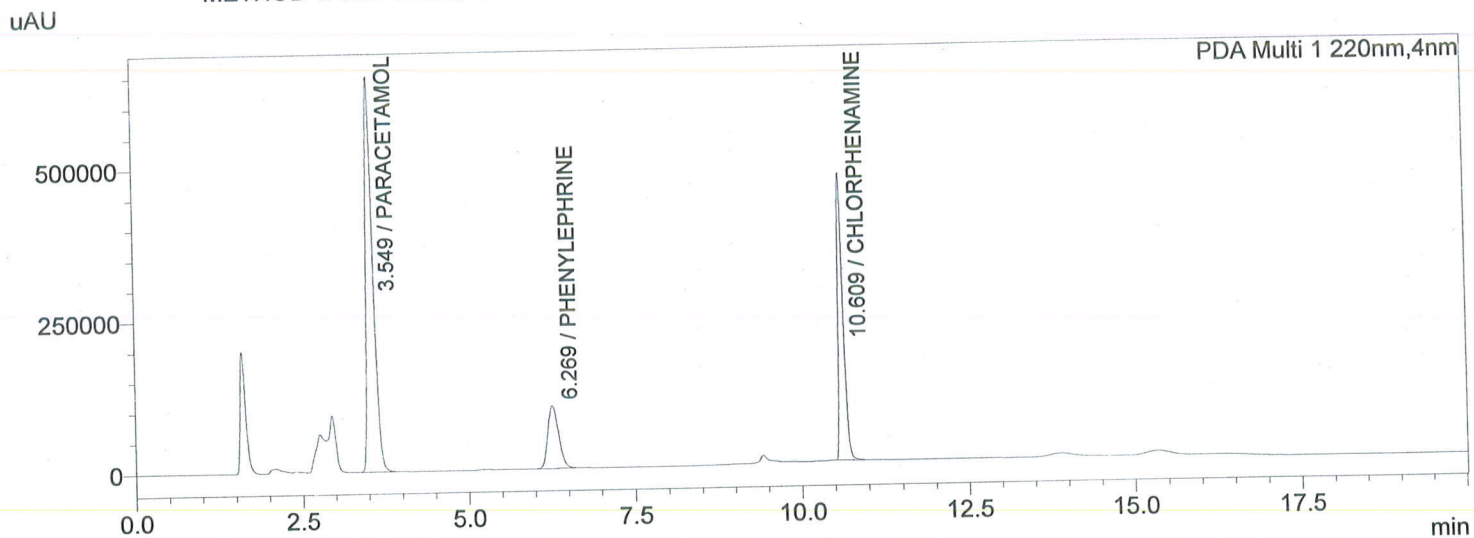
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-HF10-AS-BKT-STD  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-44.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-14  
Injection Volume : 50 uL  
Date Acquired : 10/29/2022 6:04:12 AM  
Date Processed : 10/31/2022 10:36:10 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-140-2 - 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-44.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.549     | 4794882 | 56.631  | 4564    | 1.250    | --         | --       | PARACETAMOL    |
| 2     | 6.269     | 1150788 | 13.592  | 6729    | 1.178    | 10.55      | --       | PHENYLEPHRINE  |
| 3     | 10.609    | 2521232 | 29.778  | 70430   | 1.404    | 18.64      | --       | CHLORPHENAMINE |
| Total |           | 8466902 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                                      |            |             |
|--------------|------------------------------------------------------|------------|-------------|
| Title        |                                                      |            |             |
| Product Name | GRIPEX                                               | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                          | Mfg.Date   | Sep-22      |
| Stage        | COLUMN TEMPERATURE CHANGE (AT OVEN TEMPERATURE 25°C) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet Contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |              |             |                  |            |              |                |       |
|----------------------------|--------------|-------------|------------------|------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/039 | Balance ID: | ST/QC/EQ/041&030 | WS No.:    | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.30        | mg to --->  | 100              | ml to ---> | 5            | ml to --->     | 50    |
| Std.conc (in ppm)-65.3     | 1            | ml to --->  | 1                | ml to ---> | 1            | ml to --->     | 1     |
| Test dilution.:            | Granule/Pow. | mg to --->  | 500              | ml to ---> | 5            | ml to --->     | 100   |
| Test conc(in ppm)-65.01588 | 1            | ml to --->  | 1                | ml to ---> | 1            | ml to --->     | 1     |

|                     |         |
|---------------------|---------|
| Conversion factor : | 1.0000  |
| Labeled claim :     | 650 mg  |
| Average weight :    | 4500 mg |

| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
|----------------------|---------|---------|---------|---------|---------|---------|------|----------|
| Paracetamol          | 5155668 | 5163585 | 5164024 | 5160652 | 5161539 | 5161094 | 3340 | 0.065    |
| With Bracketing std. | 5148094 |         |         |         |         | 5158927 | 6090 | 0.118    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.10                   | 5003587     | 632.92               | 97.4         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                             |              |            |     |            |   |            |              |                |      |
|-----------------------------|--------------|------------|-----|------------|---|------------|--------------|----------------|------|
|                             |              |            |     |            |   | WS No.:    | IAARI/WS/344 | % Purity (aib) | 98.9 |
| Standard dilution.:         | 40.16        | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-20.08     | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test dilution .:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test conc (in ppm)-20.00488 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 10 mg  |

| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| Phenylephrine HCL    | 1230960 | 1227594 | 1232671 | 1230512 | 1231869 | 1230721 | 1936   | 0.157    |
| With Bracketing std. | 1227708 |         |         |         |         | 1230219 | 2124.4 | 0.173    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.10                   | 1220857     | 9.85                 | 98.5         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|                            |              |            |     |            |   |            |              |                |      |
|----------------------------|--------------|------------|-----|------------|---|------------|--------------|----------------|------|
|                            |              |            |     |            |   | WS No.:    | ST/WS/22/039 | % Purity (aib) | 99.7 |
| Standard dilution.:        | 40.11        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-40.11    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test dilution .:           | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test conc(in ppm)-40.00977 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 20 mg  |

| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| Chlorphenamine maleate | 2700485 | 2709313 | 2708378 | 2707709 | 2709444 | 2707066 | 3747 | 0.138    |
| With Bracketing std.   | 2699664 |         |         |         |         | 2705832 | 4512 | 0.167    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.10                   | 2725370     | 20.13                | 100.6        |

Assay limit :90.0% to 110.0%

Calculation formula :

|                     |                                                                          |
|---------------------|--------------------------------------------------------------------------|
| Assay in mg /Sachet | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt |
|                     | Standard area x sample dilution x 100                                    |

|            |                          |
|------------|--------------------------|
| Assay in % | Assay in mg/Sachet x 100 |
|            | Labeled claim            |

Analysed by : C.ALBIN JOSE  
Date : 02-11-2022

Checked by :  
Date : 02/11/2022





# Safetab Life Science

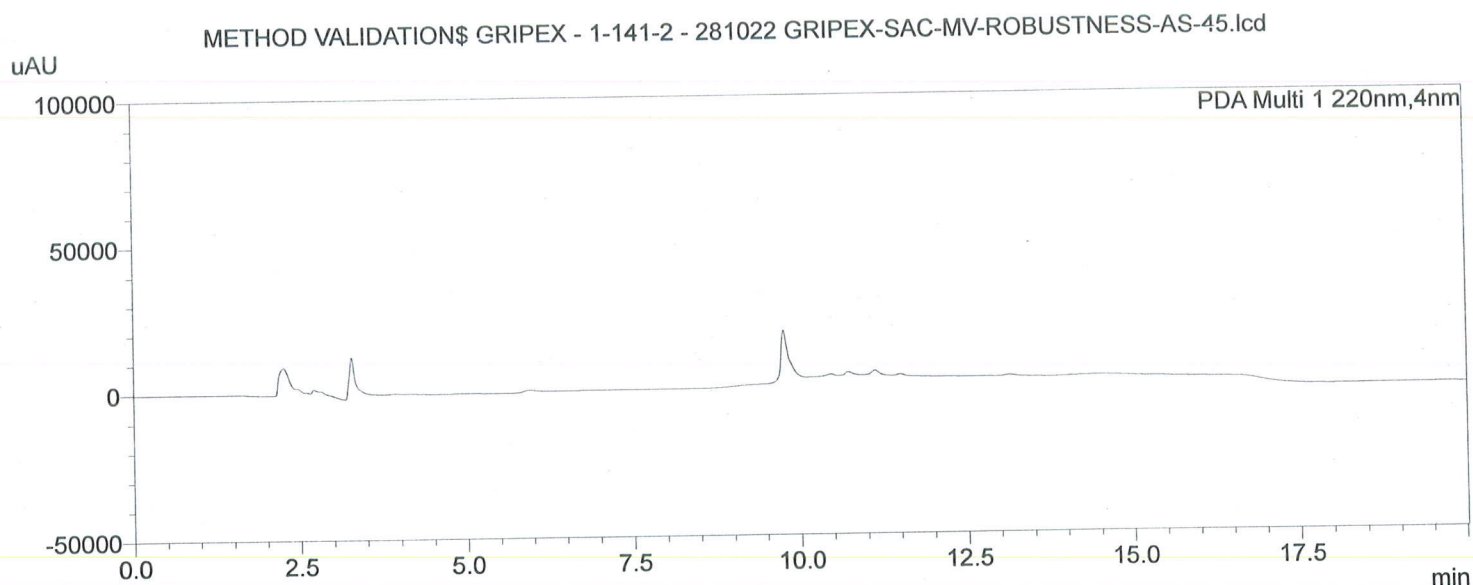
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : BLANK-AS-Low Tem  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-45.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-17  
Injection Volume : 50 uL  
Date Acquired : 10/29/2022 6:35:32 AM  
Date Processed : 10/31/2022 10:38:24 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



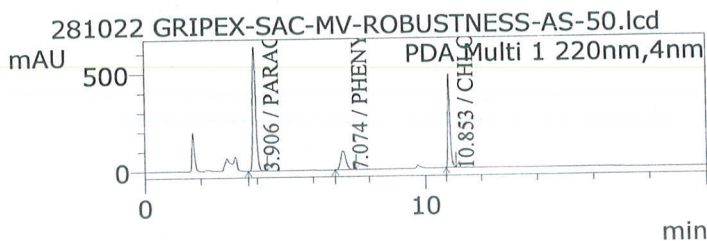
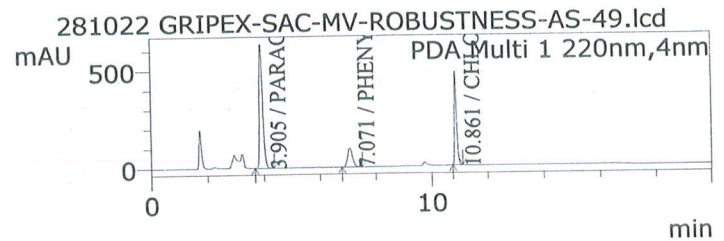
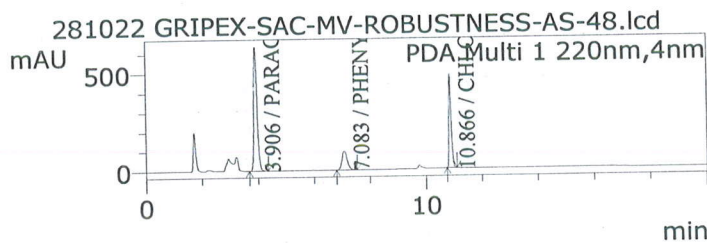
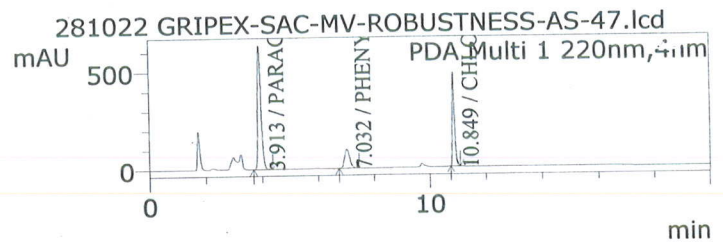
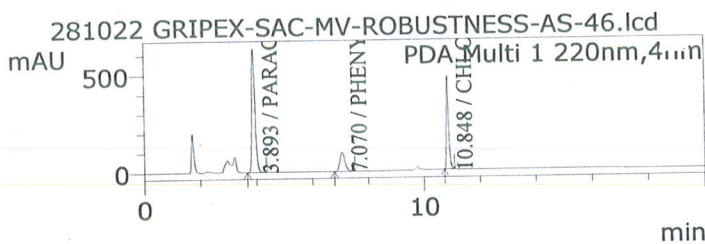
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-LTem-AS-STD-01  
Tray# : 2  
Vial# : 18  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-46.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 6:56:09 AM  
Date Processed : 10/31/2022 10:38:26 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 18    | ESS-AS-46.lcd | PARA+PHENYL+CPM-LTem-AS-STD-01 | 3.893  | 5155668 | 4644     | 1.254    |
| 18    | ESS-AS-47.lcd | PARA+PHENYL+CPM-LTem-AS-STD-02 | 3.913  | 5163585 | 4674     | 1.251    |
| 18    | ESS-AS-48.lcd | PARA+PHENYL+CPM-LTem-AS-STD-03 | 3.906  | 5164024 | 4664     | 1.256    |
| 18    | ESS-AS-49.lcd | PARA+PHENYL+CPM-LTem-AS-STD-04 | 3.905  | 5160652 | 4659     | 1.256    |
| 18    | ESS-AS-50.lcd | PARA+PHENYL+CPM-LTem-AS-STD-05 | 3.906  | 5161539 | 4660     | 1.257    |
|       | Average       |                                | 3.905  | 5161094 | 4660     | 1.255    |
|       | %RSD          |                                | 0.192  | 0.065   | 0.237    | 0.193    |



## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 18    | ESS-AS-46.lcd | PARA+PHENYL+CPM-LTem-AS-STD-01 | 7.070  | 1230960 | 6590     | 1.174    |
| 18    | ESS-AS-47.lcd | PARA+PHENYL+CPM-LTem-AS-STD-02 | 7.032  | 1227594 | 6691     | 1.176    |
| 18    | ESS-AS-48.lcd | PARA+PHENYL+CPM-LTem-AS-STD-03 | 7.083  | 1232671 | 6599     | 1.174    |
| 18    | ESS-AS-49.lcd | PARA+PHENYL+CPM-LTem-AS-STD-04 | 7.071  | 1230512 | 6564     | 1.174    |
| 18    | ESS-AS-50.lcd | PARA+PHENYL+CPM-LTem-AS-STD-05 | 7.074  | 1231869 | 6621     | 1.174    |
|       | Average       |                                | 7.066  | 1230721 | 6613     | 1.174    |
|       | %RSD          |                                | 0.278  | 0.157   | 0.726    | 0.079    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 18    | ESS-AS-46.lcd | PARA+PHENYL+CPM-LTem-AS-STD-01 | 10.848 | 2700485 | 66791    | 1.400    |
| 18    | ESS-AS-47.lcd | PARA+PHENYL+CPM-LTem-AS-STD-02 | 10.849 | 2709313 | 67071    | 1.405    |
| 18    | ESS-AS-48.lcd | PARA+PHENYL+CPM-LTem-AS-STD-03 | 10.866 | 2708378 | 65731    | 1.397    |
| 18    | ESS-AS-49.lcd | PARA+PHENYL+CPM-LTem-AS-STD-04 | 10.861 | 2707709 | 67718    | 1.416    |
| 18    | ESS-AS-50.lcd | PARA+PHENYL+CPM-LTem-AS-STD-05 | 10.853 | 2709444 | 69134    | 1.410    |
|       | Average       |                                | 10.855 | 2707066 | 67289    | 1.406    |
|       | %RSD          |                                | 0.073  | 0.138   | 1.867    | 0.538    |

Analysed By

Date :

Checked By

Date :



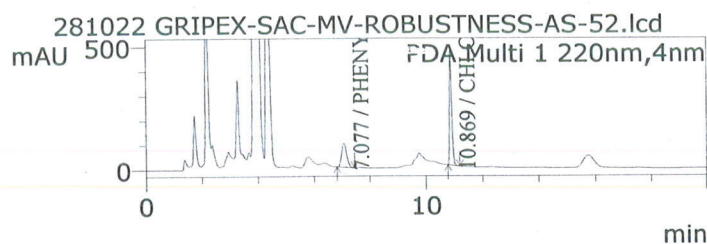
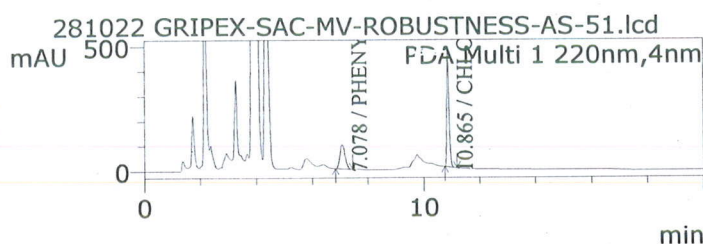
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-LTem-AS-SOL-A-01  
Tray# : 2  
Vial# : 19  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-51.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 8:39:14 AM  
Date Processed : 10/31/2022 10:46:28 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 19    | ESS-AS-51.lcd | GRIPEX-SAC-MV-LTem-AS-SOL-A-01 | 7.078  | 1220045 | 6767     | 1.155    |
| 19    | ESS-AS-52.lcd | GRIPEX-SAC-MV-LTem-AS-SOL-A-02 | 7.077  | 1221668 | 6751     | 1.154    |
|       | Average       |                                | 7.077  | 1220857 | 6759     | 1.155    |
|       | %RSD          |                                | 0.011  | 0.094   | 0.173    | 0.009    |

ID#2 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 19    | ESS-AS-51.lcd | GRIPEX-SAC-MV-LTem-AS-SOL-A-01 | 10.865 | 2720581 | 65688    | 1.405    |
| 19    | ESS-AS-52.lcd | GRIPEX-SAC-MV-LTem-AS-SOL-A-02 | 10.869 | 2730158 | 67088    | 1.402    |
|       | Average       |                                | 10.867 | 2725370 | 66388    | 1.403    |
|       | %RSD          |                                | 0.026  | 0.248   | 1.491    | 0.143    |

Analysed By

Date :

*[Signature]*  
10/31/22

Checked By

Date :

*[Signature]*  
10/31/22





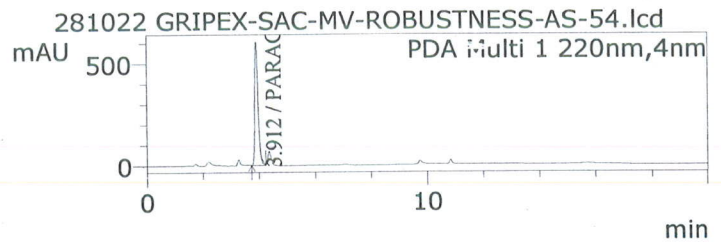
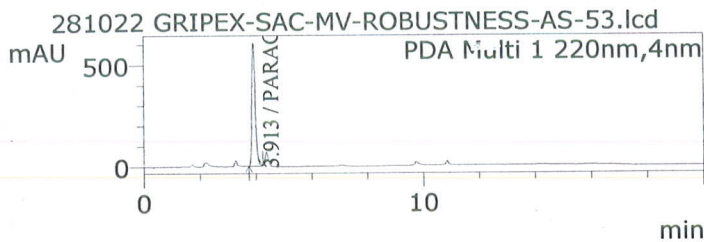
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-LTem-AS-SOL-B-01  
Tray# : 2  
Vial# : 20  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-53.lcd  
Method File : GRIPEX-AS-Low tem.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/31/2022 2:48:16 PM  
Date Processed : 11/2/2022 10:41:10 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 20    | ESS-AS-53.lcd | GRIPEX-SAC-MV-LTem-AS-SOL-B-01 | 3.913  | 5000224 | 4618     | 1.261    |
| 20    | ESS-AS-54.lcd | GRIPEX-SAC-MV-LTem-AS-SOL-B-02 | 3.912  | 5006951 | 4577     | 1.263    |
|       | Average       |                                | 3.912  | 5003587 | 4598     | 1.262    |
|       | %RSD          |                                | 0.026  | 0.095   | 0.633    | 0.124    |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

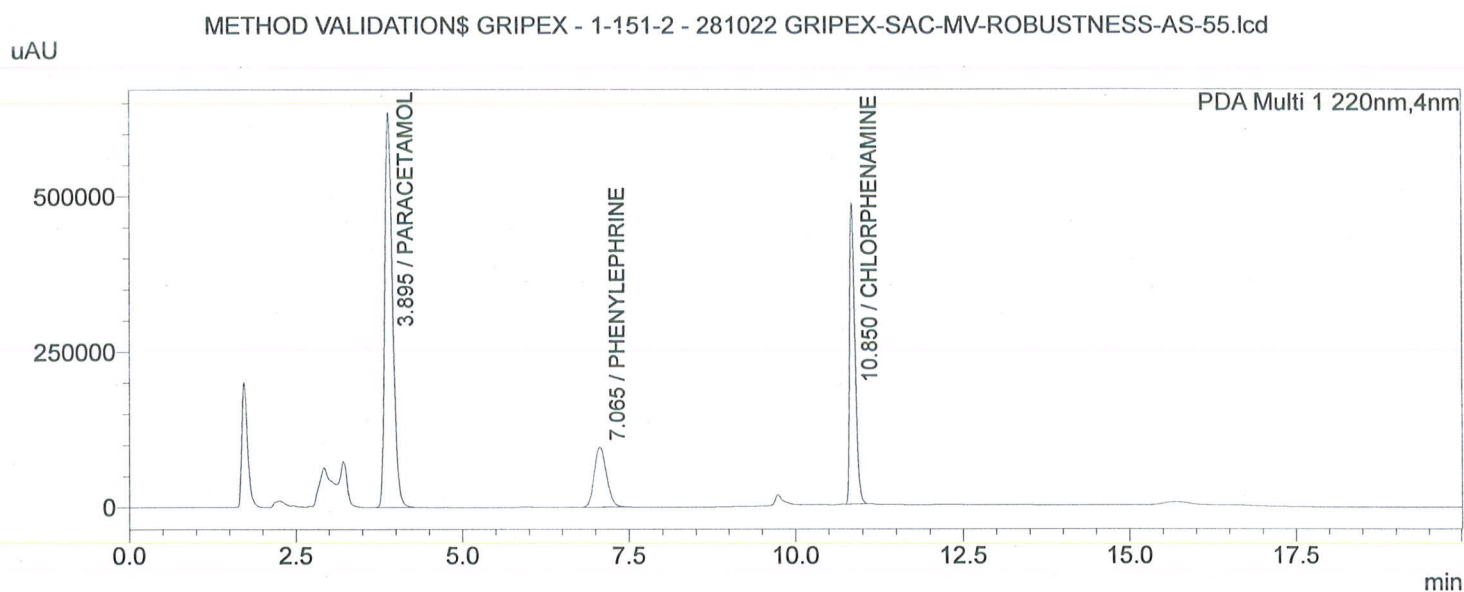
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-LTem-AS-BKT-STD  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-55.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-18  
Injection Volume : 50 uL  
Date Acquired : 10/29/2022 10:01:43 AM  
Date Processed : 10/31/2022 10:38:40 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.895     | 5148094 | 56.725  | 4663    | 1.257    | --         | --       | PARACETAMOL    |
| 2     | 7.065     | 1227708 | 13.528  | 6647    | 1.173    | 11.03      | --       | PHENYLEPHRINE  |
| 3     | 10.850    | 2699664 | 29.747  | 68229   | 1.417    | 14.76      | --       | CHLORPHENAMINE |
| Total |           | 9075466 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|----------------------|------------------|------------------------------|----------------|--------------|
|                                                                     |                                                                                                                                                                                                           | <b>Safetab Life Science</b><br>Puducherry - 605 107                                  |                      |                  |                              |                |              |
|                                                                                                                                                     |                                                                                                                                                                                                           | <b>QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET</b>                |                      |                  |                              |                |              |
| Title                                                                                                                                               |                                                                                                                                                                                                           | ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS |                      |                  |                              |                |              |
| Product Name                                                                                                                                        | GRIPEX                                                                                                                                                                                                    |                                                                                      |                      |                  |                              | Batch size     | 500 SACHETS  |
| Batch Number                                                                                                                                        | ST/T/S-1322                                                                                                                                                                                               |                                                                                      |                      |                  |                              | Mfg. Date      | Sep-22       |
| Stage                                                                                                                                               | COLUMN TEMPERATURE CHANGE (AT OVEN TEMPERATURE 35°C)                                                                                                                                                      |                                                                                      |                      |                  |                              | Exp. Date      | To be fixed  |
| Each 4500 mg of Sachet Contains:<br>Paracetamol BP ----- 650mg<br>Chlorphenamine Maleate BP ----- 20mg<br>Phenylephrine Hydrochloride BP ----- 10mg |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                |              |
| ASSAY OF PARACETAMOL                                                                                                                                |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                |              |
| Instrument ID:                                                                                                                                      | ST/QC/EQ/039                                                                                                                                                                                              |                                                                                      | Balance ID:          | ST/QC/EQ/041&030 |                              | WS No.:        | ST/WS/22/011 |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              | % Purity (aib) | 100.0        |
| Standard dilution.:                                                                                                                                 | 65.30                                                                                                                                                                                                     | mg to --->                                                                           | 100                  | ml to --->       | 5                            | ml to --->     | 50           |
| Std. conc (in ppm)-65.3                                                                                                                             | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1                            | ml to --->     | 1            |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                                           | 500                  | ml to --->       | 5                            | ml to --->     | 100          |
| Test conc (in ppm)-65.01588                                                                                                                         | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1                            | ml to --->     | 1            |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                                                      |                      |                  |                              |                |              |
| Labeled claim :                                                                                                                                     | 650                                                                                                                                                                                                       | mg                                                                                   |                      |                  |                              |                |              |
| Average weight :                                                                                                                                    | 4500                                                                                                                                                                                                      | mg                                                                                   |                      |                  |                              |                |              |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                                                    | 3                    | 4                | 5                            | MEAN           | S.D          |
| Paracetamol                                                                                                                                         | 5128595                                                                                                                                                                                                   | 5152619                                                                              | 5153021              | 5173215          | 5178299                      | 5157150        | 19738        |
| With Bracketing std.                                                                                                                                | 5140622                                                                                                                                                                                                   |                                                                                      |                      |                  |                              | 5154395        | 18900        |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                | RSD in %     |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                | 0.383        |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                | 0.367        |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                                                                                                                                                 | Sample Area                                                                          | Content in mg/Sachet | Content in %     |                              |                |              |
| 1                                                                                                                                                   | 4501.10                                                                                                                                                                                                   | 4995064                                                                              | 632.32               | 97.3             |                              |                |              |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  | Assay limit :90.0% to 110.0% |                |              |
| ASSAY OF PHENYLEPHRINE HYDROCHLORIDE                                                                                                                |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                |              |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              | WS No.:        | IAARI/WS/344 |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              | % Purity (aib) | 98.9         |
| Standard dilution.:                                                                                                                                 | 40.16                                                                                                                                                                                                     | mg to --->                                                                           | 200                  | ml to --->       | 5                            | ml to --->     | 50           |
| Std. conc (in ppm)-20.08                                                                                                                            | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1                            | ml to --->     | 1            |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                                           | 500                  | ml to --->       | 1                            | ml to --->     | 1            |
| Test conc (in ppm)-20.0048                                                                                                                          | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1                            | ml to --->     | 1            |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                                                      |                      |                  |                              |                |              |
| Labeled claim :                                                                                                                                     | 10                                                                                                                                                                                                        | mg                                                                                   |                      |                  |                              |                |              |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                                                    | 3                    | 4                | 5                            | MEAN           | S.D          |
| Phenylephrine HCL                                                                                                                                   | 1234003                                                                                                                                                                                                   | 1230386                                                                              | 1230202              | 1238544          | 1239751                      | 1234577        | 4459         |
| With Bracketing std.                                                                                                                                | 1229996                                                                                                                                                                                                   |                                                                                      |                      |                  |                              | 1233814        | 4405.3       |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                | RSD in %     |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                | 0.361        |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                | 0.357        |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                                                                                                                                                 | Sample Area                                                                          | Content in mg/Sachet | Content in %     |                              |                |              |
| 1                                                                                                                                                   | 4501.10                                                                                                                                                                                                   | 1233992                                                                              | 9.92                 | 99.2             |                              |                |              |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  | Assay limit :90.0% to 110.0% |                |              |
| ASSAY OF CHLORPHENAMINE MALEATE                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                |              |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              | WS No.:        | ST/WS/22/039 |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              | % Purity (aib) | 99.7         |
| Standard dilution.:                                                                                                                                 | 40.11                                                                                                                                                                                                     | mg to --->                                                                           | 100                  | ml to --->       | 5                            | ml to --->     | 50           |
| Std. conc (in ppm)-40.11                                                                                                                            | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1                            | ml to --->     | 1            |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                                           | 500                  | ml to --->       | 1                            | ml to --->     | 1            |
| Test conc (in ppm)-40.00977                                                                                                                         | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1                            | ml to --->     | 1            |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                                                      |                      |                  |                              |                |              |
| Labeled claim :                                                                                                                                     | 20                                                                                                                                                                                                        | mg                                                                                   |                      |                  |                              |                |              |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                                                    | 3                    | 4                | 5                            | MEAN           | S.D          |
| Chlorphenamine maleate                                                                                                                              | 2734230                                                                                                                                                                                                   | 2732234                                                                              | 2734397              | 2739615          | 2748139                      | 2737723        | 6432         |
| With Bracketing std.                                                                                                                                | 2732821                                                                                                                                                                                                   |                                                                                      |                      |                  |                              | 2736906        | 6091         |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                | RSD in %     |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                | 0.235        |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                | 0.223        |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                                                                                                                                                 | Sample Area                                                                          | Content in mg/Sachet | Content in %     |                              |                |              |
| 1                                                                                                                                                   | 4501.10                                                                                                                                                                                                   | 2721878                                                                              | 19.87                | 99.4             |                              |                |              |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  | Assay limit :90.0% to 110.0% |                |              |
| Calculation formula :                                                                                                                               |                                                                                                                                                                                                           |                                                                                      |                      |                  |                              |                |              |
| Assay in mg /Sachet                                                                                                                                 | $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$ |                                                                                      |                      |                  |                              |                |              |
| Assay in %                                                                                                                                          | $\frac{\text{Assay in mg/Sachet} \times 100}{\text{Labeled claim}}$                                                                                                                                       |                                                                                      |                      |                  |                              |                |              |
| Analysed by :                                                                                                                                       | C. ALBIN JOSE                                                                                                                                                                                             |                                                                                      |                      |                  |                              |                |              |
| Date :                                                                                                                                              | 02-11-2022                                                                                                                                                                                                |                                                                                      |                      |                  |                              |                |              |
| Checked by :                                                                                                                                        | [Signature]                                                                                                                                                                                               |                                                                                      |                      |                  |                              |                |              |
| Date :                                                                                                                                              | 02/11/2022                                                                                                                                                                                                |                                                                                      |                      |                  |                              |                |              |



# Safetab Life Science

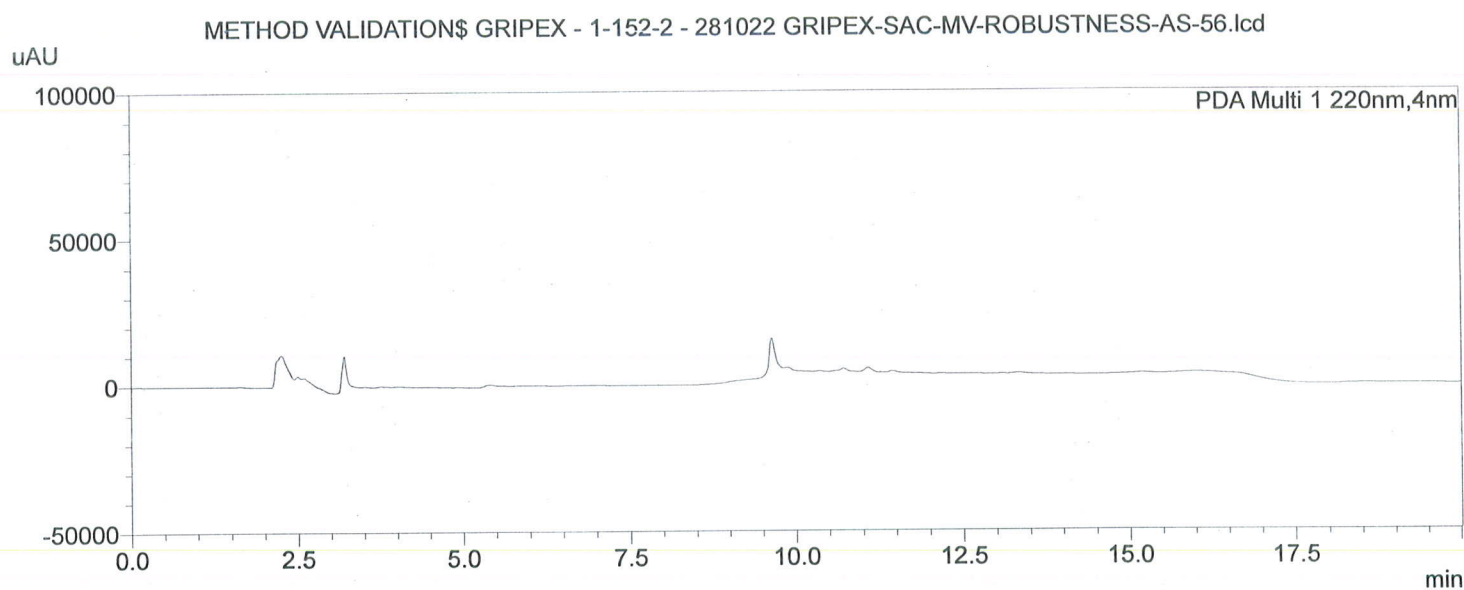
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : BLANK-AS-High Tem  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-56.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-21  
Injection Volume : 50 uL  
Date Acquired : 10/29/2022 10:30:30 AM  
Date Processed : 10/31/2022 10:39:38 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

*[Signature]*  
02/11/22

Checked By

Date :

*[Signature]*  
02/11/2022





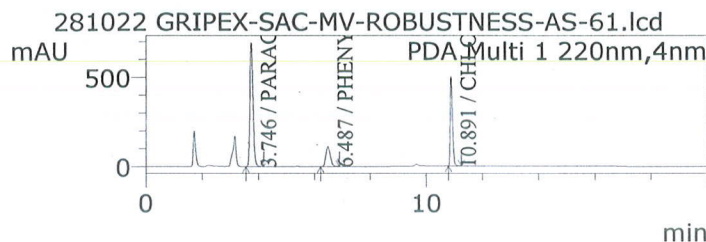
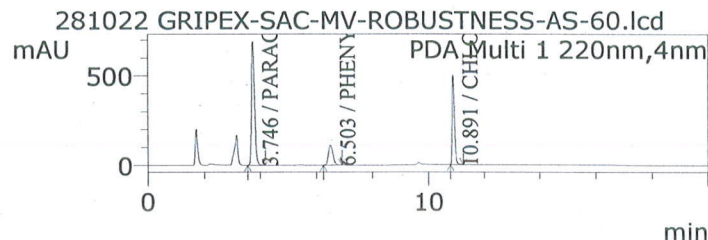
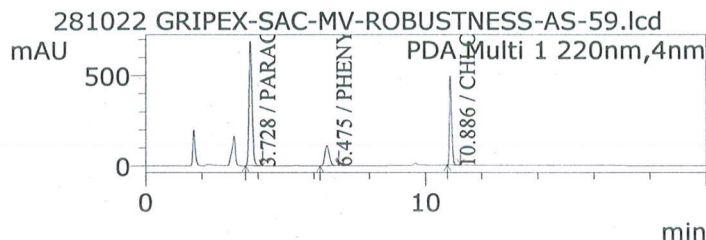
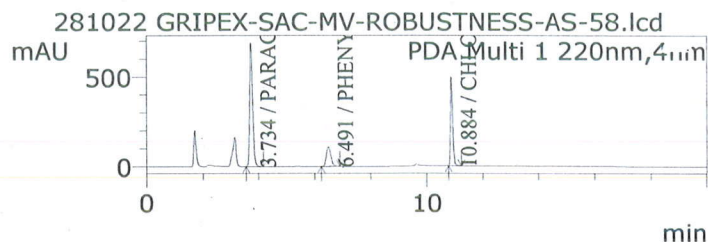
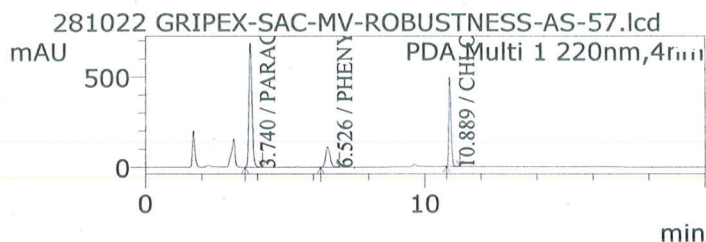
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-HTem-AS-STD-01  
Tray# : 2  
Vial# : 22  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-57.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 10:51:06 AM  
Date Processed : 10/31/2022 10:39:41 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 22    | ESS-AS-57.lcd | PARA+PHENYL+CPM-HTem-AS-STD-01 | 3.740  | 5128595 | 4950     | 1.260    |
| 22    | ESS-AS-58.lcd | PARA+PHENYL+CPM-HTem-AS-STD-02 | 3.734  | 5152619 | 4934     | 1.258    |
| 22    | ESS-AS-59.lcd | PARA+PHENYL+CPM-HTem-AS-STD-03 | 3.728  | 5153021 | 4955     | 1.261    |
| 22    | ESS-AS-60.lcd | PARA+PHENYL+CPM-HTem-AS-STD-04 | 3.746  | 5173215 | 4973     | 1.261    |
| 22    | ESS-AS-61.lcd | PARA+PHENYL+CPM-HTem-AS-STD-05 | 3.746  | 5178299 | 4981     | 1.261    |
|       | Average       |                                | 3.739  | 5157150 | 4959     | 1.260    |
|       | %RSD          |                                | 0.201  | 0.383   | 0.376    | 0.092    |

## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 22    | ESS-AS-57.lcd | PARA+PHENYL+CPM-HTem-AS-STD-01 | 6.526  | 1234003 | 7355     | 1.183    |
| 22    | ESS-AS-58.lcd | PARA+PHENYL+CPM-HTem-AS-STD-02 | 6.491  | 1230386 | 7266     | 1.184    |
| 22    | ESS-AS-59.lcd | PARA+PHENYL+CPM-HTem-AS-STD-03 | 6.475  | 1230202 | 7210     | 1.182    |
| 22    | ESS-AS-60.lcd | PARA+PHENYL+CPM-HTem-AS-STD-04 | 6.503  | 1238544 | 7335     | 1.184    |
| 22    | ESS-AS-61.lcd | PARA+PHENYL+CPM-HTem-AS-STD-05 | 6.487  | 1239751 | 7304     | 1.184    |
|       | Average       |                                | 6.496  | 1234577 | 7294     | 1.183    |
|       | %RSD          |                                | 0.295  | 0.361   | 0.793    | 0.090    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 22    | ESS-AS-57.lcd | PARA+PHENYL+CPM-HTem-AS-STD-01 | 10.889 | 2734230 | 70396    | 1.409    |
| 22    | ESS-AS-58.lcd | PARA+PHENYL+CPM-HTem-AS-STD-02 | 10.884 | 2732234 | 73591    | 1.416    |
| 22    | ESS-AS-59.lcd | PARA+PHENYL+CPM-HTem-AS-STD-03 | 10.886 | 2734397 | 69588    | 1.414    |
| 22    | ESS-AS-60.lcd | PARA+PHENYL+CPM-HTem-AS-STD-04 | 10.891 | 2739615 | 71641    | 1.422    |
| 22    | ESS-AS-61.lcd | PARA+PHENYL+CPM-HTem-AS-STD-05 | 10.891 | 2746139 | 71152    | 1.423    |
|       | Average       |                                | 10.888 | 2737723 | 71273    | 1.417    |
|       | %RSD          |                                | 0.030  | 0.235   | 2.120    | 0.411    |

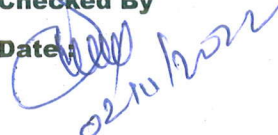
Analysed By

Date :


  
02/11/22

Checked By

Date :


  
02/10/2022





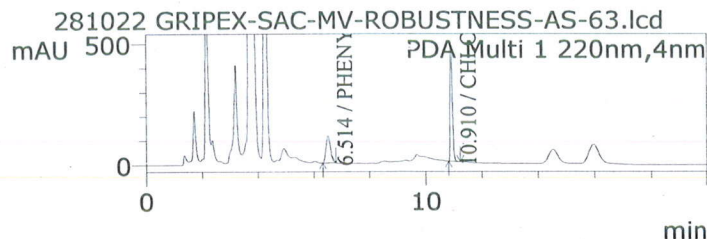
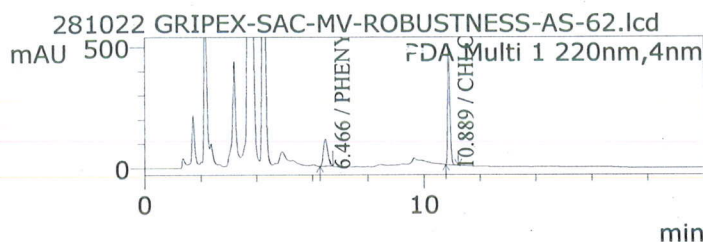
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-HTem-AS-SOL-A-01  
Tray# : 2  
Vial# : 23  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-62.lcd  
Method File : GRIPEX-AS-Low flow.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 12:34:08 PM  
Date Processed : 11/2/2022 11:28:25 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 23    | ESS-AS-62.lcd | GRIPEX-SAC-MV-HTem-AS-SOL-A-01 | 6.466  | 1230974 | 7258     | 1.177    |
| 23    | ESS-AS-63.lcd | GRIPEX-SAC-MV-HTem-AS-SOL-A-02 | 6.514  | 1237010 | 7266     | 1.192    |
|       | Average       |                                | 6.490  | 1233992 | 7262     | 1.184    |
|       | %RSD          |                                | 0.530  | 0.346   | 0.076    | 0.906    |

ID#2 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 23    | ESS-AS-62.lcd | GRIPEX-SAC-MV-HTem-AS-SOL-A-01 | 10.889 | 2726475 | 70562    | 1.404    |
| 23    | ESS-AS-63.lcd | GRIPEX-SAC-MV-HTem-AS-SOL-A-02 | 10.910 | 2717282 | 70670    | 1.399    |
|       | Average       |                                | 10.900 | 2721878 | 70616    | 1.401    |
|       | %RSD          |                                | 0.140  | 0.239   | 0.108    | 0.217    |

Analysed By

Date :

Checked By

Date :



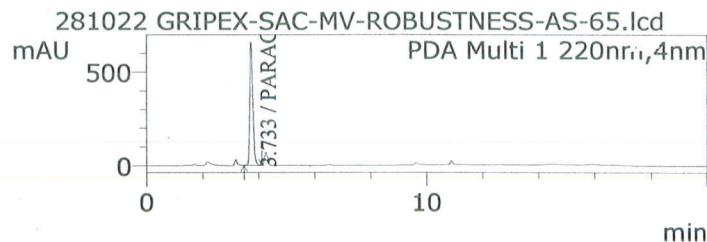
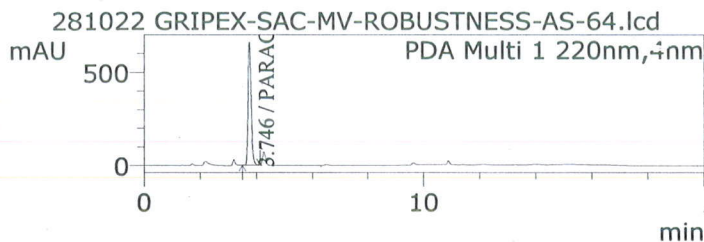
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : GRIPEX-SAC-MV-HTem-AS-SOL-B-01  
Tray# : 2  
Vial# : 24  
Injection Volume : 50  
Data File : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-64.lcd  
Method File : GRIPEX-AS-High tem.lcm  
Batch File : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/31/2022 4:24:41 PM  
Date Processed : 11/2/2022 10:48:33 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 24    | ESS-AS-64.lcd | GRIPEX-SAC-MV-HTem-AS-SOL-B-01 | 3.746  | 4992001 | 4960     | 1.274    |
| 24    | ESS-AS-65.lcd | GRIPEX-SAC-MV-HTem-AS-SOL-B-02 | 3.733  | 4998128 | 4883     | 1.272    |
|       | Average       |                                | 3.740  | 4995064 | 4921     | 1.273    |
|       | %RSD          |                                | 0.246  | 0.087   | 1.100    | 0.101    |

Analysed By

Date :

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02/11/22

Checked By

Date :

*[Signature]*  
02/11/22





# Safetab Life Science

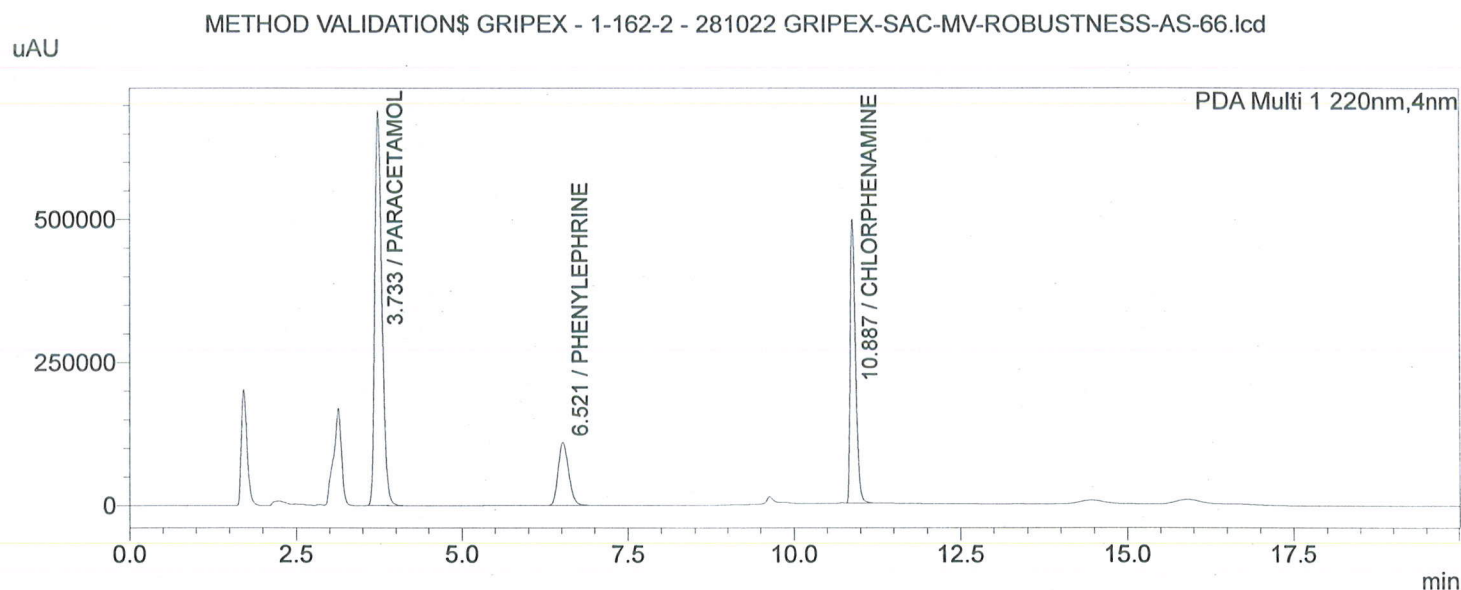
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : ROBUSTNESS-AS  
Sample ID : PARA+PHENYL+CPM-HTem-AS-BKT-STD  
Data Filename : 281022 GRIPEX-SAC-MV-ROBUSTNESS-AS-66.lcd  
Method Filename : GRIPEX-AS-Low flow.lcm  
Batch Filename : 281022 GRIPEX-SAC-MV-AS-ROBUSTNESS.lcb  
Vial # : 2-22  
Injection Volume : 50 uL  
Date Acquired : 10/29/2022 1:56:39 PM  
Date Processed : 10/31/2022 10:39:54 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plale | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.733     | 5140622 | 56.469  | 4961    | 1.258    | --         | --       | PARACETAMOL    |
| 2     | 6.521     | 1229996 | 13.511  | 7262    | 1.182    | 10.76      | --       | PHENYLEPHRINE  |
| 3     | 10.887    | 2732821 | 30.020  | 69936   | 1.413    | 18.55      | --       | CHLORPHENAMINE |
| Total |           | 9103439 | 100.000 |         |          |            |          |                |

Analysed By

Date :

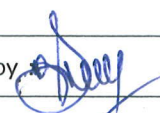
Checked By

Date :

**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

|                     |                |
|---------------------|----------------|
| Name of the Product | GRIPEX SACHETS |
| Batch No            | ST/T/S-1322    |

| S. No | TEST / OBSERVATION / LIMIT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | <p><u>Robustness</u>                      <u>Diluent</u> : 500 ml Buffer : 500 ml methanol.</p> <p><u>Stock Solution Preparation</u></p> <p><u>Stock 1</u> : 65.30g of procetamol WS + 40.11g of qm (WS) in 100 ml of volumetric flask add 70 ml of diluent Sonicate to dissolve and makeup to volume with diluent</p> <p><u>Stock 2</u> : 40.16g of phenylephrine HCl in 100 ml volumetric flask add 150 ml of diluent Sonicate to dissolve and makeup to volume with diluent.</p> <p><u>Standard Preparation</u></p> <p>Each 5 ml of Standard Stock 1) and 2) is 500 ml volumetric flask and makeup to volume with diluent.</p> <p><u>Sample Preparation</u></p> <p>4.5013g of sample in 500 ml volumetric flask add 500 ml of diluent Sonicate for 2 min to dissolve and make up to volume with same diluent. Filter the solution through 0.45 µm PDA filter paper. Use this solution as Solution (A)</p> <p>Further dilute 5 ml of (Sol. A) to 100 ml of diluent. Use this solution as Sol. B.</p> |

|                                                                                                   |                   |                                                                                                   |                   |
|---------------------------------------------------------------------------------------------------|-------------------|---------------------------------------------------------------------------------------------------|-------------------|
| Analyzed by :  | Date : 28/10/2022 | Checked by :  | Date : 28/10/2022 |
|---------------------------------------------------------------------------------------------------|-------------------|---------------------------------------------------------------------------------------------------|-------------------|





# Safetab Life Science

Puducherry- 605 107

Quality control Department

## ====BATCH TABLE=====

Batch Table

| Vial# | Tray | Inj. Vol. | Sample Name   | Sample ID                       | Method File       | Data File                | Report Format      |
|-------|------|-----------|---------------|---------------------------------|-------------------|--------------------------|--------------------|
| 1     | 2    | 50.0      | ROBUSTNESS-AS | BLANK-AS-LWL                    | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-01.lcd | system\DEFAULT.isr |
| 2     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LWL-AS-STD-01   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-02.lcd | system\DEFAULT.isr |
| 2     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LWL-AS-STD-02   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-03.lcd | system\DEFAULT.isr |
| 2     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LWL-AS-STD-03   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-04.lcd | system\DEFAULT.isr |
| 2     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LWL-AS-STD-04   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-05.lcd | system\DEFAULT.isr |
| 2     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LWL-AS-STD-05   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-06.lcd | system\DEFAULT.isr |
| 3     | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LWL-AS-SOL-A-01   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-07.lcd | system\DEFAULT.isr |
| 3     | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LWL-AS-SOL-A-02   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-08.lcd | system\DEFAULT.isr |
| 4     | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LWL-AS-SOL-B-01   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-09.lcd | system\DEFAULT.isr |
| 4     | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LWL-AS-SOL-B-02   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-10.lcd | system\DEFAULT.isr |
| 2     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LWL-AS-BKT-STD  | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-11.lcd | system\DEFAULT.isr |
| 5     | 2    | 50.0      | ROBUSTNESS-AS | BLANK-AS-HWL                    | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-12.lcd | system\DEFAULT.isr |
| 6     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HWL-AS-STD-01   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-13.lcd | system\DEFAULT.isr |
| 6     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HWL-AS-STD-02   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-14.lcd | system\DEFAULT.isr |
| 6     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HWL-AS-STD-03   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-15.lcd | system\DEFAULT.isr |
| 6     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HWL-AS-STD-04   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-16.lcd | system\DEFAULT.isr |
| 6     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HWL-AS-STD-05   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-17.lcd | system\DEFAULT.isr |
| 7     | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HWL-AS-SOL-A-01   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-18.lcd | system\DEFAULT.isr |
| 7     | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HWL-AS-SOL-A-02   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-19.lcd | system\DEFAULT.isr |
| 8     | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HWL-AS-SOL-B-01   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-20.lcd | system\DEFAULT.isr |
| 8     | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HWL-AS-SOL-B-02   | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-21.lcd | system\DEFAULT.isr |
| 6     | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HWL-AS-BKT-STD  | GRIPEX-AS.lcm     | -MV-ROBUSTNESS-AS-22.lcd | system\DEFAULT.isr |
| 9     | 2    | 50.0      | ROBUSTNESS-AS | BLANK-AS-Low Flow               | X-AS-Low flow.lcm | -MV-ROBUSTNESS-AS-23.lcd | system\DEFAULT.isr |
| 10    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LFlow-AS-STD-01 | X-AS-Low flow.lcm | -MV-ROBUSTNESS-AS-24.lcd | system\DEFAULT.isr |
| 10    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LFlow-AS-STD-02 | X-AS-Low flow.lcm | -MV-ROBUSTNESS-AS-25.lcd | system\DEFAULT.isr |
| 10    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LFlow-AS-STD-03 | X-AS-Low flow.lcm | -MV-ROBUSTNESS-AS-26.lcd | system\DEFAULT.isr |
| 10    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LFlow-AS-STD-04 | X-AS-Low flow.lcm | -MV-ROBUSTNESS-AS-27.lcd | system\DEFAULT.isr |
| 10    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LFlow-AS-STD-05 | X-AS-Low flow.lcm | -MV-ROBUSTNESS-AS-28.lcd | system\DEFAULT.isr |



| Vial# | Tray | Inj. Vol. | Sample Name   | Sample ID                        | Method File        | Data File                | Report Format      |
|-------|------|-----------|---------------|----------------------------------|--------------------|--------------------------|--------------------|
| 11    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LFlow-AS-SOL-A-01  | X-AS-Low flow.lcm  | -MV-ROBUSTNESS-AS-29.lcd | system\DEFAULT.lsr |
| 11    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LFlow-AS-SOL-A-02  | X-AS-Low flow.lcm  | -MV-ROBUSTNESS-AS-30.lcd | system\DEFAULT.lsr |
| 12    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LFlow-AS-SOL-B-01  | X-AS-Low flow.lcm  | -MV-ROBUSTNESS-AS-31.lcd | system\DEFAULT.lsr |
| 12    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LFlow-AS-SOL-B-02  | X-AS-Low flow.lcm  | -MV-ROBUSTNESS-AS-32.lcd | system\DEFAULT.lsr |
| 10    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LFlow-AS-BKT-STD | X-AS-Low flow.lcm  | -MV-ROBUSTNESS-AS-33.lcd | system\DEFAULT.lsr |
| 13    | 2    | 50.0      | ROBUSTNESS-AS | BLANK-AS-High Flow               | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-34.lcd | system\DEFAULT.lsr |
| 14    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HFlow-AS-STD-01  | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-35.lcd | system\DEFAULT.lsr |
| 14    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HFlow-AS-STD-02  | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-36.lcd | system\DEFAULT.lsr |
| 14    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HFlow-AS-STD-03  | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-37.lcd | system\DEFAULT.lsr |
| 14    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HFlow-AS-STD-04  | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-38.lcd | system\DEFAULT.lsr |
| 14    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HFlow-AS-STD-05  | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-39.lcd | system\DEFAULT.lsr |
| 15    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HFlow-AS-SOL-A-01  | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-40.lcd | system\DEFAULT.lsr |
| 15    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HFlow-AS-SOL-A-02  | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-41.lcd | system\DEFAULT.lsr |
| 16    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HFlow-AS-SOL-B-01  | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-42.lcd | system\DEFAULT.lsr |
| 16    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HFlow-AS-SOL-B-02  | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-43.lcd | system\DEFAULT.lsr |
| 14    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HFlow-AS-BKT-STD | X-AS-High flow.lcm | -MV-ROBUSTNESS-AS-44.lcd | system\DEFAULT.lsr |
| 17    | 2    | 50.0      | ROBUSTNESS-AS | BLANK-AS-Low Tem                 | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-45.lcd | system\DEFAULT.lsr |
| 18    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LTem-AS-STD-01   | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-46.lcd | system\DEFAULT.lsr |
| 18    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LTem-AS-STD-02   | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-47.lcd | system\DEFAULT.lsr |
| 18    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LTem-AS-STD-03   | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-48.lcd | system\DEFAULT.lsr |
| 18    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LTem-AS-STD-04   | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-49.lcd | system\DEFAULT.lsr |
| 18    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LTem-AS-STD-05   | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-50.lcd | system\DEFAULT.lsr |
| 19    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LTem-AS-SOL-A-01   | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-51.lcd | system\DEFAULT.lsr |
| 19    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LTem-AS-SOL-A-02   | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-52.lcd | system\DEFAULT.lsr |
| 20    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LTem-AS-SOL-B-01   | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-53.lcd | system\DEFAULT.lsr |
| 20    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-LTem-AS-SOL-B-02   | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-54.lcd | system\DEFAULT.lsr |
| 18    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-LTem-AS-BKT-STD  | X-AS-Low tem.lcm   | -MV-ROBUSTNESS-AS-55.lcd | system\DEFAULT.lsr |
| 21    | 2    | 50.0      | ROBUSTNESS-AS | BLANK-AS-High Tem                | X-AS-High tem.lcm  | -MV-ROBUSTNESS-AS-56.lcd | system\DEFAULT.lsr |
| 22    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HTem-AS-STD-01   | X-AS-High tem.lcm  | -MV-ROBUSTNESS-AS-57.lcd | system\DEFAULT.lsr |
| 22    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HTem-AS-STD-02   | X-AS-High tem.lcm  | -MV-ROBUSTNESS-AS-58.lcd | system\DEFAULT.lsr |
| 22    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HTem-AS-STD-03   | X-AS-High tem.lcm  | -MV-ROBUSTNESS-AS-59.lcd | system\DEFAULT.lsr |
| 22    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HTem-AS-STD-04   | X-AS-High tem.lcm  | -MV-ROBUSTNESS-AS-60.lcd | system\DEFAULT.lsr |
| 22    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HTem-AS-STD-05   | X-AS-High tem.lcm  | -MV-ROBUSTNESS-AS-61.lcd | system\DEFAULT.lsr |
| 23    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HTem-AS-SOL-A-01   | X-AS-High tem.lcm  | -MV-ROBUSTNESS-AS-62.lcd | system\DEFAULT.lsr |
| 23    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HTem-AS-SOL-A-02   | X-AS-High tem.lcm  | -MV-ROBUSTNESS-AS-63.lcd | system\DEFAULT.lsr |
| 24    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HTem-AS-SOL-B-01   | X-AS-High tem.lcm  | -MV-ROBUSTNESS-AS-64.lcd | system\DEFAULT.lsr |
| 24    | 2    | 50.0      | ROBUSTNESS-AS | GRIPEX-SAC-MV-HTem-AS-SOL-B-02   | X-AS-High tem.lcm  | -MV-ROBUSTNESS-AS-65.lcd | system\DEFAULT.lsr |



| Vial# | Tray | Inj. Vol. | Sample Name   | Sample ID                       | Method File       | Data File                | Report Format      |
|-------|------|-----------|---------------|---------------------------------|-------------------|--------------------------|--------------------|
| 22    | 2    | 50.0      | ROBUSTNESS-AS | PARA+PHENYL+CPM-HTem-AS-BKT-STD | X-AS-High tem.lcm | -MV-ROBUSTNESS-AS-66.lcd | system\DEFAULT.lsr |

Analysed By   
Date : 28/10/12

Checked By   
Date : 27/10/12

**Safetab Life Science ,**

Puducherry - 605 107

**QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

**ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS**

|                |                  |              |             |
|----------------|------------------|--------------|-------------|
| Product Name : | GRIPEX           | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322      | Mfg.Date :   | Sep-22      |
| Parameter :    | SYSTEM PRECISION | Exp.Date :   | To be fixed |

Each 4.5gm of sachet Contains

Paracetamol BP ----- 650mg  
Phenylephrine Hydrochloride BP ----- 10mg  
Chlorphenamine Maleate BP ----- 20mg  
Ascorbic acid BP ----- 50mg

**ASSAY OF PARACETAMOL**

|                         |              |              |              |            |              |                |       |
|-------------------------|--------------|--------------|--------------|------------|--------------|----------------|-------|
| Instrument ID:          | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041 | WS No.:    | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution :     | 65.25        | mg to --->   | 100          | ml to ---> | 5            | ml to --->     | 50    |
| Std.conc (in ppm)-65.25 | 1            | ml to --->   | 1            | ml to ---> | 1            | ml to --->     | 1     |

| No. of injections | Retention time | Area    | Theoretical plate | Tailing factor |
|-------------------|----------------|---------|-------------------|----------------|
| 1                 | 3.812          | 5071091 | 4846              | 1.261          |
| 2                 | 3.811          | 5069883 | 4845              | 1.258          |
| 3                 | 3.809          | 5069892 | 4812              | 1.258          |
| 4                 | 3.818          | 5075239 | 4821              | 1.261          |
| 5                 | 3.812          | 5072826 | 4852              | 1.259          |
| Average           | 3.823          | 5071786 | 4835              | 1.259          |
| RSD %             | 0.089          | 0.045   | Not applicable    | Not applicable |

**ASSAY OF PHENYLEPHRINE HYDROCHLORIDE**

|                        |              |              |              |            |              |                |      |
|------------------------|--------------|--------------|--------------|------------|--------------|----------------|------|
| Instrument ID:         | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041 | WS No.:    | IAARI/WS/344 | % Purity (aib) | 98.9 |
| Standard dilution :    | 40.20        | mg to --->   | 200          | ml to ---> | 5            | ml to --->     | 50   |
| Std.conc (in ppm)-20.1 | 1            | ml to --->   | 1            | ml to ---> | 1            | ml to --->     | 1    |

| No. of injections | Retention time | Area    | Theoretical plate | Tailing factor |
|-------------------|----------------|---------|-------------------|----------------|
| 1                 | 6.773          | 1227523 | 6907              | 1.179          |
| 2                 | 6.754          | 1228106 | 6799              | 1.179          |
| 3                 | 6.771          | 1227976 | 6868              | 1.179          |
| 4                 | 6.754          | 1227441 | 6945              | 1.181          |
| 5                 | 6.768          | 1227183 | 6889              | 1.182          |
| Average           | 6.764          | 1227646 | 6881              | 1.180          |
| RSD %             | 0.134          | 0.031   | Not applicable    | Not applicable |

**ASSAY OF CHLORPHENAMINE MALEATE**

|                         |              |              |              |            |              |                |      |
|-------------------------|--------------|--------------|--------------|------------|--------------|----------------|------|
| Instrument ID:          | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041 | WS No.:    | ST/WS/22/039 | % Purity (aib) | 99.7 |
| Standard dilution :     | 40.23        | mg to --->   | 100          | ml to ---> | 5            | ml to --->     | 50   |
| Std.conc (in ppm)-40.23 | 1            | ml to --->   | 1            | ml to ---> | 1            | ml to --->     | 1    |

| No. of injections | Retention time | Area    | Theoretical plate | Tailing factor |
|-------------------|----------------|---------|-------------------|----------------|
| 1                 | 10.872         | 2710886 | 70343             | 1.424          |
| 2                 | 10.875         | 2719096 | 67161             | 1.420          |
| 3                 | 10.869         | 2712960 | 68536             | 1.420          |
| 4                 | 10.872         | 2719453 | 69958             | 1.425          |
| 5                 | 10.871         | 2710557 | 69928             | 1.427          |
| Average           | 10.872         | 2714590 | 69185             | 1.423          |
| RSD %             | 0.020          | 0.161   | Not applicable    | Not applicable |

Results :

| System suitability Parameters | Paracetamol | Phenylephrine | Chlorphenamine |
|-------------------------------|-------------|---------------|----------------|
| 1) % RSD                      | 0.045       | 0.031         | 0.161          |
| 2) Theoretical plate          | 4835        | 6881          | 69185          |
| 3) Tailing factor             | 1.259       | 1.180         | 1.423          |

Acceptance criteria:

- 1) % RSD of area of Paracetamol, Phenylephrine and Chlorphenamine peak in five replicate standard injections should not be more than 2.0.
- 2) Theoretical plate for Paracetamol, Phenylephrine and Chlorphenamine peak in standard injection should not be less than 2000.
- 3) Tailing factor for Paracetamol, Phenylephrine and Chlorphenamine peak in standard injection should not be more than 2.0.

Analysed by : C. ALBIN JOSE  
Date : 01-11-2022

Checked by :  
Date : 01/11/2022





QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|                |                                                         |              |             |
|----------------|---------------------------------------------------------|--------------|-------------|
| Product Name : | GRIPEX                                                  | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322                                             | Mfg.Date :   | Sep-22      |
| Parameter :    | PRECISION (METHOD PRECISION and INTERMEDIATE PRECISION) | Exp.Date :   | To be fixed |

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE

|                |              |              |                 |         |              |                |       |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041&30 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|                |              |              |                 | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9  |
|                |              |              |                 | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7  |

|                         |       |           |     |           |   |           |    |
|-------------------------|-------|-----------|-----|-----------|---|-----------|----|
| Paracetamol Std.Dil:    | 65.25 | mg to --- | 100 | ml to --- | 5 | ml to --- | 50 |
| Std.conc (in ppm)-65.25 | 1     | ml to --- | 1   | ml to --- | 1 | ml to --- | 1  |

|                        |       |           |     |           |   |           |    |
|------------------------|-------|-----------|-----|-----------|---|-----------|----|
| Phenylephrine Std.Dil: | 40.20 | mg to --- | 200 | ml to --- | 5 | ml to --- | 50 |
| Std.conc (in ppm)-20.1 | 1     | ml to --- | 1   | ml to --- | 1 | ml to --- | 1  |

|                         |       |           |     |           |   |           |    |
|-------------------------|-------|-----------|-----|-----------|---|-----------|----|
| Chlorphenamine Std:     | 40.23 | mg to --- | 100 | ml to --- | 5 | ml to --- | 50 |
| Std.conc (in ppm)-40.23 | 1     | ml to --- | 1   | ml to --- | 1 | ml to --- | 1  |

|                  |            |           |     |           |   |           |     |
|------------------|------------|-----------|-----|-----------|---|-----------|-----|
| Test dilution .: | One Sachet | mg to --- | 500 | ml to --- | 5 | ml to --- | 100 |
|                  | 1          | ml to --- | 1   | ml to --- | 1 | ml to --- | 1   |

| METHOD PRECISION   |                        |                          |                           | INTERMEDIATE PRECISION |                          |                           | CUMMULATIVE PRECISION  |                          |                           |
|--------------------|------------------------|--------------------------|---------------------------|------------------------|--------------------------|---------------------------|------------------------|--------------------------|---------------------------|
| No. of preparation | Paracetamol assay in % | Phenylephrine assay in % | Chlorphenamine assay in % | Paracetamol assay in % | Phenylephrine assay in % | Chlorphenamine assay in % | Paracetamol assay in % | Phenylephrine assay in % | Chlorphenamine assay in % |
| 1                  | 101.0                  | 95.2                     | 99.7                      | 97.2                   | 96.2                     | 99.6                      | 98.3                   | 98.2                     | 99.9                      |
| 2                  | 98.7                   | 96.0                     | 98.7                      | 97.9                   | 98.6                     | 98.0                      |                        |                          |                           |
| 3                  | 97.4                   | 97.3                     | 103.2                     | 97.6                   | 101.9                    | 98.6                      |                        |                          |                           |
| 4                  | 98.9                   | 99.0                     | 101.5                     | 97.5                   | 99.6                     | 98.2                      | % RSD                  |                          |                           |
| 5                  | 99.5                   | 98.2                     | 101.9                     | 97.4                   | 99.7                     | 99.3                      | 1.147                  | 1.886                    | 1.854                     |
| 6                  | 98.8                   | 98.0                     | 102.0                     | 97.7                   | 98.8                     | 97.5                      |                        |                          |                           |
| Average            | 99.1                   | 97.3                     | 101.2                     | 97.6                   | 99.1                     | 98.53                     |                        |                          |                           |
| % RSD              | 1.189                  | 1.475                    | 1.637                     | 0.249                  | 1.871                    | 0.811                     |                        |                          |                           |

Results:

For Paracetamol

- 1)%RSD for Assay of six preparation of Method precision
- 2)%RSD for Assay of six preparation of Intermediate precision
- 3)Cumulative %RSD for Assay of twelve preparations

1.19

0.25

1.15

For Phenylephrine Hydrochloride

- 1)%RSD for Assay of six preparation of Method precision
- 2)%RSD for Assay of six preparation of Intermediate precision
- 3)Cumulative %RSD for Assay of twelve preparations

1.47

1.87

1.89

For Chlorphenamine Maleate

- 1)%RSD for Assay of six preparation of Method precision
- 2)%RSD for Assay of six preparation of Intermediate precision
- 3)Cumulative %RSD for Assay of twelve preparations

1.64

0.81

1.85

Acceptance criteria:

- 1) % RSD for assay of six preparations should not be more than 2.0.
- 2) Cumulative % RSD for assay of twelve preparations (i.e. method precision and intermediate precision) should not be more than 2.0.

Analysed by :

C.ALBIN JOSE

Date :

15-11-2022

Checked by :

Date :





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                       |            |             |
|--------------|---------------------------------------|------------|-------------|
| Product Name | GRIPEX                                | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                           | Mfg.Date   | Sep-22      |
| Stage        | METHOD PRECISION (TEST PREPARATION-1) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:

Paracetamol BP ----- 650mg

Chlorphenamine Maleate BP ----- 20mg

Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |              |             |             |                  |         |             |              |                |       |
|----------------------------|--------------|-------------|-------------|------------------|---------|-------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/039 |             | Balance ID: | ST/QC/EQ/041&030 |         | WS No.:     | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.25        | mg to ----> | 100         | ml to ---->      | 5       | ml to ----> | 50           |                |       |
| Std.conc (in ppm)-65.25    | 1            | ml to ----> | 1           | ml to ---->      | 1       | ml to ----> | 1            |                |       |
| Test dilution .:           | Granule/Pow. | mg to ----> | 500         | ml to ---->      | 5       | ml to ----> | 100          |                |       |
| Test conc(in ppm)-65.02166 | 1            | ml to ----> | 1           | ml to ---->      | 1       | ml to ----> | 1            |                |       |
| Conversion factor :        | 1.0000       |             |             |                  |         |             |              |                |       |
| Labeled claim :            | 650          | mg          |             |                  |         |             |              |                |       |
| Average weight :           | 4500         | mg          |             |                  |         |             |              |                |       |
| System suitability         | 1            | 2           | 3           | 4                | 5       | MEAN        | S.D          | RSD in %       |       |
| Paracetamol                | 5072934      | 5073620     | 5071231     | 5074708          | 5097031 | 5077905     | 10766        | 0.212          |       |
| With Bracketing std.       | 5100337      | 5097926     |             |                  |         | 5083970     | 13603        | 0.268          |       |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.50                   | 5112367     | 656.71               | 101.0        |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                             |              |            |         |            |         |              |                |          |
|-----------------------------|--------------|------------|---------|------------|---------|--------------|----------------|----------|
|                             |              |            |         |            | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9     |
| Standard dilution.:         | 40.20        | mg to ---> | 200     | ml to ---> | 5       | ml to --->   | 50             |          |
| Std.conc (in ppm)-20.1      | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to --->   | 1              |          |
| Test dilution.:             | Granule/Pow. | mg to ---> | 500     | ml to ---> | 1       | ml to --->   | 1              |          |
| Test conc (in ppm)-20.00666 | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to --->   | 1              |          |
| Conversion factor :         | 1.0000       |            |         |            |         |              |                |          |
| Labeled claim :             | 10           | mg         |         |            |         |              |                |          |
| System suitability          | 1            | 2          | 3       | 4          | 5       | MEAN         | S.D            | RSD in % |
| Phenylephrine HCL           | 1226814      | 1226746    | 1228435 | 1227662    | 1229731 | 1227878      | 1245           | 0.101    |
| With Bracketing std.        | 1229340      | 1234315    |         |            |         | 1229006      | 2609.8         | 0.212    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.50                   | 1175910     | 9.52                 | 95.2         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|                            |              |            |         |            |         |              |                |          |
|----------------------------|--------------|------------|---------|------------|---------|--------------|----------------|----------|
|                            |              |            |         |            | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7     |
| Standard dilution.:        | 40.23        | mg to ---> | 100     | ml to ---> | 5       | ml to --->   | 50             |          |
| Std.conc (in ppm)-40.23    | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to --->   | 1              |          |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500     | ml to ---> | 1       | ml to --->   | 1              |          |
| Test conc(in ppm)-40.01333 | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to --->   | 1              |          |
| Conversion factor :        | 1.0000       |            |         |            |         |              |                |          |
| Labeled claim :            | 20           | mg         |         |            |         |              |                |          |
| System suitability         | 1            | 2          | 3       | 4          | 5       | MEAN         | S.D            | RSD in % |
| Chlorphenamine maleate     | 2715254      | 2714748    | 2713248 | 2714366    | 2714843 | 2714492      | 764            | 0.028    |
| With Bracketing std.       | 2721365      | 2726530    |         |            |         | 2717193      | 4889           | 0.180    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.50                   | 2698552     | 19.93                | 99.7         |

Assay limit :90.0% to 110.0%

Calculation formula :

|                     |                                                                          |
|---------------------|--------------------------------------------------------------------------|
| Assay in mg /Sachet | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt |
|                     | Standard area x sample dilution x 100                                    |

|            |                          |
|------------|--------------------------|
| Assay in % | Assay in mg/Sachet x 100 |
|            | Labeled claim            |

Analysed by :

CALBIN JOSE

Date :

01-11-2022

Checked by :

Date:

01/11/2022





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                       |            |             |  |
|--------------|---------------------------------------|------------|-------------|--|
| Title        |                                       |            |             |  |
| Product Name | GRIPEX                                | Batch size | 500 SACHETS |  |
| Batch Number | ST/T/S-1322                           | Mfg.Date   | Sep-22      |  |
| Stage        | METHOD PRECISION (TEST PREPARATION-2) | Exp.Date   | To be fixed |  |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |              |             |                  |            |              |                |       |
|----------------------------|--------------|-------------|------------------|------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/039 | Balance ID: | ST/QC/EQ/041&030 | WS No.:    | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.25        | mg to --->  | 100              | ml to ---> | 5            | ml to --->     | 50    |
| Std.conc (in ppm)-65.25    | 1            | ml to --->  | 1                | ml to ---> | 1            | ml to --->     | 1     |
| Test dilution.:            | Granule/Pow. | mg to --->  | 500              | ml to ---> | 5            | ml to --->     | 100   |
| Test conc(in ppm)-64.99855 | 1            | ml to --->  | 1                | ml to ---> | 1            | ml to --->     | 1     |

Conversion factor : 1.0000

Labeled claim : 650 mg

Average weight : 4500 mg

|                      |         |         |         |         |         |         |       |          |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Paracetamol          | 5072934 | 5073620 | 5071231 | 5074708 | 5097031 | 5077905 | 10766 | 0.212    |
| With Bracketing std. | 5100337 | 5097926 |         |         |         | 5083970 | 13603 | 0.268    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4499.90                   | 4990585     | 641.29               | 98.7         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                             |              |            |     |            |         |              |                |      |
|-----------------------------|--------------|------------|-----|------------|---------|--------------|----------------|------|
|                             |              |            |     |            | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
| Standard dilution.:         | 40.23        | mg to ---> | 200 | ml to ---> | 5       | ml to --->   | 50             |      |
| Std.conc (in ppm)-20.115    | 1            | ml to ---> | 1   | ml to ---> | 1       | ml to --->   | 1              |      |
| Test dilution.:             | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1       | ml to --->   | 1              |      |
| Test conc (in ppm)-19.99955 | 1            | ml to ---> | 1   | ml to ---> | 1       | ml to --->   | 1              |      |

Conversion factor : 1.0000

Labeled claim : 10 mg

|                      |         |         |         |         |         |         |        |          |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
| Phenylephrine HCL    | 1226814 | 1226746 | 1228435 | 1227662 | 1229731 | 1227878 | 1245   | 0.101    |
| With Bracketing std. | 1229340 | 1234315 |         |         |         | 1229006 | 2609.8 | 0.212    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4499.90                   | 1185355     | 9.60                 | 96.0         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|                            |              |            |     |            |         |              |                |      |
|----------------------------|--------------|------------|-----|------------|---------|--------------|----------------|------|
|                            |              |            |     |            | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
| Standard dilution.:        | 40.23        | mg to ---> | 100 | ml to ---> | 5       | ml to --->   | 50             |      |
| Std.conc (in ppm)-40.23    | 1            | ml to ---> | 1   | ml to ---> | 1       | ml to --->   | 1              |      |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1       | ml to --->   | 1              |      |
| Test conc(in ppm)-39.99911 | 1            | ml to ---> | 1   | ml to ---> | 1       | ml to --->   | 1              |      |

Conversion factor : 1.0000

Labeled claim : 20 mg

|                        |         |         |         |         |         |         |      |          |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
| Chlorphenamine maleate | 2715254 | 2714748 | 2713248 | 2714366 | 2714843 | 2714492 | 764  | 0.028    |
| With Bracketing std.   | 2721365 | 2726530 |         |         |         | 2717193 | 4889 | 0.180    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4499.90                   | 2671276     | 19.74                | 98.7         |

Assay limit :90.0% to 110.0%

Calculation formula :

Assay in mg /Sachet =  $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$

Assay in %

Assay in mg/Sachet x 100  
Labeled claim

Analysed by :

C.ALBIN JOSE

Date :

01-11-2022

Checked by :

Date :





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

| Title                                                                                                                                               |                                                                          | ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS |                      |                  |         |                          |              |                |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------|----------------------|------------------|---------|--------------------------|--------------|----------------|------------------------------|
| Product Name                                                                                                                                        | GRIPEX                                                                   |                                                                                      |                      |                  |         | Batch size               | 500 SACHETS  |                |                              |
| Batch Number                                                                                                                                        | ST/T/S-1322                                                              |                                                                                      |                      |                  |         | Mfg.Date                 | Sep-22       |                |                              |
| Stage                                                                                                                                               | METHOD PRECISION (TEST PREPARATION-3)                                    |                                                                                      |                      |                  |         | Exp.Date                 | To be fixed  |                |                              |
| Each 4500 mg of Sachet contains:<br>Paracetamol BP ----- 650mg<br>Chlorphenamine Maleate BP ----- 20mg<br>Phenylephrine Hydrochloride BP ----- 10mg |                                                                          |                                                                                      |                      |                  |         |                          |              |                |                              |
| ASSAY OF PARACETAMOL                                                                                                                                |                                                                          |                                                                                      |                      |                  |         |                          |              |                |                              |
| Instrument ID:                                                                                                                                      | ST/QC/EQ/039                                                             |                                                                                      | Balance ID:          | ST/QC/EQ/041&030 |         | WS No.:                  | ST/WS/22/011 | % Purity (aib) | 100.0                        |
| Standard dilution.:                                                                                                                                 | 65.25                                                                    | mg to --->                                                                           | 100                  | ml to --->       | 5       | ml to --->               | 50           |                |                              |
| Std.conc (in ppm)-65.25                                                                                                                             | 1                                                                        | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->               | 1            |                |                              |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                             | mg to --->                                                                           | 500                  | ml to --->       | 5       | ml to --->               | 100          |                |                              |
| Test conc(in ppm)-65.03611                                                                                                                          | 1                                                                        | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->               | 1            |                |                              |
| Conversion factor :                                                                                                                                 | 1.0000                                                                   |                                                                                      |                      |                  |         |                          |              |                |                              |
| Labeled claim :                                                                                                                                     | 650                                                                      | mg                                                                                   |                      |                  |         |                          |              |                |                              |
| Average weight :                                                                                                                                    | 4500                                                                     | mg                                                                                   |                      |                  |         |                          |              |                |                              |
| System suitability                                                                                                                                  | 1                                                                        | 2                                                                                    | 3                    | 4                | 5       | MEAN                     | S.D          | RSD in %       |                              |
| Paracetamol                                                                                                                                         | 5072934                                                                  | 5073620                                                                              | 5071231              | 5074708          | 5097031 | 5077905                  | 10766        | 0.212          |                              |
| With Bracketing std.                                                                                                                                | 5100337                                                                  | 5097926                                                                              |                      |                  |         | 5083970                  | 13603        | 0.268          |                              |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                | Sample Area                                                                          | Content in mg/Sachet | Content in %     |         |                          |              |                |                              |
| 1                                                                                                                                                   | 4502.50                                                                  | 4929472                                                                              | 633.07               | 97.4             |         |                          |              |                | Assay limit :90.0% to 110.0% |
| ASSAY OF PHENYLEPHRINE HYDROCHLORIDE                                                                                                                |                                                                          |                                                                                      |                      |                  |         |                          |              |                |                              |
|                                                                                                                                                     |                                                                          |                                                                                      |                      |                  |         | WS No.:                  | IAARI/WS/344 | % Purity (aib) | 98.9                         |
| Standard dilution.:                                                                                                                                 | 40.23                                                                    | mg to --->                                                                           | 200                  | ml to --->       | 5       | ml to --->               | 50           |                |                              |
| Std.conc (in ppm)-20.115                                                                                                                            | 1                                                                        | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->               | 1            |                |                              |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                             | mg to --->                                                                           | 500                  | ml to --->       | 1       | ml to --->               | 1            |                |                              |
| Test conc (in ppm)-20.01111                                                                                                                         | 1                                                                        | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->               | 1            |                |                              |
| Conversion factor :                                                                                                                                 | 1.0000                                                                   |                                                                                      |                      |                  |         |                          |              |                |                              |
| Labeled claim :                                                                                                                                     | 10                                                                       | mg                                                                                   |                      |                  |         |                          |              |                |                              |
| System suitability                                                                                                                                  | 1                                                                        | 2                                                                                    | 3                    | 4                | 5       | MEAN                     | S.D          | RSD in %       |                              |
| Phenylephrine HCL                                                                                                                                   | 1226814                                                                  | 1226746                                                                              | 1228435              | 1227662          | 1229731 | 1227878                  | 1245         | 0.101          |                              |
| With Bracketing std.                                                                                                                                | 1229340                                                                  | 1234315                                                                              |                      |                  |         | 1229006                  | 2609.8       | 0.212          |                              |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                | Sample Area                                                                          | Content in mg/Sachet | Content in %     |         |                          |              |                |                              |
| 1                                                                                                                                                   | 4502.50                                                                  | 1201461                                                                              | 9.73                 | 97.3             |         |                          |              |                | Assay limit :90.0% to 110.0% |
| ASSAY OF CHLORPHENAMINE MALEATE                                                                                                                     |                                                                          |                                                                                      |                      |                  |         |                          |              |                |                              |
|                                                                                                                                                     |                                                                          |                                                                                      |                      |                  |         | WS No.:                  | ST/WS/22/039 | % Purity (aib) | 99.7                         |
| Standard dilution.:                                                                                                                                 | 40.23                                                                    | mg to --->                                                                           | 100                  | ml to --->       | 5       | ml to --->               | 50           |                |                              |
| Std.conc (in ppm)-40.23                                                                                                                             | 1                                                                        | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->               | 1            |                |                              |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                             | mg to --->                                                                           | 500                  | ml to --->       | 1       | ml to --->               | 1            |                |                              |
| Test conc(in ppm)-40.02222                                                                                                                          | 1                                                                        | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->               | 1            |                |                              |
| Conversion factor :                                                                                                                                 | 1.0000                                                                   |                                                                                      |                      |                  |         |                          |              |                |                              |
| Labeled claim :                                                                                                                                     | 20                                                                       | mg                                                                                   |                      |                  |         |                          |              |                |                              |
| System suitability                                                                                                                                  | 1                                                                        | 2                                                                                    | 3                    | 4                | 5       | MEAN                     | S.D          | RSD in %       |                              |
| Chlorphenamine maleate                                                                                                                              | 2715254                                                                  | 2714748                                                                              | 2713248              | 2714366          | 2714843 | 2714492                  | 764          | 0.028          |                              |
| With Bracketing std.                                                                                                                                | 2721365                                                                  | 2726530                                                                              |                      |                  |         | 2717193                  | 4889         | 0.180          |                              |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                | Sample Area                                                                          | Content in mg/Sachet | Content in %     |         |                          |              |                |                              |
| 1                                                                                                                                                   | 4502.50                                                                  | 2796614                                                                              | 20.65                | 103.2            |         |                          |              |                | Assay limit :90.0% to 110.0% |
| Calculation formula :                                                                                                                               |                                                                          |                                                                                      |                      |                  |         |                          |              |                |                              |
| Assay in mg /Sachet                                                                                                                                 | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt |                                                                                      |                      |                  |         | Assay in %               |              |                |                              |
|                                                                                                                                                     | Standard area x sample dilution x 100                                    |                                                                                      |                      |                  |         | Assay in mg/Sachet x 100 |              |                |                              |
|                                                                                                                                                     |                                                                          |                                                                                      |                      |                  |         | Labeled claim            |              |                |                              |
| Analysed by :                                                                                                                                       | C.ALBIN JOSE                                                             |                                                                                      |                      |                  |         |                          |              |                |                              |
| Date :                                                                                                                                              | 01-11-2022                                                               |                                                                                      |                      |                  |         |                          |              |                |                              |
| Checked by :                                                                                                                                        | [Signature]                                                              |                                                                                      |                      |                  |         |                          |              |                |                              |
| Date :                                                                                                                                              | 01/11/2022                                                               |                                                                                      |                      |                  |         |                          |              |                |                              |





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QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                       |            |             |
|--------------|---------------------------------------|------------|-------------|
| Product Name | GRIPEX                                | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                           | Mfg.Date   | Sep-22      |
| Stage        | METHOD PRECISION (TEST PREPARATION-4) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |              |             |                  |            |              |                |       |
|----------------------------|--------------|-------------|------------------|------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/039 | Balance ID: | ST/QC/EQ/041&030 | WS No.:    | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.25        | mg to --->  | 100              | ml to ---> | 5            | ml to --->     | 50    |
| Std.conc (in ppm)-65.25    | 1            | ml to --->  | 1                | ml to ---> | 1            | ml to --->     | 1     |
| Test dilution.:            | Granule/Pow. | mg to --->  | 500              | ml to ---> | 5            | ml to --->     | 100   |
| Test conc(in ppm)-65.02166 | 1            | ml to --->  | 1                | ml to ---> | 1            | ml to --->     | 1     |

Conversion factor : 1.0000

Labeled claim : 650 mg

Average weight : 4500 mg

| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| Paracetamol          | 5072934 | 5073620 | 5071231 | 5074708 | 5097031 | 5077905 | 10766 | 0.212    |
| With Bracketing std. | 5100337 | 5097926 |         |         |         | 5083970 | 13603 | 0.268    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.50                   | 5004119     | 642.80               | 98.9         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                            |              |            |     |            |         |              |                |      |
|----------------------------|--------------|------------|-----|------------|---------|--------------|----------------|------|
|                            |              |            |     |            | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
| Standard dilution.:        | 40.23        | mg to ---> | 200 | ml to ---> | 5       | ml to --->   | 50             |      |
| Std.conc (in ppm)-20.115   | 1            | ml to ---> | 1   | ml to ---> | 1       | ml to --->   | 1              |      |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1       | ml to --->   | 1              |      |
| Test conc (in ppm)-20.0066 | 1            | ml to ---> | 1   | ml to ---> | 1       | ml to --->   | 1              |      |

Conversion factor : 1.0000

Labeled claim : 10 mg

| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| Phenylephrine HCL    | 1226814 | 1226746 | 1228435 | 1227662 | 1229731 | 1227878 | 1245   | 0.101    |
| With Bracketing std. | 1229340 | 1234315 |         |         |         | 1229006 | 2609.8 | 0.212    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.50                   | 1222173     | 9.90                 | 99.0         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|                            |              |            |     |            |         |              |                |      |
|----------------------------|--------------|------------|-----|------------|---------|--------------|----------------|------|
|                            |              |            |     |            | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
| Standard dilution.:        | 40.23        | mg to ---> | 100 | ml to ---> | 5       | ml to --->   | 50             |      |
| Std.conc (in ppm)-40.23    | 1            | ml to ---> | 1   | ml to ---> | 1       | ml to --->   | 1              |      |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1       | ml to --->   | 1              |      |
| Test conc(in ppm)-40.01333 | 1            | ml to ---> | 1   | ml to ---> | 1       | ml to --->   | 1              |      |

Conversion factor : 1.0000

Labeled claim : 20 mg

| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| Chlorphenamine maleate | 2715254 | 2714748 | 2713248 | 2714366 | 2714843 | 2714492 | 764  | 0.028    |
| With Bracketing std.   | 2721365 | 2726530 |         |         |         | 2717193 | 4889 | 0.180    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.50                   | 2747809     | 20.29                | 101.5        |

Assay limit :90.0% to 110.0%

Calculation formula :

Assay in mg /Sachet =  $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$

Assay in %

Assay in mg/Sachet x 100  
Labeled claim

Analysed by :

C.ALBIN JOSE

Date :

01-11-2022

Checked by  
Date: 01/11/2022





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                       |  |  |  |            |             |
|--------------|---------------------------------------|--|--|--|------------|-------------|
| Title        |                                       |  |  |  |            |             |
| Product Name | GRIPEX                                |  |  |  | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                           |  |  |  | Mfg. Date  | Sep-22      |
| Stage        | METHOD PRECISION (TEST PREPARATION-5) |  |  |  | Exp. Date  | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                             |              |             |                  |            |              |                |       |
|-----------------------------|--------------|-------------|------------------|------------|--------------|----------------|-------|
| Instrument ID:              | ST/QC/EQ/039 | Balance ID: | ST/QC/EQ/041&030 | WS No.:    | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:         | 65.25        | mg to --->  | 100              | ml to ---> | 5            | ml to --->     | 50    |
| Std. conc (in ppm)-65.25    | 1            | ml to --->  | 1                | ml to ---> | 1            | ml to --->     | 1     |
| Test dilution.:             | Granule/Pow. | mg to --->  | 500              | ml to ---> | 5            | ml to --->     | 100   |
| Test conc (in ppm)-65.01877 | 1            | ml to --->  | 1                | ml to ---> | 1            | ml to --->     | 1     |

Conversion factor : 1.0000

Labeled claim : 650 mg

Average weight : 4500 mg

| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| Paracetamol          | 5072934 | 5073620 | 5071231 | 5074708 | 5097031 | 5077905 | 10766 | 0.212    |
| With Bracketing std. | 5100337 | 5097926 |         |         |         | 5083970 | 13603 | 0.268    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.30                   | 5034620     | 646.75               | 99.5         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                            |              |            |     |            |   |            |              |                |      |
|----------------------------|--------------|------------|-----|------------|---|------------|--------------|----------------|------|
|                            |              |            |     |            |   | WS No.:    | IAARI/WS/344 | % Purity (aib) | 98.9 |
| Standard dilution.:        | 40.23        | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-20.115   | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test dilution .:           | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test.conc (in ppm)-20.0057 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |

Conversion factor : 1.0000

Labeled claim : 10 mg

| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| Phenylephrine HCL    | 1226814 | 1226746 | 1228435 | 1227662 | 1229731 | 1227878 | 1245   | 0.101    |
| With Bracketing std. | 1229340 | 1234315 |         |         |         | 1229006 | 2609.8 | 0.212    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.30                   | 1212269     | 9.82                 | 98.2         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|                            |              |            |     |            |   |            |              |                |      |
|----------------------------|--------------|------------|-----|------------|---|------------|--------------|----------------|------|
|                            |              |            |     |            |   | WS No.:    | ST/WS/22/039 | % Purity (aib) | 99.7 |
| Standard dilution.:        | 40.23        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-40.23    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test dilution .:           | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test conc(in ppm)-40.01155 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |

Conversion factor : 1.0000

Labeled claim : 20 mg

| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| Chlorphenamine maleate | 2715254 | 2714748 | 2713248 | 2714366 | 2714843 | 2714492 | 764  | 0.028    |
| With Bracketing std.   | 2721365 | 2726530 |         |         |         | 2717193 | 4889 | 0.180    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4501.30                   | 2760287     | 20.39                | 101.9        |

Assay limit :90.0% to 110.0%

Calculation formula :

Assay in mg /Sachet =  $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$

Assay in %

Assay in mg/Sachet x 100  
Labeled claim

Analysed by :

C.ALBIN JOSE

Date :

01-11-2022

Checked by :

Date :





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Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                       |            |             |
|--------------|---------------------------------------|------------|-------------|
| Product Name | GRIPEX                                | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                           | Mfg.Date   | Sep-22      |
| Stage        | METHOD PRECISION (TEST PREPARATION-6) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |              |            |             |                  |         |            |              |                |       |
|----------------------------|--------------|------------|-------------|------------------|---------|------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/039 |            | Balance ID: | ST/QC/EQ/041&030 |         | WS No.:    | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.25        | mg to ---> | 100         | ml to --->       | 5       | ml to ---> | 50           |                |       |
| Std.conc (in ppm)-65.25    | 1            | ml to ---> | 1           | ml to --->       | 1       | ml to ---> | 1            |                |       |
| Test dilution .:           | Granule/Pow. | mg to ---> | 500         | ml to --->       | 5       | ml to ---> | 100          |                |       |
| Test conc(in ppm)-65.11555 | 1            | ml to ---> | 1           | ml to --->       | 1       | ml to ---> | 1            |                |       |
| Conversion factor :        | 1.0000       | mg         |             |                  |         |            |              |                |       |
| Labeled claim :            | 650          |            |             |                  |         |            |              |                |       |
| Average weight :           | 4500         |            | mg          |                  |         |            |              |                |       |
| System suitability         | 1            | 2          | 3           | 4                | 5       | MEAN       | S.D          | RSD in %       |       |
| Paracetamol                | 5072934      | 5073620    | 5071231     | 5074708          | 5097031 | 5077905    | 10766        | 0.212          |       |
| With Bracketing std.       | 5100337      | 5097926    |             |                  |         | 5083970    | 13603        | 0.268          |       |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4508.00                   | 5005264     | 642.02               | 98.8         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                            |              |            |         |            |         |            |              |                |      |
|----------------------------|--------------|------------|---------|------------|---------|------------|--------------|----------------|------|
|                            |              |            |         |            |         | WS No.:    | IAARI/WS/344 | % Purity (aib) | 98.9 |
| Standard dilution.:        | 40.23        | mg to ---> | 200     | ml to ---> | 5       | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-20.115   | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500     | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Test conc (in ppm)-20.0355 | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Conversion factor :        | 1.0000       |            |         |            |         |            |              |                |      |
| Labeled claim :            | 10           | mg         |         |            |         |            |              |                |      |
| System suitability         | 1            | 2          | 3       | 4          | 5       | MEAN       | S.D          | RSD in %       |      |
| Phenylephrine HCL          | 1226814      | 1226746    | 1228435 | 1227662    | 1229731 | 1227878    | 1245         | 0.101          |      |
| With Bracketing std.       | 1229340      | 1234315    |         |            |         | 1229006    | 2609.8       | 0.212          |      |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4508.00                   | 1211401     | 9.80                 | 98.0         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|                            |              |            |         |            |         |            |              |                |      |
|----------------------------|--------------|------------|---------|------------|---------|------------|--------------|----------------|------|
|                            |              |            |         |            |         | WS No.:    | ST/WS/22/039 | % Purity (aib) | 99.7 |
| Standard dilution.:        | 40.23        | mg to ---> | 100     | ml to ---> | 5       | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-40.23    | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500     | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Test conc(in ppm)-40.07111 | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Conversion factor :        | 1.0000       |            |         |            |         |            |              |                |      |
| Labeled claim :            | 20           | mg         |         |            |         |            |              |                |      |
| System suitability         | 1            | 2          | 3       | 4          | 5       | MEAN       | S.D          | RSD in %       |      |
| Chlorphenamine maleate     | 2715254      | 2714748    | 2713248 | 2714366    | 2714843 | 2714492    | 764          | 0.028          |      |
| With Bracketing std.       | 2721365      | 2726530    |         |            |         | 2717193    | 4889         | 0.180          |      |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4508.00                   | 2766348     | 20.40                | 102.0        |

Assay limit :90.0% to 110.0%

Calculation formula :

|                     |                                                                          |
|---------------------|--------------------------------------------------------------------------|
| Assay in mg /Sachet | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt |
|                     | Standard area x sample dilution x 100                                    |

Assay in %

|                          |
|--------------------------|
| Assay in mg/Sachet x 100 |
| Labeled claim            |

Analysed by :

C.ALBIN JOSE

Date :

01-11-2022

Checked by :

Date :

01/11/2022

**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

|                     |             |
|---------------------|-------------|
| Name of the Product | GRIPEX      |
| Batch No            | ST/T/S-1322 |

Precision

Diluent Preparation

2000 g of Buffer : 2000 g of methanol.

Standard Stock solution Preparation

Stock sol'n (1)

60.25g of Paracetamol (100) and 40.23g of chlorpheniramine maleate in 100ml volumetric flask added 70ml of diluent Sonicate to dissolve and make up to volume with same diluent.

Stock sol'n (2)

40.23g of Phylephrine HCl (100) in 2000 g of volumetric flask add 150ml of diluent Sonicate to dissolve and make up to volume with diluent.

Standard preparation

Each 50ml of standard Stock solution A or B is 50ml volumetric flask and make up to volume with diluent.

Analyzed by :

*[Signature]*

Date : 29/10/20

Checked by :

*[Signature]*

Date :

29/10/20





# Safetab Life Science

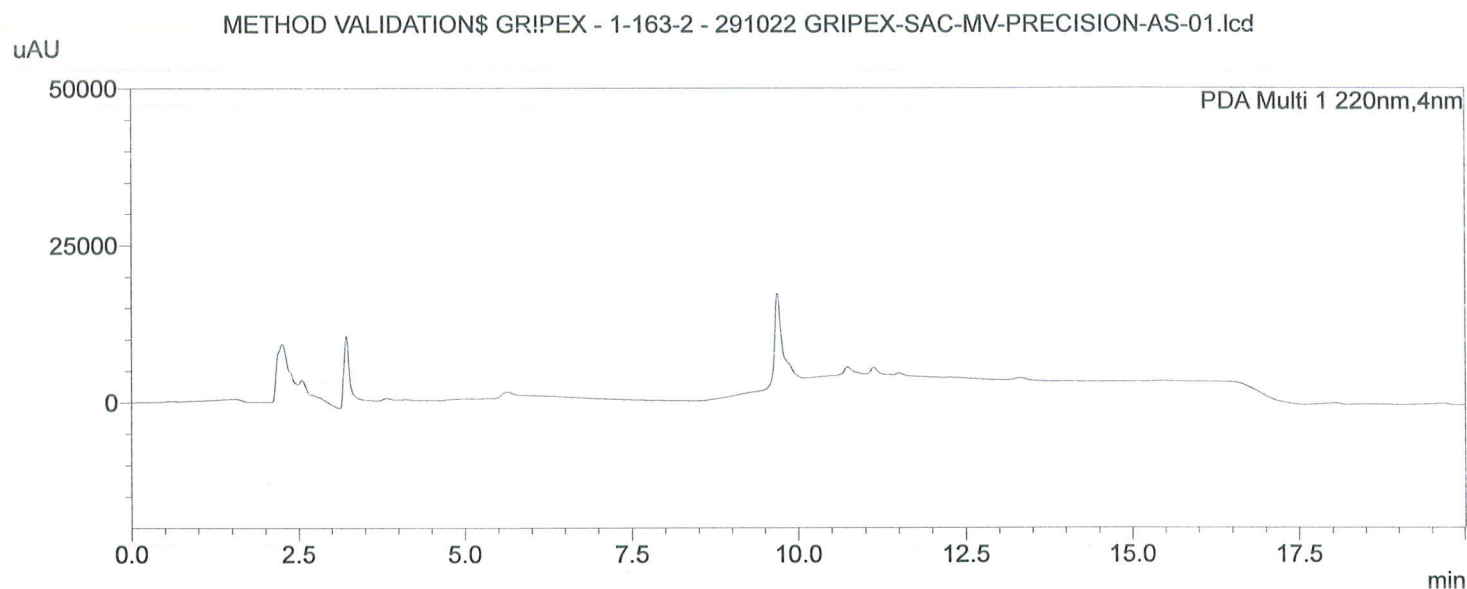
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SYSTEM PRECISION  
Sample ID : BLANK-AS  
Data Filename : 291022 GRIPEX-SAC-MV-PRECISION-AS-01.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Vial # : 1-37  
Injection Volume : 50 uL  
Date Acquired : 10/29/2022 3:35:09 PM  
Date Processed : 11/1/2022 8:26:11 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

*[Signature]*  
01/11/22

Checked By

Date :

*[Signature]*  
01/11/22



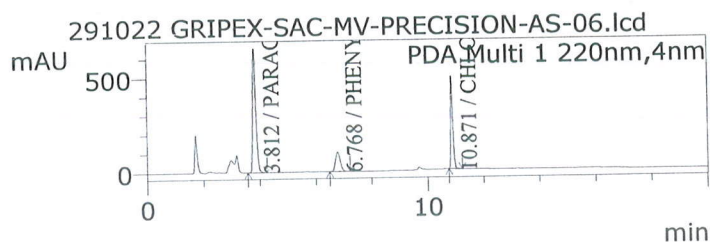
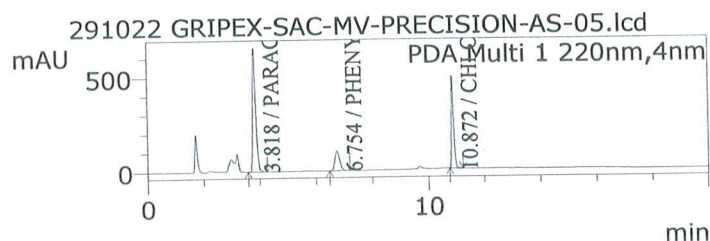
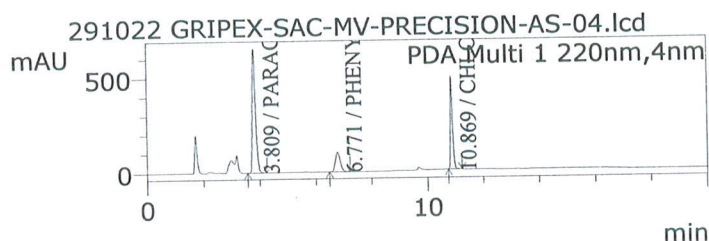
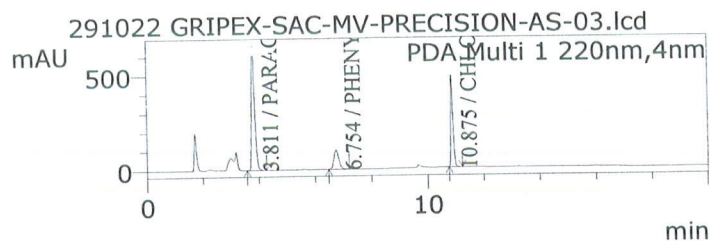
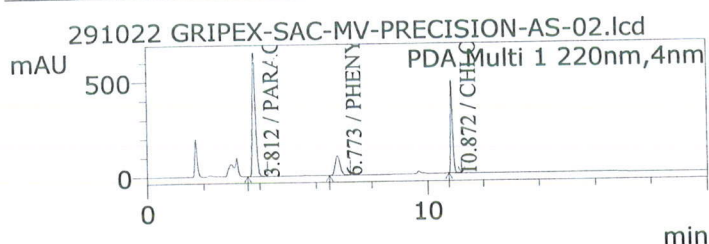
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Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : SYSTEM PRECISION  
Sample ID : PARA+PHENYL+CPM-AS-STD-01  
Tray# : 1  
Vial# : 38  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-02.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 3:55:44 PM  
Date Processed : 11/1/2022 8:26:15 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 38    | ION-AS-02.lcd | PARA+PHENYL+CPM-AS-STD-01 | 3.812  | 5071091 | 4846     | 1.261    |
| 38    | ION-AS-03.lcd | PARA+PHENYL+CPM-AS-STD-02 | 3.811  | 5069883 | 4845     | 1.258    |
| 38    | ION-AS-04.lcd | PARA+PHENYL+CPM-AS-STD-03 | 3.809  | 5069892 | 4812     | 1.258    |
| 38    | ION-AS-05.lcd | PARA+PHENYL+CPM-AS-STD-04 | 3.818  | 5075239 | 4821     | 1.261    |
| 38    | ION-AS-06.lcd | PARA+PHENYL+CPM-AS-STD-05 | 3.812  | 5072826 | 4852     | 1.259    |
|       | Average       |                           | 3.812  | 5071786 | 4835     | 1.260    |
|       | %RSD          |                           | 0.089  | 0.045   | 0.357    | 0.092    |



ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 38    | ION-AS-02.lcd | PARA+PHENYL+CPM-AS-STD-01 | 6.773  | 1227523 | 6907     | 1.179    |
| 38    | ION-AS-03.lcd | PARA+PHENYL+CPM-AS-STD-02 | 6.754  | 1228106 | 6799     | 1.179    |
| 38    | ION-AS-04.lcd | PARA+PHENYL+CPM-AS-STD-03 | 6.771  | 1227976 | 6868     | 1.179    |
| 38    | ION-AS-05.lcd | PARA+PHENYL+CPM-AS-STD-04 | 6.754  | 1227441 | 6945     | 1.181    |
| 38    | ION-AS-06.lcd | PARA+PHENYL+CPM-AS-STD-05 | 6.768  | 1227183 | 6889     | 1.182    |
|       | Average       |                           | 6.764  | 1227646 | 6881     | 1.180    |
|       | %RSD          |                           | 0.134  | 0.031   | 0.787    | 0.132    |

ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 38    | ION-AS-02.lcd | PARA+PHENYL+CPM-AS-STD-01 | 10.872 | 2710886 | 70343    | 1.424    |
| 38    | ION-AS-03.lcd | PARA+PHENYL+CPM-AS-STD-02 | 10.875 | 2719096 | 67161    | 1.420    |
| 38    | ION-AS-04.lcd | PARA+PHENYL+CPM-AS-STD-03 | 10.869 | 2712960 | 68536    | 1.420    |
| 38    | ION-AS-05.lcd | PARA+PHENYL+CPM-AS-STD-04 | 10.872 | 2719453 | 69958    | 1.425    |
| 38    | ION-AS-06.lcd | PARA+PHENYL+CPM-AS-STD-05 | 10.871 | 2710557 | 69928    | 1.427    |
|       | Average       |                           | 10.872 | 2714590 | 69185    | 1.423    |
|       | %RSD          |                           | 0.020  | 0.161   | 1.913    | 0.244    |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

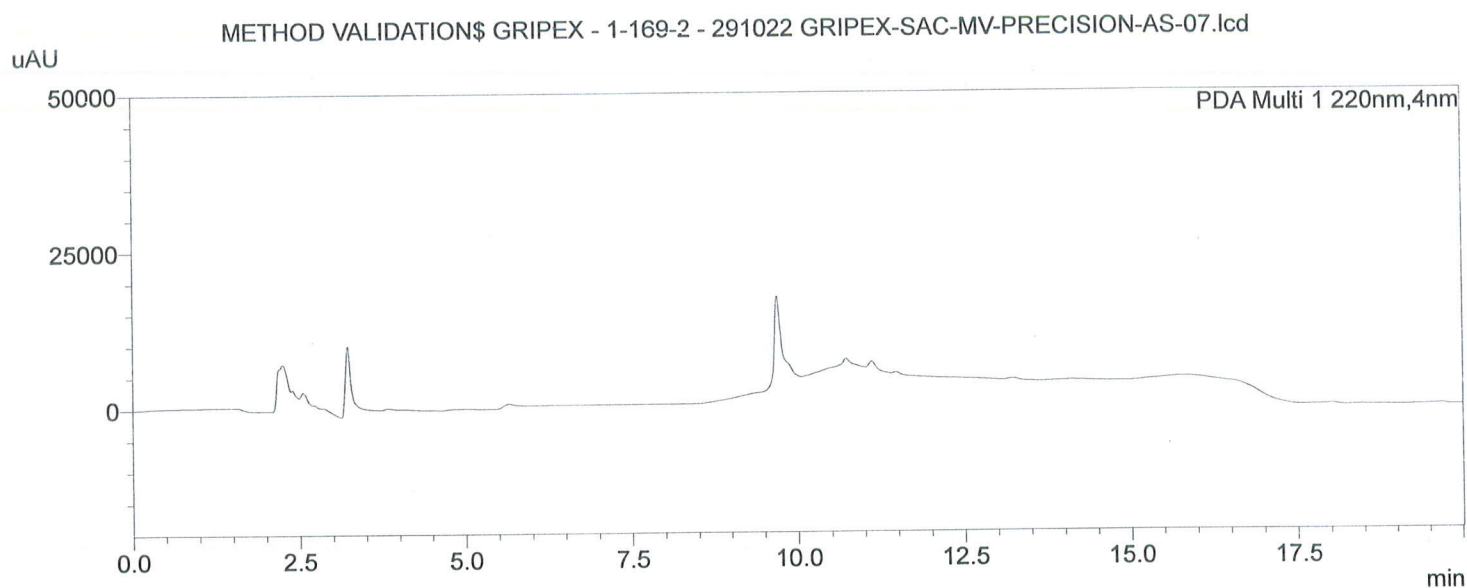
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : BLANK-AS  
Data Filename : 291022 GRIPEX-SAC-MV-PRECISION-AS-07.lcd  
Method Filename : GRIPEX-AS p.lcm  
Batch Filename : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Vial # : 1-39  
Injection Volume : 50 uL  
Date Acquired : 10/29/2022 5:38:40 PM  
Date Processed : 11/1/2022 8:26:30 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :





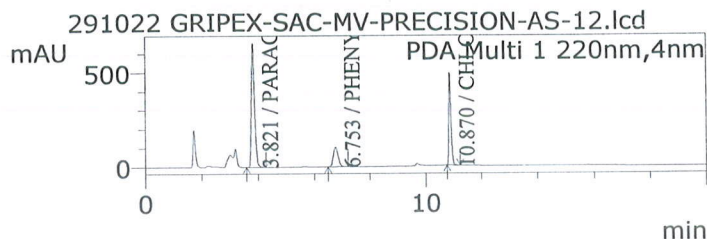
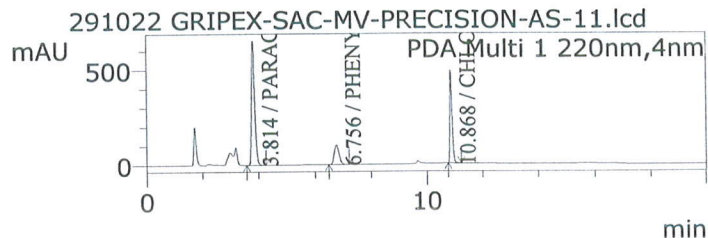
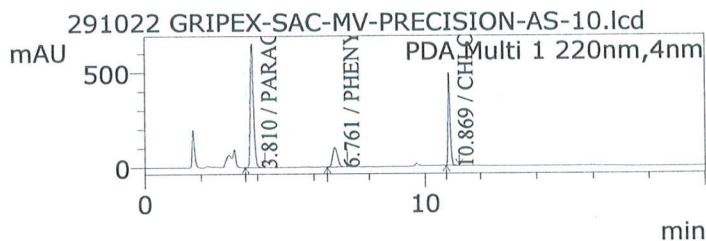
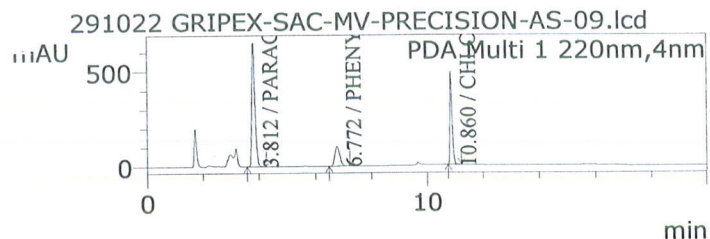
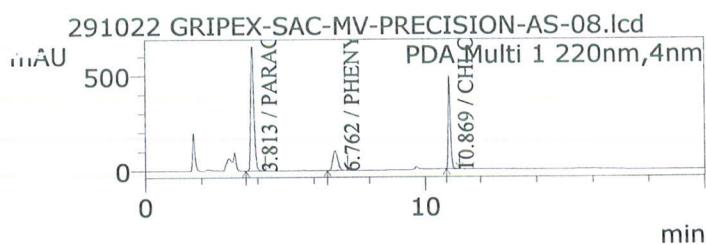
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : PARA+PHENYL+CPM-AS-STD-01  
Tray# : 1  
Vial# : 40  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-08.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 5:59:16 PM  
Date Processed : 11/1/2022 8:26:33 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 40    | ION-AS-08.lcd | PARA+PHENYL+CPM-AS-STD-01 | 3.813  | 5072934 | 4856     | 1.263    |
| 40    | ION-AS-09.lcd | PARA+PHENYL+CPM-AS-STD-02 | 3.812  | 5073620 | 4848     | 1.260    |
| 40    | ION-AS-10.lcd | PARA+PHENYL+CPM-AS-STD-03 | 3.810  | 5071231 | 4842     | 1.259    |
| 40    | ION-AS-11.lcd | PARA+PHENYL+CPM-AS-STD-04 | 3.814  | 5074708 | 4854     | 1.264    |
| 40    | ION-AS-12.lcd | PARA+PHENYL+CPM-AS-STD-05 | 3.821  | 5097031 | 4839     | 1.259    |
|       | Average       |                           | 3.814  | 5077905 | 4848     | 1.261    |
|       | %RSD          |                           | 0.109  | 0.212   | 0.157    | 0.179    |

## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 40    | ION-AS-08.lcd | PARA+PHENYL+CPM-AS-STD-01 | 6.762  | 1226814 | 6925     | 1.178    |
| 40    | ION-AS-09.lcd | PARA+PHENYL+CPM-AS-STD-02 | 6.772  | 1226746 | 6932     | 1.179    |
| 40    | ION-AS-10.lcd | PARA+PHENYL+CPM-AS-STD-03 | 6.761  | 1228435 | 6906     | 1.179    |
| 40    | ION-AS-11.lcd | PARA+PHENYL+CPM-AS-STD-04 | 6.756  | 1227662 | 6919     | 1.183    |
| 40    | ION-AS-12.lcd | PARA+PHENYL+CPM-AS-STD-05 | 6.753  | 1229731 | 6940     | 1.180    |
|       | Average       |                           | 6.761  | 1227878 | 6924     | 1.180    |
|       | %RSD          |                           | 0.105  | 0.101   | 0.183    | 0.157    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 40    | ION-AS-08.lcd | PARA+PHENYL+CPM-AS-STD-01 | 10.869 | 2715254 | 69391    | 1.425    |
| 40    | ION-AS-09.lcd | PARA+PHENYL+CPM-AS-STD-02 | 10.860 | 2714748 | 69847    | 1.430    |
| 40    | ION-AS-10.lcd | PARA+PHENYL+CPM-AS-STD-03 | 10.869 | 2713248 | 69174    | 1.423    |
| 40    | ION-AS-11.lcd | PARA+PHENYL+CPM-AS-STD-04 | 10.868 | 2714366 | 68317    | 1.417    |
| 40    | ION-AS-12.lcd | PARA+PHENYL+CPM-AS-STD-05 | 10.870 | 2714843 | 69552    | 1.432    |
|       | Average       |                           | 10.867 | 2714492 | 69256    | 1.425    |
|       | %RSD          |                           | 0.038  | 0.028   | 0.837    | 0.411    |

Analysed By

Date :

Checked By

Date :





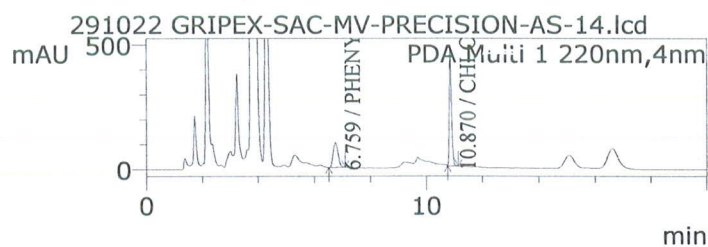
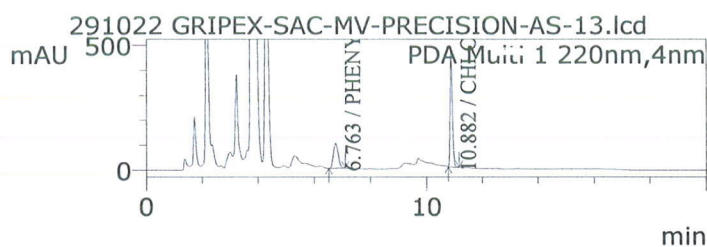
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-A-1-01  
Tray# : 1  
Vial# : 41  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-13.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 7:42:12 PM  
Date Processed : 11/1/2022 10:39:27 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 41    | ION-AS-13.lcd | GRIPEX-MV-MET PRE-SOL-A-1-01 | 6.763  | 1177480 | 7032     | 1.162    |
| 41    | ION-AS-14.lcd | GRIPEX-MV-MET PRE-SOL-A-1-02 | 6.759  | 1174340 | 7056     | 1.163    |
|       | Average       |                              | 6.761  | 1175910 | 7044     | 1.163    |
|       | %RSD          |                              | 0.036  | 0.189   | 0.249    | 0.023    |

ID#2 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 41    | ION-AS-13.lcd | GRIPEX-MV-MET PRE-SOL-A-1-01 | 10.882 | 2697002 | 69294    | 1.421    |
| 41    | ION-AS-14.lcd | GRIPEX-MV-MET PRE-SOL-A-1-02 | 10.870 | 2700102 | 69054    | 1.414    |
|       | Average       |                              | 10.876 | 2698552 | 69174    | 1.417    |
|       | %RSD          |                              | 0.073  | 0.081   | 0.246    | 0.394    |

Analysed By

Date :

Checked By

Date :



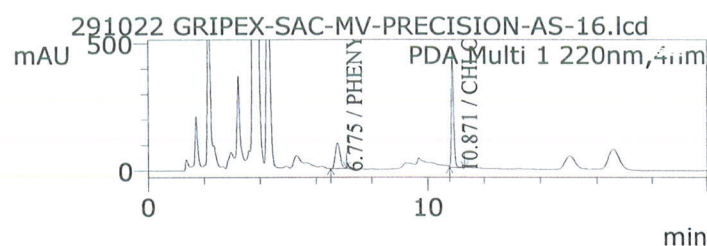
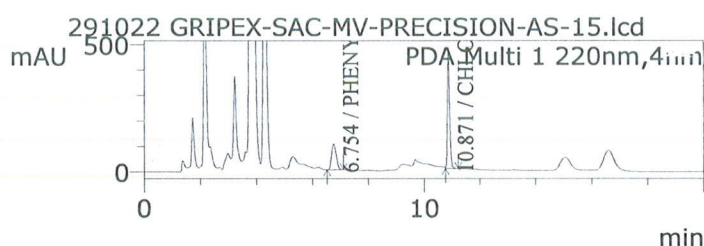
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-A-2-01  
Tray# : 1  
Vial# : 42  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-15.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 8:23:22 PM  
Date Processed : 11/1/2022 10:47:11 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 42    | ION-AS-15.lcd | GRIPEX-MV-MET PRE-SOL-A-2-01 | 6.754  | 1187943 | 7037     | 1.162    |
| 42    | ION-AS-16.lcd | GRIPEX-MV-MET PRE-SOL-A-2-02 | 6.775  | 1182768 | 7069     | 1.155    |
|       | Average       |                              | 6.765  | 1185355 | 7053     | 1.159    |
|       | %RSD          |                              | 0.222  | 0.309   | 0.321    | 0.424    |

ID#2 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 42    | ION-AS-15.lcd | GRIPEX-MV-MET PRE-SOL-A-2-01 | 10.871 | 2662625 | 68797    | 1.418    |
| 42    | ION-AS-16.lcd | GRIPEX-MV-MET PRE-SOL-A-2-02 | 10.871 | 2679928 | 68797    | 1.420    |
|       | Average       |                              | 10.871 | 2671276 | 68797    | 1.419    |
|       | %RSD          |                              | 0.000  | 0.458   | 0.000    | 0.067    |

Analysed By

Date :

Checked By

Date :





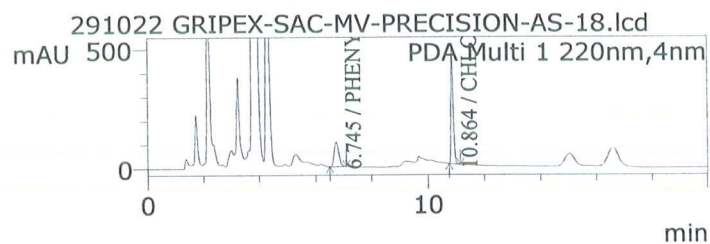
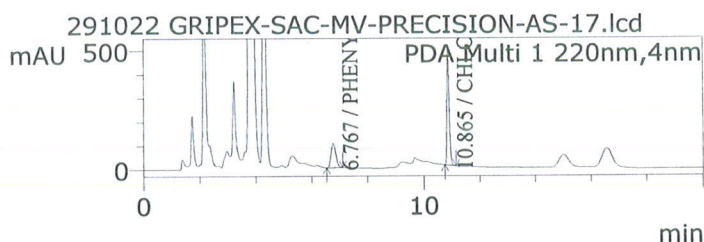
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Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-A-3-01  
Tray# : 1  
Vial# : 43  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-17.lcd  
Method File : GRIPEX-AS-A p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 9:04:33 PM  
Date Processed : 11/1/2022 8:27:57 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 43    | ION-AS-17.lcd | GRIPEX-MV-MET PRE-SOL-A-3-01 | 6.767  | 1197357 | 7050     | 1.159    |
| 43    | ION-AS-18.lcd | GRIPEX-MV-MET PRE-SOL-A-3-02 | 6.745  | 1205566 | 6972     | 1.168    |
|       | Average       |                              | 6.756  | 1201461 | 7011     | 1.163    |
|       | %RSD          |                              | 0.230  | 0.483   | 0.790    | 0.537    |

ID#2 Compound Name: CHLORPHENAMINE MALEATE

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 43    | ION-AS-17.lcd | GRIPEX-MV-MET PRE-SOL-A-3-01 | 10.865 | 2797876 | 67955    | 1.413    |
| 43    | ION-AS-18.lcd | GRIPEX-MV-MET PRE-SOL-A-3-02 | 10.864 | 2795353 | 67893    | 1.416    |
|       | Average       |                              | 10.865 | 2796614 | 67924    | 1.414    |
|       | %RSD          |                              | 0.004  | 0.064   | 0.065    | 0.160    |

Analysed By

Date :

Checked By

Date :



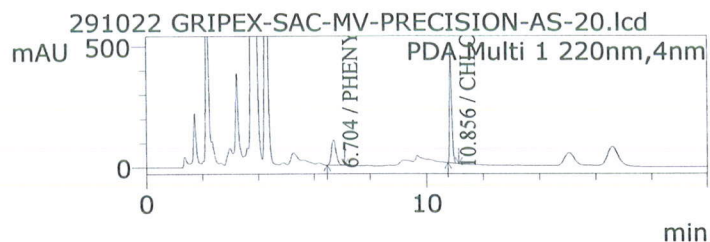
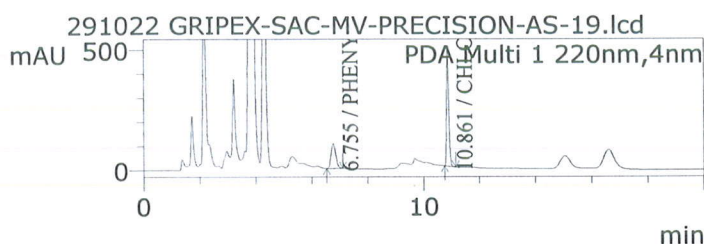
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-A-4-01  
Tray# : 1  
Vial# : 44  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-19.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 9:45:45 PM  
Date Processed : 11/1/2022 8:28:02 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 44    | ION-AS-19.lcd | GRIPEX-MV-MET PRE-SOL-A-4-01 | 6.755  | 1208175 | 7005     | 1.162    |
| 44    | ION-AS-20.lcd | GRIPEX-MV-MET PRE-SOL-A-4-02 | 6.704  | 1236171 | 6953     | 1.200    |
|       | Average       |                              | 6.729  | 1222173 | 6979     | 1.181    |
|       | %RSD          |                              | 0.539  | 1.620   | 0.522    | 2.293    |

ID#2 Compound Name: CHLORPHENAMINE MALEATE

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 44    | ION-AS-19.lcd | GRIPEX-MV-MET PRE-SOL-A-4-01 | 10.861 | 2749431 | 70388    | 1.419    |
| 44    | ION-AS-20.lcd | GRIPEX-MV-MET PRE-SOL-A-4-02 | 10.856 | 2746186 | 68288    | 1.409    |
|       | Average       |                              | 10.858 | 2747809 | 69338    | 1.414    |
|       | %RSD          |                              | 0.035  | 0.083   | 2.142    | 0.523    |

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Date :





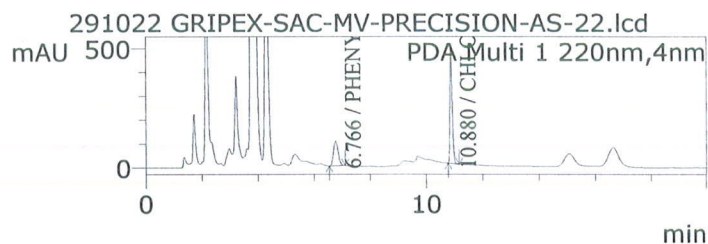
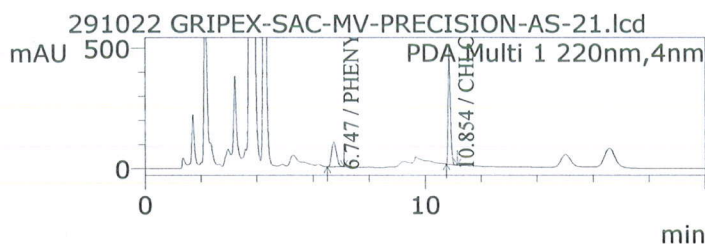
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-A-5-01  
Tray# : 1  
Vial# : 45  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-21.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 10:26:56 PM  
Date Processed : 11/1/2022 8:28:07 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 45    | ION-AS-21.lcd | GRIPEX-MV-MET PRE-SOL-A-5-01 | 6.747  | 1210932 | 6980     | 1.163    |
| 45    | ION-AS-22.lcd | GRIPEX-MV-MET PRE-SOL-A-5-02 | 6.766  | 1213606 | 7050     | 1.163    |
|       | Average       |                              | 6.757  | 1212269 | 7015     | 1.163    |
|       | %RSD          |                              | 0.200  | 0.156   | 0.707    | 0.019    |

ID#2 Compound Name: CHLORPHENAMINE MALEATE

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 45    | ION-AS-21.lcd | GRIPEX-MV-MET PRE-SOL-A-5-01 | 10.854 | 2755007 | 67859    | 1.415    |
| 45    | ION-AS-22.lcd | GRIPEX-MV-MET PRE-SOL-A-5-02 | 10.880 | 2765567 | 69683    | 1.423    |
|       | Average       |                              | 10.867 | 2760287 | 68771    | 1.419    |
|       | %RSD          |                              | 0.170  | 0.271   | 1.876    | 0.384    |

Analysed By

Date :

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Date :



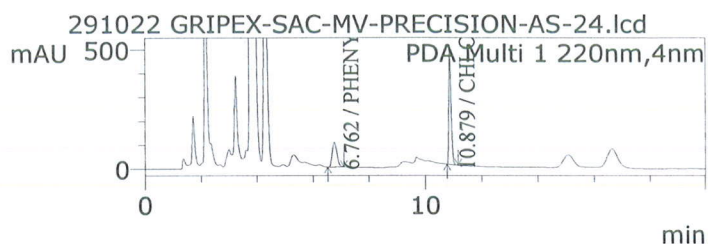
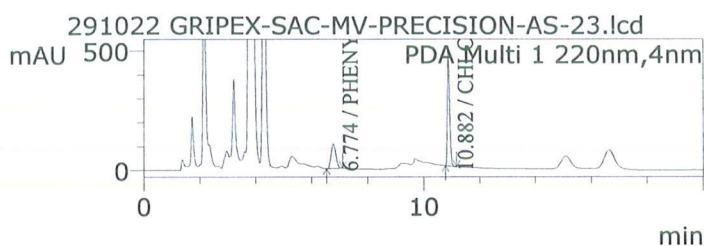
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-A-6-01  
Tray# : 1  
Vial# : 46  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-23.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/29/2022 11:08:11 PM  
Date Processed : 11/1/2022 8:28:12 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 46    | ION-AS-23.lcd | GRIPEX-MV-MET PRE-SOL-A-6-01 | 6.774  | 1207634 | 7014     | 1.154    |
| 46    | ION-AS-24.lcd | GRIPEX-MV-MET PRE-SOL-A-6-02 | 6.762  | 1215168 | 7035     | 1.163    |
|       | Average       |                              | 6.768  | 1211401 | 7024     | 1.159    |
|       | %RSD          |                              | 0.127  | 0.440   | 0.212    | 0.531    |

ID#2 Compound Name: CHLORPHENAMINE MALEATE

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 46    | ION-AS-23.lcd | GRIPEX-MV-MET PRE-SOL-A-6-01 | 10.882 | 2765328 | 70492    | 1.421    |
| 46    | ION-AS-24.lcd | GRIPEX-MV-MET PRE-SOL-A-6-02 | 10.879 | 2767368 | 68900    | 1.416    |
|       | Average       |                              | 10.881 | 2766348 | 69696    | 1.419    |
|       | %RSD          |                              | 0.021  | 0.052   | 1.615    | 0.292    |

Analysed By

Date

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Date





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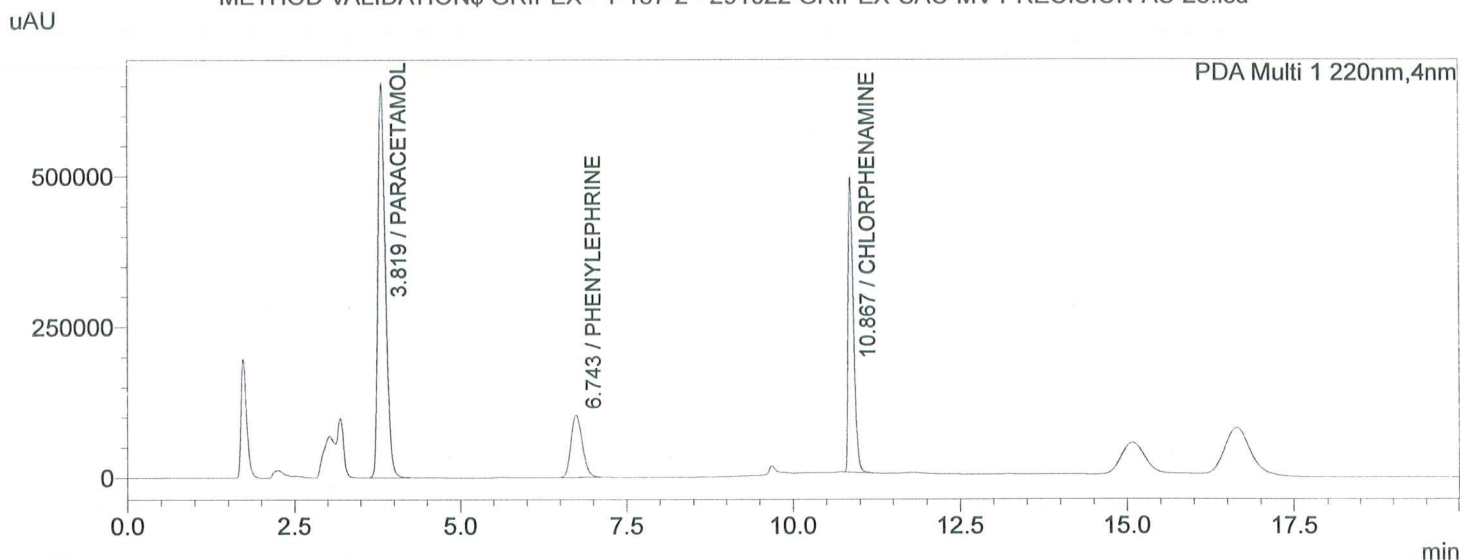
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : PARA+PHENYL+CPM-AS-BKT-STD-1  
Data Filename : 291022 GRIPEX-SAC-MV-PRECISION-AS-25.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Vial # : 1-40  
Injection Volume : 50 uL  
Date Acquired : 10/29/2022 11:49:27 PM  
Date Processed : 11/1/2022 8:26:47 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-187-2 - 291022 GRIPEX-SAC-MV-PRECISION-AS-25.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.819     | 5100337 | 56.351  | 4799    | 1.260    | --         | --       | PARACETAMOL    |
| 2     | 6.743     | 1229340 | 13.582  | 6897    | 1.179    | 10.73      | --       | PHENYLEPHRINE  |
| 3     | 10.867    | 2721365 | 30.067  | 68361   | 1.421    | 16.80      | --       | CHLORPHENAMINE |
| Total |           | 9051042 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



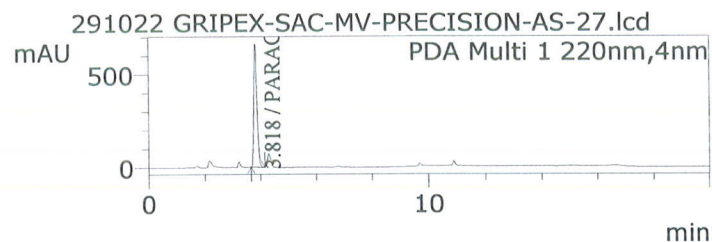
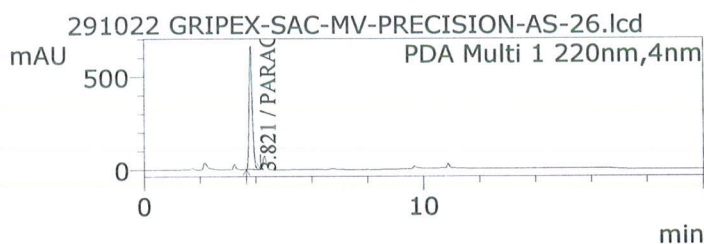
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-B-1-01  
Tray# : 1  
Vial# : 47  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-26.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/30/2022 12:10:02 AM  
Date Processed : 11/1/2022 8:29:06 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 47    | ION-AS-26.lcd | GRIPEX-MV-MET PRE-SOL-B-1-01 | 3.821  | 5112939 | 4858     | 1.258    |
| 47    | ION-AS-27.lcd | GRIPEX-MV-MET PRE-SOL-B-1-02 | 3.818  | 5111796 | 4829     | 1.260    |
|       | Average       |                              | 3.819  | 5112367 | 4844     | 1.259    |
|       | %RSD          |                              | 0.045  | 0.016   | 0.433    | 0.110    |

Analysed By

Date

Checked By

Date





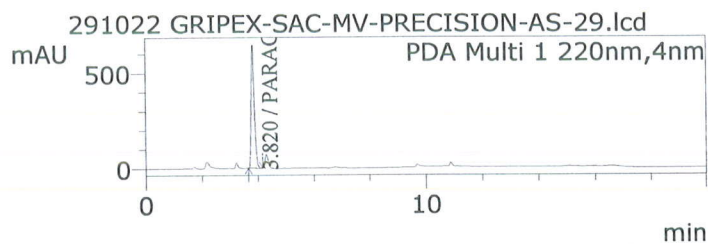
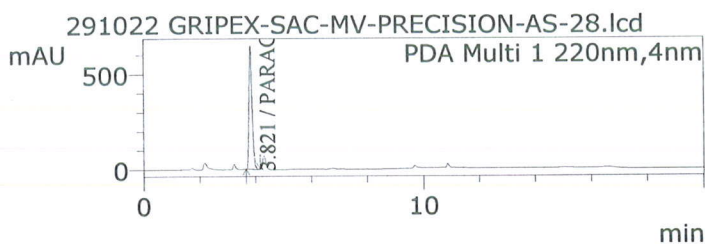
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Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-B-2-01  
Tray# : 1  
Vial# : 48  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-28.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/30/2022 12:51:13 AM  
Date Processed : 11/1/2022 8:29:11 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 48    | ION-AS-28.lcd | GRIPEX-MV-MET PRE-SOL-B-2-01 | 3.821  | 4991820 | 4864     | 1.259    |
| 48    | ION-AS-29.lcd | GRIPEX-MV-MET PRE-SOL-B-2-02 | 3.820  | 4989349 | 4850     | 1.259    |
|       | Average       |                              | 3.820  | 4990585 | 4857     | 1.259    |
|       | %RSD          |                              | 0.021  | 0.035   | 0.192    | 0.018    |

Analysed By

Date :

Checked By

Date :



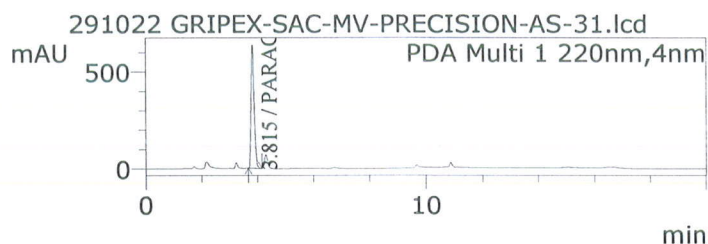
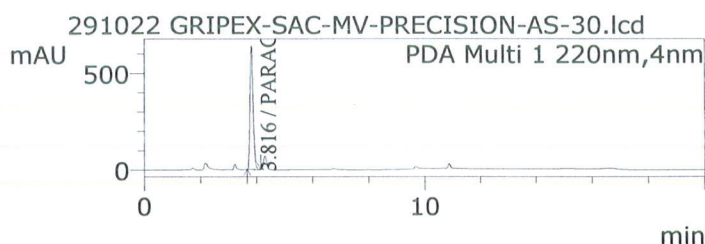
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Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-B-3-01  
Tray# : 1  
Vial# : 49  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-30.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/30/2022 1:32:22 AM  
Date Processed : 11/1/2022 8:29:15 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 49    | ION-AS-30.lcd | GRIPEX-MV-MET PRE-SOL-B-3-01 | 3.816  | 4930873 | 4802     | 1.263    |
| 49    | ION-AS-31.lcd | GRIPEX-MV-MET PRE-SOL-B-3-02 | 3.815  | 4928071 | 4856     | 1.264    |
|       | Average       |                              | 3.816  | 4929472 | 4829     | 1.264    |
|       | %RSD          |                              | 0.013  | 0.040   | 0.790    | 0.051    |

Analysed By

Date :

Checked By

Date :





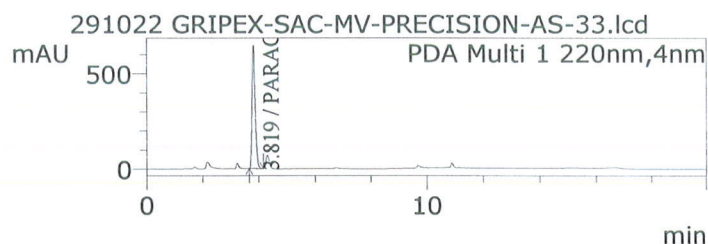
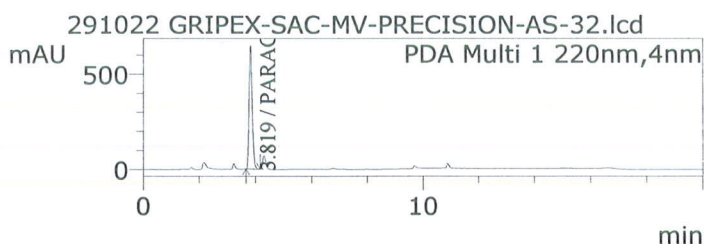
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Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-B-4-01  
Tray# : 1  
Vial# : 50  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-32.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/30/2022 2:13:31 AM  
Date Processed : 11/1/2022 8:29:20 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 50    | ION-AS-32.lcd | GRIPEX-MV-MET PRE-SOL-B-4-01 | 3.819  | 5004361 | 4839     | 1.259    |
| 50    | ION-AS-33.lcd | GRIPEX-MV-MET PRE-SOL-B-4-02 | 3.819  | 5003876 | 4833     | 1.257    |
|       | Average       |                              | 3.819  | 5004119 | 4836     | 1.258    |
|       | %RSD          |                              | 0.002  | 0.007   | 0.079    | 0.116    |

Analysed By

Date :

Checked By

Date :



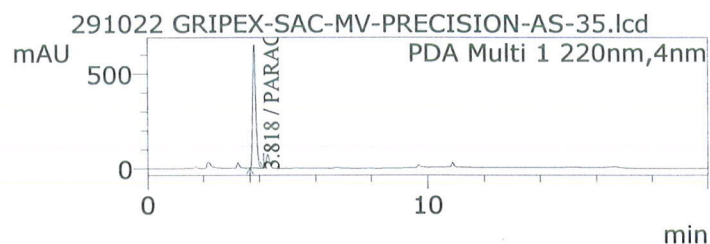
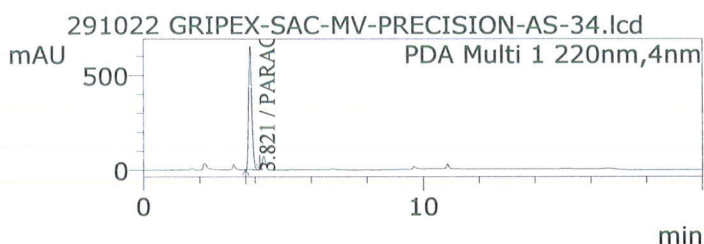
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Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-B-5-01  
Tray# : 1  
Vial# : 51  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-34.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/30/2022 2:54:41 AM  
Date Processed : 11/1/2022 8:29:25 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 51    | ION-AS-34.lcd | GRIPEX-MV-MET PRE-SOL-B-5-01 | 3.821  | 5035440 | 4864     | 1.257    |
| 51    | ION-AS-35.lcd | GRIPEX-MV-MET PRE-SOL-B-5-02 | 3.818  | 5033801 | 4806     | 1.260    |
|       | Average       |                              | 3.820  | 5034620 | 4835     | 1.258    |
|       | %RSD          |                              | 0.061  | 0.023   | 0.841    | 0.136    |

Analysed By

Date :

Checked By

Date :





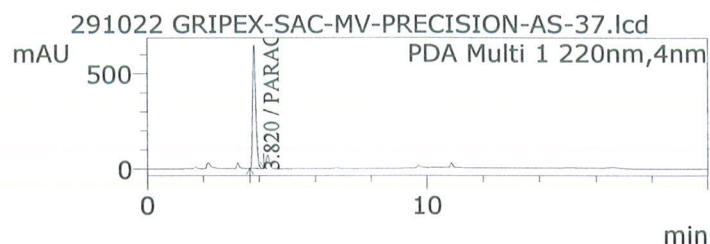
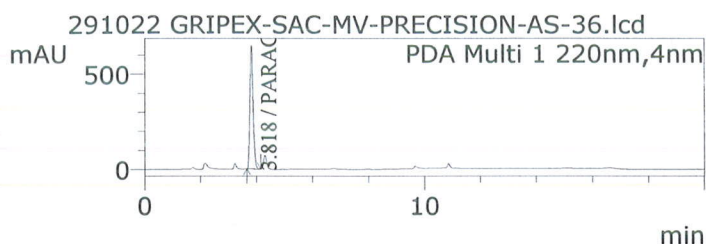
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : GRIPEX-MV-MET PRE-SOL-B-6-01  
Tray# : 1  
Vial# : 52  
Injection Volume : 50  
Data File : 291022 GRIPEX-SAC-MV-PRECISION-AS-36.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/30/2022 3:35:51 AM  
Date Processed : 11/1/2022 8:29:29 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 52    | ION-AS-36.lcd | GRIPEX-MV-MET PRE-SOL-B-6-01 | 3.818  | 5005192 | 4813     | 1.259    |
| 52    | ION-AS-37.lcd | GRIPEX-MV-MET PRE-SOL-B-6-02 | 3.820  | 5005336 | 4841     | 1.258    |
|       | Average       |                              | 3.819  | 5005264 | 4827     | 1.259    |
|       | %RSD          |                              | 0.033  | 0.002   | 0.420    | 0.094    |

Analysed By

Date :

Checked By

Date :



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Puducherry- 605 107

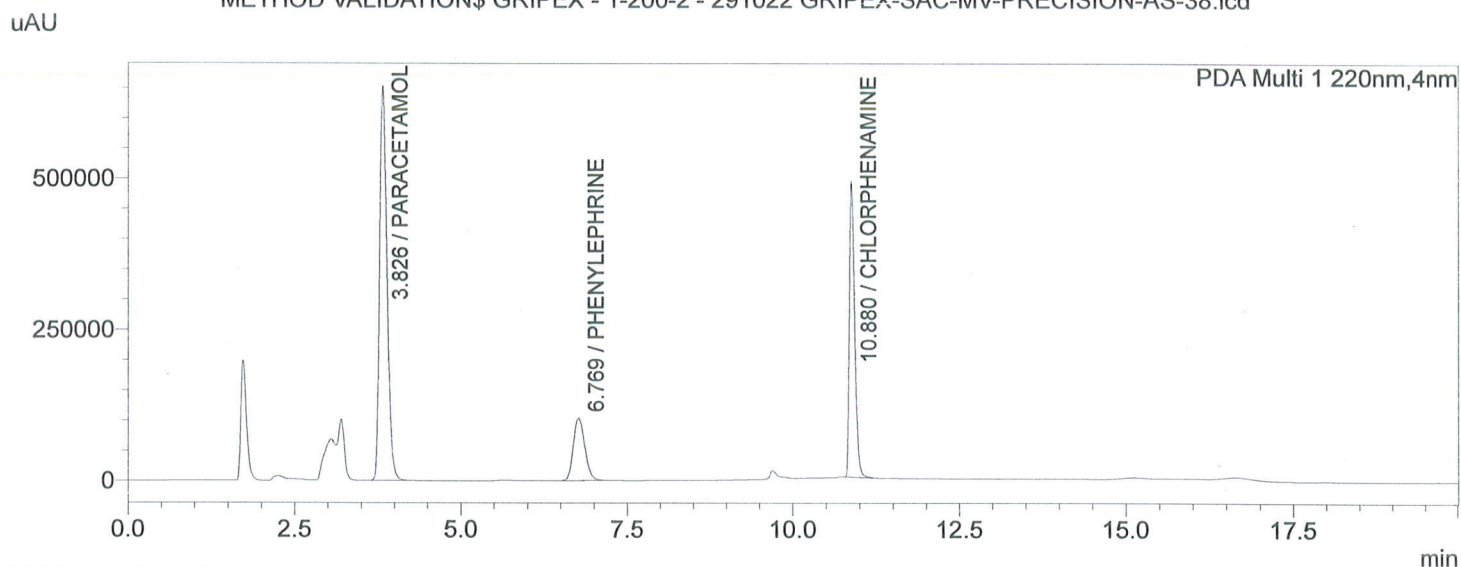
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : METHOD PRECISION  
Sample ID : PARA+PHENYL+CPM-AS-BKT-STD-2  
Data Filename : 291022 GRIPEX-SAC-MV-PRECISION-AS-38.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 391022 GRIPEX-SAC-MV-AS-PRECISION.lcb  
Vial # : 1-40  
Injection Volume : 50 uL  
Date Acquired : 10/30/2022 4:17:00 AM  
Date Processed : 11/1/2022 8:26:49 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-200-2 - 291022 GRIPEX-SAC-MV-PRECISION-AS-38.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plale | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.826     | 5097926 | 56.276  | 4847    | 1.265    | --         | --       | PARACETAMOL    |
| 2     | 6.769     | 1234315 | 13.626  | 6887    | 1.181    | 10.78      | --       | PHENYLEPHRINE  |
| 3     | 10.880    | 2726530 | 30.098  | 69335   | 1.431    | 16.73      | --       | CHLORPHENAMINE |
| Total |           | 9058772 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

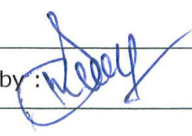
|                     |                 |
|---------------------|-----------------|
| Name of the Product | Kripore Sachet. |
| Batch No            | ST/7/S-1322     |

Sample Preparation:- (1)

4.5015 gm of sample is sum of  
Volumetric flask added 30ml diluent and Sonicate for 10 minutes.  
to dissolve and makeup to volume with diluent. Filter the  
Solution through 0.45 µm PTFE filter. Use this Solution as (Soln. A)  
5ml of above sample solution (A) into 100ml  
volumetric flask and makeup to volume with diluent.  
Use this Solution as Solution 'B'.

Ans:

Further preparation is prepared as same as  
above sample preparation.

|                                                                                                   |                 |                                                                                                   |                 |
|---------------------------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------------------------|-----------------|
| Analyzed by :  | Date : 29/10/22 | Checked by :  | Date : 29/10/22 |
|---------------------------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------------------------|-----------------|



# Safetab Life Science

Puducherry- 605 107

*Quality control Department*

## ====BATCH TABLE=====

| Batch Table |      |           |                  |                              |               |                           |
|-------------|------|-----------|------------------|------------------------------|---------------|---------------------------|
| Vial#       | Tray | Inj. Vol. | Sample Name      | Sample ID                    | Method File   | Data File                 |
| 37          | 1    | 50.0      | SYSTEM PRECISION | BLANK-AS                     | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-01.lcd |
| 38          | 1    | 50.0      | SYSTEM PRECISION | PARA+PHENYL+CPM-AS-STD-01    | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-02.lcd |
| 38          | 1    | 50.0      | SYSTEM PRECISION | PARA+PHENYL+CPM-AS-STD-02    | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-03.lcd |
| 38          | 1    | 50.0      | SYSTEM PRECISION | PARA+PHENYL+CPM-AS-STD-03    | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-04.lcd |
| 38          | 1    | 50.0      | SYSTEM PRECISION | PARA+PHENYL+CPM-AS-STD-04    | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-05.lcd |
| 38          | 1    | 50.0      | SYSTEM PRECISION | PARA+PHENYL+CPM-AS-STD-05    | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-06.lcd |
| 39          | 1    | 50.0      | METHOD PRECISION | BLANK-AS                     | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-07.lcd |
| 40          | 1    | 50.0      | METHOD PRECISION | PARA+PHENYL+CPM-AS-STD-01    | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-08.lcd |
| 40          | 1    | 50.0      | METHOD PRECISION | PARA+PHENYL+CPM-AS-STD-02    | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-09.lcd |
| 40          | 1    | 50.0      | METHOD PRECISION | PARA+PHENYL+CPM-AS-STD-03    | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-10.lcd |
| 40          | 1    | 50.0      | METHOD PRECISION | PARA+PHENYL+CPM-AS-STD-04    | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-11.lcd |
| 40          | 1    | 50.0      | METHOD PRECISION | PARA+PHENYL+CPM-AS-STD-05    | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-12.lcd |
| 41          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-1-01 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-13.lcd |
| 41          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-1-02 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-14.lcd |
| 42          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-2-01 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-15.lcd |
| 42          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-2-02 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-16.lcd |
| 43          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-3-01 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-17.lcd |
| 43          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-3-02 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-18.lcd |
| 44          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-4-01 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-19.lcd |
| 44          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-4-02 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-20.lcd |
| 45          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-5-01 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-21.lcd |
| 45          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-5-02 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-22.lcd |
| 46          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-6-01 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-23.lcd |
| 46          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-A-6-02 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-24.lcd |
| 40          | 1    | 50.0      | METHOD PRECISION | PARA+PHENYL+CPM-AS-BKT-STD-1 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-25.lcd |
| 47          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-1-01 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-26.lcd |
| 47          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-1-02 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-27.lcd |
| 48          | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-2-01 | GRIPEX-AS.lcm | AC-MV-PRECISION-AS-28.lcd |



| Vial# | Tray | Inj. Vol. | Sample Name      | Sample ID                    | Method File    | Data File                 | Report Format      |
|-------|------|-----------|------------------|------------------------------|----------------|---------------------------|--------------------|
| 48    | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-2-02 | GRIPEX-AS.lcm  | AC-MV-PRECISION-AS-29.lcd | system\DEFAULT.lsr |
| 49    | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-3-01 | GRIPEX-AS.lcm  | AC-MV-PRECISION-AS-30.lcd | system\DEFAULT.lsr |
| 49    | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-3-02 | GRIPEX-AS.lcm  | AC-MV-PRECISION-AS-31.lcd | system\DEFAULT.lsr |
| 50    | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-4-01 | GRIPEX-AS.lcm  | AC-MV-PRECISION-AS-32.lcd | system\DEFAULT.lsr |
| 50    | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-4-02 | GRIPEX-AS.lcm  | AC-MV-PRECISION-AS-33.lcd | system\DEFAULT.lsr |
| 51    | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-5-01 | GRIPEX-AS.lcm  | AC-MV-PRECISION-AS-34.lcd | system\DEFAULT.lsr |
| 51    | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-5-02 | GRIPEX-AS.lcm  | AC-MV-PRECISION-AS-35.lcd | system\DEFAULT.lsr |
| 52    | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-6-01 | GRIPEX-AS.lcm  | AC-MV-PRECISION-AS-36.lcd | system\DEFAULT.lsr |
| 52    | 1    | 50.0      | METHOD PRECISION | GRIPEX-MV-MET PRE-SOL-B-6-02 | GRIPEX-AS.lcm  | AC-MV-PRECISION-AS-37.lcd | system\DEFAULT.lsr |
| 40    | 1    | 50.0      | METHOD PRECISION | PARA+PHENYL+CPM-AS-BKT-STD-2 | GRIPEX-AS.lcm  | AC-MV-PRECISION-AS-38.lcd | system\DEFAULT.lsr |
| -1    | 1    | 50.0      | METHOD PRECISION | SHUT                         | OWN METHOD.lcm | AC-MV-PRECISION-AS-39.lcd | system\DEFAULT.lsr |

Analysed By

Date:

Checked By

Date:



|                                                                                                                                                     |                                                                                                                                                                                                           |                    |                           |                  |                      |              |                                                                     |                |       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---------------------------|------------------|----------------------|--------------|---------------------------------------------------------------------|----------------|-------|
|                                                                                                                                                     | <b>Safetab Life Science</b><br>Puducherry - 605 107                                                                                                                                                       |                    |                           |                  |                      |              |                                                                     |                |       |
|                                                                                                                                                     | <b>QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET</b>                                                                                                                                     |                    |                           |                  |                      |              |                                                                     |                |       |
| Title                                                                                                                                               | <b>ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS</b>                                                                                                               |                    |                           |                  |                      |              |                                                                     |                |       |
| Product Name                                                                                                                                        | GRIPEX                                                                                                                                                                                                    |                    |                           |                  |                      | Batch size   | 500 SACHETS                                                         |                |       |
| Batch Number                                                                                                                                        | ST/T/S-1322                                                                                                                                                                                               |                    |                           |                  |                      | Mfg. Date    | Sep-22                                                              |                |       |
| Stage                                                                                                                                               | INTERMEDIATE PRECISION (TEST PREPARATION-1)                                                                                                                                                               |                    |                           |                  |                      | Exp. Date    | To be fixed                                                         |                |       |
| Each 4500 mg of Sachet contains:<br>Paracetamol BP ----- 650mg<br>Chlorphenamine Maleate BP ----- 20mg<br>Phenylephrine Hydrochloride BP ----- 10mg |                                                                                                                                                                                                           |                    |                           |                  |                      |              |                                                                     |                |       |
| <b>ASSAY OF PARACETAMOL</b>                                                                                                                         |                                                                                                                                                                                                           |                    |                           |                  |                      |              |                                                                     |                |       |
| Instrument ID:                                                                                                                                      | ST/QC/EQ/045                                                                                                                                                                                              |                    | Balance ID:               | ST/QC/EQ/041&030 |                      | WS No.:      | ST/WS/22/011                                                        | % Purity (aib) | 100.0 |
| Standard dilution.:                                                                                                                                 | 65.47                                                                                                                                                                                                     | mg to --->         | 100                       | ml to --->       | 5                    | ml to --->   | 50                                                                  |                |       |
| Std.conc (in ppm)-65.47                                                                                                                             | 1                                                                                                                                                                                                         | ml to --->         | 1                         | ml to --->       | 1                    | ml to --->   | 1                                                                   |                |       |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->         | 500                       | ml to --->       | 5                    | ml to --->   | 100                                                                 |                |       |
| Test conc(in ppm)-64.99711                                                                                                                          | 1                                                                                                                                                                                                         | ml to --->         | 1                         | ml to --->       | 1                    | ml to --->   | 1                                                                   |                |       |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                    |                           |                  |                      |              |                                                                     |                |       |
| Labeled claim :                                                                                                                                     | 650                                                                                                                                                                                                       | mg                 |                           |                  |                      |              |                                                                     |                |       |
| Average weight :                                                                                                                                    | 4500                                                                                                                                                                                                      | mg                 |                           |                  |                      |              |                                                                     |                |       |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                  | 3                         | 4                | 5                    | MEAN         | S.D                                                                 | RSD in %       |       |
| Paracetamol                                                                                                                                         | 5107709                                                                                                                                                                                                   | 5102778            | 5094844                   | 5104757          | 5087478              | 5099513      | 8246                                                                | 0.162          |       |
| With Bracketing std.                                                                                                                                | 5176989                                                                                                                                                                                                   | 5160224            |                           |                  |                      | 5119254      | 34719                                                               | 0.678          |       |
|                                                                                                                                                     |                                                                                                                                                                                                           | Sample preparation | Sample Weight taken in mg | Sample Area      | Content in mg/Sachet | Content in % |                                                                     |                |       |
|                                                                                                                                                     |                                                                                                                                                                                                           | 1                  | 4499.80                   | 4922678          | 632.03               | 97.2         | Assay limit :90.0% to 110.0%                                        |                |       |
| <b>ASSAY OF PHENYLEPHRINE HYDROCHLORIDE</b>                                                                                                         |                                                                                                                                                                                                           |                    |                           |                  |                      |              |                                                                     |                |       |
|                                                                                                                                                     |                                                                                                                                                                                                           |                    |                           |                  |                      | WS No.:      | IAARI/WS/344                                                        | % Purity (aib) | 98.9  |
| Standard dilution.:                                                                                                                                 | 40.22                                                                                                                                                                                                     | mg to --->         | 200                       | ml to --->       | 5                    | ml to --->   | 50                                                                  |                |       |
| Std.conc (in ppm)-20.11                                                                                                                             | 1                                                                                                                                                                                                         | ml to --->         | 1                         | ml to --->       | 1                    | ml to --->   | 1                                                                   |                |       |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->         | 500                       | ml to --->       | 1                    | ml to --->   | 1                                                                   |                |       |
| Test conc (in ppm)-19.99911                                                                                                                         | 1                                                                                                                                                                                                         | ml to --->         | 1                         | ml to --->       | 1                    | ml to --->   | 1                                                                   |                |       |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                    |                           |                  |                      |              |                                                                     |                |       |
| Labeled claim :                                                                                                                                     | 10                                                                                                                                                                                                        | mg                 |                           |                  |                      |              |                                                                     |                |       |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                  | 3                         | 4                | 5                    | MEAN         | S.D                                                                 | RSD in %       |       |
| Phenylephrine HCL                                                                                                                                   | 1228966                                                                                                                                                                                                   | 1231835            | 1229654                   | 1230478          | 1231479              | 1230482      | 1205                                                                | 0.098          |       |
| With Bracketing std.                                                                                                                                | 1234641                                                                                                                                                                                                   | 1238561            |                           |                  |                      | 1232231      | 3341.0                                                              | 0.271          |       |
|                                                                                                                                                     |                                                                                                                                                                                                           | Sample preparation | Sample Weight taken in mg | Sample Area      | Content in mg/Sachet | Content in % |                                                                     |                |       |
|                                                                                                                                                     |                                                                                                                                                                                                           | 1                  | 4499.80                   | 1190172          | 9.62                 | 96.2         | Assay limit :90.0% to 110.0%                                        |                |       |
| <b>ASSAY OF CHLORPHENAMINE MALEATE</b>                                                                                                              |                                                                                                                                                                                                           |                    |                           |                  |                      |              |                                                                     |                |       |
|                                                                                                                                                     |                                                                                                                                                                                                           |                    |                           |                  |                      | WS No.:      | ST/WS/22/039                                                        | % Purity (aib) | 99.7  |
| Standard dilution.:                                                                                                                                 | 40.15                                                                                                                                                                                                     | mg to --->         | 100                       | ml to --->       | 5                    | ml to --->   | 50                                                                  |                |       |
| Std.conc (in ppm)-40.15                                                                                                                             | 1                                                                                                                                                                                                         | ml to --->         | 1                         | ml to --->       | 1                    | ml to --->   | 1                                                                   |                |       |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->         | 500                       | ml to --->       | 1                    | ml to --->   | 1                                                                   |                |       |
| Test conc(in ppm)-39.99822                                                                                                                          | 1                                                                                                                                                                                                         | ml to --->         | 1                         | ml to --->       | 1                    | ml to --->   | 1                                                                   |                |       |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                    |                           |                  |                      |              |                                                                     |                |       |
| Labeled claim :                                                                                                                                     | 20                                                                                                                                                                                                        | mg                 |                           |                  |                      |              |                                                                     |                |       |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                  | 3                         | 4                | 5                    | MEAN         | S.D                                                                 | RSD in %       |       |
| Chlorphenamine maleate                                                                                                                              | 2878277                                                                                                                                                                                                   | 2871486            | 2871940                   | 2868881          | 2867242              | 2871565      | 4216                                                                | 0.147          |       |
| With Bracketing std.                                                                                                                                | 2874539                                                                                                                                                                                                   | 2875646            |                           |                  |                      | 2872573      | 3862                                                                | 0.134          |       |
|                                                                                                                                                     |                                                                                                                                                                                                           | Sample preparation | Sample Weight taken in mg | Sample Area      | Content in mg/Sachet | Content in % |                                                                     |                |       |
|                                                                                                                                                     |                                                                                                                                                                                                           | 1                  | 4499.80                   | 2856865          | 19.91                | 99.6         | Assay limit :90.0% to 110.0%                                        |                |       |
| <b>Calculation formula :</b>                                                                                                                        |                                                                                                                                                                                                           |                    |                           |                  |                      |              |                                                                     |                |       |
| Assay in mg /Sachet                                                                                                                                 | $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$ |                    |                           |                  |                      | Assay in %   | $\frac{\text{Assay in mg/Sachet} \times 100}{\text{Labeled claim}}$ |                |       |
| Analysed by : T.MARUTHI<br>Date : 15.11.2022                                                                                                        |                                                                                                                                                                                                           |                    |                           |                  |                      |              |                                                                     |                |       |
| Checked by :<br>Date : 15/11/2022                                                                                                                   |                                                                                                                                                                                                           |                    |                           |                  |                      |              |                                                                     |                |       |





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                             |            |             |
|--------------|---------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                      | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                 | Mfg.Date   | Sep-22      |
| Stage        | INTERMEDIATE PRECISION (TEST PREPARATION-2) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |                    |                           |             |                      |              |                              |              |                |       |
|----------------------------|--------------------|---------------------------|-------------|----------------------|--------------|------------------------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/045       |                           | Balance ID: | ST/QC/EQ/041&030     |              | WS No.:                      | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.47              | mg to --->                | 100         | ml to --->           | 5            | ml to --->                   | 50           |                |       |
| Std.conc (in ppm)-65.47    | 1                  | ml to --->                | 1           | ml to --->           | 1            | ml to --->                   | 1            |                |       |
| Test dilution .:           | Granule/Pow.       | mg to --->                | 500         | ml to --->           | 5            | ml to --->                   | 100          |                |       |
| Test conc(in ppm)-64.99711 | 1                  | ml to --->                | 1           | ml to --->           | 1            | ml to --->                   | 1            |                |       |
| Conversion factor :        | 1.0000             | mg                        |             |                      |              |                              |              |                |       |
| Labeled claim :            | 650                |                           |             |                      |              |                              |              |                |       |
| Average weight :           | 4500               |                           |             |                      |              |                              |              |                |       |
| System suitability         | 1                  | 2                         | 3           | 4                    | 5            | MEAN                         | S.D          | RSD in %       |       |
| Paracetamol                | 5107709            | 5102778                   | 5094844     | 5104757              | 5087478      | 5099513                      | 8246         | 0.162          |       |
| With Bracketing std.       | 5176989            | 5160224                   |             |                      |              | 5119254                      | 34719        | 0.678          |       |
|                            | Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |                              |              |                |       |
|                            | 1                  | 4499.80                   | 4955371     | 636.22               | 97.9         | Assay limit :90.0% to 110.0% |              |                |       |

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                             |                           |             |                      |              |         |              |                |                              |
|-----------------------------|---------------------------|-------------|----------------------|--------------|---------|--------------|----------------|------------------------------|
|                             |                           |             |                      |              | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9                         |
| Standard dilution.:         | 40.22                     | mg to --->  | 200                  | ml to --->   | 5       | ml to --->   | 50             |                              |
| Std.conc (in ppm)-20.11     | 1                         | ml to --->  | 1                    | ml to --->   | 1       | ml to --->   | 1              |                              |
| Test dilution.:             | Granule/Pow.              | mg to --->  | 500                  | ml to --->   | 1       | ml to --->   | 1              |                              |
| Test conc (in ppm)-19.99911 | 1                         | ml to --->  | 1                    | ml to --->   | 1       | ml to --->   | 1              |                              |
| Conversion factor :         | 1.0000                    |             |                      |              |         |              |                |                              |
| Labeled claim :             | 10                        | mg          |                      |              |         |              |                |                              |
| System suitability          | 1                         | 2           | 3                    | 4            | 5       | MEAN         | S.D            | RSD in %                     |
| Phenylephrine HCL           | 1228966                   | 1231835     | 1229654              | 1230478      | 1231479 | 1230482      | 1205           | 0.098                        |
| With Bracketing std.        | 1234641                   | 1238561     |                      |              |         | 1232231      | 3341.0         | 0.271                        |
| Sample preparation          | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |         |              |                |                              |
| 1                           | 4499.80                   | 1220249     | 9.86                 | 98.6         |         |              |                | Assay limit :90.0% to 110.0% |

ASSAY OF CHLORPHENAMINE MALEATE

|                            |                           |             |                      |              |         |              |                |                              |
|----------------------------|---------------------------|-------------|----------------------|--------------|---------|--------------|----------------|------------------------------|
|                            |                           |             |                      |              | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7                         |
| Standard dilution.:        | 40.15                     | mg to --->  | 100                  | ml to --->   | 5       | ml to --->   | 50             |                              |
| Std.conc (in ppm)-40.15    | 1                         | ml to --->  | 1                    | ml to --->   | 1       | ml to --->   | 1              |                              |
| Test dilution.:            | Granule/Pow.              | mg to --->  | 500                  | ml to --->   | 1       | ml to --->   | 1              |                              |
| Test conc(in ppm)-39.99822 | 1                         | ml to --->  | 1                    | ml to --->   | 1       | ml to --->   | 1              |                              |
| Conversion factor :        | 1.0000                    |             |                      |              |         |              |                |                              |
| Labeled claim :            | 20                        | mg          |                      |              |         |              |                |                              |
| System suitability         | 1                         | 2           | 3                    | 4            | 5       | MEAN         | S.D            | RSD in %                     |
| Chlorphenamine maleate     | 2878277                   | 2871486     | 2871940              | 2868881      | 2867242 | 2871565      | 4216           | 0.147                        |
| With Bracketing std.       | 2874539                   | 2875646     |                      |              |         | 2872573      | 3862           | 0.134                        |
| Sample preparation         | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |         |              |                |                              |
| 1                          | 4499.80                   | 2810745     | 19.59                | 98.0         |         |              |                | Assay limit :90.0% to 110.0% |

Calculation formula :

|                     |                                                                          |
|---------------------|--------------------------------------------------------------------------|
| Assay in mg /Sachet | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt |
|                     | Standard area x sample dilution x 100                                    |

|            |                          |
|------------|--------------------------|
| Assay in % | Assay in mg/Sachet x 100 |
|            | Labeled claim            |

Analysed by :

T.MARUTHI

Date :

15.11.2022

Checked by :

Date :

15/11/2022





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

| Title                                                                                                                                               |                                                                                                                                                                                                           | ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS |                      |                  |         |              |                |                |                              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|----------------------|------------------|---------|--------------|----------------|----------------|------------------------------|
| Product Name                                                                                                                                        | GRIPEX                                                                                                                                                                                                    |                                                                                      |                      |                  |         | Batch size   | 500 SACHETS    |                |                              |
| Batch Number                                                                                                                                        | ST/T/S-1322                                                                                                                                                                                               |                                                                                      |                      |                  |         | Mfg. Date    | Sep-22         |                |                              |
| Stage                                                                                                                                               | INTERMEDIATE PRECISION (TEST PREPARATION-3)                                                                                                                                                               |                                                                                      |                      |                  |         | Exp. Date    | To be fixed    |                |                              |
| Each 4500 mg of Sachet contains:<br>Paracetamol BP ----- 650mg<br>Chlorphenamine Maleate BP ----- 20mg<br>Phenylephrine Hydrochloride BP ----- 10mg |                                                                                                                                                                                                           |                                                                                      |                      |                  |         |              |                |                |                              |
| ASSAY OF PARACETAMOL                                                                                                                                |                                                                                                                                                                                                           |                                                                                      |                      |                  |         |              |                |                |                              |
| Instrument ID:                                                                                                                                      | ST/QC/EQ/045                                                                                                                                                                                              |                                                                                      | Balance ID:          | ST/QC/EQ/041&030 |         | WS No.:      | ST/WS/22/011   | % Purity (aib) | 100.0                        |
| Standard dilution.:                                                                                                                                 | 65.47                                                                                                                                                                                                     | mg to --->                                                                           | 100                  | ml to --->       | 5       | ml to --->   | 50             |                |                              |
| Std. conc (in ppm)-65.47                                                                                                                            | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->   | 1              |                |                              |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                                           | 500                  | ml to --->       | 5       | ml to --->   | 100            |                |                              |
| Test conc (in ppm)-65.013                                                                                                                           | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->   | 1              |                |                              |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                                                      |                      |                  |         |              |                |                |                              |
| Labeled claim :                                                                                                                                     | 650                                                                                                                                                                                                       | mg                                                                                   |                      |                  |         |              |                |                |                              |
| Average weight :                                                                                                                                    | 4500                                                                                                                                                                                                      | mg                                                                                   |                      |                  |         |              |                |                |                              |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                                                    | 3                    | 4                | 5       | MEAN         | S.D            | RSD in %       |                              |
| Paracetamol                                                                                                                                         | 5107709                                                                                                                                                                                                   | 5102778                                                                              | 5094844              | 5104757          | 5087478 | 5099513      | 8246           | 0.162          |                              |
| With Bracketing std.                                                                                                                                | 5176989                                                                                                                                                                                                   | 5160224                                                                              |                      |                  |         | 5119254      | 34719          | 0.678          |                              |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                                                                                                                                                 | Sample Area                                                                          | Content in mg/Sachet | Content in %     |         |              |                |                |                              |
| 1                                                                                                                                                   | 4500.90                                                                                                                                                                                                   | 4942614                                                                              | 634.43               | 97.6             |         |              |                |                | Assay limit :90.0% to 110.0% |
| ASSAY OF PHENYLEPHRINE HYDROCHLORIDE                                                                                                                |                                                                                                                                                                                                           |                                                                                      |                      |                  |         |              |                |                |                              |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9           |                              |
| Standard dilution.:                                                                                                                                 | 40.22                                                                                                                                                                                                     | mg to --->                                                                           | 200                  | ml to --->       | 5       | ml to --->   | 50             |                |                              |
| Std. conc (in ppm)-20.11                                                                                                                            | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->   | 1              |                |                              |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                                           | 500                  | ml to --->       | 1       | ml to --->   | 1              |                |                              |
| Test conc (in ppm)-20.004                                                                                                                           | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->   | 1              |                |                              |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                                                      |                      |                  |         |              |                |                |                              |
| Labeled claim :                                                                                                                                     | 10                                                                                                                                                                                                        | mg                                                                                   |                      |                  |         |              |                |                |                              |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                                                    | 3                    | 4                | 5       | MEAN         | S.D            | RSD in %       |                              |
| Phenylephrine HCL                                                                                                                                   | 1228966                                                                                                                                                                                                   | 1231835                                                                              | 1229654              | 1230478          | 1231479 | 1230482      | 1205           | 0.098          |                              |
| With Bracketing std.                                                                                                                                | 1234641                                                                                                                                                                                                   | 1238561                                                                              |                      |                  |         | 1232231      | 3341.0         | 0.271          |                              |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                                                                                                                                                 | Sample Area                                                                          | Content in mg/Sachet | Content in %     |         |              |                |                |                              |
| 1                                                                                                                                                   | 4500.90                                                                                                                                                                                                   | 1260810                                                                              | 10.19                | 101.9            |         |              |                |                | Assay limit :90.0% to 110.0% |
| ASSAY OF CHLORPHENAMINE MALEATE                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  |         |              |                |                |                              |
|                                                                                                                                                     |                                                                                                                                                                                                           |                                                                                      |                      |                  | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7           |                              |
| Standard dilution.:                                                                                                                                 | 40.15                                                                                                                                                                                                     | mg to --->                                                                           | 100                  | ml to --->       | 5       | ml to --->   | 50             |                |                              |
| Std. conc (in ppm)-40.15                                                                                                                            | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->   | 1              |                |                              |
| Test dilution.:                                                                                                                                     | Granule/Pow.                                                                                                                                                                                              | mg to --->                                                                           | 500                  | ml to --->       | 1       | ml to --->   | 1              |                |                              |
| Test conc (in ppm)-40.008                                                                                                                           | 1                                                                                                                                                                                                         | ml to --->                                                                           | 1                    | ml to --->       | 1       | ml to --->   | 1              |                |                              |
| Conversion factor :                                                                                                                                 | 1.0000                                                                                                                                                                                                    |                                                                                      |                      |                  |         |              |                |                |                              |
| Labeled claim :                                                                                                                                     | 20                                                                                                                                                                                                        | mg                                                                                   |                      |                  |         |              |                |                |                              |
| System suitability                                                                                                                                  | 1                                                                                                                                                                                                         | 2                                                                                    | 3                    | 4                | 5       | MEAN         | S.D            | RSD in %       |                              |
| Chlorphenamine maleate                                                                                                                              | 2878277                                                                                                                                                                                                   | 2871486                                                                              | 2871940              | 2868881          | 2867242 | 2871565      | 4216           | 0.147          |                              |
| With Bracketing std.                                                                                                                                | 2874539                                                                                                                                                                                                   | 2875646                                                                              |                      |                  |         | 2872573      | 3862           | 0.134          |                              |
| Sample preparation                                                                                                                                  | Sample Weight taken in mg                                                                                                                                                                                 | Sample Area                                                                          | Content in mg/Sachet | Content in %     |         |              |                |                |                              |
| 1                                                                                                                                                   | 4500.90                                                                                                                                                                                                   | 2829674                                                                              | 19.72                | 98.6             |         |              |                |                | Assay limit :90.0% to 110.0% |
| Calculation formula :                                                                                                                               |                                                                                                                                                                                                           |                                                                                      |                      |                  |         |              |                |                |                              |
| Assay in mg /Sachet                                                                                                                                 | $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$ |                                                                                      |                      |                  |         |              |                |                |                              |
| Assay in %                                                                                                                                          | $\frac{\text{Assay in mg/Sachet} \times 100}{\text{Labeled claim}}$                                                                                                                                       |                                                                                      |                      |                  |         |              |                |                |                              |
| Analysed by :                                                                                                                                       | T.MARUTHI                                                                                                                                                                                                 |                                                                                      |                      |                  |         |              |                |                |                              |
| Date :                                                                                                                                              | 15.11.2022                                                                                                                                                                                                |                                                                                      |                      |                  |         |              |                |                |                              |
| Checked by :                                                                                                                                        |                                                                                                                                                                                                           |                                                                                      |                      |                  |         |              |                |                |                              |
| Date :                                                                                                                                              | 15.11.2022                                                                                                                                                                                                |                                                                                      |                      |                  |         |              |                |                |                              |





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                             |            |             |
|--------------|---------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                      | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                 | Mfg.Date   | Sep-22      |
| Stage        | INTERMEDIATE PRECISION (TEST PREPARATION-4) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |                    |                           |             |                      |              |                              |              |                |       |
|----------------------------|--------------------|---------------------------|-------------|----------------------|--------------|------------------------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/045       |                           | Balance ID: | ST/QC/EQ/041&030     |              | WS No.:                      | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.47              | mg to --->                | 100         | ml to --->           | 5            | ml to --->                   | 50           |                |       |
| Std.conc (in ppm)-65.47    | 1                  | ml to --->                | 1           | ml to --->           | 1            | ml to --->                   | 1            |                |       |
| Test dilution.:            | Granule/Pow.       | mg to --->                | 500         | ml to --->           | 5            | ml to --->                   | 100          |                |       |
| Test conc(in ppm)-65.03755 | 1                  | ml to --->                | 1           | ml to --->           | 1            | ml to --->                   | 1            |                |       |
| Conversion factor :        | 1.0000             | mg                        |             |                      |              |                              |              |                |       |
| Labeled claim :            | 650                |                           |             |                      |              |                              |              |                |       |
| Average weight :           | 4500               |                           | mg          |                      |              |                              |              |                |       |
| System suitability         | 1                  | 2                         | 3           | 4                    | 5            | MEAN                         | S.D          | RSD in %       |       |
| Paracetamol                | 5107709            | 5102778                   | 5094844     | 5104757              | 5087478      | 5099513                      | 8246         | 0.162          |       |
| With Bracketing std.       | 5176989            | 5160224                   |             |                      |              | 5119254                      | 34719        | 0.678          |       |
|                            | Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |                              |              |                |       |
|                            | 1                  | 4502.60                   | 4941618     | 634.06               | 97.5         | Assay limit :90.0% to 110.0% |              |                |       |

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                              |                           |             |                      |              |         |              |                |          |
|------------------------------|---------------------------|-------------|----------------------|--------------|---------|--------------|----------------|----------|
|                              |                           |             |                      |              | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9     |
| Standard dilution.:          | 40.22                     | mg to --->  | 200                  | ml to --->   | 5       | ml to --->   | 50             |          |
| Std.conc (in ppm)-20.11      | 1                         | ml to --->  | 1                    | ml to --->   | 1       | ml to --->   | 1              |          |
| Test dilution.:              | Granule/Pow.              | mg to --->  | 500                  | ml to --->   | 1       | ml to --->   | 1              |          |
| Test conc (in ppm)-20.01155  | 1                         | ml to --->  | 1                    | ml to --->   | 1       | ml to --->   | 1              |          |
| Conversion factor :          | 1.0000                    |             |                      |              |         |              |                |          |
| Labeled claim :              | 10                        | mg          |                      |              |         |              |                |          |
| System suitability           | 1                         | 2           | 3                    | 4            | 5       | MEAN         | S.D            | RSD in % |
| Phenylephrine HCL            | 1228966                   | 1231835     | 1229654              | 1230478      | 1231479 | 1230482      | 1205           | 0.098    |
| With Bracketing std.         | 1234641                   | 1238561     |                      |              |         | 1232231      | 3341.0         | 0.271    |
| Sample preparation           | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |         |              |                |          |
| 1                            | 4502.60                   | 1232992     | 9.96                 | 99.6         |         |              |                |          |
| Assay limit :90.0% to 110.0% |                           |             |                      |              |         |              |                |          |

ASSAY OF CHLORPHENAMINE MALEATE

|                              |                           |             |                      |              |         |              |                |          |
|------------------------------|---------------------------|-------------|----------------------|--------------|---------|--------------|----------------|----------|
|                              |                           |             |                      |              | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7     |
| Standard dilution.:          | 40.15                     | mg to --->  | 100                  | ml to --->   | 5       | ml to --->   | 50             |          |
| Std.conc (in ppm)-40.15      | 1                         | ml to --->  | 1                    | ml to --->   | 1       | ml to --->   | 1              |          |
| Test dilution.:              | Granule/Pow.              | mg to --->  | 500                  | ml to --->   | 1       | ml to --->   | 1              |          |
| Test conc(in ppm)-40.02311   | 1                         | ml to --->  | 1                    | ml to --->   | 1       | ml to --->   | 1              |          |
| Conversion factor :          | 1.0000                    |             |                      |              |         |              |                |          |
| Labeled claim :              | 20                        | mg          |                      |              |         |              |                |          |
| System suitability           | 1                         | 2           | 3                    | 4            | 5       | MEAN         | S.D            | RSD in % |
| Chlorphenamine maleate       | 2878277                   | 2871486     | 2871940              | 2868881      | 2867242 | 2871565      | 4216           | 0.147    |
| With Bracketing std.         | 2874539                   | 2875646     |                      |              |         | 2872573      | 3862           | 0.134    |
| Sample preparation           | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |         |              |                |          |
| 1                            | 4502.60                   | 2818017     | 19.63                | 98.2         |         |              |                |          |
| Assay limit :90.0% to 110.0% |                           |             |                      |              |         |              |                |          |

Calculation formula :

Assay in mg /Sachet

Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt  
Standard area x sample dilution x 100

Assay in %

Assay in mg/Sachet x 100  
Labeled claim

Analysed by :

T.MARUTHI

Date :

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Date:

15/11/22





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Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                             |            |             |
|--------------|---------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                      | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                 | Mfg.Date   | Sep-22      |
| Stage        | INTERMEDIATE PRECISION (TEST PREPARATION-5) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                |              |             |                  |         |              |                |       |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/045 | Balance ID: | ST/QC/EQ/041&030 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|

|                            |              |            |     |            |   |            |     |
|----------------------------|--------------|------------|-----|------------|---|------------|-----|
| Standard dilution.:        | 65.47        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50  |
| Std.conc (in ppm)-65.47    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
| Test conc(in ppm)-65.01588 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

|                     |         |
|---------------------|---------|
| Conversion factor : | 1.0000  |
| Labeled claim :     | 650 mg  |
| Average weight :    | 4500 mg |

|                      |         |         |         |         |         |         |       |          |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Paracetamol          | 5107709 | 5102778 | 5094844 | 5104757 | 5087478 | 5099513 | 8246  | 0.162    |
| With Bracketing std. | 5176989 | 5160224 |         |         |         | 5119254 | 34719 | 0.678    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4501.10                   | 4933172     | 633.19               | 97.4         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|         |              |                |      |
|---------|--------------|----------------|------|
| WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
|---------|--------------|----------------|------|

|                            |              |            |     |            |   |            |    |
|----------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:        | 40.22        | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-20.11    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc (in ppm)-20.0048 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 10 mg  |

|                      |         |         |         |         |         |         |        |          |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
| Phenylephrine HCL    | 1228966 | 1231835 | 1229654 | 1230478 | 1231479 | 1230482 | 1205   | 0.098    |
| With Bracketing std. | 1234641 | 1238561 |         |         |         | 1232231 | 3341.0 | 0.271    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4501.10                   | 1234538     | 9.97                 | 99.7         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|         |              |                |      |
|---------|--------------|----------------|------|
| WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
|---------|--------------|----------------|------|

|                            |              |            |     |            |   |            |    |
|----------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:        | 40.15        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-40.15    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc(in ppm)-40.00977 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 20 mg  |

|                        |         |         |         |         |         |         |      |          |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
| Chlorphenamine maleate | 2878277 | 2871486 | 2871940 | 2868881 | 2867242 | 2871565 | 4216 | 0.147    |
| With Bracketing std.   | 2874539 | 2875646 |         |         |         | 2872573 | 3862 | 0.134    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4501.10                   | 2850553     | 19.86                | 99.3         |

Assay limit :90.0% to 110.0%

Calculation formula :

|                     |                                                                          |
|---------------------|--------------------------------------------------------------------------|
| Assay in mg /Sachet | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt |
|                     | Standard area x sample dilution x 100                                    |

Assay in %

|                          |
|--------------------------|
| Assay in mg/Sachet x 100 |
| Labeled claim            |

Analysed by :

T.MARUTHI

Date :

15.11.2022

Checked by :

Date :

15/11/2022





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Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                             |            |             |
|--------------|---------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                      | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                 | Mfg.Date   | Sep-22      |
| Stage        | INTERMEDIATE PRECISION (TEST PREPARATION-6) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |              |             |                  |            |              |                |       |
|----------------------------|--------------|-------------|------------------|------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/045 | Balance ID: | ST/QC/EQ/041&030 | WS No.:    | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.47        | mg to --->  | 100              | ml to ---> | 5            | ml to --->     | 50    |
| Std.conc (in ppm)-65.47    | 1            | ml to --->  | 1                | ml to ---> | 1            | ml to --->     | 1     |
| Test dilution.:            | Granule/Pow. | mg to --->  | 500              | ml to ---> | 5            | ml to --->     | 100   |
| Test conc(in ppm)-65.05633 | 1            | ml to --->  | 1                | ml to ---> | 1            | ml to --->     | 1     |

|                     |         |
|---------------------|---------|
| Conversion factor : | 1.0000  |
| Labeled claim :     | 650 mg  |
| Average weight :    | 4500 mg |

| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| Paracetamol          | 5107709 | 5102778 | 5094844 | 5104757 | 5087478 | 5099513 | 8246  | 0.162    |
| With Bracketing std. | 5176989 | 5160224 |         |         |         | 5119254 | 34719 | 0.678    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4503.90                   | 4951317     | 635.12               | 97.7         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                             |              |            |     |            |   |            |              |                |      |
|-----------------------------|--------------|------------|-----|------------|---|------------|--------------|----------------|------|
|                             |              |            |     |            |   | WS No.:    | IAARI/WS/344 | % Purity (aib) | 98.9 |
| Standard dilution.:         | 40.22        | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-20.11     | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |
|                             |              |            |     |            |   |            |              |                |      |
| Test dilution .:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test.conc (in ppm)-20.01733 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 10 mg  |

| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| Phenylephrine HCL    | 1228966 | 1231835 | 1229654 | 1230478 | 1231479 | 1230482 | 1205   | 0.098    |
| With Bracketing std. | 1234641 | 1238561 |         |         |         | 1232231 | 3341.0 | 0.271    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4503.90                   | 1223106     | 9.88                 | 98.8         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|                            |              |            |     |            |   |            |              |                |      |
|----------------------------|--------------|------------|-----|------------|---|------------|--------------|----------------|------|
|                            |              |            |     |            |   | WS No.:    | ST/WS/22/039 | % Purity (aib) | 99.7 |
| Standard dilution.:        | 40.15        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-40.15    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test dilution .:           | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1            |                |      |
| Test conc(in ppm)-40.03466 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1            |                |      |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 20 mg  |

| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| Chlorphenamine maleate | 2878277 | 2871486 | 2871940 | 2868881 | 2867242 | 2871565 | 4216 | 0.147    |
| With Bracketing std.   | 2874539 | 2875646 |         |         |         | 2872573 | 3862 | 0.134    |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4503.90                   | 2799100     | 19.49                | 97.5         |

Assay limit :90.0% to 110.0%

Calculation formula :

Assay in mg /Sachet

Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt  
Standard area x sample dilution x 100

Assay in %

Assay in mg/Sachet x 100  
Labeled claim

Analysed by : T.MARUTHI  
Date : 15.11.2022

15/11/22

Checked by :  
Date : 15/11/2022

15/11/2022



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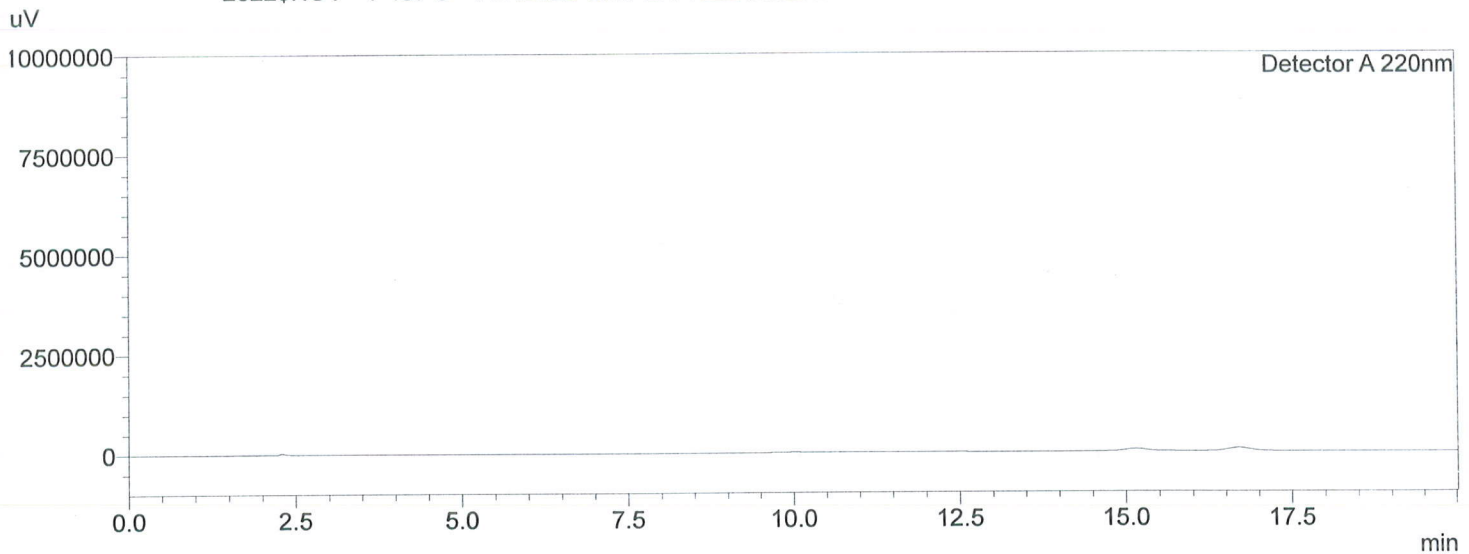
## Quality control Department

### <Sample Information>

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : BLANK-AS  
Data Filename : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-01.lcd  
Method Filename : GRIPEX-AS\_P.lcm  
Batch Filename : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Vial # : 2-1  
Injection Volume : 50 uL  
Date Acquired : 14-11-2022 6:32:02 PM  
Date Processed : 15-11-2022 3:26:36 PM

### <Chromatogram>

2022\$NOV - 1-437-3 - 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-01.lcd



### <Peak Table>

Detector A 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

T. Z  
15/11/22

Date :

Checked By

Date :

15/11/22





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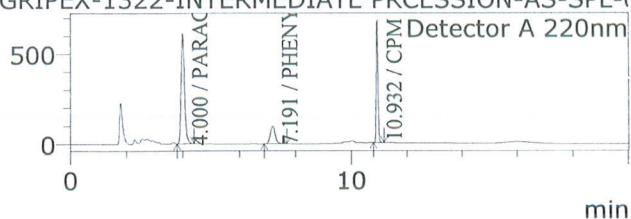
Puducherry- 605 107

## Quality control Department

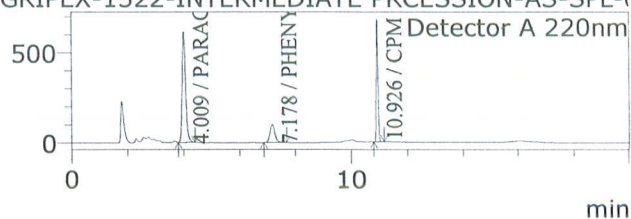
### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : PHENYL+PARA+CPM-AS-STD-01  
Tray# : 2  
Vial# : 2  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-02.lcd  
Method File : GRIPEX-AS\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
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Date Processed : 15-11-2022 9:40:16 AM

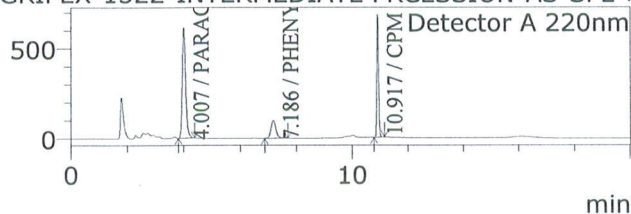
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mV



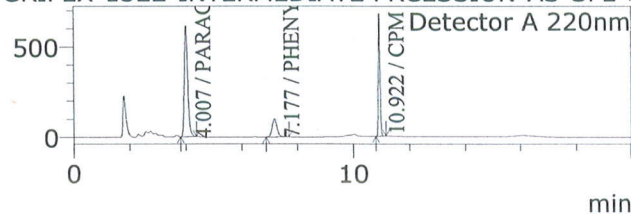
2022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-03.lcd  
mV



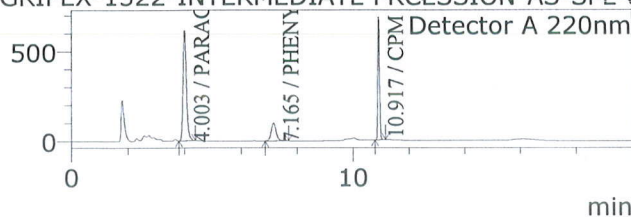
2022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-04.lcd  
mV



2022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-05.lcd  
mV



2022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-06.lcd  
mV



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 2     | AS-SPL-02.lcd | PHENYL+PARA+CPM-AS-STD-01 | 4.000  | 5107709 | 5128     | 1.233    |
| 2     | AS-SPL-03.lcd | PHENYL+PARA+CPM-AS-STD-02 | 4.009  | 5102778 | 5186     | 1.232    |
| 2     | AS-SPL-04.lcd | PHENYL+PARA+CPM-AS-STD-03 | 4.007  | 5094844 | 5171     | 1.234    |
| 2     | AS-SPL-05.lcd | PHENYL+PARA+CPM-AS-STD-04 | 4.007  | 5104757 | 5159     | 1.233    |
| 2     | AS-SPL-06.lcd | PHENYL+PARA+CPM-AS-STD-05 | 4.003  | 5087478 | 5202     | 1.237    |
|       | Average       |                           | 4.005  | 5099513 | 5169     | 1.234    |
|       | %RSD          |                           | 0.097  | 0.162   | 0.544    | 0.157    |

## ID#2 Compound Name: PHENYEPHERINE HCL

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 2     | AS-SPL-02.lcd | PHENYL+PARA+CPM-AS-STD-01 | 7.191  | 1228966 | 7806     | 1.131    |
| 2     | AS-SPL-03.lcd | PHENYL+PARA+CPM-AS-STD-02 | 7.178  | 1231835 | 7905     | 1.135    |
| 2     | AS-SPL-04.lcd | PHENYL+PARA+CPM-AS-STD-03 | 7.186  | 1229654 | 7876     | 1.135    |
| 2     | AS-SPL-05.lcd | PHENYL+PARA+CPM-AS-STD-04 | 7.177  | 1230478 | 7939     | 1.137    |
| 2     | AS-SPL-06.lcd | PHENYL+PARA+CPM-AS-STD-05 | 7.165  | 1231479 | 7871     | 1.139    |
|       | Average       |                           | 7.180  | 1230482 | 7880     | 1.135    |
|       | %RSD          |                           | 0.138  | 0.098   | 0.625    | 0.258    |

## ID#3 Compound Name: CPM

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 2     | AS-SPL-02.lcd | PHENYL+PARA+CPM-AS-STD-01 | 10.932 | 2878277 | 116045   | 1.128    |
| 2     | AS-SPL-03.lcd | PHENYL+PARA+CPM-AS-STD-02 | 10.926 | 2871486 | 116701   | 1.133    |
| 2     | AS-SPL-04.lcd | PHENYL+PARA+CPM-AS-STD-03 | 10.917 | 2871940 | 117095   | 1.133    |
| 2     | AS-SPL-05.lcd | PHENYL+PARA+CPM-AS-STD-04 | 10.922 | 2868881 | 116590   | 1.133    |
| 2     | AS-SPL-06.lcd | PHENYL+PARA+CPM-AS-STD-05 | 10.917 | 2867242 | 118137   | 1.136    |
|       | Average       |                           | 10.923 | 2871565 | 116914   | 1.133    |
|       | %RSD          |                           | 0.058  | 0.147   | 0.667    | 0.270    |

Analysed By

Date :

T.J  
15/11/22

Checked By

Date :

[Signature]  
15/11/22





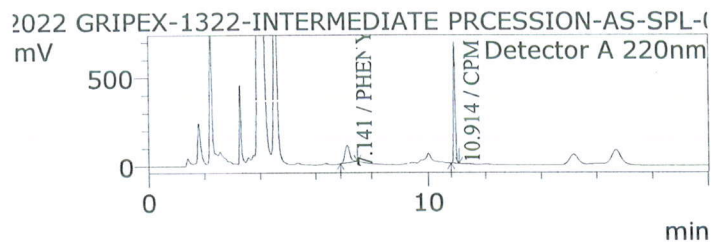
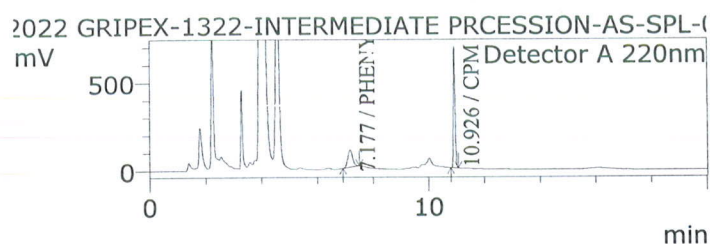
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P1-A-AS-SPL-1  
Tray# : 2  
Vial# : 3  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-07.lcd  
Method File : GRIPEX-AS\_SOLN-A\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 14-11-2022 8:36:29 PM  
Date Processed : 15-11-2022 9:43:29 AM



<< Detector A >>

ID#1 Compound Name: PHENYEPHERINE HCL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 3     | AS-SPL-07.lcd | GRIPEX-1322-INTER-P1-A-AS-SPL-1 | 7.177  | 1181184 | 8117     | 1.141    |
| 3     | AS-SPL-08.lcd | GRIPEX-1322-INTER-P1-A-AS-SPL-2 | 7.141  | 1199161 | 7982     | 1.186    |
|       | Average       |                                 | 7.159  | 1190172 | 8049     | 1.163    |
|       | %RSD          |                                 | 0.354  | 1.068   | 1.181    | 2.729    |

ID#2 Compound Name: CPM

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 3     | AS-SPL-07.lcd | GRIPEX-1322-INTER-P1-A-AS-SPL-1 | 10.926 | 2857460 | 119963   | 1.136    |
| 3     | AS-SPL-08.lcd | GRIPEX-1322-INTER-P1-A-AS-SPL-2 | 10.914 | 2856271 | 118495   | 1.132    |
|       | Average       |                                 | 10.920 | 2856865 | 119229   | 1.134    |
|       | %RSD          |                                 | 0.081  | 0.029   | 0.871    | 0.285    |

Analysed By

T. Z

Date :

15/11/22

Checked By

Date :

15/11/22



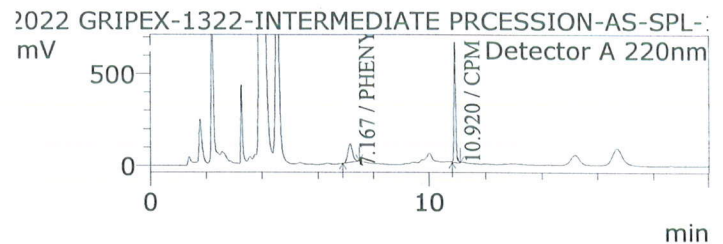
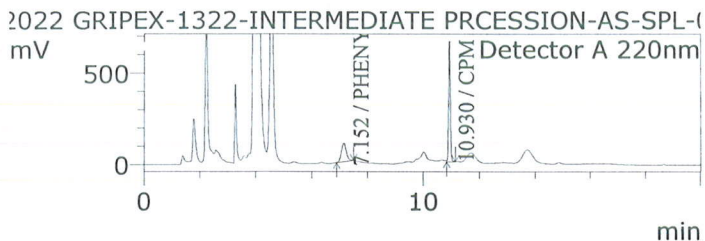
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P2-A-AS-SPL-1  
Tray# : 2  
Vial# : 4  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-09.lcd  
Method File : GRIPEX-AS\_SOLN-A\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 15-11-2022 1:19:19 PM  
Date Processed : 15-11-2022 3:19:48 PM



<< Detector A >>

ID#1 Compound Name: PHENYEPHERINE HCL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 4     | AS-SPL-09.lcd | GRIPEX-1322-INTER-P2-A-AS-SPL-1 | 7.152  | 1228304 | 7857     | 1.172    |
| 4     | AS-SPL-10.lcd | GRIPEX-1322-INTER-P2-A-AS-SPL-2 | 7.167  | 1212195 | 7801     | 1.140    |
|       | Average       |                                 | 7.159  | 1220249 | 7829     | 1.156    |
|       | %RSD          |                                 | 0.148  | 0.934   | 0.505    | 1.929    |

ID#2 Compound Name: CPM

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 4     | AS-SPL-09.lcd | GRIPEX-1322-INTER-P2-A-AS-SPL-1 | 10.930 | 2809031 | 120713   | 1.133    |
| 4     | AS-SPL-10.lcd | GRIPEX-1322-INTER-P2-A-AS-SPL-2 | 10.920 | 2812458 | 120532   | 1.142    |
|       | Average       |                                 | 10.925 | 2810745 | 120622   | 1.137    |
|       | %RSD          |                                 | 0.062  | 0.086   | 0.106    | 0.572    |

Analysed By

Date :

T.J  
15/11/22

Checked By

Date :

Deep  
15/11/22





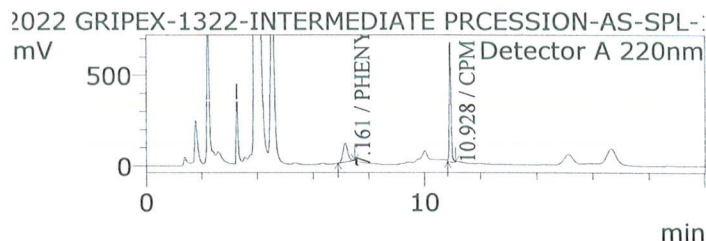
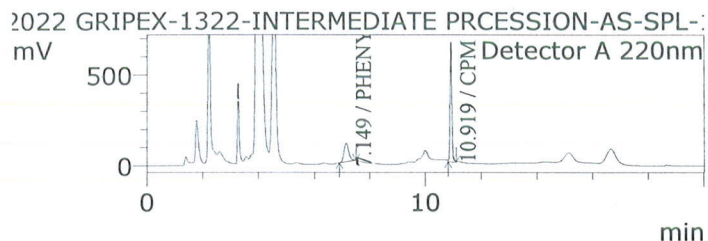
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P3-A-AS-SPL-1  
Tray# : 2  
Vial# : 5  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-11.lcd  
Method File : GRIPEX-AS\_SOLN-A\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 15-11-2022 2:00:43 PM  
Date Processed : 15-11-2022 3:13:19 PM



<< Detector A >>

ID#1 Compound Name: PHENYEPHERINE HCL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 5     | AS-SPL-11.lcd | GRIPEX-1322-INTER-P3-A-AS-SPL-1 | 7.149  | 1262152 | 7659     | 1.211    |
| 5     | AS-SPL-12.lcd | GRIPEX-1322-INTER-P3-A-AS-SPL-2 | 7.161  | 1259467 | 7749     | 1.193    |
|       | Average       |                                 | 7.155  | 1260810 | 7704     | 1.202    |
|       | %RSD          |                                 | 0.116  | 0.151   | 0.826    | 1.061    |

ID#2 Compound Name: CPM

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 5     | AS-SPL-11.lcd | GRIPEX-1322-INTER-P3-A-AS-SPL-1 | 10.919 | 2826202 | 119304   | 1.130    |
| 5     | AS-SPL-12.lcd | GRIPEX-1322-INTER-P3-A-AS-SPL-2 | 10.928 | 2833145 | 119584   | 1.131    |
|       | Average       |                                 | 10.923 | 2829674 | 119444   | 1.131    |
|       | %RSD          |                                 | 0.055  | 0.173   | 0.165    | 0.094    |

Analysed By

T. Z

Date :

15/11/22

Checked By

Date :

15/11/22



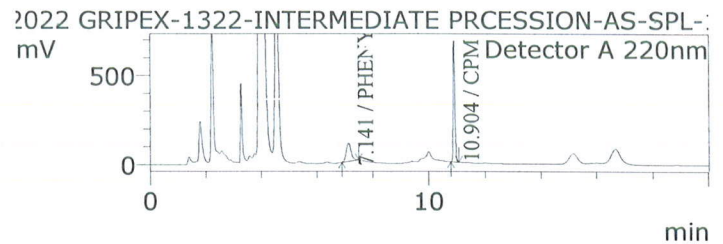
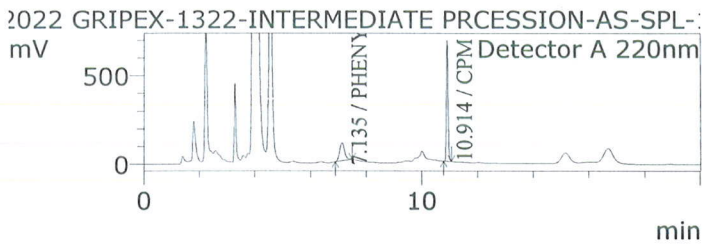
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P4-A-AS-SPL-1  
Tray# : 2  
Vial# : 6  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-13.lcd  
Method File : GRIPEX-AS\_SOLN-A\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 14-11-2022 10:40:50 PM  
Date Processed : 15-11-2022 9:43:34 AM



<< Detector A >>

ID#1 Compound Name: PHENYEPHERINE HCL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 6     | AS-SPL-13.lcd | GRIPEX-1322-INTER-P4-A-AS-SPL-1 | 7.135  | 1236658 | 8030     | 1.215    |
| 6     | AS-SPL-14.lcd | GRIPEX-1322-INTER-P4-A-AS-SPL-2 | 7.141  | 1229325 | 8023     | 1.189    |
|       | Average       |                                 | 7.138  | 1232992 | 8027     | 1.202    |
|       | %RSD          |                                 | 0.066  | 0.421   | 0.060    | 1.578    |

ID#2 Compound Name: CPM

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 6     | AS-SPL-13.lcd | GRIPEX-1322-INTER-P4-A-AS-SPL-1 | 10.914 | 2818807 | 120521   | 1.130    |
| 6     | AS-SPL-14.lcd | GRIPEX-1322-INTER-P4-A-AS-SPL-2 | 10.904 | 2817228 | 128623   | 1.134    |
|       | Average       |                                 | 10.909 | 2818017 | 124572   | 1.132    |
|       | %RSD          |                                 | 0.063  | 0.040   | 4.599    | 0.294    |

Analysed By

T.J  
15/11/22

Date :

Checked By

Date :

15/11/22





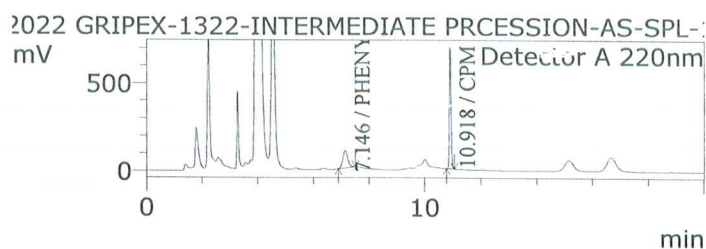
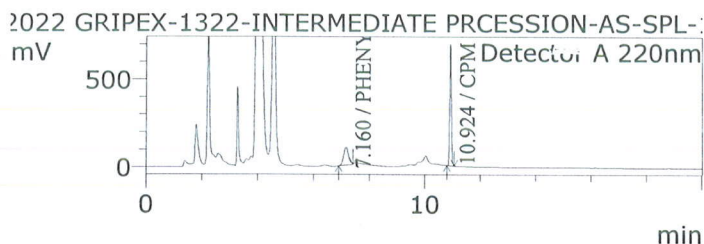
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P5-A-AS-SPL-1  
Tray# : 2  
Vial# : 7  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-15.lcd  
Method File : GRIPEX-AS\_SOLN-A\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 15-11-2022 10:22:48 AM  
Date Processed : 15-11-2022 3:14:16 PM



<< Detector A >>

ID#1 Compound Name: PHENYEPHERINE HCL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 7     | AS-SPL-15.lcd | GRIPEX-1322-INTER-P5-A-AS-SPL-1 | 7.160  | 1235038 | 7967     | --       |
| 7     | AS-SPL-16.lcd | GRIPEX-1322-INTER-P5-A-AS-SPL-2 | 7.146  | 1234038 | 7753     | 1.243    |
|       | Average       |                                 | 7.153  | 1234538 | 7860     | 1.243    |
|       | %RSD          |                                 | 0.135  | 0.057   | 1.920    | 0.000    |

ID#2 Compound Name: CPM

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 7     | AS-SPL-15.lcd | GRIPEX-1322-INTER-P5-A-AS-SPL-1 | 10.924 | 2850797 | 121067   | 1.124    |
| 7     | AS-SPL-16.lcd | GRIPEX-1322-INTER-P5-A-AS-SPL-2 | 10.918 | 2850310 | 121381   | 1.134    |
|       | Average       |                                 | 10.921 | 2850553 | 121224   | 1.129    |
|       | %RSD          |                                 | 0.040  | 0.012   | 0.183    | 0.600    |

Analysed By T.F

Date :

15/11/22

Checked By

Date :

15/11/22



# Safetab Life Science

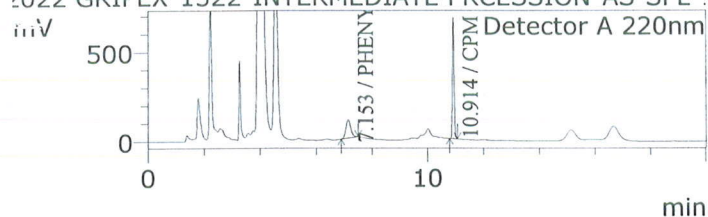
Puducherry- 605 107

## Quality control Department

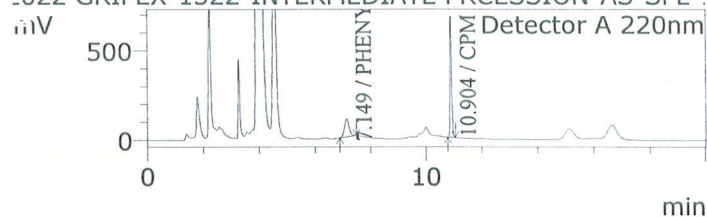
### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P6-A-AS-SPL-1  
Tray# : 2  
Vial# : 8  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-17.lcd  
Method File : GRIPEX-AS\_SOLN-A\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 15-11-2022 11:04:13 AM  
Date Processed : 15-11-2022 12:02:00 PM

2022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-17.lcd



2022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-18.lcd



<< Detector A >>

ID#1 Compound Name: PHENYEPHERINE HCL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 8     | AS-SPL-17.lcd | GRIPEX-1322-INTER-P6-A-AS-SPL-1 | 7.153  | 1223617 | 7974     | 1.135    |
| 8     | AS-SPL-18.lcd | GRIPEX-1322-INTER-P6-A-AS-SPL-2 | 7.149  | 1222596 | 7928     | 1.139    |
|       | Average       |                                 | 7.151  | 1223106 | 7951     | 1.137    |
|       | %RSD          |                                 | 0.047  | 0.059   | 0.402    | 0.250    |

ID#2 Compound Name: CPM

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 8     | AS-SPL-17.lcd | GRIPEX-1322-INTER-P6-A-AS-SPL-1 | 10.914 | 2797800 | 120624   | 1.127    |
| 8     | AS-SPL-18.lcd | GRIPEX-1322-INTER-P6-A-AS-SPL-2 | 10.904 | 2800400 | 127491   | 1.136    |
|       | Average       |                                 | 10.909 | 2799100 | 124057   | 1.131    |
|       | %RSD          |                                 | 0.068  | 0.066   | 3.914    | 0.556    |

Analysed By

Date :

T.7  
15/11/22

Checked By

Date :

15/11/22





# Safetab Life Science

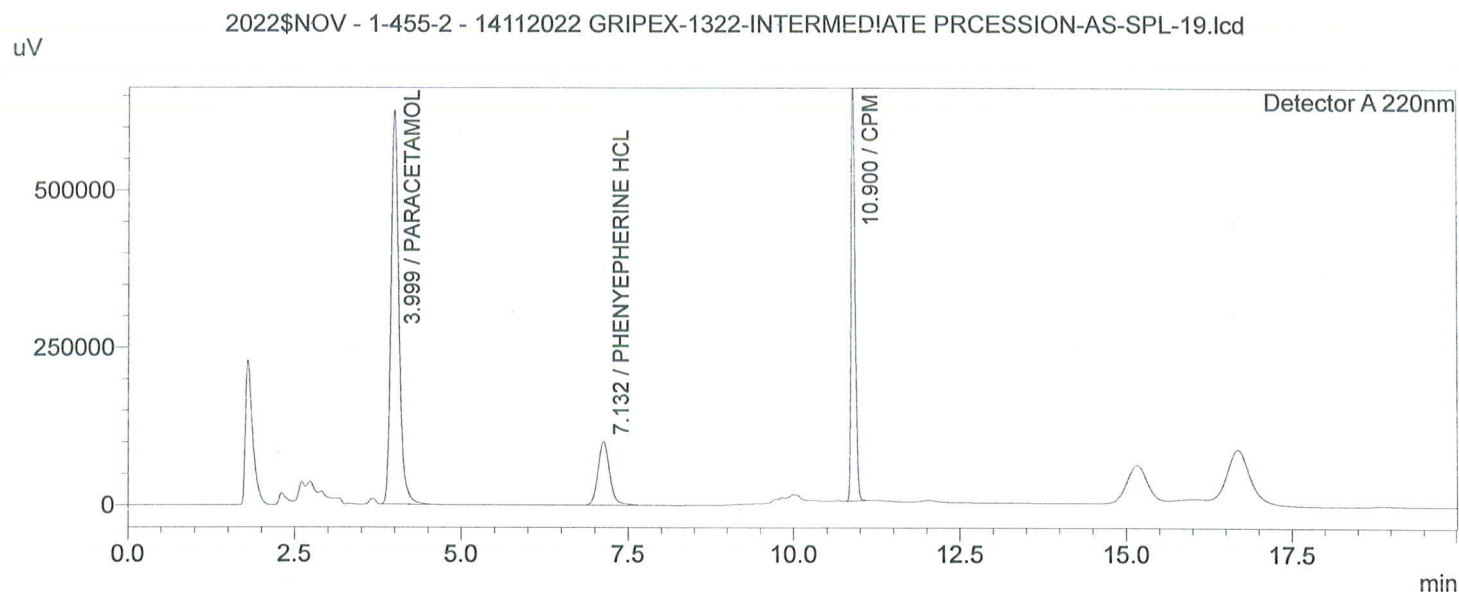
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : PHENYL+PARA+CPM-AS-STD-BKT-1  
Data Filename : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-19.lcd  
Method Filename : GRIPEX-AS\_P.lcm  
Batch Filename : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Vial # : 2-2  
Injection Volume : 50 uL  
Date Acquired : 15-11-2022 12:45:31 AM  
Date Processed : 15-11-2022 9:40:21 AM

### <Chromatogram>



### <Peak Table>

Detector A 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name              |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------------|
| 1     | 3.999     | 5176989 | 55.749  | 5270    | 1.236    | --         | --       | PARACETAMOL       |
| 2     | 7.132     | 1234641 | 13.295  | 7915    | 1.125    | 11.58      | --       | PHENYEPHERINE HCL |
| 3     | 10.900    | 2874539 | 30.955  | 122109  | 1.133    | 16.92      | --       | CPM               |
| Total |           | 9286169 | 100.000 |         |          |            |          |                   |

Analysed By

T.F

Date :

15/11/22

Checked By

Date :

15/11/22



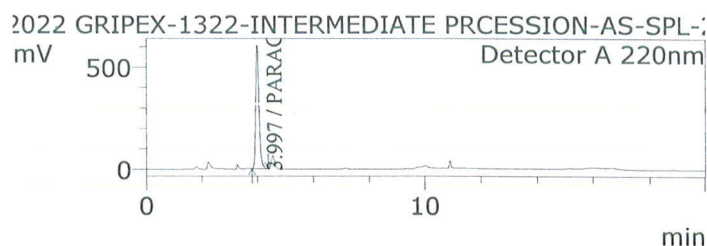
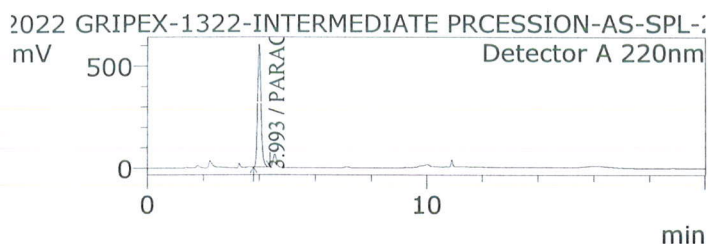
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P1-B-AS-SPL-1  
Tray# : 2  
Vial# : 9  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-20.lcd  
Method File : GRIPEX-AS SOLN-B P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 15-11-2022 1:06:14 AM  
Date Processed : 15-11-2022 9:45:09 AM



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 9     | AS-SPL-20.lcd | GRIPEX-1322-INTER-P1-B-AS-SPL-1 | 3.993  | 4925213 | 5261     | 1.220    |
| 9     | AS-SPL-21.lcd | GRIPEX-1322-INTER-P1-B-AS-SPL-2 | 3.997  | 4920144 | 5303     | 1.216    |
|       | Average       |                                 | 3.995  | 4922678 | 5282     | 1.218    |
|       | %RSD          |                                 | 0.071  | 0.073   | 0.570    | 0.232    |

Analysed By

Date :

P. Z  
15/11/22

Checked By

Date :

15/11/2022





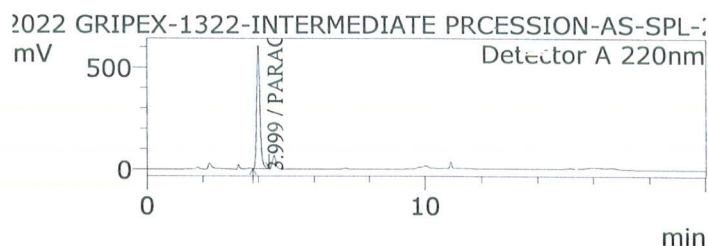
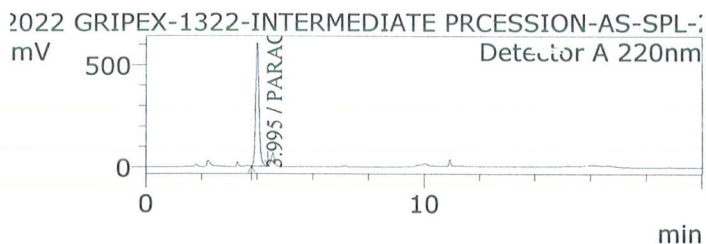
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P2-B-AS-SPL-1  
Tray# : 2  
Vial# : 10  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-22.lcd  
Method File : GRIPEX-AS\_SOLN-B\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 15-11-2022 1:47:38 AM  
Date Processed : 15-11-2022 9:45:10 AM



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 10    | AS-SPL-22.lcd | GRIPEX-1322-INTER-P2-B-AS-SPL-1 | 3.995  | 4955090 | 5226     | 1.219    |
| 10    | AS-SPL-23.lcd | GRIPEX-1322-INTER-P2-B-AS-SPL-2 | 3.999  | 4955651 | 5243     | 1.215    |
|       | Average       |                                 | 3.997  | 4955371 | 5235     | 1.217    |
|       | %RSD          |                                 | 0.062  | 0.008   | 0.231    | 0.231    |

Analysed By

T.J

Date :

15/11/22

Checked By

Date :

15/11/22



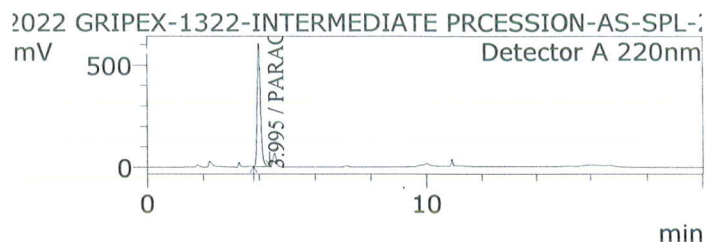
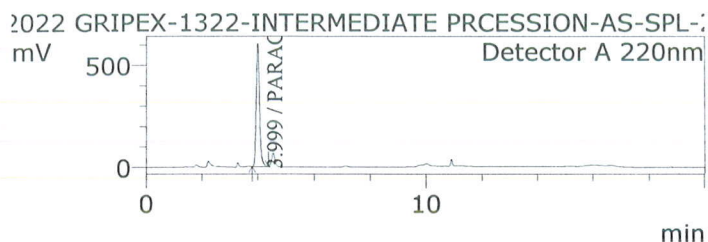
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P3-B-AS-SPL-1  
Tray# : 2  
Vial# : 11  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-24.lcd  
Method File : GRIPEX-AS\_SOLN-B\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 15-11-2022 2:29:03 AM  
Date Processed : 15-11-2022 9:45:11 AM



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 11    | AS-SPL-24.lcd | GRIPEX-1322-INTER-P3-B-AS-SPL-1 | 3.999  | 4940645 | 5252     | 1.215    |
| 11    | AS-SPL-25.lcd | GRIPEX-1322-INTER-P3-B-AS-SPL-2 | 3.995  | 4944583 | 5254     | 1.217    |
|       | Average       |                                 | 3.997  | 4942614 | 5253     | 1.216    |
|       | %RSD          |                                 | 0.065  | 0.056   | 0.020    | 0.083    |

Analysed By

Date :

P. Z  
15/11/22

Checked By

Date :

15/11/22





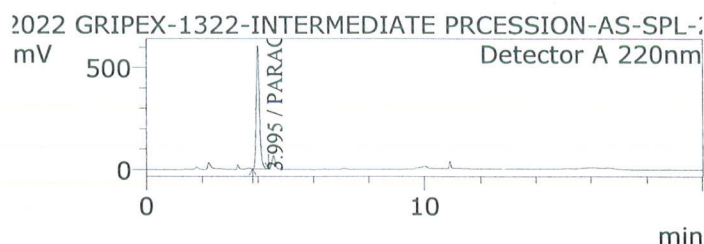
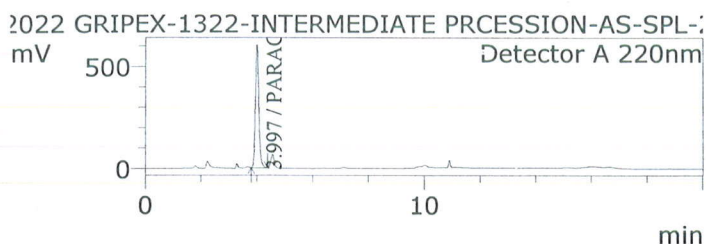
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P4-B-AS-SPL-1  
Tray# : 2  
Vial# : 12  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-26.lcd  
Method File : GRIPEX-AS SOLN-B P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 15-11-2022 3:10:29 AM  
Date Processed : 15-11-2022 9:45:13 AM



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 12    | AS-SPL-26.lcd | GRIPEX-1322-INTER-P4-B-AS-SPL-1 | 3.997  | 4937378 | 5272     | 1.214    |
| 12    | AS-SPL-27.lcd | GRIPEX-1322-INTER-P4-B-AS-SPL-2 | 3.995  | 4945857 | 5260     | 1.216    |
|       | Average       |                                 | 3.996  | 4941618 | 5266     | 1.215    |
|       | %RSD          |                                 | 0.027  | 0.121   | 0.149    | 0.112    |

Analysed By

T.J

Date :

15/11/22

Checked By

Date:

15/11/22



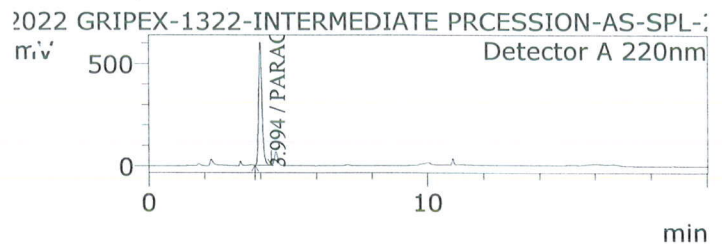
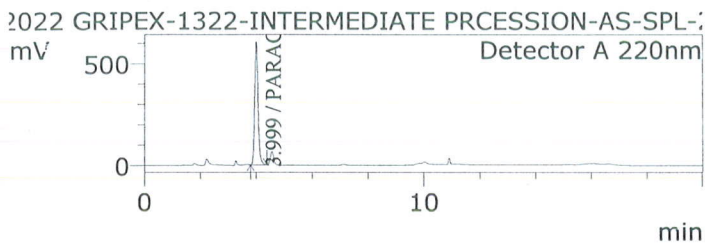
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P5-B-AS-SPL-1  
Tray# : 2  
Vial# : 13  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-28.lcd  
Method File : GRIPEX-AS\_SOLN-B\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 15-11-2022 3:51:54 AM  
Date Processed : 15-11-2022 9:45:15 AM



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 13    | AS-SPL-28.lcd | GRIPEX-1322-INTER-P5-B-AS-SPL-1 | 3.999  | 4939729 | 5266     | 1.214    |
| 13    | AS-SPL-29.lcd | GRIPEX-1322-INTER-P5-B-AS-SPL-2 | 3.994  | 4926614 | 5225     | 1.215    |
|       | Average       |                                 | 3.996  | 4933172 | 5245     | 1.214    |
|       | %RSD          |                                 | 0.092  | 0.188   | 0.557    | 0.050    |

Analysed By

*T. Maruthi*  
16/11/22

Date :

Checked By

Date :

*[Signature]*  
15/11/22





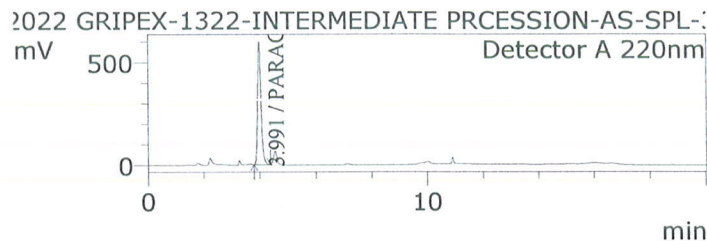
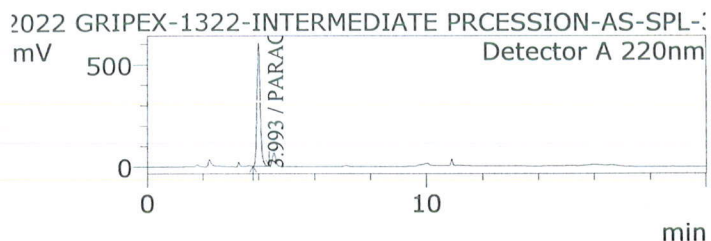
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : T.MARUTHI  
Sample Name : GRIPEX  
Sample ID : GRIPEX-1322-INTER-P6-B-AS-SPL-1  
Tray# : 2  
Vial# : 14  
Injection Volume : 50  
Data File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS-SPL-30.lcd  
Method File : GRIPEX-AS\_SOLN-B\_P.lcm  
Batch File : 14112022 GRIPEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 15-11-2022 4:33:18 AM  
Date Processed : 15-11-2022 9:45:16 AM



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 14    | AS-SPL-30.lcd | GRIPEX-1322-INTER-P6-B-AS-SPL-1 | 3.993  | 4949798 | 5198     | 1.213    |
| 14    | AS-SPL-31.lcd | GRIPEX-1322-INTER-P6-B-AS-SPL-2 | 3.991  | 4952837 | 5110     | 1.214    |
|       | Average       |                                 | 3.992  | 4951317 | 5154     | 1.214    |
|       | %RSD          |                                 | 0.033  | 0.043   | 1.199    | 0.075    |

Analysed By

T.J

Date :

15/11/22

Checked By

Date :

Deep  
15/11/22

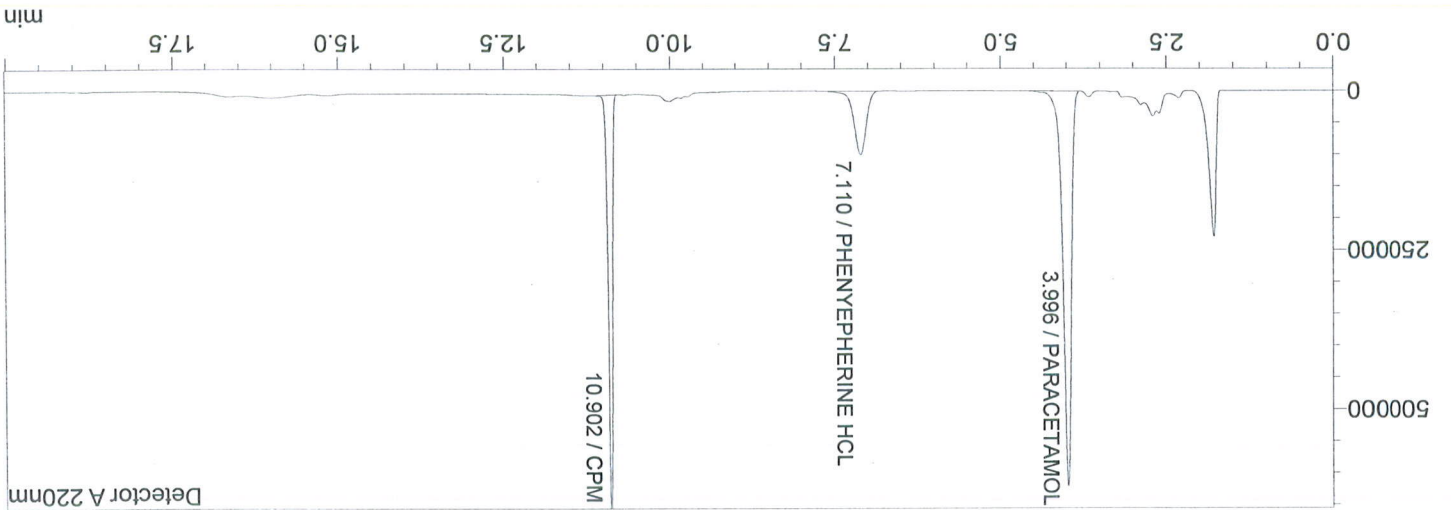


**<Sample Information>**

Acquired by : T.MARUTHI  
Sample Name : GRIPLEX  
Sample ID : PHENYL+PARA+CPM-AS-STD-BKT-2  
Data Filename : 14112022 GRIPLEX-1322-INTERMEDIATE PRESSION-AS-SPL-32.lcd  
Method Filename : GRIPLEX-AS\_P.lcm  
Batch Filename : 14112022 GRIPLEX-1322-INTERMEDIATE PRESSION-AS.lcb  
Vial # : 2-2  
Injection Volume : 50 uL  
Date Acquired : 15-11-2022 5:14:43 AM  
Date Processed : 15-11-2022 9:40:22 AM

**<Chromatogram>**

2022\$NOV - 1-468-2 - 14112022 GRIPLEX-1322-INTERMEDIATE PRESSION-AS-SPL-32.lcd



**<Peak Table>**

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name              |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------------|
| 1     | 3.996     | 5160224 | 55.639  | 5179    | 1.230    | --         | --       | PARACETAMOL       |
| 2     | 7.110     | 1238561 | 13.355  | 7656    | 1.131    | 11.38      | --       | PHENYEPHERINE HCL |
| 3     | 10.902    | 2875646 | 31.006  | 122041  | 1.139    | 16.86      | --       | CPM               |
| Total |           | 9274430 | 100.000 |         |          |            |          |                   |

Analysed By : *T.L*

Date : *16/11/22*

Checked By : *[Signature]*

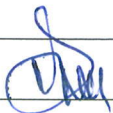
Date : *16/11/2022*



**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

|                     |             |
|---------------------|-------------|
| Name of the Product | Gripex      |
| Batch No            | SJ/T/S-1322 |

| S. No | TEST / OBSERVATION / LIMIT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1     | <p>Intermediate Precision:</p> <p>diluent : 50 Butter : 50 methanol.</p> <p>Std preparation:</p> <p>Stock 1 :</p> <p>65.47 of paracetamol and 40.15 mg of cpm in 100ml volumetric flask add 70ml of diluent Sonificate and dissolve. make up to volume with diluent</p> <p>Stock 2 :</p> <p>40.22 mg of Phenylphrine in 200ml volumetric flask add 130ml of diluent volume for dissolved and make up to volume with diluent</p> <p>Std preparation:</p> <p>Each 15 ml of Stock 1, and Stock 2 to 50ml with diluent</p> <p>Spl preparation:</p> <p>4.9989 g of Spl in 500ml volumetric flask add 250ml of diluent Sonificate for 20mins and make up with volume with diluent. filter with PVDF filter in solution (A).</p> <p>Solution (b) 5 to 100 ml with volumetric flask with diluent then filter with PVDF filter</p> <p>further 5 preparation prepared by same as above procedure.</p> |

|                    |                 |                                                                                                    |                 |
|--------------------|-----------------|----------------------------------------------------------------------------------------------------|-----------------|
| Analyzed by : T. J | Date : 15/11/22 | Checked by :  | Date : 15/11/22 |
|--------------------|-----------------|----------------------------------------------------------------------------------------------------|-----------------|



# Safetab Life Science

Puducherry- 605 107

*Quality control Department*

## =====BATCH TABLE=====

Batch Table

| Vial# | Tray | Inj. Vol. | Sample Name | Sample ID                       | Method File   | Data File                         | Data Comment |
|-------|------|-----------|-------------|---------------------------------|---------------|-----------------------------------|--------------|
| 1     | 2    | 50.0      | GRIPEX      | BLANK-AS                        | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-01.lcd | QC/CL/19/009 |
| 2     | 2    | 50.0      | GRIPEX      | PHENYL+PARA+CPM-AS-STD-01       | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-02.lcd | QC/CL/19/009 |
| 2     | 2    | 50.0      | GRIPEX      | PHENYL+PARA+CPM-AS-STD-02       | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-03.lcd | QC/CL/19/009 |
| 2     | 2    | 50.0      | GRIPEX      | PHENYL+PARA+CPM-AS-STD-03       | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-04.lcd | QC/CL/19/009 |
| 2     | 2    | 50.0      | GRIPEX      | PHENYL+PARA+CPM-AS-STD-04       | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-05.lcd | QC/CL/19/009 |
| 2     | 2    | 50.0      | GRIPEX      | PHENYL+PARA+CPM-AS-STD-05       | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-06.lcd | QC/CL/19/009 |
| 3     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P1-A-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-07.lcd | QC/CL/19/009 |
| 3     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P1-A-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-08.lcd | QC/CL/19/009 |
| 4     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P2-A-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-09.lcd | QC/CL/19/009 |
| 4     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P2-A-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-10.lcd | QC/CL/19/009 |
| 5     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P3-A-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-11.lcd | QC/CL/19/009 |
| 5     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P3-A-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-12.lcd | QC/CL/19/009 |
| 6     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P4-A-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-13.lcd | QC/CL/19/009 |
| 6     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P4-A-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-14.lcd | QC/CL/19/009 |
| 7     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P5-A-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-15.lcd | QC/CL/19/009 |
| 7     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P5-A-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-16.lcd | QC/CL/19/009 |
| 8     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P6-A-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-17.lcd | QC/CL/19/009 |
| 8     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P6-A-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-18.lcd | QC/CL/19/009 |
| 2     | 2    | 50.0      | GRIPEX      | PHENYL+PARA+CPM-AS-STD-BKT-1    | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-19.lcd | QC/CL/19/009 |
| 9     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P1-B-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-20.lcd | QC/CL/19/009 |
| 9     | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P1-B-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-21.lcd | QC/CL/19/009 |
| 10    | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P2-B-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-22.lcd | QC/CL/19/009 |
| 10    | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P2-B-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-23.lcd | QC/CL/19/009 |
| 11    | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P3-B-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-24.lcd | QC/CL/19/009 |
| 11    | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P3-B-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-25.lcd | QC/CL/19/009 |
| 12    | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P4-B-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-26.lcd | QC/CL/19/009 |
| 12    | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P4-B-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-27.lcd | QC/CL/19/009 |
| 13    | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P5-B-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-28.lcd | QC/CL/19/009 |



| Vial# | Tray | Inj. Vol. | Sample Name | Sample ID                       | Method File   | Data File                         | Data Comment |
|-------|------|-----------|-------------|---------------------------------|---------------|-----------------------------------|--------------|
| 13    | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P5-B-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-29.lcd | QC/CL/19/009 |
| 14    | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P6-B-AS-SPL-1 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-30.lcd | QC/CL/19/009 |
| 14    | 2    | 50.0      | GRIPEX      | GRIPEX-1322-INTER-P6-B-AS-SPL-2 | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-31.lcd | QC/CL/19/009 |
| 2     | 2    | 50.0      | GRIPEX      | PHENYL+PARA+CPM-AS-STD-BKT-2    | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-32.lcd | QC/CL/19/009 |
| 15    | 2    | 50.0      | GRIPEX      | GRIPEX-GR-094-SOL-A-AS-SPL-1    | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-33.lcd | QC/CL/19/009 |
| 15    | 2    | 50.0      | GRIPEX      | GRIPEX-GR-094-SOL-A-AS-SPL-2    | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-34.lcd | QC/CL/19/009 |
| 16    | 2    | 50.0      | GRIPEX      | GRIPEX-GR-094-SOL-B-AS-SPL-1    | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-35.lcd | QC/CL/19/009 |
| 16    | 2    | 50.0      | GRIPEX      | GRIPEX-GR-094-SOL-B-AS-SPL-2    | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-36.lcd | QC/CL/19/009 |
| 2     | 2    | 50.0      | GRIPEX      | PHENYL+PARA+CPM-AS-STD-BKT-3    | GRIPEX-AS.lcm | ERMEDIATE PRCESSION-AS-SPL-37.lcd | QC/CL/19/009 |

Analysed By

J.F

Date :

14/11/22

Checked By

Date :

14/11/22

**Safetab Life Science ,**

Puducherry - 605 107

**QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

| Title                                                                                                                                                                           |                    | ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS |                |              |                   |                |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------------------------------------------------------------------------|----------------|--------------|-------------------|----------------|--------------|
| Product Name :                                                                                                                                                                  | GRIPEX             |                                                                                      |                |              |                   | Batch size :   | 500 SACHETS  |
| Batch Number :                                                                                                                                                                  | ST/T/S-1322        |                                                                                      |                |              |                   | Mfg.Date :     | Sep-22       |
| Parameter :                                                                                                                                                                     | SYSTEM SUITABILITY |                                                                                      |                |              |                   | Exp.Date :     | To be fixed  |
| Each 4.5gm of sachet Contains<br>Paracetamol BP ----- 650mg<br>Phenylephrine Hydrochloride BP ----- 10mg<br>Chlorphenamine Maleate BP ----- 20mg<br>Ascorbic acid BP ----- 50mg |                    |                                                                                      |                |              |                   |                |              |
| <b>ASSAY OF PARACETAMOL</b>                                                                                                                                                     |                    |                                                                                      |                |              |                   |                |              |
| Instrument ID:                                                                                                                                                                  | ST/QC/EQ/039       |                                                                                      | Balance ID :   | ST/QC/EQ/041 |                   | WS No.:        | ST/WS/22/011 |
| Standard dilution :                                                                                                                                                             | 65.57              | mg to --->                                                                           | 100            | ml to --->   | 5                 | ml to --->     | 50           |
| Std.conc (in ppm)-65.57                                                                                                                                                         | 1                  | ml to --->                                                                           | 1              | ml to --->   | 1                 | ml to --->     | 1            |
|                                                                                                                                                                                 |                    | No. of injections                                                                    | Retention time | Area         | Theoretical plate | Tailing factor |              |
|                                                                                                                                                                                 |                    | 1                                                                                    | 3.824          | 5299765      | 4798              | 1.266          |              |
|                                                                                                                                                                                 |                    | 2                                                                                    | 3.822          | 5304398      | 4749              | 1.266          |              |
|                                                                                                                                                                                 |                    | 3                                                                                    | 3.825          | 5298864      | 4761              | 1.265          |              |
|                                                                                                                                                                                 |                    | 4                                                                                    | 3.823          | 5298686      | 4730              | 1.268          |              |
|                                                                                                                                                                                 |                    | 5                                                                                    | 3.824          | 5297760      | 4750              | 1.269          |              |
|                                                                                                                                                                                 |                    | Average                                                                              | 3.823          | 5299895      | 4758              | 1.267          |              |
|                                                                                                                                                                                 |                    | RSD %                                                                                | 0.026          | 0.049        | Not applicable    | Not applicable |              |
| <b>ASSAY OF PHENYLEPHRINE HYDROCHLORIDE</b>                                                                                                                                     |                    |                                                                                      |                |              |                   |                |              |
| Instrument ID:                                                                                                                                                                  | ST/QC/EQ/039       |                                                                                      | Balance ID :   | ST/QC/EQ/041 |                   | WS No.:        | IAARI/WS/344 |
| Standard dilution :                                                                                                                                                             | 40.68              | mg to --->                                                                           | 200            | ml to --->   | 5                 | ml to --->     | 50           |
| Std.conc (in ppm)-20.34                                                                                                                                                         | 1                  | ml to --->                                                                           | 1              | ml to --->   | 1                 | ml to --->     | 1            |
|                                                                                                                                                                                 |                    | No. of injections                                                                    | Retention time | Area         | Theoretical plate | Tailing factor |              |
|                                                                                                                                                                                 |                    | 1                                                                                    | 6.679          | 1234812      | 7291              | 1.210          |              |
|                                                                                                                                                                                 |                    | 2                                                                                    | 6.676          | 1234933      | 7241              | 1.210          |              |
|                                                                                                                                                                                 |                    | 3                                                                                    | 6.677          | 1234415      | 7273              | 1.208          |              |
|                                                                                                                                                                                 |                    | 4                                                                                    | 6.675          | 1234160      | 7210              | 1.208          |              |
|                                                                                                                                                                                 |                    | 5                                                                                    | 6.666          | 1234096      | 7208              | 1.208          |              |
|                                                                                                                                                                                 |                    | Average                                                                              | 6.675          | 1234483      | 7245              | 1.209          |              |
|                                                                                                                                                                                 |                    | RSD %                                                                                | 0.075          | 0.031        | Not applicable    | Not applicable |              |
| <b>ASSAY OF CHLORPHENAMINE MALEATE</b>                                                                                                                                          |                    |                                                                                      |                |              |                   |                |              |
| Instrument ID:                                                                                                                                                                  | ST/QC/EQ/039       |                                                                                      | Balance ID :   | ST/QC/EQ/041 |                   | WS No.:        | ST/WS/22/039 |
| Standard dilution :                                                                                                                                                             | 40.02              | mg to --->                                                                           | 100            | ml to --->   | 5                 | ml to --->     | 50           |
| Std.conc (in ppm)-40.02                                                                                                                                                         | 1                  | ml to --->                                                                           | 1              | ml to --->   | 1                 | ml to --->     | 1            |
|                                                                                                                                                                                 |                    | No. of injections                                                                    | Retention time | Area         | Theoretical plate | Tailing factor |              |
|                                                                                                                                                                                 |                    | 1                                                                                    | 10.890         | 2742713      | 78123             | 1.471          |              |
|                                                                                                                                                                                 |                    | 2                                                                                    | 10.885         | 2756022      | 79919             | 1.459          |              |
|                                                                                                                                                                                 |                    | 3                                                                                    | 10.887         | 2759392      | 81415             | 1.468          |              |
|                                                                                                                                                                                 |                    | 4                                                                                    | 10.889         | 2765344      | 76358             | 1.467          |              |
|                                                                                                                                                                                 |                    | 5                                                                                    | 10.879         | 2759498      | 76924             | 1.475          |              |
|                                                                                                                                                                                 |                    | Average                                                                              | 10.886         | 2756594      | 78548             | 1.468          |              |
|                                                                                                                                                                                 |                    | RSD %                                                                                | 0.040          | 0.307        | Not applicable    | Not applicable |              |
| <b>Results :</b>                                                                                                                                                                |                    | System suitability Parameters                                                        |                | Paracetamol  | Phenylephrine     | Chlorphenamine |              |
|                                                                                                                                                                                 |                    | 1) % RSD                                                                             |                | 0.049        | 0.031             | 0.307          |              |
|                                                                                                                                                                                 |                    | 2) Theoretical plate                                                                 |                | 4758         | 7245              | 78548          |              |
|                                                                                                                                                                                 |                    | 3) Tailing factor                                                                    |                | 1.267        | 1.209             | 1.468          |              |
| <b>Acceptance criteria:</b>                                                                                                                                                     |                    |                                                                                      |                |              |                   |                |              |
| 1) % RSD of area of Paracetamol, Phenylephrine and Chlorphenamine peak in five replicate standard injections should not be more than 2.0.                                       |                    |                                                                                      |                |              |                   |                |              |
| 2) Theoretical plate for Paracetamol, Phenylephrine and Chlorphenamine peak in standard injection should not be less than 2000.                                                 |                    |                                                                                      |                |              |                   |                |              |
| 3) Tailing factor for Paracetamol, Phenylephrine and Chlorphenamine peak in standard injection should not be more than 2.0.                                                     |                    |                                                                                      |                |              |                   |                |              |
| Analysed by :                                                                                                                                                                   | C. ALBIN JOSE      |                                                                                      |                |              |                   |                |              |
| Date :                                                                                                                                                                          | 13-10-2022         |                                                                                      |                |              |                   |                |              |
| Checked by :                                                                                                                                                                    |                    |                                                                                      |                |              |                   |                |              |
| Date :                                                                                                                                                                          | 13/10/2022         |                                                                                      |                |              |                   |                |              |





# Safetab Life Science

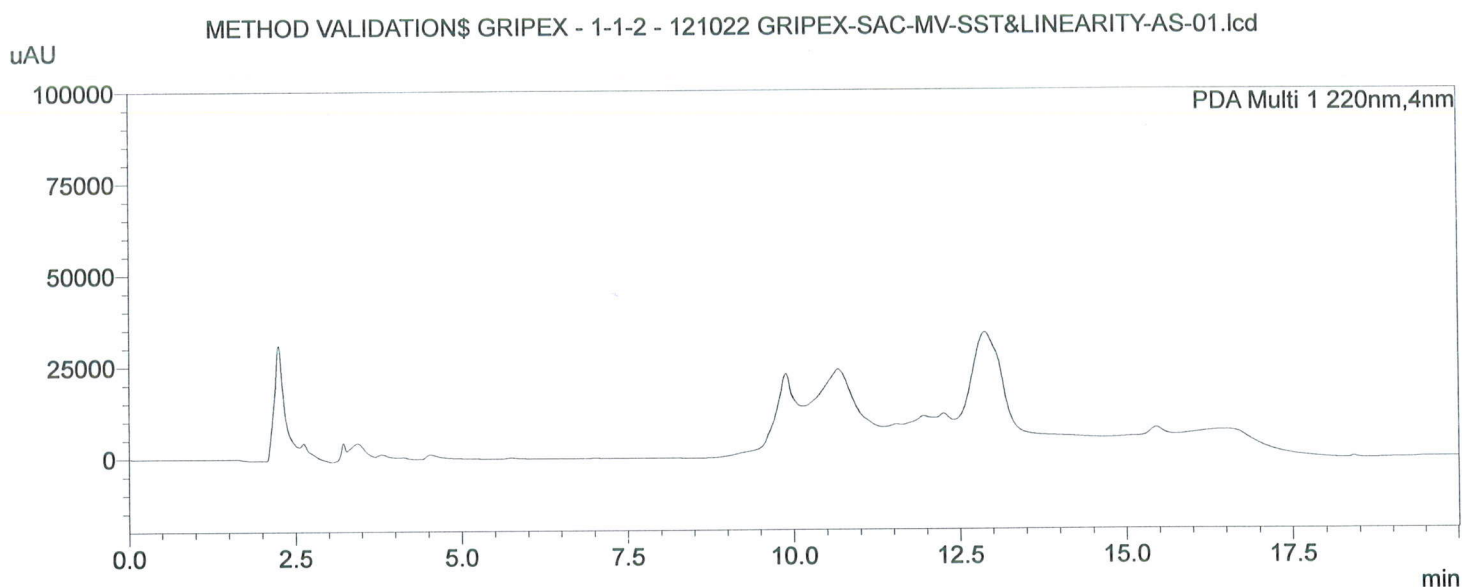
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SYSTEM SUITABILITY-AS  
Sample ID : BLANK-AS  
Data Filename : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-01.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Vial # : 3-1  
Injection Volume : 50 uL  
Date Acquired : 10/12/2022 12:21:47 PM  
Date Processed : 10/13/2022 6:36:24 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plake | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



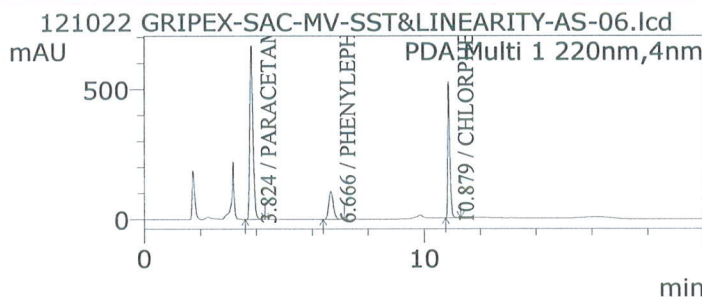
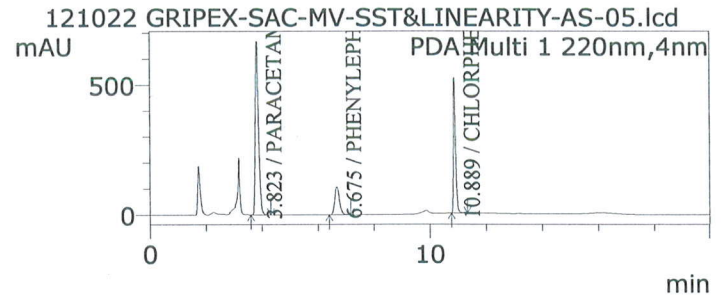
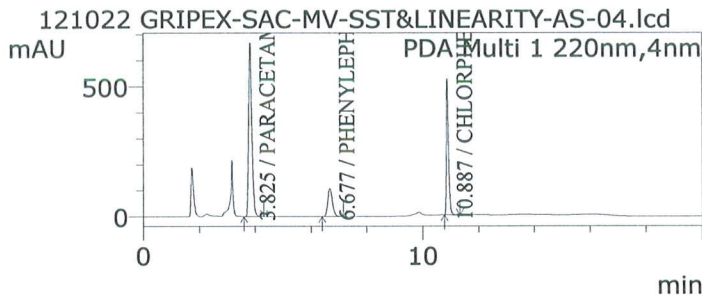
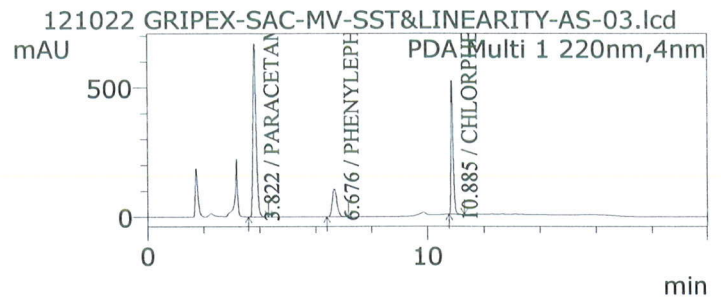
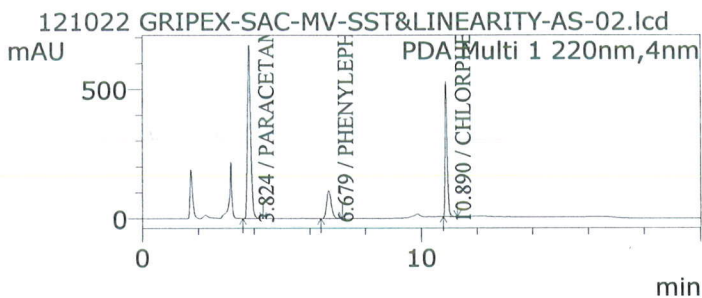
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : SYSTEM SUITABILITY-AS  
Sample ID : PARA+CPM+PNENYL-SST-AS-STD-01  
Tray# : 3  
Vial# : 2  
Injection Volume : 50  
Data File : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-02.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/12/2022 12:42:25 PM  
Date Processed : 10/13/2022 6:36:20 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 2     | ITY-AS-02.lcd | PARA+CPM+PNENYL-SST-AS-STD-01 | 3.824  | 5299765 | 4798     | 1.266    |
| 2     | ITY-AS-03.lcd | PARA+CPM+PNENYL-SST-AS-STD-02 | 3.822  | 5304398 | 4749     | 1.266    |
| 2     | ITY-AS-04.lcd | PARA+CPM+PNENYL-SST-AS-STD-03 | 3.825  | 5298864 | 4761     | 1.265    |
| 2     | ITY-AS-05.lcd | PARA+CPM+PNENYL-SST-AS-STD-04 | 3.823  | 5298686 | 4730     | 1.268    |
| 2     | ITY-AS-06.lcd | PARA+CPM+PNENYL-SST-AS-STD-05 | 3.824  | 5297760 | 4750     | 1.269    |
|       | Average       |                               | 3.823  | 5299895 | 4757     | 1.267    |
|       | %RSD          |                               | 0.026  | 0.049   | 0.531    | 0.131    |



## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title          | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|----------------|-------------------------------|--------|---------|----------|----------|
| 2     | RITY-AS-02.lcd | PARA+CPM+PNENYL-SST-AS-STD-01 | 6.679  | 1234812 | 7291     | 1.210    |
| 2     | RITY-AS-03.lcd | PARA+CPM+PNENYL-SST-AS-STD-02 | 6.676  | 1234933 | 7241     | 1.210    |
| 2     | RITY-AS-04.lcd | PARA+CPM+PNENYL-SST-AS-STD-03 | 6.677  | 1234415 | 7273     | 1.208    |
| 2     | RITY-AS-05.lcd | PARA+CPM+PNENYL-SST-AS-STD-04 | 6.675  | 1234160 | 7210     | 1.208    |
| 2     | RITY-AS-06.lcd | PARA+CPM+PNENYL-SST-AS-STD-05 | 6.666  | 1234096 | 7208     | 1.208    |
|       | Average        |                               | 6.675  | 1234483 | 7245     | 1.209    |
|       | %RSD           |                               | 0.075  | 0.031   | 0.510    | 0.082    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title          | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|----------------|-------------------------------|--------|---------|----------|----------|
| 2     | RITY-AS-02.lcd | PARA+CPM+PNENYL-SST-AS-STD-01 | 10.890 | 2742713 | 78123    | 1.471    |
| 2     | RITY-AS-03.lcd | PARA+CPM+PNENYL-SST-AS-STD-02 | 10.885 | 2756022 | 79919    | 1.459    |
| 2     | RITY-AS-04.lcd | PARA+CPM+PNENYL-SST-AS-STD-03 | 10.887 | 2759392 | 81415    | 1.468    |
| 2     | RITY-AS-05.lcd | PARA+CPM+PNENYL-SST-AS-STD-04 | 10.889 | 2765344 | 76358    | 1.467    |
| 2     | RITY-AS-06.lcd | PARA+CPM+PNENYL-SST-AS-STD-05 | 10.879 | 2759498 | 76924    | 1.475    |
|       | Average        |                               | 10.886 | 2756594 | 78548    | 1.468    |
|       | %RSD           |                               | 0.039  | 0.307   | 2.679    | 0.386    |

Analysed By

Date :

Checked By

Date :



**Safetab Life Science,**  
Puducherry - 605 107

**QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

**Title**

**ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS**

|                       |                            |                     |                    |
|-----------------------|----------------------------|---------------------|--------------------|
| <b>Product Name :</b> | <b>GRIPEX</b>              | <b>Batch size :</b> | <b>500 SACHETS</b> |
| <b>Batch Number :</b> | <b>ST/T/S-1322</b>         | <b>Mfg.Date :</b>   | <b>Sep-22</b>      |
| <b>Parameter :</b>    | <b>LINEARITY and RANGE</b> | <b>Exp.Date :</b>   | <b>To be fixed</b> |

Each 4.5gm of sachet Contains

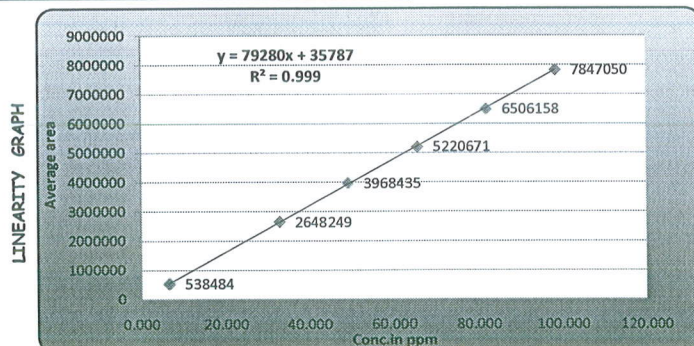
Paracetamol BP ----- 650mg  
Phenylephrine Hydrochloride BP ----- 10mg  
Chlorphenamine Maleate BP ----- 20mg  
Ascorbic acid BP ----- 50mg

**ASSAY OF PARACETAMOL**

|                              |              |                     |              |                |              |                       |       |
|------------------------------|--------------|---------------------|--------------|----------------|--------------|-----------------------|-------|
| <b>Instrument ID:</b>        | ST/QC/EQ/039 | <b>Balance ID :</b> | ST/QC/EQ/041 | <b>WS No.:</b> | ST/WS/22/011 | <b>% Purity (aib)</b> | 100.0 |
| <b>Linearity Level-I :</b>   | 81.97        | mg to --->          | 100          | ml to --->     | 2            | ml to --->            | 250   |
| Std.conc (in ppm)-6.5576     | 1            | ml to --->          | 1            | ml to --->     | 1            | ml to --->            | 1     |
| <b>Linearity Level-II :</b>  | 81.97        | mg to --->          | 100          | ml to --->     | 2            | ml to --->            | 50    |
| Std.conc (in ppm)-32.788     | 1            | ml to --->          | 1            | ml to --->     | 1            | ml to --->            | 1     |
| <b>Linearity Level-III :</b> | 81.97        | mg to --->          | 100          | ml to --->     | 3            | ml to --->            | 50    |
| Std.conc (in ppm)-49.182     | 1            | ml to --->          | 1            | ml to --->     | 1            | ml to --->            | 1     |
| <b>Linearity Level-IV :</b>  | 81.97        | mg to --->          | 100          | ml to --->     | 4            | ml to --->            | 50    |
| Std.conc (in ppm)-65.576     | 1            | ml to --->          | 1            | ml to --->     | 1            | ml to --->            | 1     |
| <b>Linearity Level-V :</b>   | 81.97        | mg to --->          | 100          | ml to --->     | 5            | ml to --->            | 50    |
| Std.conc (in ppm)-81.97      | 1            | ml to --->          | 1            | ml to --->     | 1            | ml to --->            | 1     |
| <b>Linearity Level-VI :</b>  | 81.97        | mg to --->          | 100          | ml to --->     | 6            | ml to --->            | 50    |
| Std.conc (in ppm)-98.364     | 1            | ml to --->          | 1            | ml to --->     | 1            | ml to --->            | 1     |

| Level"s           | I      | II      | III     | IV      | V       | VI      |
|-------------------|--------|---------|---------|---------|---------|---------|
| No.of injections. | 10%    | 50%     | 75%     | 100%    | 125%    | 150%    |
| 1                 | 538509 | 2647511 | 3970894 | 5219614 | 6503320 | 7846153 |
| 2                 | 538459 | 2648987 | 3965976 | 5221727 | 6508995 | 7847947 |
| Average           | 538484 | 2648249 | 3968435 | 5220671 | 6506158 | 7847050 |
| RSD%              | 0.019  | 0.039   | 0.088   | 0.029   | 0.062   | 0.016   |

| LEVEL"s | Conc.in ppm (X-axis) | Average area (Y-axis) |
|---------|----------------------|-----------------------|
| I       | 6.558                | 538484                |
| II      | 32.788               | 2648249               |
| III     | 49.182               | 3968435               |
| IV      | 65.576               | 5220671               |
| V       | 81.970               | 6506158               |
| VI      | 98.364               | 7847050               |



**Results :**

- 1) Squared correlation coefficient of Paracetamol **0.999**
- 2) In Range, %RSD of areas at 10%, 50%, 75%, 100%, 125 & 150% levels within limits.

**Acceptance criteria:**

- 1) To conclude the linearity, the squared correlation coefficient ( $r^2$ ) should be Not less than 0.995
- 2) To conclude the range, %RSD of areas at 10%, 50%, 75%, 100%, 125 & 150% levels should be Not more than 2.0.

Analysed by :

C.ALBIN JOSE

Date :

13-10-2022

Checked by :

Date :





Safetab Life Science,  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|                |                     |              |             |
|----------------|---------------------|--------------|-------------|
| Product Name : | GRIPEX              | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322         | Mfg.Date :   | Sep-22      |
| Parameter :    | LINEARITY and RANGE | Exp.Date :   | To be fixed |

Each 4.5gm of sachet Contains

Paracetamol BP ----- 650mg  
Phenylephrine Hydrochloride BP ----- 10mg  
Chlorphenamine Maleate BP ----- 20mg  
Ascorbic acid BP ----- 50mg

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                |              |              |              |         |              |                |      |
|----------------|--------------|--------------|--------------|---------|--------------|----------------|------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041 | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
|----------------|--------------|--------------|--------------|---------|--------------|----------------|------|

|                          |       |            |     |            |   |            |     |
|--------------------------|-------|------------|-----|------------|---|------------|-----|
| Linearity Level-I :      | 25.77 | mg to ---> | 100 | ml to ---> | 2 | ml to ---> | 250 |
| Std.conc (in ppm)-2.0616 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

|                          |       |            |     |            |   |            |    |
|--------------------------|-------|------------|-----|------------|---|------------|----|
| Linearity Level-II :     | 25.77 | mg to ---> | 100 | ml to ---> | 2 | ml to ---> | 50 |
| Std.conc (in ppm)-10.308 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                          |       |            |     |            |   |            |    |
|--------------------------|-------|------------|-----|------------|---|------------|----|
| Linearity Level-III :    | 25.77 | mg to ---> | 100 | ml to ---> | 3 | ml to ---> | 50 |
| Std.conc (in ppm)-15.462 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

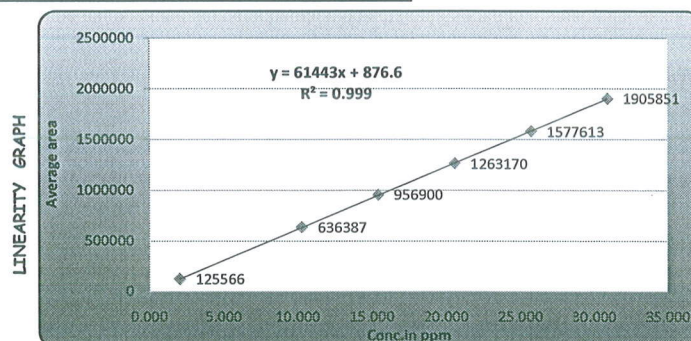
|                          |       |            |     |            |   |            |    |
|--------------------------|-------|------------|-----|------------|---|------------|----|
| Linearity Level-IV :     | 25.77 | mg to ---> | 100 | ml to ---> | 4 | ml to ---> | 50 |
| Std.conc (in ppm)-20.616 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                         |       |            |     |            |   |            |    |
|-------------------------|-------|------------|-----|------------|---|------------|----|
| Linearity Level-V :     | 25.77 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-25.77 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                          |       |            |     |            |   |            |    |
|--------------------------|-------|------------|-----|------------|---|------------|----|
| Linearity Level-VI :     | 25.77 | mg to ---> | 100 | ml to ---> | 6 | ml to ---> | 50 |
| Std.conc (in ppm)-30.924 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

| Level's            | I      | II     | III    | IV      | V       | VI      |
|--------------------|--------|--------|--------|---------|---------|---------|
| No. of injections. | 10%    | 50%    | 75%    | 100%    | 125%    | 150%    |
| 1                  | 125670 | 635879 | 957272 | 1263272 | 1579020 | 1903063 |
| 2                  | 125461 | 636895 | 956527 | 1263068 | 1576205 | 1908639 |
| Average            | 125566 | 636387 | 956900 | 1263170 | 1577613 | 1905851 |
| RSD%               | 0.118  | 0.113  | 0.055  | 0.011   | 0.126   | 0.207   |

| LEVEL's | Conc.in ppm (X-axis) | Average area (Y-axis) |
|---------|----------------------|-----------------------|
| I       | 2.062                | 125566                |
| II      | 10.308               | 636387                |
| III     | 15.462               | 956900                |
| IV      | 20.616               | 1263170               |
| V       | 25.770               | 1577613               |
| VI      | 30.924               | 1905851               |



Results :

- Squared correlation coefficient of Phenylephrine HCL **0.999**
- In Range, %RSD of areas at 10%, 50%, 75%, 100%, 125 & 150% levels within limits.

Acceptance criteria:

- To conclude the linearity, the squared correlation coefficient ( $r^2$ ) should be Not less than 0.995
- To conclude the range, %RSD of areas at 10%, 50%, 75%, 100%, 125 & 150% levels should be Not more than 2.0.

Analysed by : C. ALBIN JOSE  
Date : 13-10-2022

Checked by :  
Date : 13/10/2022





Safetab Life Science,  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|                |                     |              |             |
|----------------|---------------------|--------------|-------------|
| Product Name : | GRIPEX              | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322         | Mfg.Date :   | Sep-22      |
| Parameter :    | LINEARITY and RANGE | Exp.Date :   | To be fixed |

Each 4.5gm of sachet Contains

Paracetamol BP ----- 650mg  
Phenylephrine Hydrochloride BP ----- 10mg  
Chlorphenamine Maleate BP ----- 20mg  
Ascorbic acid BP ----- 50mg

ASSAY OF CHLORPHENAMINE MALEATE

|                |              |              |              |         |              |                |      |
|----------------|--------------|--------------|--------------|---------|--------------|----------------|------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041 | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
|----------------|--------------|--------------|--------------|---------|--------------|----------------|------|

|                          |       |            |     |            |   |            |     |
|--------------------------|-------|------------|-----|------------|---|------------|-----|
| Linearity Level-I :      | 50.56 | mg to ---> | 100 | ml to ---> | 2 | ml to ---> | 250 |
| Std.conc (in ppm)-4.0448 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

|                          |       |            |     |            |   |            |    |
|--------------------------|-------|------------|-----|------------|---|------------|----|
| Linearity Level-II :     | 50.56 | mg to ---> | 100 | ml to ---> | 2 | ml to ---> | 50 |
| Std.conc (in ppm)-20.224 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                          |       |            |     |            |   |            |    |
|--------------------------|-------|------------|-----|------------|---|------------|----|
| Linearity Level-III :    | 50.56 | mg to ---> | 100 | ml to ---> | 3 | ml to ---> | 50 |
| Std.conc (in ppm)-30.336 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

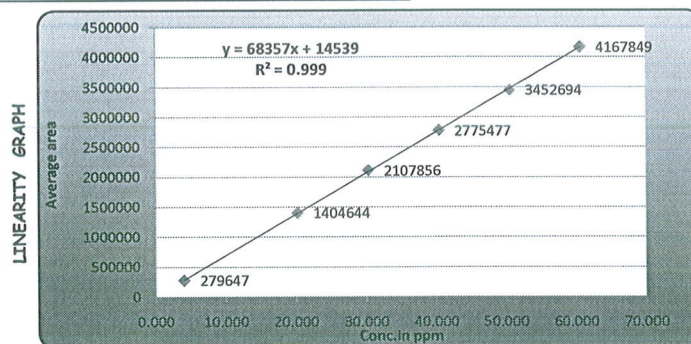
|                          |       |            |     |            |   |            |    |
|--------------------------|-------|------------|-----|------------|---|------------|----|
| Linearity Level-IV :     | 50.56 | mg to ---> | 100 | ml to ---> | 4 | ml to ---> | 50 |
| Std.conc (in ppm)-40.448 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                         |       |            |     |            |   |            |    |
|-------------------------|-------|------------|-----|------------|---|------------|----|
| Linearity Level-V :     | 50.56 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-50.56 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                          |       |            |     |            |   |            |    |
|--------------------------|-------|------------|-----|------------|---|------------|----|
| Linearity Level-VI :     | 50.56 | mg to ---> | 100 | ml to ---> | 6 | ml to ---> | 50 |
| Std.conc (in ppm)-60.672 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

| Level's           | I      | II      | III     | IV      | V       | VI      |
|-------------------|--------|---------|---------|---------|---------|---------|
| No.of injections. | 10%    | 50%     | 75%     | 100%    | 125%    | 150%    |
| 1                 | 279289 | 1404372 | 2109577 | 2774500 | 3453640 | 4162208 |
| 2                 | 280004 | 1404916 | 2106135 | 2776453 | 3451747 | 4173489 |
| Average           | 279647 | 1404644 | 2107856 | 2775477 | 3452694 | 4167849 |
| RSD%              | 0.181  | 0.027   | 0.115   | 0.050   | 0.039   | 0.191   |

| LEVEL's | Conc. in ppm (X-axis) | Average area (Y-axis) |
|---------|-----------------------|-----------------------|
| I       | 4.045                 | 279647                |
| II      | 20.224                | 1404644               |
| III     | 30.336                | 2107856               |
| IV      | 40.448                | 2775477               |
| V       | 50.560                | 3452694               |
| VI      | 60.672                | 4167849               |



Results :

- Squared correlation coefficient of Chlorphenamine **0.999**
- In Range, %RSD of areas at 10%, 50%, 75%, 100%, 125 & 150% levels within limits.

Acceptance criteria:

- To conclude the linearity, the squared correlation coefficient ( $r^2$ ) should be Not less than 0.995
- To conclude the range, %RSD of areas at 10%, 50%, 75%, 100%, 125 & 150% levels should be Not more than 2.0.

Analysed by :

C.ALBIN JOSE

Date :

13-10-2022

Checked by :

Date :

13/10/2022





# Safetab Life Science

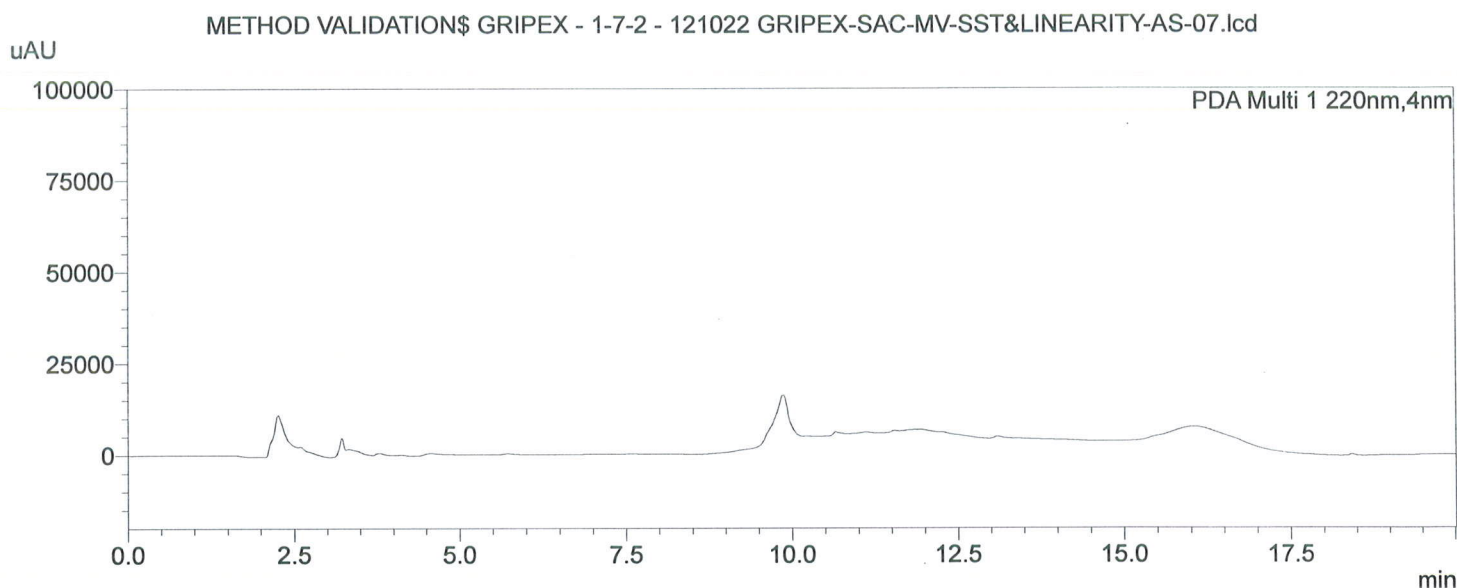
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : BLANK  
Data Filename : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-07.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 10/12/2022 2:26:21 PM  
Date Processed : 10/13/2022 6:36:04 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plake | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

*[Signature]*  
13/12/22

Checked By

Date :

*[Signature]*  
13/12/22



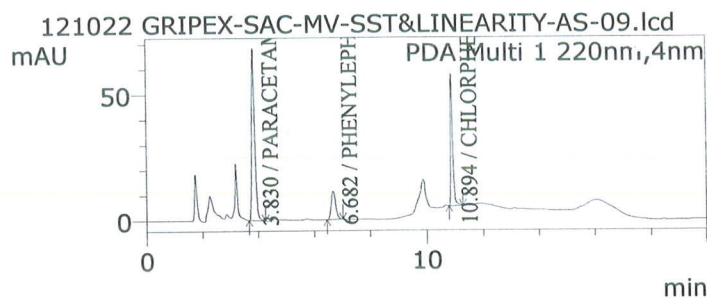
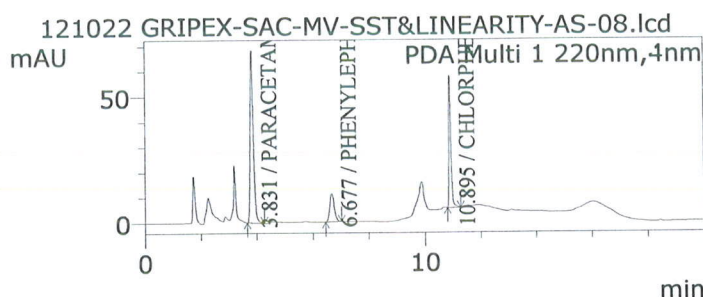
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : GRIPEX-MV-LINEARITY-10%-SPL-1  
Tray# : 3  
Vial# : 4  
Injection Volume : 50  
Data File : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-08.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/12/2022 2:46:56 PM  
Date Processed : 10/13/2022 6:36:01 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area   | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|--------|----------|----------|
| 4     | ITY-AS-08.lcd | GRIPEX-MV-LINEARITY-10%-SPL-1 | 3.831  | 538509 | 4854     | 1.274    |
| 4     | ITY-AS-09.lcd | GRIPEX-MV-LINEARITY-10%-SPL-1 | 3.830  | 538459 | 4837     | 1.274    |
|       | Average       |                               | 3.830  | 538484 | 4845     | 1.274    |
|       | %RSD          |                               | 0.019  | 0.007  | 0.252    | 0.007    |

ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                     | R.Time | Area   | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|--------|----------|----------|
| 4     | ITY-AS-08.lcd | GRIPEX-MV-LINEARITY-10%-SPL-1 | 6.677  | 125670 | 7482     | 1.193    |
| 4     | ITY-AS-09.lcd | GRIPEX-MV-LINEARITY-10%-SPL-1 | 6.682  | 125461 | 7504     | 1.193    |
|       | Average       |                               | 6.679  | 125565 | 7493     | 1.193    |
|       | %RSD          |                               | 0.046  | 0.118  | 0.206    | 0.009    |

ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                     | R.Time | Area   | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|--------|----------|----------|
| 4     | ITY-AS-08.lcd | GRIPEX-MV-LINEARITY-10%-SPL-1 | 10.895 | 279289 | 80808    | 1.473    |
| 4     | ITY-AS-09.lcd | GRIPEX-MV-LINEARITY-10%-SPL-1 | 10.894 | 280004 | 80516    | 1.476    |
|       | Average       |                               | 10.894 | 279646 | 80662    | 1.474    |
|       | %RSD          |                               | 0.005  | 0.181  | 0.255    | 0.146    |

Analysed By

Date : 13/10/2022

Checked By

Date : 13/10/2022





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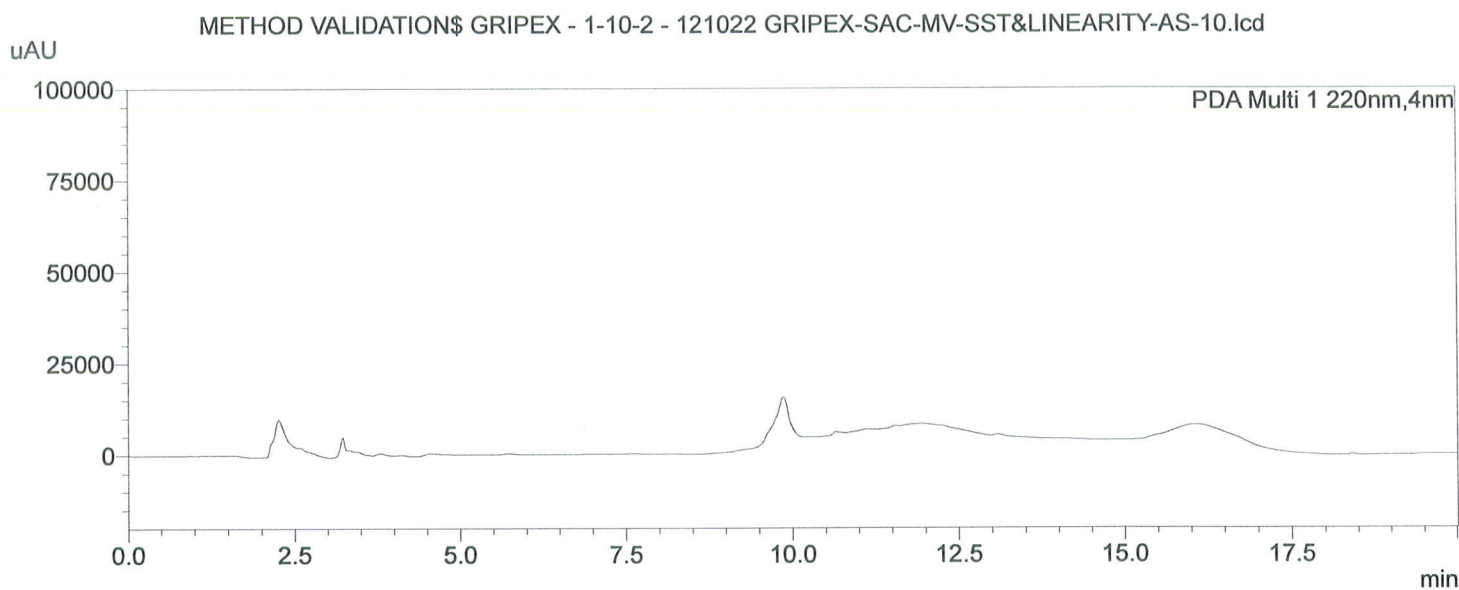
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : BLANK  
Data Filename : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-10.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 10/12/2022 3:28:07 PM  
Date Processed : 10/13/2022 6:35:54 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plake | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



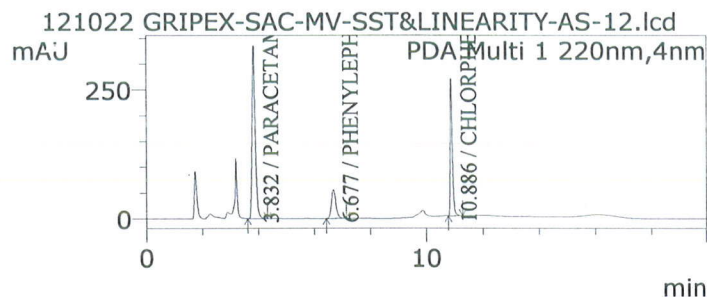
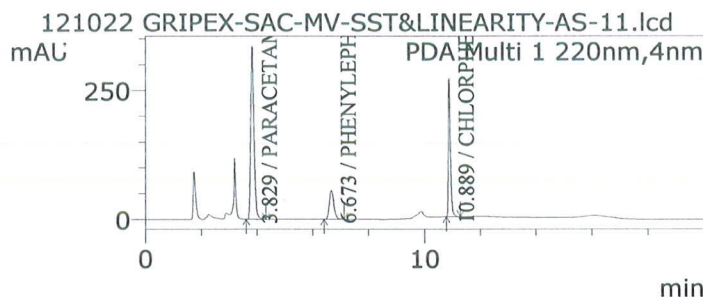
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : GRIPEX-MV-LINEARITY-50%-SPL-1  
Tray# : 3  
Vial# : 5  
Injection Volume : 50  
Data File : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-11.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/12/2022 3:48:44 PM  
Date Processed : 10/13/2022 6:35:50 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 5     | ITY-AS-11.lcd | GRIPEX-MV-LINEARITY-50%-SPL-1 | 3.829  | 2647511 | 4791     | 1.274    |
| 5     | ITY-AS-12.lcd | GRIPEX-MV-LINEARITY-50%-SPL-2 | 3.832  | 2648987 | 4838     | 1.270    |
|       | Average       |                               | 3.830  | 2648249 | 4814     | 1.272    |
|       | %RSD          |                               | 0.042  | 0.039   | 0.683    | 0.217    |

ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                     | R.Time | Area   | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|--------|----------|----------|
| 5     | ITY-AS-11.lcd | GRIPEX-MV-LINEARITY-50%-SPL-1 | 6.673  | 635879 | 7363     | 1.215    |
| 5     | ITY-AS-12.lcd | GRIPEX-MV-LINEARITY-50%-SPL-2 | 6.677  | 636895 | 7350     | 1.213    |
|       | Average       |                               | 6.675  | 636387 | 7356     | 1.214    |
|       | %RSD          |                               | 0.037  | 0.113  | 0.124    | 0.081    |

ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 5     | ITY-AS-11.lcd | GRIPEX-MV-LINEARITY-50%-SPL-1 | 10.889 | 1404372 | 79163    | 1.464    |
| 5     | ITY-AS-12.lcd | GRIPEX-MV-LINEARITY-50%-SPL-2 | 10.886 | 1404916 | 82028    | 1.458    |
|       | Average       |                               | 10.887 | 1404644 | 80596    | 1.461    |
|       | %RSD          |                               | 0.019  | 0.027   | 2.513    | 0.283    |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

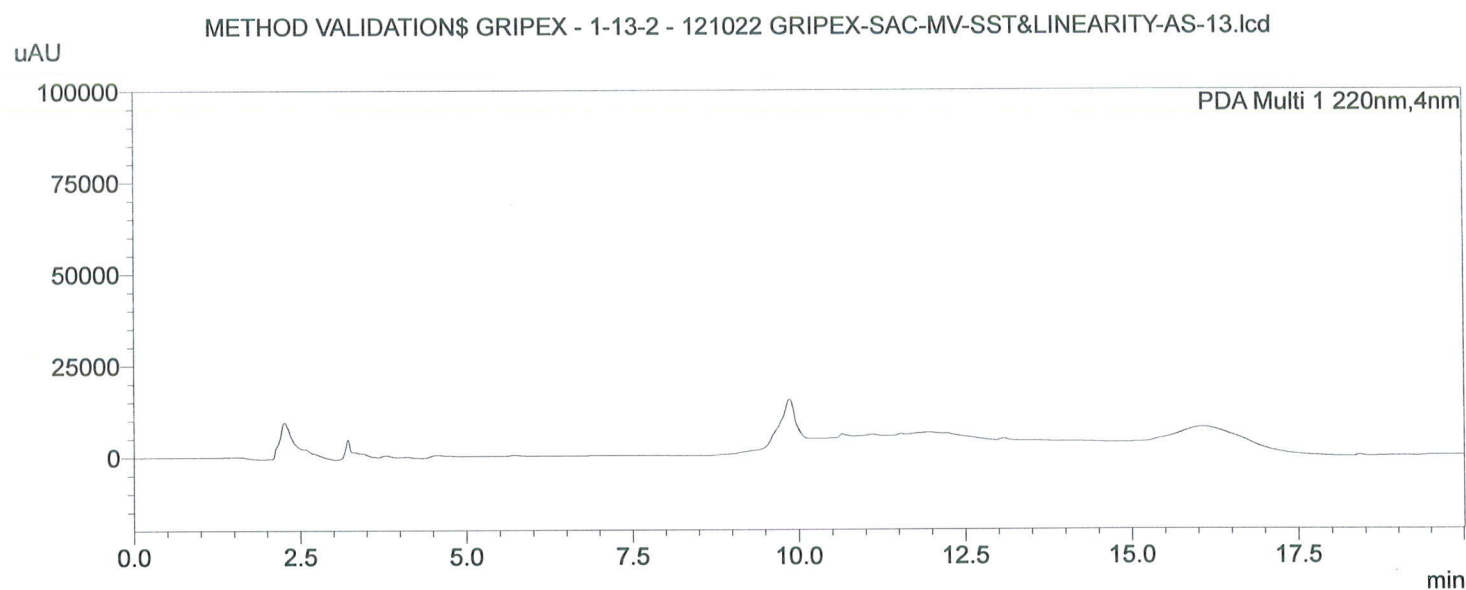
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : BLANK  
Data Filename : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-13.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 10/12/2022 4:29:54 PM  
Date Processed : 10/13/2022 6:35:44 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date

Checked By

Date



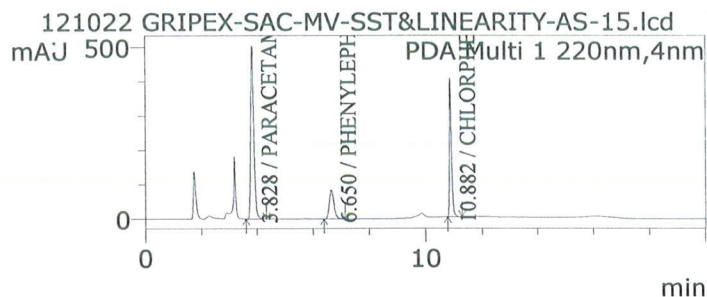
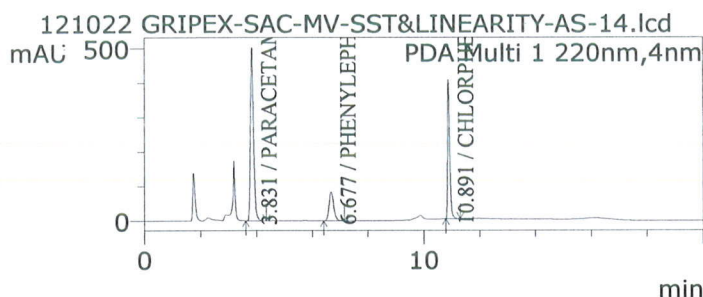
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : GRIPEX-MV-LINEARITY-75%-SPL-1  
Tray# : 3  
Vial# : 6  
Injection Volume : 50  
Data File : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-14.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/12/2022 4:50:29 PM  
Date Processed : 10/13/2022 6:35:41 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 6     | ITY-AS-14.lcd | GRIPEX-MV-LINEARITY-75%-SPL-1 | 3.831  | 3970894 | 4822     | 1.271    |
| 6     | ITY-AS-15.lcd | GRIPEX-MV-LINEARITY-75%-SPL-2 | 3.828  | 3965976 | 4818     | 1.272    |
|       | Average       |                               | 3.830  | 3968435 | 4820     | 1.271    |
|       | %RSD          |                               | 0.052  | 0.088   | 0.061    | 0.090    |

ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                     | R.Time | Area   | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|--------|----------|----------|
| 6     | ITY-AS-14.lcd | GRIPEX-MV-LINEARITY-75%-SPL-1 | 6.677  | 957272 | 7343     | 1.216    |
| 6     | ITY-AS-15.lcd | GRIPEX-MV-LINEARITY-75%-SPL-2 | 6.650  | 956527 | 7328     | 1.217    |
|       | Average       |                               | 6.663  | 956900 | 7336     | 1.217    |
|       | %RSD          |                               | 0.280  | 0.055  | 0.151    | 0.068    |

ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 6     | ITY-AS-14.lcd | GRIPEX-MV-LINEARITY-75%-SPL-1 | 10.891 | 2109577 | 79805    | 1.462    |
| 6     | ITY-AS-15.lcd | GRIPEX-MV-LINEARITY-75%-SPL-2 | 10.882 | 2106135 | 80784    | 1.456    |
|       | Average       |                               | 10.887 | 2107856 | 80294    | 1.459    |
|       | %RSD          |                               | 0.060  | 0.115   | 0.862    | 0.264    |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

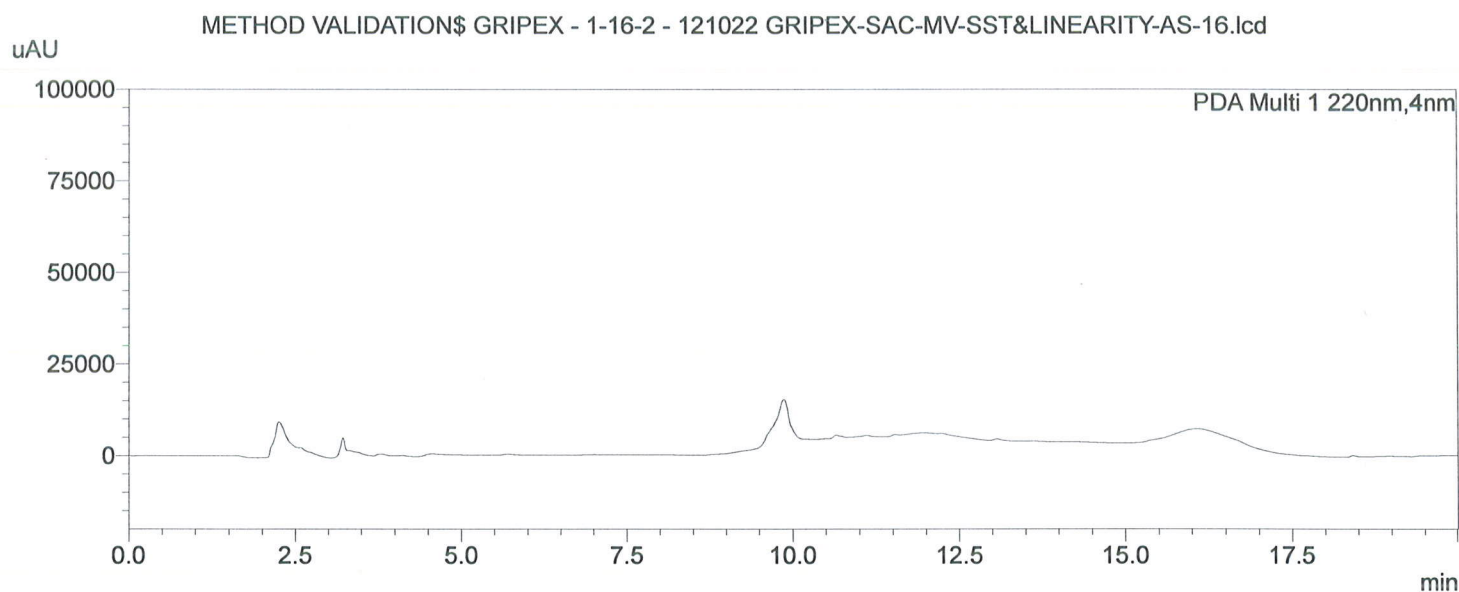
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : BLANK  
Data Filename : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-16.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 10/12/2022 5:31:38 PM  
Date Processed : 10/13/2022 6:35:33 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



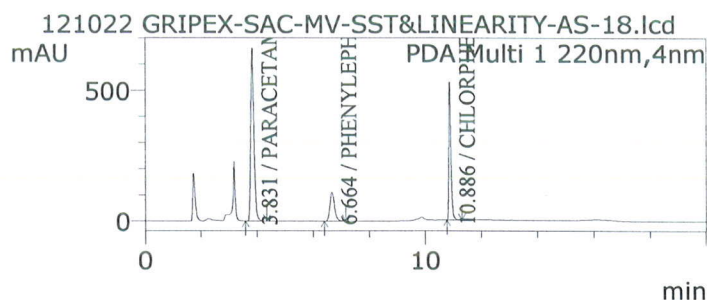
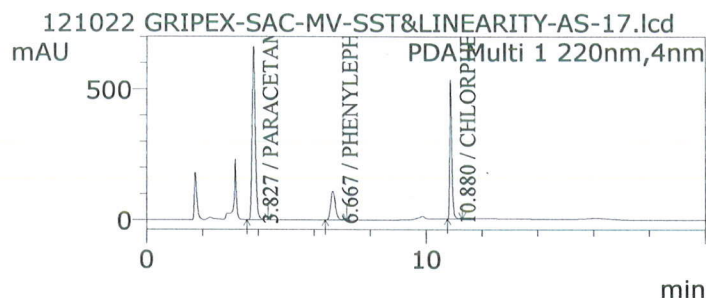
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : GRIPEX-MV-LINEARITY-100%-SPL-1  
Tray# : 3  
Vial# : 7  
Injection Volume : 50  
Data File : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-17.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/12/2022 5:52:14 PM  
Date Processed : 10/13/2022 6:35:29 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 7     | ITY-AS-17.lcd | GRIPEX-MV-LINEARITY-100%-SPL-1 | 3.827  | 5219614 | 4809     | 1.269    |
| 7     | ITY-AS-18.lcd | GRIPEX-MV-LINEARITY-100%-SPL-2 | 3.831  | 5221727 | 4847     | 1.271    |
|       | Average       |                                | 3.829  | 5220670 | 4828     | 1.270    |
|       | %RSD          |                                | 0.078  | 0.029   | 0.563    | 0.073    |

ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 7     | ITY-AS-17.lcd | GRIPEX-MV-LINEARITY-100%-SPL-1 | 6.667  | 1263272 | 7278     | 1.218    |
| 7     | ITY-AS-18.lcd | GRIPEX-MV-LINEARITY-100%-SPL-2 | 6.664  | 1263068 | 7302     | 1.220    |
|       | Average       |                                | 6.665  | 1263170 | 7290     | 1.219    |
|       | %RSD          |                                | 0.033  | 0.011   | 0.237    | 0.123    |

ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 7     | ITY-AS-17.lcd | GRIPEX-MV-LINEARITY-100%-SPL-1 | 10.880 | 2774500 | 79756    | 1.461    |
| 7     | ITY-AS-18.lcd | GRIPEX-MV-LINEARITY-100%-SPL-2 | 10.886 | 2776453 | 82304    | 1.451    |
|       | Average       |                                | 10.883 | 2775476 | 81030    | 1.456    |
|       | %RSD          |                                | 0.041  | 0.050   | 2.224    | 0.490    |

Analysed By

Date :

Checked By

Date :





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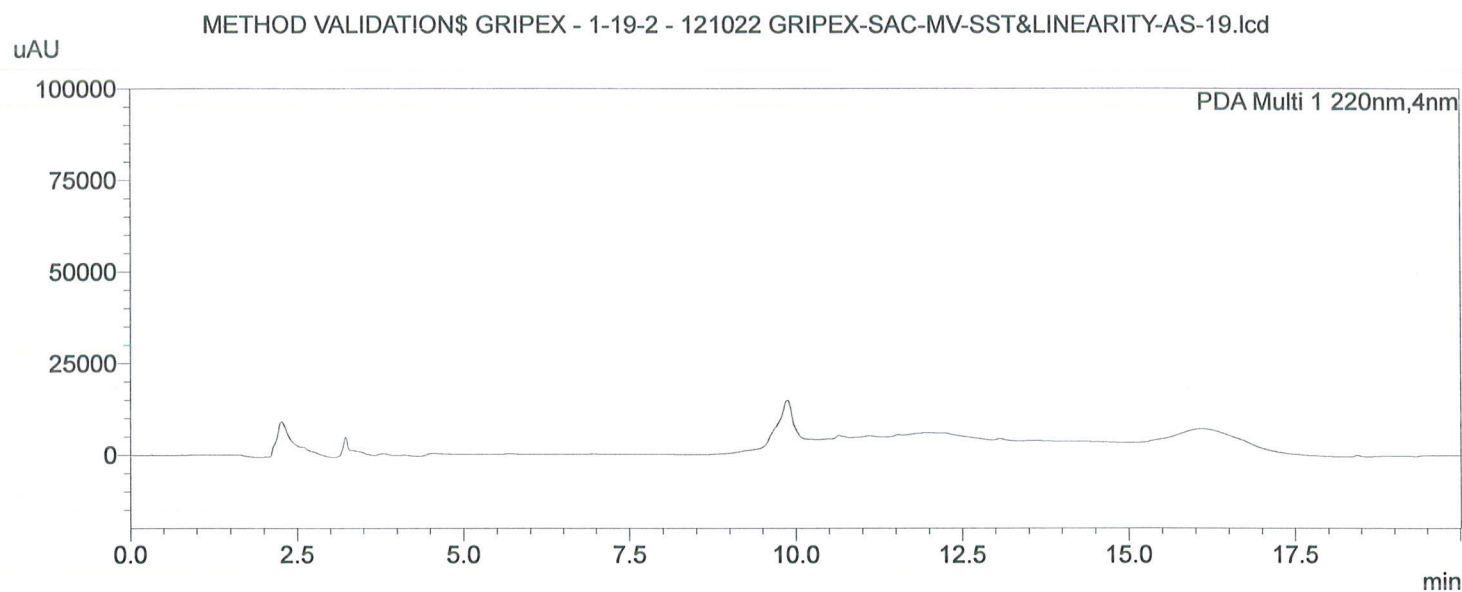
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : BLANK  
Data Filename : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-19.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 10/12/2022 6:33:24 PM  
Date Processed : 10/13/2022 6:35:23 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plake | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



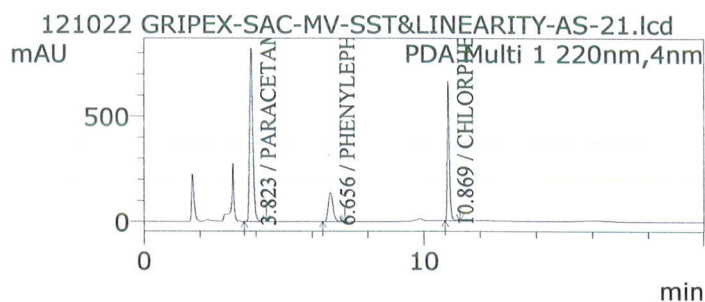
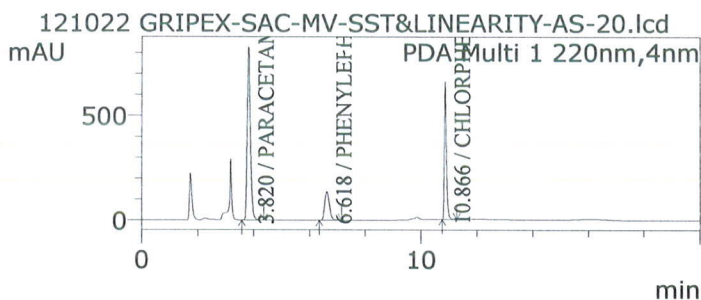
# Safetab Life Science

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## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : GRIPEX-MV-LINEARITY-125%-SPL-1  
Tray# : 3  
Vial# : 8  
Injection Volume : 50  
Data File : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-20.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/12/2022 6:54:02 PM  
Date Processed : 10/13/2022 6:35:19 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 8     | ITY-AS-20.lcd | GRIPEX-MV-LINEARITY-125%-SPL-1 | 3.820  | 6503320 | 4838     | 1.272    |
| 8     | ITY-AS-21.lcd | GRIPEX-MV-LINEARITY-125%-SPL-2 | 3.823  | 6508995 | 4843     | 1.270    |
|       | Average       |                                | 3.822  | 6506157 | 4840     | 1.271    |
|       | %RSD          |                                | 0.064  | 0.062   | 0.075    | 0.093    |

ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 8     | ITY-AS-20.lcd | GRIPEX-MV-LINEARITY-125%-SPL-1 | 6.618  | 1579020 | 7234     | 1.223    |
| 8     | ITY-AS-21.lcd | GRIPEX-MV-LINEARITY-125%-SPL-2 | 6.656  | 1576205 | 7291     | 1.223    |
|       | Average       |                                | 6.637  | 1577612 | 7263     | 1.223    |
|       | %RSD          |                                | 0.404  | 0.126   | 0.559    | 0.017    |

ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 8     | ITY-AS-20.lcd | GRIPEX-MV-LINEARITY-125%-SPL-1 | 10.866 | 3453640 | 82048    | 1.450    |
| 8     | ITY-AS-21.lcd | GRIPEX-MV-LINEARITY-125%-SPL-2 | 10.869 | 3451747 | 79757    | 1.461    |
|       | Average       |                                | 10.867 | 3452694 | 80902    | 1.456    |
|       | %RSD          |                                | 0.024  | 0.039   | 2.002    | 0.552    |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

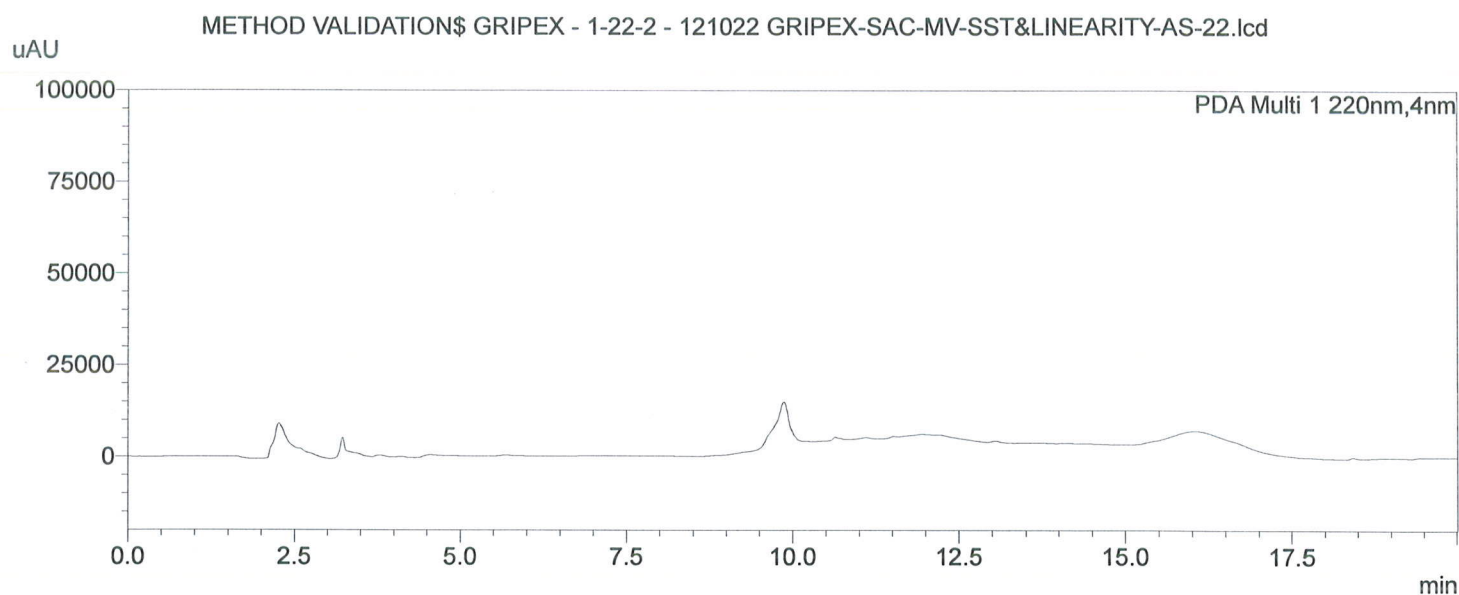
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : BLANK  
Data Filename : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-22.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 10/12/2022 7:35:12 PM  
Date Processed : 10/13/2022 6:35:14 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plake | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



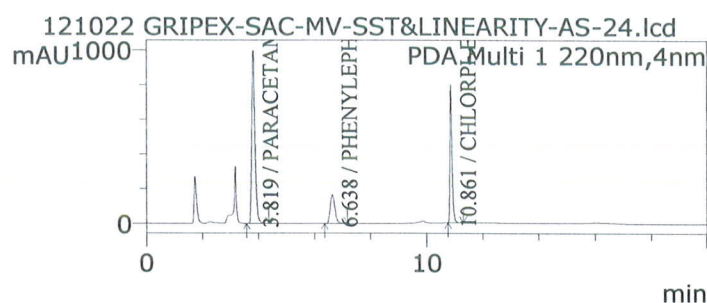
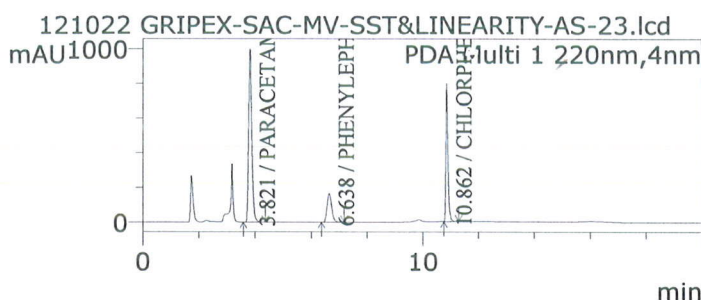
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : LINEARITY-AS  
Sample ID : GRIPEX-MV-LINEARITY-150%-SPL-1  
Tray# : 3  
Vial# : 9  
Injection Volume : 50  
Data File : 121022 GRIPEX-SAC-MV-SST&LINEARITY-AS-23.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 121022 GRIPEX-SAC-MV-AS-SST&LINEARITY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/12/2022 7:55:49 PM  
Date Processed : 10/13/2022 6:35:11 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 9     | ITY-AS-23.lcd | GRIPEX-MV-LINEARITY-150%-SPL-1 | 3.821  | 7846153 | 4849     | 1.271    |
| 9     | ITY-AS-24.lcd | GRIPEX-MV-LINEARITY-150%-SPL-2 | 3.819  | 7847947 | 4820     | 1.274    |
|       | Average       |                                | 3.820  | 7847050 | 4835     | 1.273    |
|       | %RSD          |                                | 0.030  | 0.016   | 0.424    | 0.186    |

ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 9     | ITY-AS-23.lcd | GRIPEX-MV-LINEARITY-150%-SPL-1 | 6.638  | 1903063 | 7286     | 1.227    |
| 9     | ITY-AS-24.lcd | GRIPEX-MV-LINEARITY-150%-SPL-2 | 6.638  | 1908639 | 7264     | 1.227    |
|       | Average       |                                | 6.638  | 1905851 | 7275     | 1.227    |
|       | %RSD          |                                | 0.001  | 0.207   | 0.217    | 0.014    |

ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                      | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|--------------------------------|--------|---------|----------|----------|
| 9     | ITY-AS-23.lcd | GRIPEX-MV-LINEARITY-150%-SPL-1 | 10.862 | 4162208 | 80746    | 1.454    |
| 9     | ITY-AS-24.lcd | GRIPEX-MV-LINEARITY-150%-SPL-2 | 10.861 | 4173489 | 80457    | 1.455    |
|       | Average       |                                | 10.862 | 4167848 | 80602    | 1.455    |
|       | %RSD          |                                | 0.004  | 0.191   | 0.254    | 0.052    |

Analysed By

Date

13/10/22

Checked By

Date

13/10/22





# Safetab Life Science

Puducherry- 605 107

Quality control Department

## =====BATCH TABLE=====

Batch Table

| Vial# | Tray | Inj. Vol. | Sample Name           | Sample ID                      | Method File    | Data File                 | Report Format      |
|-------|------|-----------|-----------------------|--------------------------------|----------------|---------------------------|--------------------|
| 1     | 3    | 50.0      | SYSTEM SUITABILITY-AS | BLANK-AS                       | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-01.lcd | system\DEFAULT.lsr |
| 2     | 3    | 50.0      | SYSTEM SUITABILITY-AS | PARA+CPM+PNENYL-SST-AS-STD-01  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-02.lcd | system\DEFAULT.lsr |
| 2     | 3    | 50.0      | SYSTEM SUITABILITY-AS | PARA+CPM+PNENYL-SST-AS-STD-02  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-03.lcd | system\DEFAULT.lsr |
| 2     | 3    | 50.0      | SYSTEM SUITABILITY-AS | PARA+CPM+PNENYL-SST-AS-STD-03  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-04.lcd | system\DEFAULT.lsr |
| 2     | 3    | 50.0      | SYSTEM SUITABILITY-AS | PARA+CPM+PNENYL-SST-AS-STD-04  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-05.lcd | system\DEFAULT.lsr |
| 2     | 3    | 50.0      | SYSTEM SUITABILITY-AS | PARA+CPM+PNENYL-SST-AS-STD-05  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-06.lcd | system\DEFAULT.lsr |
| 3     | 3    | 50.0      | LINEARITY-AS          | BLANK                          | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-07.lcd | system\DEFAULT.lsr |
| 4     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-10%-SPL-1  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-08.lcd | system\DEFAULT.lsr |
| 4     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-10%-SPL-1  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-09.lcd | system\DEFAULT.lsr |
| 3     | 3    | 50.0      | LINEARITY-AS          | BLANK                          | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-10.lcd | system\DEFAULT.lsr |
| 5     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-50%-SPL-1  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-11.lcd | system\DEFAULT.lsr |
| 5     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-50%-SPL-2  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-12.lcd | system\DEFAULT.lsr |
| 3     | 3    | 50.0      | LINEARITY-AS          | BLANK                          | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-13.lcd | system\DEFAULT.lsr |
| 6     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-75%-SPL-1  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-14.lcd | system\DEFAULT.lsr |
| 6     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-75%-SPL-2  | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-15.lcd | system\DEFAULT.lsr |
| 3     | 3    | 50.0      | LINEARITY-AS          | BLANK                          | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-16.lcd | system\DEFAULT.lsr |
| 7     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-100%-SPL-1 | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-17.lcd | system\DEFAULT.lsr |
| 7     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-100%-SPL-2 | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-18.lcd | system\DEFAULT.lsr |
| 3     | 3    | 50.0      | LINEARITY-AS          | BLANK                          | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-19.lcd | system\DEFAULT.lsr |
| 8     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-125%-SPL-1 | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-20.lcd | system\DEFAULT.lsr |
| 8     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-125%-SPL-2 | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-21.lcd | system\DEFAULT.lsr |
| 3     | 3    | 50.0      | LINEARITY-AS          | BLANK                          | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-22.lcd | system\DEFAULT.lsr |
| 9     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-150%-SPL-1 | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-23.lcd | system\DEFAULT.lsr |
| 9     | 3    | 50.0      | LINEARITY-AS          | GRIPEX-MV-LINEARITY-150%-SPL-2 | GRIPEX-AS.lcm  | V-SST&LINEARITY-AS-24.lcd | system\DEFAULT.lsr |
| -1    | 3    | 50.0      | LINEARITY-AS          | SHUT                           | OWN METHOD.lcm | V-SST&LINEARITY-AS-25.lcd | system\DEFAULT.lsr |

Analysed By  
Date: 12/01/2020

Checked By  
Date: 12/01/2020



**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

|                            |              |
|----------------------------|--------------|
| <b>Name of the Product</b> | GRIPEX 500mg |
| <b>Batch No</b>            | S1/T/S-1322  |

① SYSTEM SUITABILITY: Diluent: 50 volume Buffer; 50 volume Methanol

Std. Preparation:

Stock - 1

65.57mg of Paracetamol and 40.0mg of cpm in 100ml volumetric flask add 70ml of diluent Sonicate for 10min and make up to volume with diluent.

Stock - 2

40.0mg of Phosphoric acid in 100ml volumetric flask add about 150ml of diluent Sonicate for 10min and make up to volume with diluent.

System suitability Std Preparation:

Each 5ml of Stock 1 and 2 to 50ml with.

Diluent.

② LINEARITY:

Stock Solution Preparation:

81.97mg Paracetamol (w), 25.77mg of Phosphoric acid and 50.0mg Chlorpheniramine maleate in a 100ml volumetric flask add 70ml of diluent Sonicate for 5min to dissolve. and make up to volume with diluent.

Analyzed by:

*[Signature]*

Date:

12/10/22

Checked by:

*[Signature]*

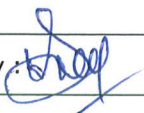
Date:

12/10/22

**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

|                            |                |
|----------------------------|----------------|
| <b>Name of the Product</b> | ARIPEN SACHETS |
| <b>Batch No</b>            | ST/T/S-1322    |

| S. No | TEST / OBSERVATION / LIMIT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | <p><u>Lineary Level I</u> (10%)<br/>2ml of Stock Solution → 20ml is defunct</p> <p><u>Lineary Level II</u> (20%)<br/>2ml of Stock Solution → 50ml is defunct</p> <p><u>Lineary Level III</u> (75%)<br/>3ml of Stock Solution → 50ml with defunct</p> <p><u>Lineary Level IV</u> (100%)<br/>4ml of Stock Solution → 50ml is defunct.</p> <p><u>Lineary Level V</u> (125%)<br/>5ml of Stock Solution → 50ml is defunct.</p> <p><u>Lineary Level VI</u> (150%)<br/>6ml of Stock Solution → 50ml is defunct</p> |

|                                                                                                   |                 |                                                                                                   |                 |
|---------------------------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------------------------|-----------------|
| Analyzed by :  | Date : 12/10/22 | Checked by :  | Date : 12/10/22 |
|---------------------------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------------------------|-----------------|





Safetab Life Science,  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|                |                          |              |             |
|----------------|--------------------------|--------------|-------------|
| Product Name : | GRIPEX                   | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322              | Mfg.Date :   | Sep-22      |
| Parameter :    | ACCURACY STUDY(RECOVERY) | Exp.Date :   | To be fixed |

Each 4.5gm of sachet Contains  
Paracetamol BP ----- 650mg  
Phenylephrine Hydrochloride BP ----- 10mg  
Chlorphenamine Maleate BP ----- 20mg  
Ascorbic acid BP ----- 50mg

ASSAY OF PARACETAMOL

|                |              |              |                 |         |              |                |       |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041&30 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|-------|

|                     |       |            |     |            |   |            |    |
|---------------------|-------|------------|-----|------------|---|------------|----|
| Standard dilution : | 64.81 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
|---------------------|-------|------------|-----|------------|---|------------|----|

|                         |   |            |   |            |   |            |   |
|-------------------------|---|------------|---|------------|---|------------|---|
| Std.conc (in ppm)-64.81 | 1 | ml to ---> | 1 | ml to ---> | 1 | ml to ---> | 1 |
|-------------------------|---|------------|---|------------|---|------------|---|

|                        |        |            |      |            |   |            |     |
|------------------------|--------|------------|------|------------|---|------------|-----|
| Recovery 50% Dilution: | 650.38 | mg to ---> | 1000 | ml to ---> | 5 | ml to ---> | 100 |
|------------------------|--------|------------|------|------------|---|------------|-----|

|                          |   |            |   |            |   |            |   |
|--------------------------|---|------------|---|------------|---|------------|---|
| Std.conc (in ppm)-32.519 | 1 | ml to ---> | 1 | ml to ---> | 1 | ml to ---> | 1 |
|--------------------------|---|------------|---|------------|---|------------|---|

|                         |        |            |     |            |   |            |     |
|-------------------------|--------|------------|-----|------------|---|------------|-----|
| Recovery 100% Dilution: | 649.90 | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
|-------------------------|--------|------------|-----|------------|---|------------|-----|

|                         |   |            |   |            |   |            |   |
|-------------------------|---|------------|---|------------|---|------------|---|
| Std.conc (in ppm)-64.99 | 1 | ml to ---> | 1 | ml to ---> | 1 | ml to ---> | 1 |
|-------------------------|---|------------|---|------------|---|------------|---|

|                         |        |            |     |            |   |            |     |
|-------------------------|--------|------------|-----|------------|---|------------|-----|
| Recovery 150% Dilution: | 974.24 | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
|-------------------------|--------|------------|-----|------------|---|------------|-----|

|                          |   |            |   |            |   |            |   |
|--------------------------|---|------------|---|------------|---|------------|---|
| Std.conc (in ppm)-97.424 | 1 | ml to ---> | 1 | ml to ---> | 1 | ml to ---> | 1 |
|--------------------------|---|------------|---|------------|---|------------|---|

| System suitability    | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
|-----------------------|---------|---------|---------|---------|---------|---------|------|----------|
| Paracetamol           | 5222764 | 5218374 | 5231710 | 5235190 | 5219803 | 5225568 | 7469 | 0.143    |
| Standard con. in ppm. | 64.81   |         |         |         |         |         |      |          |

| Level's   | Injection No. | Observed area | Quantity added in ppm | Quantity Recovered in ppm | % Recovery |
|-----------|---------------|---------------|-----------------------|---------------------------|------------|
| I(50%)    | 1             | 2586685       | 32.519                | 32.08                     | 98.65      |
|           | 2             | 2588664       | 32.519                | 32.11                     | 98.73      |
|           | 3             | 2585054       | 32.519                | 32.06                     | 98.59      |
|           |               |               |                       | MEAN                      | 98.66      |
|           |               |               |                       | %RSD                      | 0.070      |
| II(100%)  | 1             | 5188454       | 64.990                | 64.35                     | 99.01      |
|           | 2             | 5174417       | 64.990                | 64.18                     | 98.75      |
|           | 3             | 5189915       | 64.990                | 64.37                     | 99.04      |
|           |               |               |                       | MEAN                      | 98.93      |
|           |               |               |                       | %RSD                      | 0.165      |
| III(150%) | 1             | 7706149       | 97.424                | 95.58                     | 98.10      |
|           | 2             | 7712411       | 97.424                | 95.65                     | 98.18      |
|           | 3             | 7751348       | 97.424                | 96.14                     | 98.68      |
|           |               |               |                       | MEAN                      | 98.32      |
|           |               |               |                       | %RSD                      | 0.317      |

CALCULATION FORMULA

Quantity added in ppm

$\frac{\text{Standard weight} \times \text{dilution} \times 1000}{100}$

Quantity recovered in ppm

$\frac{\text{Sample area} \times \text{std.conc in ppm}}{\text{Standard average area}}$

% Recovery

$\frac{\text{Quantity recovered in ppm} \times 100}{\text{Quantity added in ppm}}$

Results:

The % recovery was complies at each levels.

Acceptance criteria:

The mean % recovery at each level should be 98.0 to 102.0.

Analysed by : C.ALBIN JOSE  
Date : 09-11-2022

Checked by :  
Date : 09/11/2022





Safetab Life Science,  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|                |                          |              |             |
|----------------|--------------------------|--------------|-------------|
| Product Name : | GRIPEX                   | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322              | Mfg.Date :   | Sep-22      |
| Parameter :    | ACCURACY STUDY(RECOVERY) | Exp.Date :   | To be fixed |

Each 4.5gm of sachet Contains

|                                |       |
|--------------------------------|-------|
| Paracetamol BP                 | 650mg |
| Phenylephrine Hydrochloride BP | 10mg  |
| Chlorphenamine Maleate BP      | 20mg  |
| Ascorbic acid BP               | 50mg  |

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                |              |              |                 |         |              |                |      |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041&30 | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|------|

|                     |       |            |     |            |   |            |    |
|---------------------|-------|------------|-----|------------|---|------------|----|
| Standard dilution : | 40.53 | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
|---------------------|-------|------------|-----|------------|---|------------|----|

|                          |   |            |   |            |   |            |   |
|--------------------------|---|------------|---|------------|---|------------|---|
| Std.conc (in ppm)-20.265 | 1 | ml to ---> | 1 | ml to ---> | 1 | ml to ---> | 1 |
|--------------------------|---|------------|---|------------|---|------------|---|

|                        |       |            |      |            |   |            |   |
|------------------------|-------|------------|------|------------|---|------------|---|
| Recovery 50% Dilution: | 10.29 | mg to ---> | 1000 | ml to ---> | 1 | ml to ---> | 1 |
|------------------------|-------|------------|------|------------|---|------------|---|

|                         |   |            |   |            |   |            |   |
|-------------------------|---|------------|---|------------|---|------------|---|
| Std.conc (in ppm)-10.29 | 1 | ml to ---> | 1 | ml to ---> | 1 | ml to ---> | 1 |
|-------------------------|---|------------|---|------------|---|------------|---|

|                         |       |            |     |            |   |            |   |
|-------------------------|-------|------------|-----|------------|---|------------|---|
| Recovery 100% Dilution: | 10.21 | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1 |
|-------------------------|-------|------------|-----|------------|---|------------|---|

|                         |   |            |   |            |   |            |   |
|-------------------------|---|------------|---|------------|---|------------|---|
| Std.conc (in ppm)-20.42 | 1 | ml to ---> | 1 | ml to ---> | 1 | ml to ---> | 1 |
|-------------------------|---|------------|---|------------|---|------------|---|

|                         |       |            |     |            |   |            |   |
|-------------------------|-------|------------|-----|------------|---|------------|---|
| Recovery 150% Dilution: | 15.12 | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1 |
|-------------------------|-------|------------|-----|------------|---|------------|---|

|                         |   |            |   |            |   |            |   |
|-------------------------|---|------------|---|------------|---|------------|---|
| Std.conc (in ppm)-30.24 | 1 | ml to ---> | 1 | ml to ---> | 1 | ml to ---> | 1 |
|-------------------------|---|------------|---|------------|---|------------|---|

| System suitability    | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
|-----------------------|---------|---------|---------|---------|---------|---------|------|----------|
| Phenylephrine HCL     | 1220243 | 1223248 | 1224266 | 1223409 | 1225996 | 1223432 | 2090 | 0.171    |
| Standard con. in ppm. | 20.265  |         |         |         |         |         |      |          |

| Level's   | Injection No. | Observed area | Quantity added in ppm | Quantity Recovered in ppm | % Recovery |
|-----------|---------------|---------------|-----------------------|---------------------------|------------|
| I(50%)    | 1             | 628396        | 10.290                | 10.41                     | 101.15     |
|           | 2             | 631127        | 10.290                | 10.45                     | 101.59     |
|           | 3             | 633619        | 10.290                | 10.50                     | 102.00     |
|           |               |               |                       | MEAN                      | 101.58     |
|           |               |               |                       | %RSD                      | 0.414      |
| II(100%)  | 1             | 1224361       | 20.420                | 20.28                     | 99.32      |
|           | 2             | 1215587       | 20.420                | 20.14                     | 98.60      |
|           | 3             | 1219732       | 20.420                | 20.20                     | 98.94      |
|           |               |               |                       | MEAN                      | 98.95      |
|           |               |               |                       | %RSD                      | 0.360      |
| III(150%) | 1             | 1852604       | 30.240                | 30.69                     | 101.48     |
|           | 2             | 1850763       | 30.240                | 30.66                     | 101.38     |
|           | 3             | 1842580       | 30.240                | 30.52                     | 100.93     |
|           |               |               |                       | MEAN                      | 101.26     |
|           |               |               |                       | %RSD                      | 0.289      |

CALCULATION FORMULA

Quantity added in ppm

$$\frac{\text{Standard weight} \times \text{dilution} \times 1000}{100}$$

Quantity recovered in ppm

$$\frac{\text{Sample area} \times \text{std.conc in ppm}}{\text{Standard average area}}$$

% Recovery

$$\frac{\text{Quantity recovered in ppm} \times 100}{\text{Quantity added in ppm}}$$

Results:

The % recovery was complies at each levels.

Acceptance criteria:

The mean % recovery at each level should be 98.0 to 102.0.

Analysed by : C.ALBIN JOSE  
Date : 09-11-2022

Checked by :  
Date :





Safetab Life Science,  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

|       |                                                                                      |
|-------|--------------------------------------------------------------------------------------|
| Title | ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS |
|-------|--------------------------------------------------------------------------------------|

|                |                          |              |             |
|----------------|--------------------------|--------------|-------------|
| Product Name : | GRIPEX                   | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322              | Mfg.Date :   | Sep-22      |
| Parameter :    | ACCURACY STUDY(RECOVERY) | Exp.Date :   | To be fixed |

Each 4.5gm of sachet Contains  
Paracetamol BP ----- 650mg  
Phenylephrine Hydrochloride BP ----- 10mg  
Chlorphenamine Maleate BP ----- 20mg  
Ascorbic acid BP ----- 50mg

ASSAY OF CHLORPHENAMINE MALEATE

|                |              |              |                 |         |              |                |      |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041&30 | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|------|

|                         |       |            |      |            |   |            |    |
|-------------------------|-------|------------|------|------------|---|------------|----|
| Standard dilution :     | 40.21 | mg to ---> | 100  | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-40.21 | 1     | ml to ---> | 1    | ml to ---> | 1 | ml to ---> | 1  |
| Recovery 50% Dilution:  | 20.24 | mg to ---> | 1000 | ml to ---> | 1 | ml to ---> | 1  |
| Std.conc (in ppm)-20.24 | 1     | ml to ---> | 1    | ml to ---> | 1 | ml to ---> | 1  |
| Recovery 100% Dilution: | 20.39 | mg to ---> | 500  | ml to ---> | 1 | ml to ---> | 1  |
| Std.conc (in ppm)-40.78 | 1     | ml to ---> | 1    | ml to ---> | 1 | ml to ---> | 1  |
| Recovery 150% Dilution: | 30.53 | mg to ---> | 500  | ml to ---> | 1 | ml to ---> | 1  |
| Std.conc (in ppm)-61.06 | 1     | ml to ---> | 1    | ml to ---> | 1 | ml to ---> | 1  |

|                        |         |         |         |         |         |         |      |          |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
| Chlorphenamine Maleate | 2806891 | 2821746 | 2822504 | 2827128 | 2827291 | 2821112 | 8351 | 0.296    |
| Standard con. in ppm.  | 40.21   |         |         |         |         |         |      |          |

| Level"s   | Injection No. | Observed area | Quantity added in ppm | Quantity Recovered in ppm | % Recovery |
|-----------|---------------|---------------|-----------------------|---------------------------|------------|
| I(50%)    | 1             | 1394774       | 20.240                | 19.88                     | 98.22      |
|           | 2             | 1402753       | 20.240                | 19.99                     | 98.78      |
|           | 3             | 1409743       | 20.240                | 20.09                     | 99.28      |
|           |               |               |                       | MEAN                      | 98.76      |
|           |               |               |                       | %RSD                      | 0.534      |
| II(100%)  | 1             | 2877921       | 40.780                | 41.02                     | 100.59     |
|           | 2             | 2853727       | 40.780                | 40.67                     | 99.74      |
|           | 3             | 2892017       | 40.780                | 41.22                     | 101.08     |
|           |               |               |                       | MEAN                      | 100.47     |
|           |               |               |                       | %RSD                      | 0.674      |
| III(150%) | 1             | 4210534       | 61.060                | 60.01                     | 98.29      |
|           | 2             | 4220515       | 61.060                | 60.16                     | 98.52      |
|           | 3             | 4248802       | 61.060                | 60.56                     | 99.18      |
|           |               |               |                       | MEAN                      | 98.66      |
|           |               |               |                       | %RSD                      | 0.470      |

CALCULATION FORMULA

Quantity added in ppm

$\frac{\text{Standard weight} \times \text{dilution} \times 1000}{100}$

Quantity recovered in ppm

$\frac{\text{Sample area} \times \text{std.conc in ppm}}{\text{Standard average area}}$

% Recovery

$\frac{\text{Quantity recovered in ppm} \times 100}{\text{Quantity added in ppm}}$

Results:

The % recovery was complies at each levels.

Acceptance criteria:

The mean % recovery at each level should be 98.0 to 102.0.

Analysed by :

C.ALBIN JOSE

Date :

09-11-2022

Checked by :

Date :



# Safetab Life Science

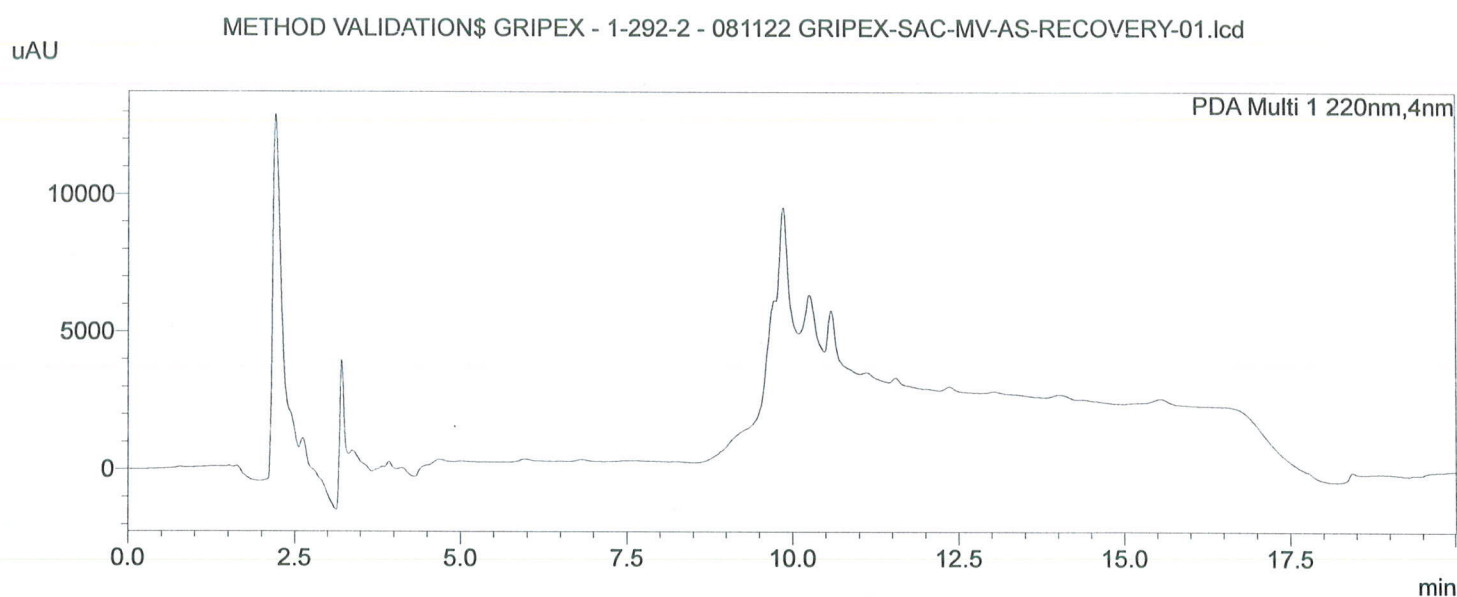
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : BLANK-AS  
Data Filename : 081122 GRIPEX-SAC-MV-AS-RECOVERY-01.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Vial # : 3-1  
Injection Volume : 50 uL  
Date Acquired : 11/8/2022 12:34:08 PM  
Date Processed : 11/9/2022 9:14:52 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :





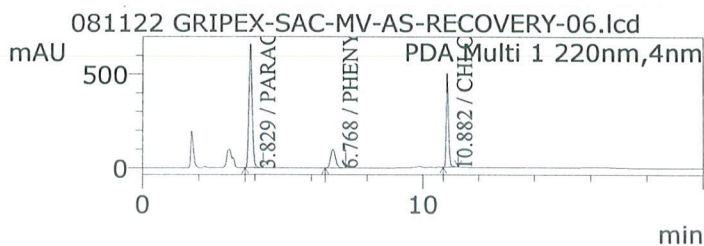
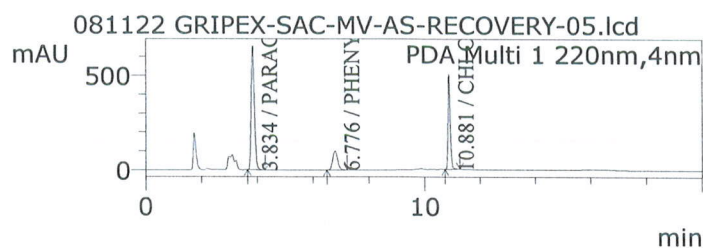
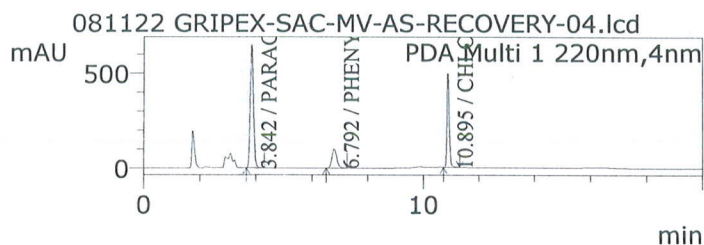
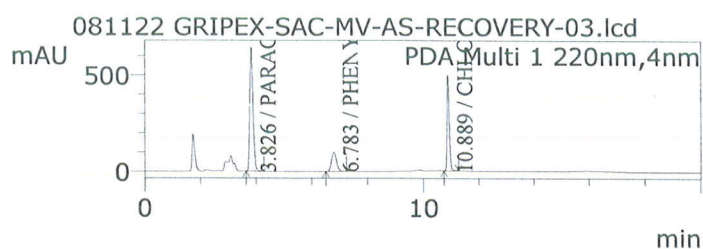
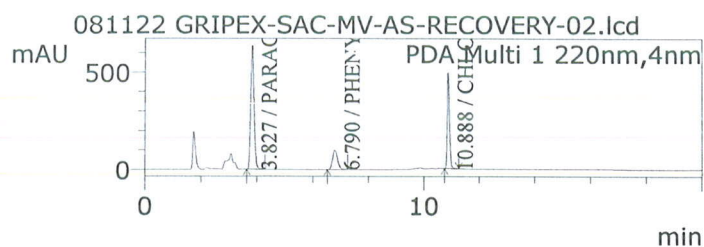
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : PARA+CPM+PHENYL-RECOVERY-STD-01  
Tray# : 3  
Vial# : 2  
Injection Volume : 50  
Data File : 081122 GRIPEX-SAC-MV-AS-RECOVERY-02.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/8/2022 12:54:43 PM  
Date Processed : 11/9/2022 9:14:49 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 2     | COVERY-02.lcd | PARA+CPM+PHENYL-RECOVERY-STD-01 | 3.827  | 5222764 | 4407     | 1.234    |
| 2     | COVERY-03.lcd | PARA+CPM+PHENYL-RECOVERY-STD-02 | 3.826  | 5218374 | 4494     | 1.235    |
| 2     | COVERY-04.lcd | PARA+CPM+PHENYL-RECOVERY-STD-03 | 3.842  | 5231710 | 4636     | 1.239    |
| 2     | COVERY-05.lcd | PARA+CPM+PHENYL-RECOVERY-STD-04 | 3.834  | 5235190 | 4672     | 1.242    |
| 2     | COVERY-06.lcd | PARA+CPM+PHENYL-RECOVERY-STD-05 | 3.829  | 5219803 | 4671     | 1.245    |
|       | Average       |                                 | 3.831  | 5225568 | 4576     | 1.239    |
|       | %RSD          |                                 | 0.175  | 0.143   | 2.615    | 0.396    |

ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 2     | COVERY-02.lcd | PARA+CPM+PHENYL-RECOVERY-STD-01 | 6.790  | 1220243 | 6559     | 1.174    |
| 2     | COVERY-03.lcd | PARA+CPM+PHENYL-RECOVERY-STD-02 | 6.783  | 1223248 | 6513     | 1.163    |
| 2     | COVERY-04.lcd | PARA+CPM+PHENYL-RECOVERY-STD-03 | 6.792  | 1224266 | 6574     | 1.153    |
| 2     | COVERY-05.lcd | PARA+CPM+PHENYL-RECOVERY-STD-04 | 6.776  | 1223409 | 6608     | 1.151    |
| 2     | COVERY-06.lcd | PARA+CPM+PHENYL-RECOVERY-STD-05 | 6.768  | 1225996 | 6535     | 1.146    |
|       | Average       |                                 | 6.782  | 1223433 | 6558     | 1.157    |
|       | %RSD          |                                 | 0.143  | 0.171   | 0.552    | 0.946    |

ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 2     | COVERY-02.lcd | PARA+CPM+PHENYL-RECOVERY-STD-01 | 10.888 | 2806891 | 66038    | 1.354    |
| 2     | COVERY-03.lcd | PARA+CPM+PHENYL-RECOVERY-STD-02 | 10.889 | 2821746 | 66304    | 1.334    |
| 2     | COVERY-04.lcd | PARA+CPM+PHENYL-RECOVERY-STD-03 | 10.895 | 2822504 | 68369    | 1.327    |
| 2     | COVERY-05.lcd | PARA+CPM+PHENYL-RECOVERY-STD-04 | 10.881 | 2827128 | 67308    | 1.314    |
| 2     | COVERY-06.lcd | PARA+CPM+PHENYL-RECOVERY-STD-05 | 10.882 | 2827291 | 68204    | 1.304    |
|       | Average       |                                 | 10.887 | 2821112 | 67245    | 1.326    |
|       | %RSD          |                                 | 0.052  | 0.296   | 1.583    | 1.457    |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

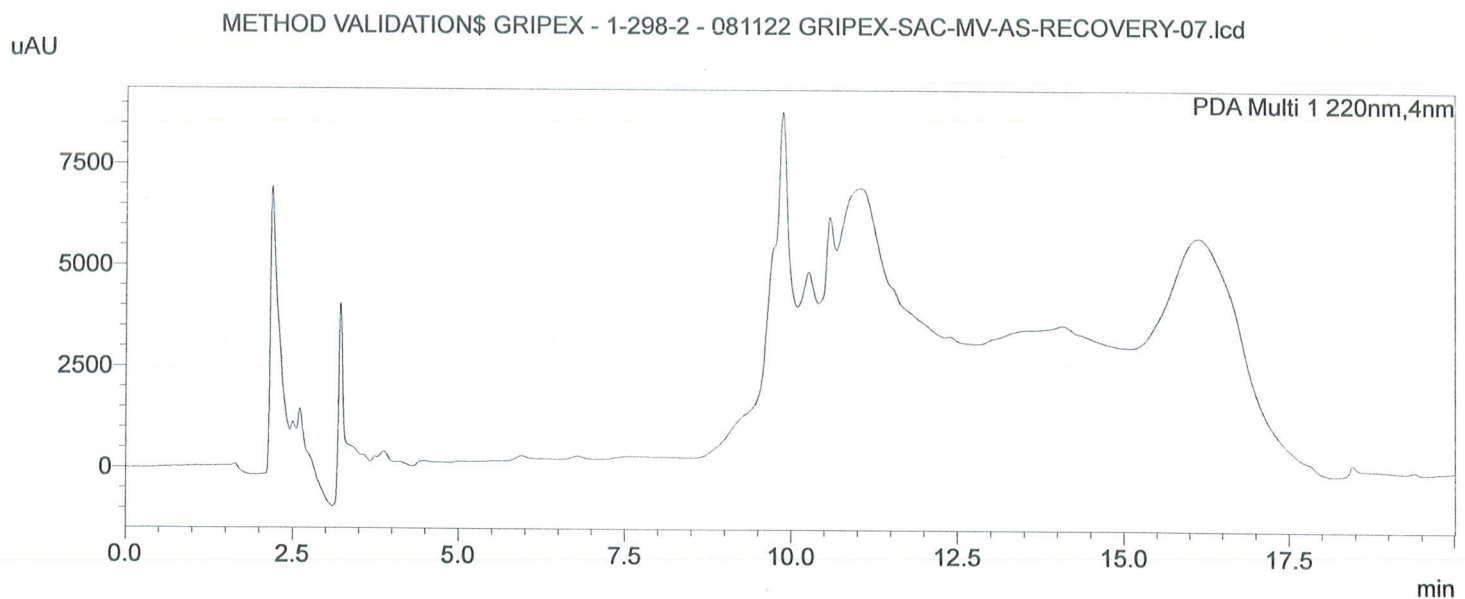
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : BLANK-AS  
Data Filename : 081122 GRIPEX-SAC-MV-AS-RECOVERY-07.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Vial # : 3-1  
Injection Volume : 50 uL  
Date Acquired : 11/8/2022 2:37:39 PM  
Date Processed : 11/9/2022 9:14:56 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plata | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



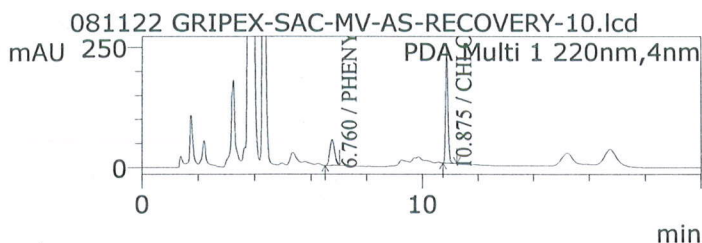
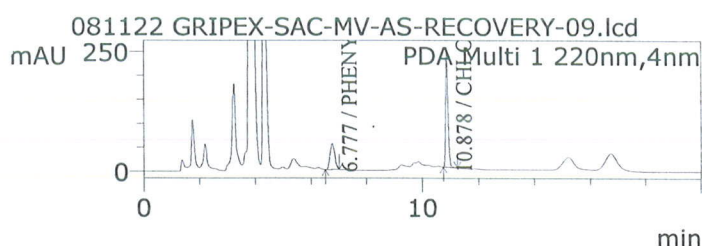
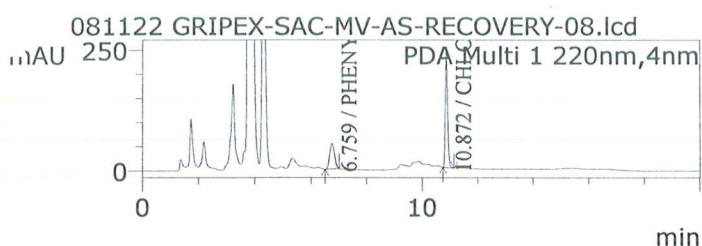
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : GRIPEX-RECOVERY-50%-A-PPN-1  
Tray# : 3  
Vial# : 3  
Injection Volume : 50  
Data File : 081122 GRIPEX-SAC-MV-AS-RECOVERY-08.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Report Format File : DEFAULT.Isr  
Date Acquired : 11/8/2022 3:14:04 PM  
Date Processed : 11/9/2022 10:04:27 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

| Vial# | Title         | Sample ID                   | R.Time | Area   | T. Plate | T.Factor |
|-------|---------------|-----------------------------|--------|--------|----------|----------|
| 3     | COVERY-08.lcd | GRIPEX-RECOVERY-50%-A-PPN-1 | 6.759  | 628396 | 6845     | 1.087    |
| 4     | COVERY-09.lcd | GRIPEX-RECOVERY-50%-A-PPN-2 | 6.777  | 631127 | 6971     | 1.090    |
| 5     | COVERY-10.lcd | GRIPEX-RECOVERY-50%-A-PPN-3 | 6.760  | 633619 | 6953     | 1.094    |
|       | Average       |                             | 6.765  | 631047 | 6923     | 1.090    |
|       | %RSD          |                             | 0.150  | 0.414  | 0.985    | 0.301    |

ID#2 Compound Name: CHLORPHENAMINE MALEATE

| Vial# | Title         | Sample ID                   | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-----------------------------|--------|---------|----------|----------|
| 3     | COVERY-08.lcd | GRIPEX-RECOVERY-50%-A-PPN-1 | 10.872 | 1394774 | 68620    | 1.276    |
| 4     | COVERY-09.lcd | GRIPEX-RECOVERY-50%-A-PPN-2 | 10.878 | 1402753 | 67039    | 1.271    |
| 5     | COVERY-10.lcd | GRIPEX-RECOVERY-50%-A-PPN-3 | 10.875 | 1409743 | 66243    | 1.275    |
|       | Average       |                             | 10.875 | 1402423 | 67301    | 1.274    |
|       | %RSD          |                             | 0.026  | 0.534   | 1.798    | 0.213    |

Analysed By

Date :

Checked By

Date :





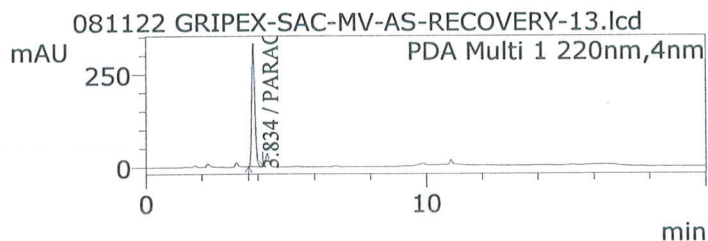
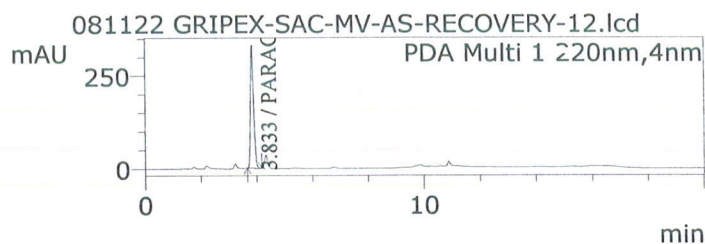
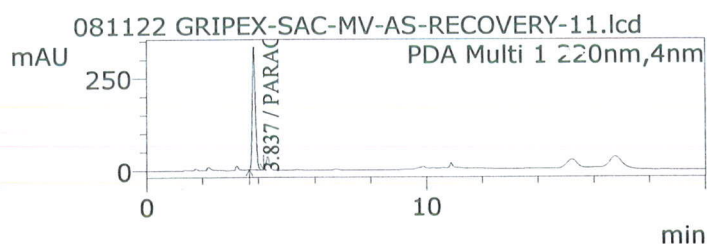
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : GRIPEX-RECOVERY-50%-B-PPN-1  
Tray# : 3  
Vial# : 6  
Injection Volume : 50  
Data File : 081122 GRIPEX-SAC-MV-AS-RECOVERY-11.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/8/2022 4:15:48 PM  
Date Processed : 11/9/2022 9:21:38 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                   | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-----------------------------|--------|---------|----------|----------|
| 6     | COVERY-11.lcd | GRIPEX-RECOVERY-50%-B-PPN-1 | 3.837  | 2586685 | 4878     | 1.237    |
| 7     | COVERY-12.lcd | GRIPEX-RECOVERY-50%-B-PPN-2 | 3.833  | 2588664 | 4842     | 1.239    |
| 8     | COVERY-13.lcd | GRIPEX-RECOVERY-50%-B-PPN-3 | 3.834  | 2585054 | 4866     | 1.238    |
|       | Average       |                             | 3.835  | 2586801 | 4862     | 1.238    |
|       | %RSD          |                             | 0.061  | 0.070   | 0.386    | 0.085    |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

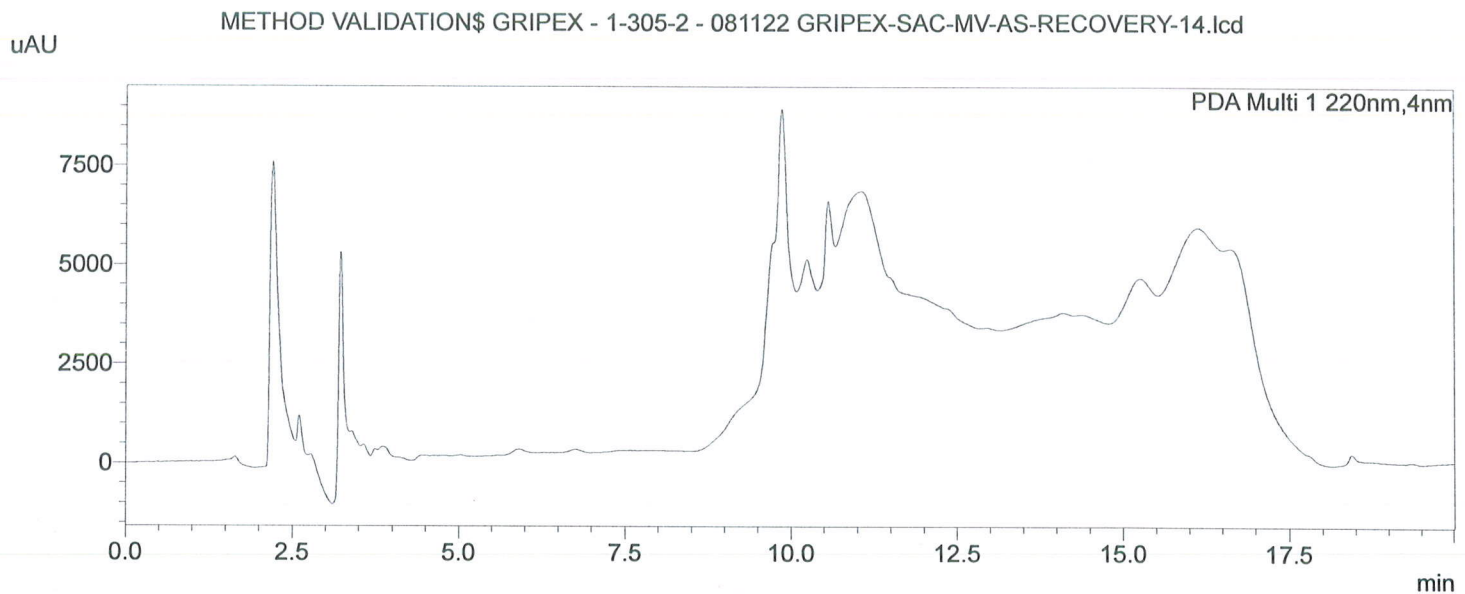
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : BLANK-AS  
Data Filename : 081122 GRIPEX-SAC-MV-AS-RECOVERY-14.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Vial # : 3-1  
Injection Volume : 50 uL  
Date Acquired : 11/8/2022 5:17:33 PM  
Date Processed : 11/9/2022 9:14:58 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plata | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :





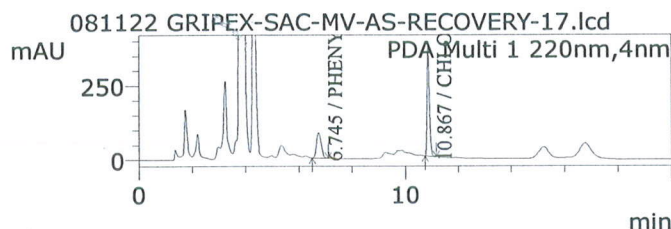
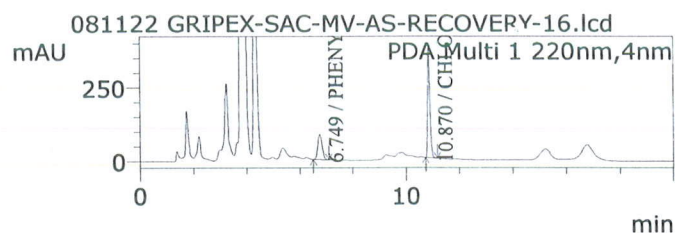
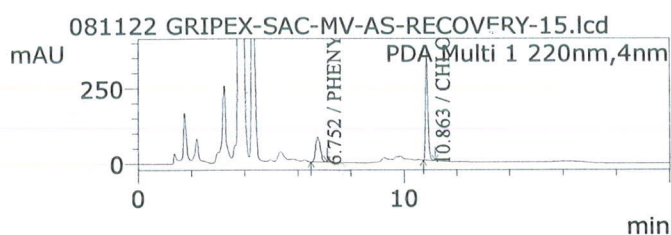
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : GRIPEX-RECOVERY-100%-A-PPN-1  
Tray# : 3  
Vial# : 9  
Injection Volume : 50  
Data File : 081122 GRIPEX-SAC-MV-AS-RECOVERY-15.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/8/2022 5:38:09 PM  
Date Processed : 11/9/2022 9:20:00 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 9     | COVERY-15.lcd | GRIPEX-RECOVERY-100%-A-PPN-1 | 6.752  | 1224361 | 6832     | 1.113    |
| 10    | COVERY-16.lcd | GRIPEX-RECOVERY-100%-A-PPN-2 | 6.749  | 1215587 | 6839     | 1.112    |
| 11    | COVERY-17.lcd | GRIPEX-RECOVERY-100%-A-PPN-3 | 6.745  | 1219732 | 6868     | 1.112    |
|       | Average       |                              | 6.749  | 1219893 | 6846     | 1.112    |
|       | %RSD          |                              | 0.055  | 0.360   | 0.279    | 0.051    |

ID#2 Compound Name: CHLORPHENAMINE MALEATE

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 9     | COVERY-15.lcd | GRIPEX-RECOVERY-100%-A-PPN-1 | 10.863 | 2877921 | 69481    | 1.287    |
| 10    | COVERY-16.lcd | GRIPEX-RECOVERY-100%-A-PPN-2 | 10.870 | 2853727 | 66104    | 1.284    |
| 11    | COVERY-17.lcd | GRIPEX-RECOVERY-100%-A-PPN-3 | 10.867 | 2892017 | 65747    | 1.275    |
|       | Average       |                              | 10.867 | 2874555 | 67111    | 1.282    |
|       | %RSD          |                              | 0.032  | 0.673   | 3.070    | 0.486    |

Analysed By

Date

Checked By

Date



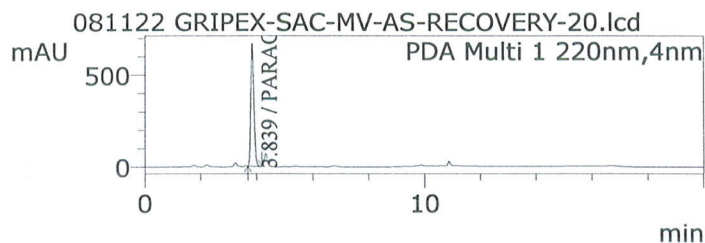
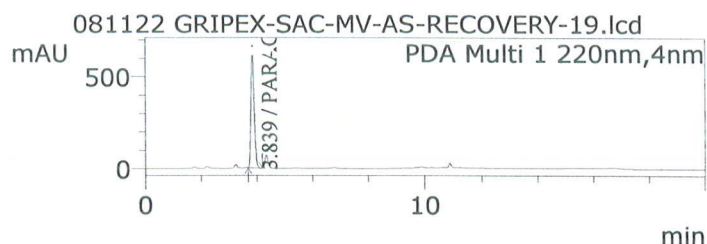
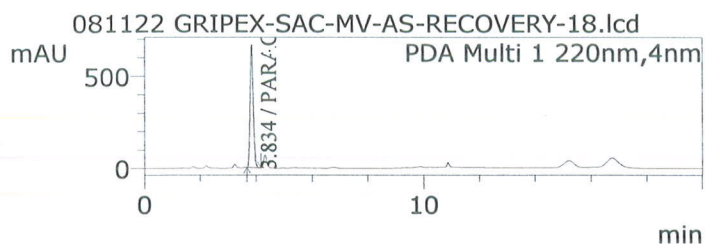
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : GRIPEX-RECOVERY-100%-B-PPN-1  
Tray# : 3  
Vial# : 12  
Injection Volume : 50  
Data File : 081122 GRIPEX-SAC-MV-AS-RECOVERY-18.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/8/2022 6:39:56 PM  
Date Processed : 11/9/2022 9:21:46 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 12    | COVERY-18.lcd | GRIPEX-RECOVERY-100%-B-PPN-1 | 3.834  | 5188454 | 4894     | 1.242    |
| 13    | COVERY-19.lcd | GRIPEX-RECOVERY-100%-B-PPN-2 | 3.839  | 5174417 | 4859     | 1.244    |
| 14    | COVERY-20.lcd | GRIPEX-RECOVERY-100%-B-PPN-3 | 3.839  | 5189915 | 4861     | 1.243    |
|       | Average       |                              | 3.837  | 5184262 | 4871     | 1.243    |
|       | %RSD          |                              | 0.070  | 0.165   | 0.406    | 0.084    |

Analysed By

Date :

Checked By

Date :





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Puducherry- 605 107

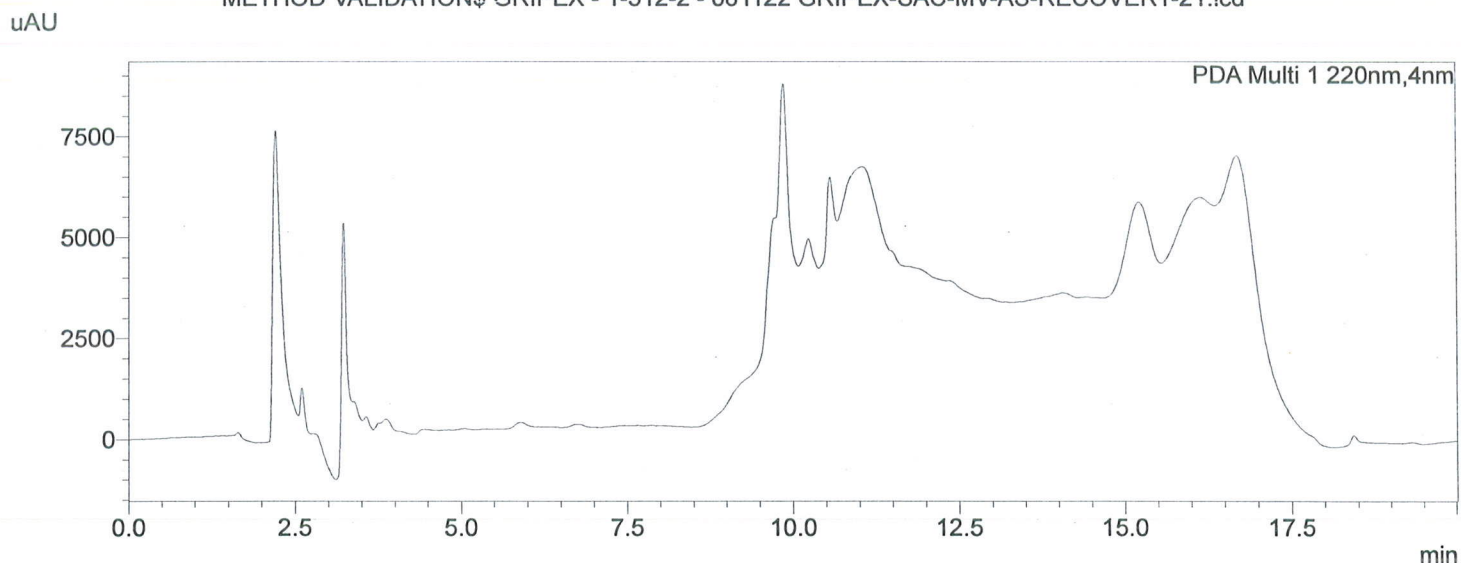
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : BLANK-AS  
Data Filename : 081122 GRIPEX-SAC-MV-AS-RECOVERY-21.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Vial # : 3-1  
Injection Volume : 50 uL  
Date Acquired : 11/8/2022 7:41:41 PM  
Date Processed : 11/9/2022 9:15:01 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-312-2 - 081122 GRIPEX-SAC-MV-AS-RECOVERY-21.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



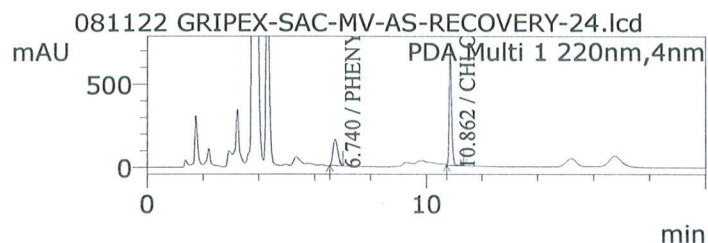
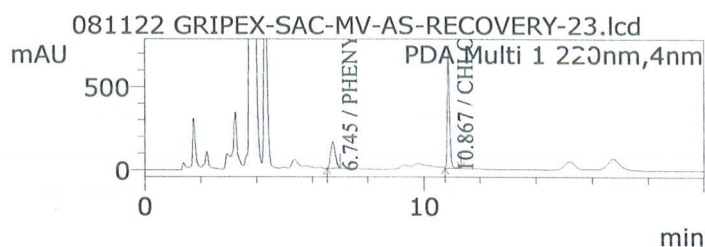
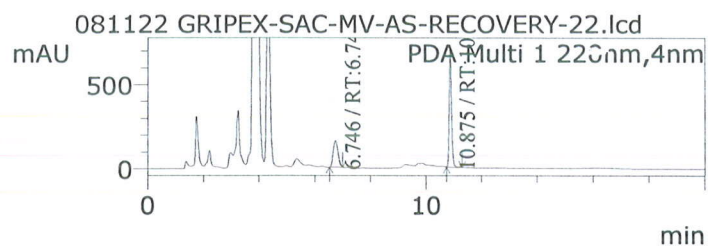
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : GRIPEX-RECOVERY-150%-A-PPN-1  
Tray# : 3  
Vial# : 15  
Injection Volume : 50  
Data File : 081122 GRIPEX-SAC-MV-AS-RECOVERY-22.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/8/2022 8:02:16 PM  
Date Processed : 11/9/2022 9:58:36 AM



<< PDA >>

ID#1 Compound Name: RT:6.746

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 15    | COVERY-22.lcd | GRIPEX-RECOVERY-150%-A-PPN-1 | 6.746  | 1852604 | 6913     | 1.104    |
| 16    | COVERY-23.lcd | GRIPEX-RECOVERY-150%-A-PPN-2 | 6.745  | 1850763 | 6938     | 1.105    |
| 17    | COVERY-24.lcd | GRIPEX-RECOVERY-150%-A-PPN-3 | 6.740  | 1842580 | 6994     | 1.130    |
|       | Average       |                              | 6.744  | 1848649 | 6948     | 1.113    |
|       | %RSD          |                              | 0.046  | 0.289   | 0.597    | 1.329    |

ID#2 Compound Name: RT:10.875

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 15    | COVERY-22.lcd | GRIPEX-RECOVERY-150%-A-PPN-1 | 10.875 | 4210534 | 68650    | 1.283    |
| 16    | COVERY-23.lcd | GRIPEX-RECOVERY-150%-A-PPN-2 | 10.867 | 4220515 | 64869    | 1.279    |
| 17    | COVERY-24.lcd | GRIPEX-RECOVERY-150%-A-PPN-3 | 10.862 | 4248802 | 66270    | 1.292    |
|       | Average       |                              | 10.868 | 4226617 | 66597    | 1.284    |
|       | %RSD          |                              | 0.056  | 0.470   | 2.870    | 0.510    |

Analysed By

Date :

Checked By

Date :





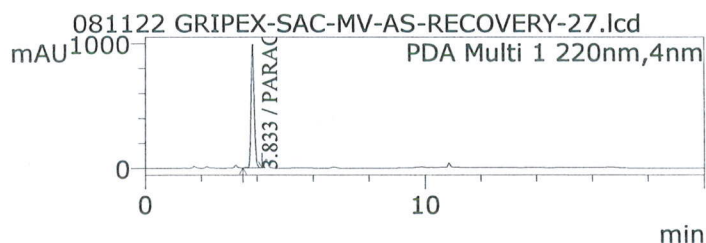
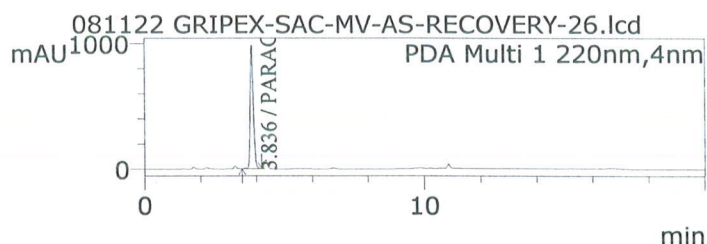
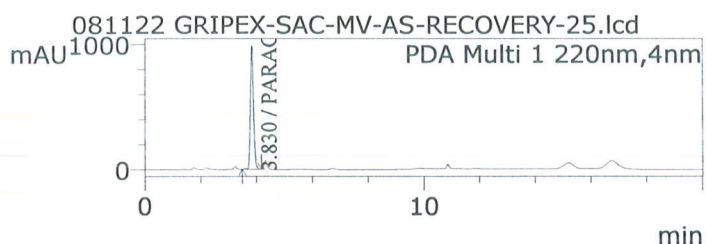
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : RECOVERY-AS  
Sample ID : GRIPEX-RECOVERY-150%-B-PPN-1  
Tray# : 3  
Vial# : 18  
Injection Volume : 50  
Data File : 081122 GRIPEX-SAC-MV-AS-RECOVERY-25.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 081122 GRIPEX-SAC-MV-AS-RECOVERY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/8/2022 9:04:03 PM  
Date Processed : 11/9/2022 9:51:49 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                    | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------------|--------|---------|----------|----------|
| 18    | COVERY-25.lcd | GRIPEX-RECOVERY-150%-B-PPN-1 | 3.830  | 7706149 | 4851     | 1.241    |
| 19    | COVERY-26.lcd | GRIPEX-RECOVERY-150%-B-PPN-2 | 3.836  | 7712411 | 4890     | 1.240    |
| 20    | COVERY-27.lcd | GRIPEX-RECOVERY-150%-B-PPN-3 | 3.833  | 7751348 | 4890     | 1.238    |
|       | Average       |                              | 3.833  | 7723303 | 4877     | 1.240    |
|       | %RSD          |                              | 0.071  | 0.317   | 0.464    | 0.145    |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

Puducherry- 605 107

*Quality control Department*

## ====BATCH TABLE=====

Batch Table

| Vial# | Tray | Inj. Vol. | Sample Name | Sample ID                       | Method File   | Data File                        | Report Format      |
|-------|------|-----------|-------------|---------------------------------|---------------|----------------------------------|--------------------|
| 1     | 3    | 50.0      | RECOVERY-AS | BLANK-AS                        | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-01.lcd | system\DEFAULT.lsr |
| 2     | 3    | 50.0      | RECOVERY-AS | PARA+CPM+PHENYL-RECOVERY-STD-01 | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-02.lcd | system\DEFAULT.lsr |
| 2     | 3    | 50.0      | RECOVERY-AS | PARA+CPM+PHENYL-RECOVERY-STD-02 | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-03.lcd | system\DEFAULT.lsr |
| 2     | 3    | 50.0      | RECOVERY-AS | PARA+CPM+PHENYL-RECOVERY-STD-03 | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-04.lcd | system\DEFAULT.lsr |
| 2     | 3    | 50.0      | RECOVERY-AS | PARA+CPM+PHENYL-RECOVERY-STD-04 | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-05.lcd | system\DEFAULT.lsr |
| 2     | 3    | 50.0      | RECOVERY-AS | PARA+CPM+PHENYL-RECOVERY-STD-05 | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-06.lcd | system\DEFAULT.lsr |
| 1     | 3    | 50.0      | RECOVERY-AS | BLANK-AS                        | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-07.lcd | system\DEFAULT.lsr |
| 3     | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-50%-A-PPN-1     | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-08.lcd | system\DEFAULT.lsr |
| 4     | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-50%-A-PPN-2     | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-09.lcd | system\DEFAULT.lsr |
| 5     | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-50%-A-PPN-3     | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-10.lcd | system\DEFAULT.lsr |
| 6     | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-50%-B-PPN-1     | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-11.lcd | system\DEFAULT.lsr |
| 7     | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-50%-B-PPN-2     | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-12.lcd | system\DEFAULT.lsr |
| 8     | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-50%-B-PPN-3     | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-13.lcd | system\DEFAULT.lsr |
| 1     | 3    | 50.0      | RECOVERY-AS | BLANK-AS                        | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-14.lcd | system\DEFAULT.lsr |
| 9     | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-100%-A-PPN-1    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-15.lcd | system\DEFAULT.lsr |
| 10    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-100%-A-PPN-2    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-16.lcd | system\DEFAULT.lsr |
| 11    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-100%-A-PPN-3    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-17.lcd | system\DEFAULT.lsr |
| 12    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-100%-B-PPN-1    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-18.lcd | system\DEFAULT.lsr |
| 13    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-100%-B-PPN-2    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-19.lcd | system\DEFAULT.lsr |
| 14    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-100%-B-PPN-3    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-20.lcd | system\DEFAULT.lsr |
| 1     | 3    | 50.0      | RECOVERY-AS | BLANK-AS                        | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-21.lcd | system\DEFAULT.lsr |
| 15    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-150%-A-PPN-1    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-22.lcd | system\DEFAULT.lsr |
| 16    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-150%-A-PPN-2    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-23.lcd | system\DEFAULT.lsr |
| 17    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-150%-A-PPN-3    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-24.lcd | system\DEFAULT.lsr |
| 18    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-150%-B-PPN-1    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-25.lcd | system\DEFAULT.lsr |
| 19    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-150%-B-PPN-2    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-26.lcd | system\DEFAULT.lsr |
| 20    | 3    | 50.0      | RECOVERY-AS | GRIPEX-RECOVERY-150%-B-PPN-3    | GRIPEX-AS.lcm | GRIPEX-SAC-MV-AS-RECOVERY-27.lcd | system\DEFAULT.lsr |



| Vial# | Tray | Inj. Vol. | Sample Name      | Sample ID | Method File        | Data File                                           | Report Format |
|-------|------|-----------|------------------|-----------|--------------------|-----------------------------------------------------|---------------|
| -1    | 3    | 50.0      | RECOVERY-AS SHUT |           | HUTDOWN METHOD.lcm | GRIPEX-SAC-MV-AS-RECOVERY-28.lcd\system\DEFAULT.lsr |               |

Analysed By

Date :

*[Signature]*  
08/11/2022

Checked By

Date :

*[Signature]*  
08/11/2022

**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

|                     |                |
|---------------------|----------------|
| Name of the Product | GRIPEX SACHETS |
| Batch No            | ST/TS-1322     |

| S. No | TEST / OBSERVATION / LIMIT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | <p><u>ACCURACY STUDY (RECOVERY)</u></p> <p><u>Std Stock Preparation:</u></p> <p><u>Solution A:</u><br/>         Weighing of Paracetamol 10g and dissolving of Chlorpheniramine maleate in 100ml volumetric flask added 70ml of distilled water to dissolve and make up to volume with distilled.</p> <p><u>Solution B:</u><br/>         10.53mg of Phenyphrine added in 100ml volumetric flask added 130ml of distilled water to dissolve and make up to volume with distilled.</p> <p><u>Standard Preparation:</u><br/>         5ml of each solution A and B to 50ml with distilled water</p> <p><u>50% Recovery:</u><br/>         50.38mg of paracetamol, 10.29g of Phenyphrine added, 10.29g of cpm and 3.8218g of Plain phlo in 1000ml of volumetric flask added 70ml of distilled water and Sonicate for 10min to dissolve. And make up to volume with distilled. After the solution through 0.45µm filter (Sol. A). Further distilled 5ml of solution to 100ml of distilled (Sol. B)</p> |

Analyzed by :

Date

Checked by :

Date :



**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

|                     |                |
|---------------------|----------------|
| Name of the Product | GRIPEX SACHETS |
| Batch No            | ST/T/S-1322    |

100 % Recovery Study :

649.90mg of Paracetamol, 10.21g phenylephrine HCl, 3.8213 gm plain Placebo and 20.39 gm in a 50ml volumetric flask add 30ml of diluent and Sonicate for 20 minutes. to dissolve. and make up volume with diluent. Filter the solution through 0.45µm PVD filter (Soln A). Further dilute 5ml of this solution to 100ml with diluent (Soln B)

150 % Recovery Study :

974.24 mg Paracetamol, 15.12 mg phenylephrine HCl, 30.53 mg cpm and 3.8212 gm plain Placebo in 150ml volumetric flask add 30ml of diluent Sonicate for 20 minutes to dissolve. Filter the solution through 0.45µm PVD filter (Soln A). Further dilute 5ml of this solution to 100ml with diluent.

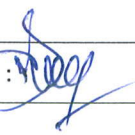
Analyzed by :



Date :

08/11/22

Checked by :



Date :

08/11/2022

**Safetab Life Science ,**

Puducherry - 605 107

**QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

**ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS**

|                |                                  |              |             |
|----------------|----------------------------------|--------------|-------------|
| Product Name : | GRIPEX                           | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322                      | Mfg.Date :   | Sep-22      |
| Parameter :    | STABILITY OF ANALYTICAL SOLUTION | Exp.Date :   | To be fixed |

Each 4500 mg of Sachet Contains;  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

**ASSAY OF PARACETAMOL**

|                |              |              |                 |         |              |                |       |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041&30 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|-------|

|                            |         |            |     |            |   |            |     |
|----------------------------|---------|------------|-----|------------|---|------------|-----|
| Standard dilution :        | 40.48   | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50  |
| Std.conc (in ppm)-40.48    | 1       | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |
| Sample dilution :          | 4501.10 | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
| Test.conc (in ppm)-65.0156 | 1       | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

|                     |         |
|---------------------|---------|
| Conversion factor : | 1.0000  |
| Labelled claim :    | 650 mg  |
| Average weight :    | 4500 mg |

|                      |         |         |         |         |         |         |        |          |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
| Paracetamol          | 3224777 | 3215937 | 3224599 | 3224076 | 3228756 | 3223629 | 4688.1 | 0.145    |
| With Bracketing std. |         |         |         |         |         | 3223629 | 4688.1 | 0.145    |

| Time interval | Paracetamol Standard area | Absolute % difference of standard area | Paracetamol Sample area | Absolute % difference of sample area | Assay in % | Absolute % difference of Assay preparation |
|---------------|---------------------------|----------------------------------------|-------------------------|--------------------------------------|------------|--------------------------------------------|
| Initial       | 3223629                   | Not applicable                         | 4925079                 | Not applicable                       | 95.12      | Not applicable                             |
| 2 Hours       | 3228202                   | -0.14                                  | 4925345                 | -0.01                                | 95.13      | -0.01                                      |
| 4 Hours       | 3227028                   | -0.11                                  | 4928358                 | -0.07                                | 95.19      | -0.07                                      |
| 6 Hours       | 3226423                   | -0.09                                  | 4930168                 | -0.10                                | 95.22      | -0.10                                      |
| 8 Hours       | 3226648                   | -0.09                                  | 4932849                 | -0.16                                | 95.27      | -0.16                                      |
| 10 Hours      | 3223569                   | 0.00                                   | 4929737                 | -0.09                                | 95.21      | -0.09                                      |
| 12 Hours      | 3220281                   | 0.10                                   | 4908573                 | 0.34                                 | 94.80      | 0.34                                       |
| 16 Hours      | 3234620                   | -0.34                                  | 4947677                 | -0.46                                | 95.56      | -0.46                                      |
| 20 Hours      | 3239548                   | -0.49                                  | 4982290                 | -1.15                                | 96.23      | -1.15                                      |
| 24 Hours      | 3233798                   | -0.31                                  | 4966235                 | -0.83                                | 95.92      | -0.83                                      |
| 28 Hours      | 3231066                   | -0.23                                  | 4936853                 | -0.24                                | 95.35      | -0.24                                      |
| 32 Hours      | 3233265                   | -0.30                                  | 4958588                 | -0.68                                | 95.77      | -0.68                                      |
| 36 Hours      | 3224184                   | -0.02                                  | 4947666                 | -0.46                                | 95.56      | -0.46                                      |
| 40 Hours      | 3225424                   | -0.06                                  | 4959520                 | -0.69                                | 95.79      | -0.69                                      |
| 44 Hours      | 3224404                   | -0.02                                  | 4966015                 | -0.82                                | 95.91      | -0.82                                      |
| Average       | 3228139                   | -0.15                                  | 4942997                 | -0.39                                | 95.5       | -0.39                                      |
| % RSD         | 0.163                     | Not applicable                         | 0.408                   | Not applicable                       | 0.408      | Not applicable                             |

**Results :**

Standard solution and Sample solution was stable upto 44 hrs at room temperature.

**Acceptance criteria:**The Standard Solution and Sample solution shall be considered stable for the final period till which the area difference between initial and next periodic interval should not be more than  $\pm 2\%$ .

Analysed by :

C.ALBIN JOSE

Date :

11-11-2022

Checked by :

Date :





**Safetab Life Science ,**  
Puducherry - 605 107

**QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

**Title**

**ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS**

|                       |                                         |                     |                    |
|-----------------------|-----------------------------------------|---------------------|--------------------|
| <b>Product Name :</b> | <b>GRIPEX</b>                           | <b>Batch size :</b> | <b>500 SACHETS</b> |
| <b>Batch Number :</b> | <b>ST/T/S-1322</b>                      | <b>Mfg.Date :</b>   | <b>Sep-22</b>      |
| <b>Parameter :</b>    | <b>STABILITY OF ANALYTICAL SOLUTION</b> | <b>Exp.Date :</b>   | <b>To be fixed</b> |

Each 4500 mg of Sachet Contains;  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

**ASSAY OF PHENYLEPHRINE HYDROCHLORIDE**

|                           |              |            |              |                 |         |            |              |                |          |
|---------------------------|--------------|------------|--------------|-----------------|---------|------------|--------------|----------------|----------|
| Instrument ID:            | ST/QC/EQ/039 |            | Balance ID : | ST/QC/EQ/041&30 |         | WS No.:    | IAARI/WS/344 | % Purity (aib) |          |
| Standard dilution :       | 40.44        | mg to ---> | 200          | ml to --->      | 5       | ml to ---> | 50           |                |          |
| Std.conc (in ppm)-20.22   | 1            | ml to ---> | 1            | ml to --->      | 1       | ml to ---> | 1            |                |          |
| Sample dilution :         | 4501.10      | mg to ---> | 500          | ml to --->      | 1       | ml to ---> | 1            |                |          |
| Test.conc (in ppm)-20.004 | 1            | ml to ---> | 1            | ml to --->      | 1       | ml to ---> | 1            |                |          |
| Conversion factor :       | 1.0000       |            | mg           |                 |         |            |              |                |          |
| Labelled claim :          | 10           |            |              |                 |         |            |              |                |          |
| Average weight :          | 4500         |            |              | mg              |         |            |              |                |          |
| System suitability        | 1            | 2          | 3            |                 | 4       | 5          | MEAN         | S.D            | RSD in % |
| Phenylephrine HCL         | 1218400      | 1216161    | 1216485      |                 | 1221796 | 1223049    | 1219178      | 3114.4         | 0.255    |
| With Bracketing std.      |              |            |              |                 |         | 1219178    | 3114.4       | 0.255          |          |

| Time interval | Phenylephrine Standard area | Absolute % difference of standard area | Phenylephrine Sample area | Absolute % difference of sample area | Assay in % | Absolute % difference of Assay preparation |
|---------------|-----------------------------|----------------------------------------|---------------------------|--------------------------------------|------------|--------------------------------------------|
| Initial       | 1219178                     | Not applicable                         | 1165981                   | Not applicable                       | 95.60      | Not applicable                             |
| 2 Hours       | 1223704                     | -0.37                                  | 1165416                   | 0.05                                 | 95.56      | 0.05                                       |
| 4 Hours       | 1220297                     | -0.09                                  | 1165174                   | 0.07                                 | 95.54      | 0.07                                       |
| 6 Hours       | 1217218                     | 0.16                                   | 1162951                   | 0.26                                 | 95.35      | 0.26                                       |
| 8 Hours       | 1219763                     | -0.05                                  | 1161638                   | 0.37                                 | 95.25      | 0.37                                       |
| 10 Hours      | 1217414                     | 0.14                                   | 1161012                   | 0.43                                 | 95.19      | 0.43                                       |
| 12 Hours      | 1220624                     | -0.12                                  | 1153456                   | 1.09                                 | 94.57      | 1.09                                       |
| 16 Hours      | 1219779                     | -0.05                                  | 1161420                   | 0.39                                 | 95.23      | 0.39                                       |
| 20 Hours      | 1225065                     | -0.48                                  | 1161276                   | 0.41                                 | 95.22      | 0.41                                       |
| 24 Hours      | 1227808                     | -0.70                                  | 1162495                   | 0.30                                 | 95.32      | 0.30                                       |
| 28 Hours      | 1225894                     | -0.55                                  | 1161262                   | 0.41                                 | 95.21      | 0.41                                       |
| 32 Hours      | 1226790                     | -0.62                                  | 1162011                   | 0.34                                 | 95.28      | 0.34                                       |
| 36 Hours      | 1221998                     | -0.23                                  | 1159390                   | 0.57                                 | 95.06      | 0.57                                       |
| 40 Hours      | 1222884                     | -0.30                                  | 1161765                   | 0.36                                 | 95.26      | 0.36                                       |
| 44 Hours      | 1224314                     | -0.42                                  | 1162439                   | 0.30                                 | 95.31      | 0.30                                       |
| Average       | 1222182                     | -0.26                                  | 1161846                   | 0.38                                 | 95.3       | 0.38                                       |
| % RSD         | 0.273                       | Not applicable                         | 0.253                     | Not applicable                       | 0.253      | Not applicable                             |

**Results :**

Standard solution and Sample solution was stable upto 44 hrs at room temperature.

**Acceptance criteria:**

The Standard Solution and Sample solution shall be considered stable for the final period till which the area difference between initial and next periodic interval should not be more than  $\pm 2\%$ .

Analysed by : C.ALBIN JOSE  
Date : 11-11-2022

Checked by :  
Date : 11/11/2022





**Safetab Life Science,**  
Puducherry - 605 107

**QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

**Title**

**ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS**

|                |                                  |              |             |
|----------------|----------------------------------|--------------|-------------|
| Product Name : | GRIPEX                           | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322                      | Mfg.Date :   | Sep-22      |
| Parameter :    | STABILITY OF ANALYTICAL SOLUTION | Exp.Date :   | To be fixed |

Each 4500 mg of Sachet Contains;  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

**ASSAY OF CHLORPHENAMINE MALEATE**

|                           |  |              |            |              |         |                 |         |         |            |              |    |                |  |      |  |
|---------------------------|--|--------------|------------|--------------|---------|-----------------|---------|---------|------------|--------------|----|----------------|--|------|--|
| Instrument ID:            |  | ST/QC/EQ/039 |            | Balance ID : |         | ST/QC/EQ/041&30 |         | WS No.: |            | ST/WS/22/039 |    | % Purity (aib) |  | 99.7 |  |
| Standard dilution :       |  | 40.30        | mg to ---> | 100          |         | ml to --->      |         | 5       | ml to ---> |              | 50 |                |  |      |  |
| Std.conc (in ppm)-40.3    |  | 1            | ml to ---> | 1            |         | ml to --->      |         | 1       | ml to ---> |              | 1  |                |  |      |  |
| Sample dilution :         |  | 4501.10      | mg to ---> | 500          |         | ml to --->      |         | 1       | ml to ---> |              | 1  |                |  |      |  |
| Test.conc (in ppm)-40.009 |  | 1            | ml to ---> | 1            |         | ml to --->      |         | 1       | ml to ---> |              | 1  |                |  |      |  |
| Conversion factor :       |  | 1.0000       |            | mg           |         |                 |         |         |            |              |    |                |  |      |  |
| Labelled claim :          |  | 20           |            |              |         |                 |         |         |            |              |    |                |  |      |  |
| Average weight :          |  | 4500         |            |              |         |                 |         |         |            |              |    |                |  |      |  |
| System suitability        |  | 1            | 2          | 3            | 4       | 5               | MEAN    | S.D     | RSD in %   |              |    |                |  |      |  |
| Chlorphenamine Maleate    |  | 2750843      | 2737917    | 2741755      | 2752800 | 2751955         | 2747054 | 6763.1  | 0.246      |              |    |                |  |      |  |
| With Bracketing std.      |  |              |            |              |         |                 | 2747054 | 6763.1  | 0.246      |              |    |                |  |      |  |

| Time interval | Chlorphenamine Standard area | Absolute % difference of standard area | Chlorphenamine Sample area | Absolute % difference of sample area | Assay in % | Absolute % difference of Assay preparation |
|---------------|------------------------------|----------------------------------------|----------------------------|--------------------------------------|------------|--------------------------------------------|
| Initial       | 2747054                      | Not applicable                         | 2670400                    | Not applicable                       | 97.62      | Not applicable                             |
| 2 Hours       | 2748152                      | -0.04                                  | 2671178                    | -0.03                                | 97.65      | -0.03                                      |
| 4 Hours       | 2744905                      | 0.08                                   | 2669563                    | 0.03                                 | 97.59      | 0.03                                       |
| 6 Hours       | 2750153                      | -0.11                                  | 2660606                    | 0.37                                 | 97.26      | 0.37                                       |
| 8 Hours       | 2750671                      | -0.13                                  | 2663302                    | 0.27                                 | 97.36      | 0.27                                       |
| 10 Hours      | 2740710                      | 0.23                                   | 2668062                    | 0.09                                 | 97.54      | 0.09                                       |
| 12 Hours      | 2741408                      | 0.21                                   | 2664088                    | 0.24                                 | 97.39      | 0.24                                       |
| 16 Hours      | 2761349                      | -0.52                                  | 2652937                    | 0.66                                 | 96.98      | 0.66                                       |
| 20 Hours      | 2757052                      | -0.36                                  | 2653169                    | 0.65                                 | 96.99      | 0.65                                       |
| 24 Hours      | 2756651                      | -0.35                                  | 2651393                    | 0.72                                 | 96.93      | 0.72                                       |
| 28 Hours      | 2747570                      | -0.02                                  | 2660799                    | 0.36                                 | 97.27      | 0.36                                       |
| 32 Hours      | 2756336                      | -0.34                                  | 2658650                    | 0.44                                 | 97.19      | 0.44                                       |
| 36 Hours      | 2755310                      | -0.30                                  | 2645749                    | 0.93                                 | 96.72      | 0.93                                       |
| 40 Hours      | 2751333                      | -0.16                                  | 2664706                    | 0.21                                 | 97.41      | 0.21                                       |
| 44 Hours      | 2753930                      | -0.25                                  | 2652746                    | 0.67                                 | 96.98      | 0.67                                       |
| Average       | 2750839                      | -0.15                                  | 2660490                    | 0.40                                 | 97.3       | 0.40                                       |
| % RSD         | 0.218                        | Not applicable                         | 0.295                      | Not applicable                       | 0.295      | Not applicable                             |

**Results :**

Standard solution and Sample solution was stable upto 44 hrs at room temperature.

**Acceptance criteria:**

The Standard Solution and Sample solution shall be considered stable for the final period till which the area difference between initial and next periodic interval should not be more than  $\pm 2\%$ .

Analysed by :

C.ALBIN JOSE

Date :

11-11-2022

Checked by :

Date :

*[Signature]*  
11/11/2022





# Safetab Life Science

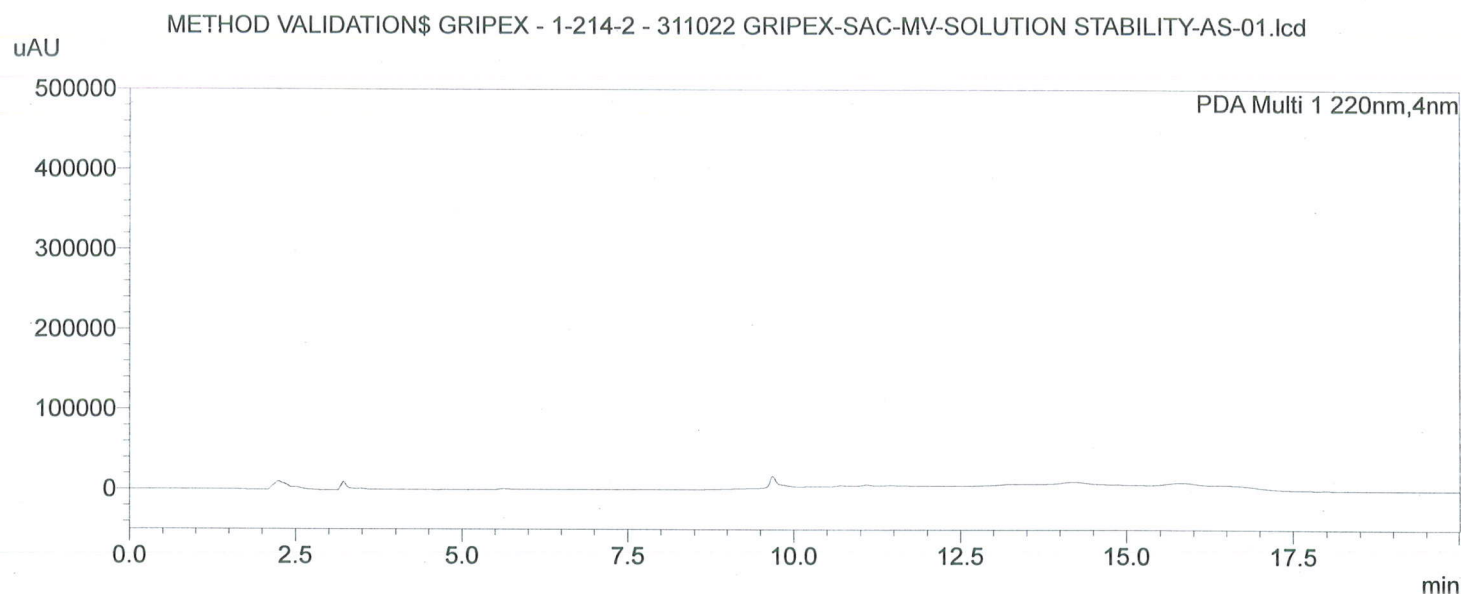
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : BLANK-AS  
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Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-1  
Injection Volume : 50 uL  
Date Acquired : 10/31/2022 5:15:34 PM  
Date Processed : 11/11/2022 1:17:09 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



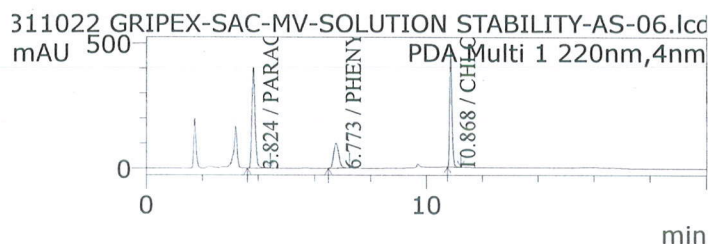
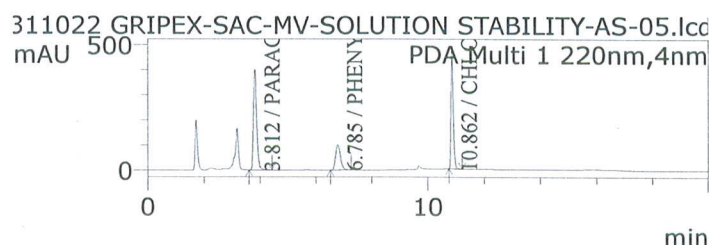
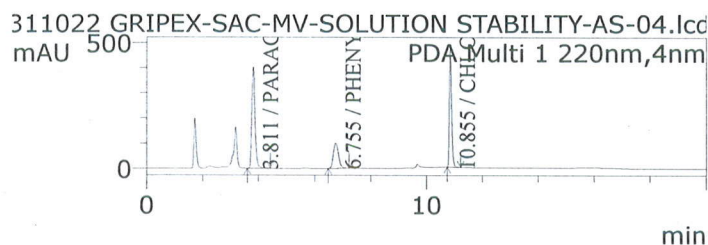
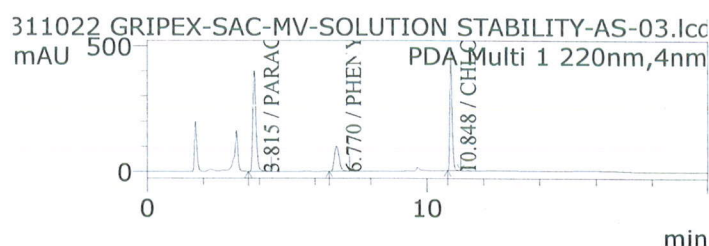
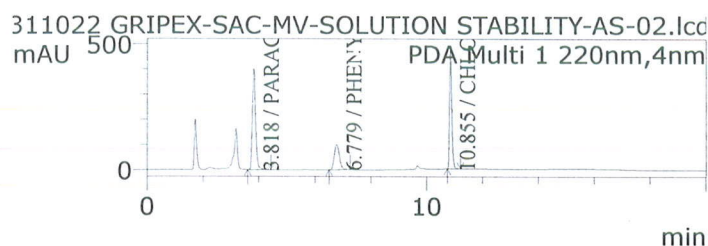
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENYL+CPM-SST-AS-STD-01  
Tray# : 3  
Vial# : 2  
Injection Volume : 50  
Data File : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-02.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/31/2022 5:36:09 PM  
Date Processed : 11/11/2022 1:17:13 PM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 2     | ITY-AS-02.lcd | PARA+PHENYL+CPM-SST-AS-STD-01 | 3.818  | 3224777 | 4648     | 1.275    |
| 2     | ITY-AS-03.lcd | PARA+PHENYL+CPM-SST-AS-STD-02 | 3.815  | 3215937 | 4704     | 1.271    |
| 2     | ITY-AS-04.lcd | PARA+PHENYL+CPM-SST-AS-STD-03 | 3.811  | 3224599 | 4695     | 1.273    |
| 2     | ITY-AS-05.lcd | PARA+PHENYL+CPM-SST-AS-STD-04 | 3.812  | 3224076 | 4673     | 1.272    |
| 2     | ITY-AS-06.lcd | PARA+PHENYL+CPM-SST-AS-STD-05 | 3.824  | 3228756 | 4704     | 1.272    |
|       | Average       |                               | 3.816  | 3223629 | 4685     | 1.273    |
|       | %RSD          |                               | 0.140  | 0.145   | 0.517    | 0.110    |



## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 2     | ITY-AS-02.lcd | PARA+PHENYL+CPM-SST-AS-STD-01 | 6.779  | 1218400 | 6807     | 1.188    |
| 2     | ITY-AS-03.lcd | PARA+PHENYL+CPM-SST-AS-STD-02 | 6.770  | 1216161 | 6797     | 1.187    |
| 2     | ITY-AS-04.lcd | PARA+PHENYL+CPM-SST-AS-STD-03 | 6.755  | 1216485 | 6731     | 1.185    |
| 2     | ITY-AS-05.lcd | PARA+PHENYL+CPM-SST-AS-STD-04 | 6.785  | 1221796 | 6769     | 1.185    |
| 2     | ITY-AS-06.lcd | PARA+PHENYL+CPM-SST-AS-STD-05 | 6.773  | 1223049 | 6758     | 1.188    |
|       | Average       |                               | 6.772  | 1219178 | 6772     | 1.186    |
|       | %RSD          |                               | 0.167  | 0.255   | 0.450    | 0.111    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 2     | ITY-AS-02.lcd | PARA+PHENYL+CPM-SST-AS-STD-01 | 10.855 | 2750843 | 66486    | 1.392    |
| 2     | ITY-AS-03.lcd | PARA+PHENYL+CPM-SST-AS-STD-02 | 10.848 | 2737917 | 68179    | 1.394    |
| 2     | ITY-AS-04.lcd | PARA+PHENYL+CPM-SST-AS-STD-03 | 10.855 | 2741755 | 66703    | 1.395    |
| 2     | ITY-AS-05.lcd | PARA+PHENYL+CPM-SST-AS-STD-04 | 10.862 | 2752800 | 69161    | 1.406    |
| 2     | ITY-AS-06.lcd | PARA+PHENYL+CPM-SST-AS-STD-05 | 10.868 | 2751955 | 67000    | 1.390    |
|       | Average       |                               | 10.858 | 2747054 | 67506    | 1.395    |
|       | %RSD          |                               | 0.071  | 0.246   | 1.678    | 0.444    |

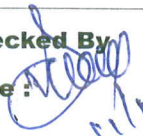
Analysed By

Date :



Checked By

Date :





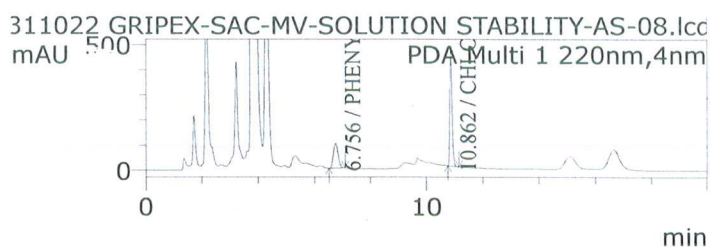
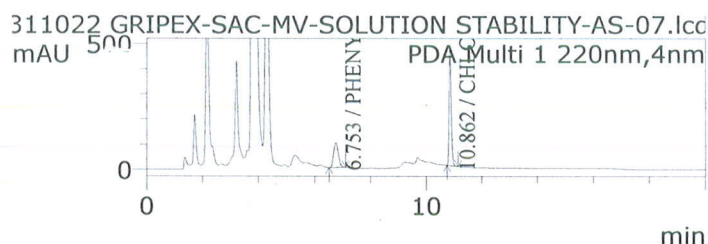
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-SST-INI-AS-SOL-A-01  
Tray# : 3  
Vial# : 3  
Injection Volume : 50  
Data File : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-07.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/31/2022 7:19:01 PM  
Date Processed : 11/11/2022 3:23:42 PM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 3     | ITY-AS-07.lcd | GRIPEX-MV-SST-INI-AS-SOL-A-01 | 6.753  | 1165297 | 6914     | 1.152    |
| 3     | ITY-AS-08.lcd | GRIPEX-MV-SST-INI-AS-SOL-A-02 | 6.756  | 1166665 | 6929     | 1.155    |
|       | Average       |                               | 6.754  | 1165981 | 6922     | 1.153    |
|       | %RSD          |                               | 0.038  | 0.083   | 0.155    | 0.189    |

ID#2 Compound Name: CHLORPHENAMINE MALEATE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 3     | ITY-AS-07.lcd | GRIPEX-MV-SST-INI-AS-SOL-A-01 | 10.862 | 2674776 | 69231    | 1.399    |
| 3     | ITY-AS-08.lcd | GRIPEX-MV-SST-INI-AS-SOL-A-02 | 10.862 | 2666024 | 69310    | 1.398    |
|       | Average       |                               | 10.862 | 2670400 | 69271    | 1.399    |
|       | %RSD          |                               | 0.002  | 0.232   | 0.082    | 0.028    |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

Puducherry- 605 107

## Quality control Department

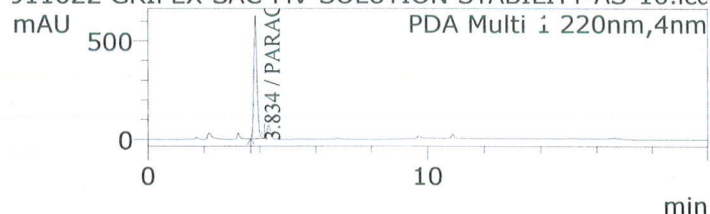
### Sample Information

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-SST-INI-AS-SOL-B-01  
Tray# : 3  
Vial# : 4  
Injection Volume : 50  
Data File : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-09.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/31/2022 8:00:12 PM  
Date Processed : 11/11/2022 3:34:42 PM

311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-09.lcd



311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-10.lcd



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 4     | ITY-AS-09.lcd | GRIPEX-MV-SST-INI-AS-SOL-B-01 | 3.819  | 4915923 | 4751     | 1.260    |
| 4     | ITY-AS-10.lcd | GRIPEX-MV-SST-INI-AS-SOL-B-02 | 3.834  | 4934235 | 4789     | 1.261    |
|       | Average       |                               | 3.827  | 4925079 | 4770     | 1.261    |
|       | %RSD          |                               | 0.266  | 0.263   | 0.565    | 0.095    |

Analysed By

Date

Checked By

Date



# Safetab Life Science

Puducherry- 605 107

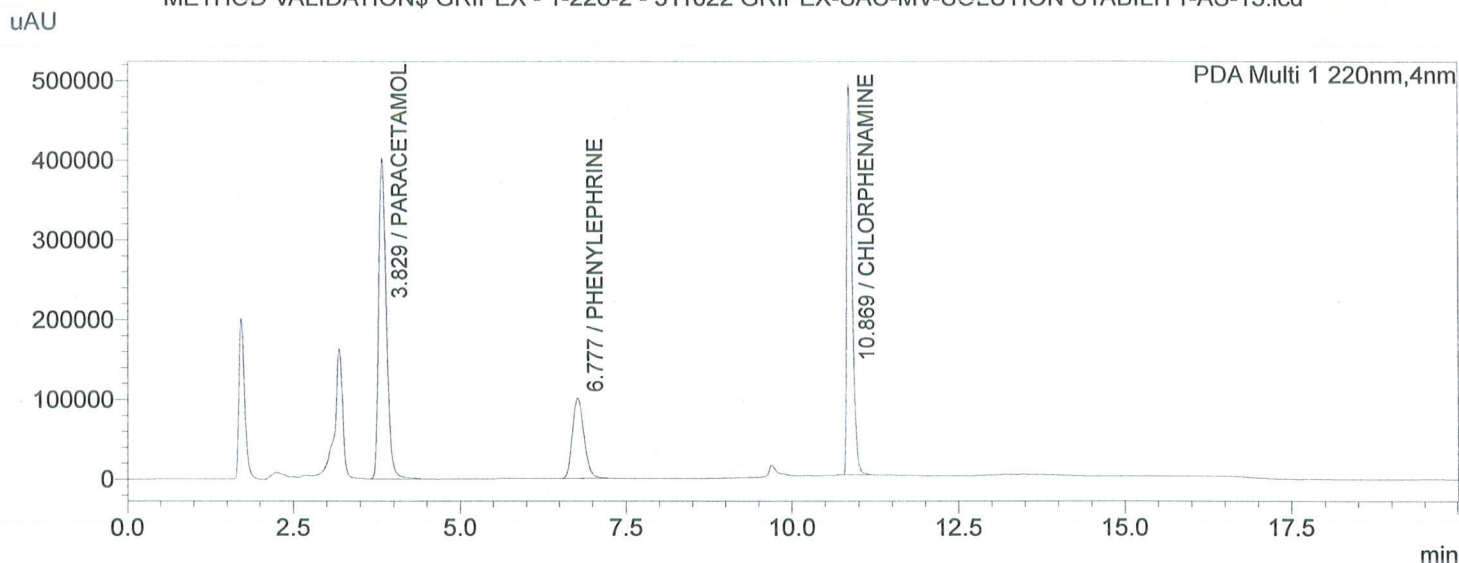
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENYL+CPM-SST-AS-2Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-13.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 10/31/2022 9:37:30 PM  
Date Processed : 11/11/2022 1:17:26 PM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-226-2 - 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-13.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plates | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|----------|----------|------------|----------|----------------|
| 1     | 3.829     | 3228202 | 44.836  | 4678     | 1.276    | --         | --       | PARACETAMOL    |
| 2     | 6.777     | 1223704 | 16.996  | 6755     | 1.187    | 10.65      | --       | PHENYLEPHRINE  |
| 3     | 10.869    | 2748152 | 38.168  | 68267    | 1.398    | 16.49      | --       | CHLORPHENAMINE |
| Total |           | 7200058 | 100.000 |          |          |            |          |                |

Analysed By

Date

Checked By

Date





# Safetab Life Science

Puducherry- 605 107

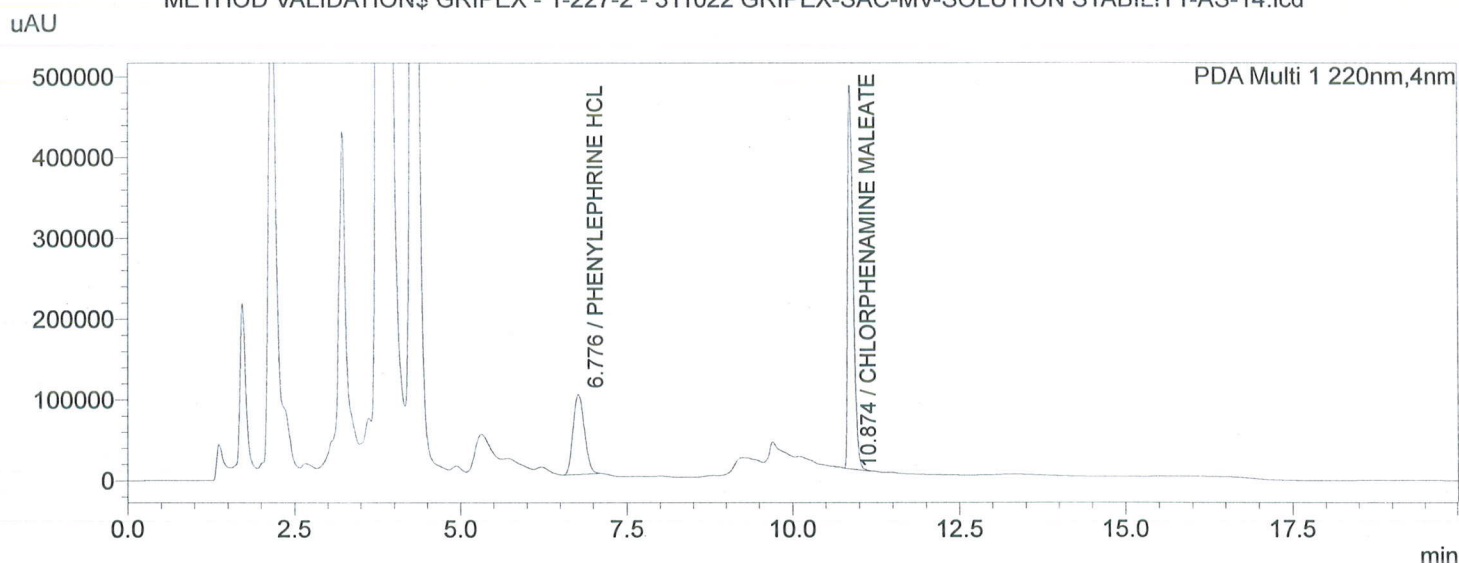
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-2Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-14.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 10/31/2022 9:58:06 PM  
Date Processed : 11/11/2022 3:23:49 PM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-227-2 - 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-14.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.776     | 1165416 | 30.376  | 6976    | 1.150    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.874    | 2671178 | 69.624  | 70922   | 1.401    | 16.80      | --       | CHLORPHENAMINE MALE |
| Total |           | 3836594 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :



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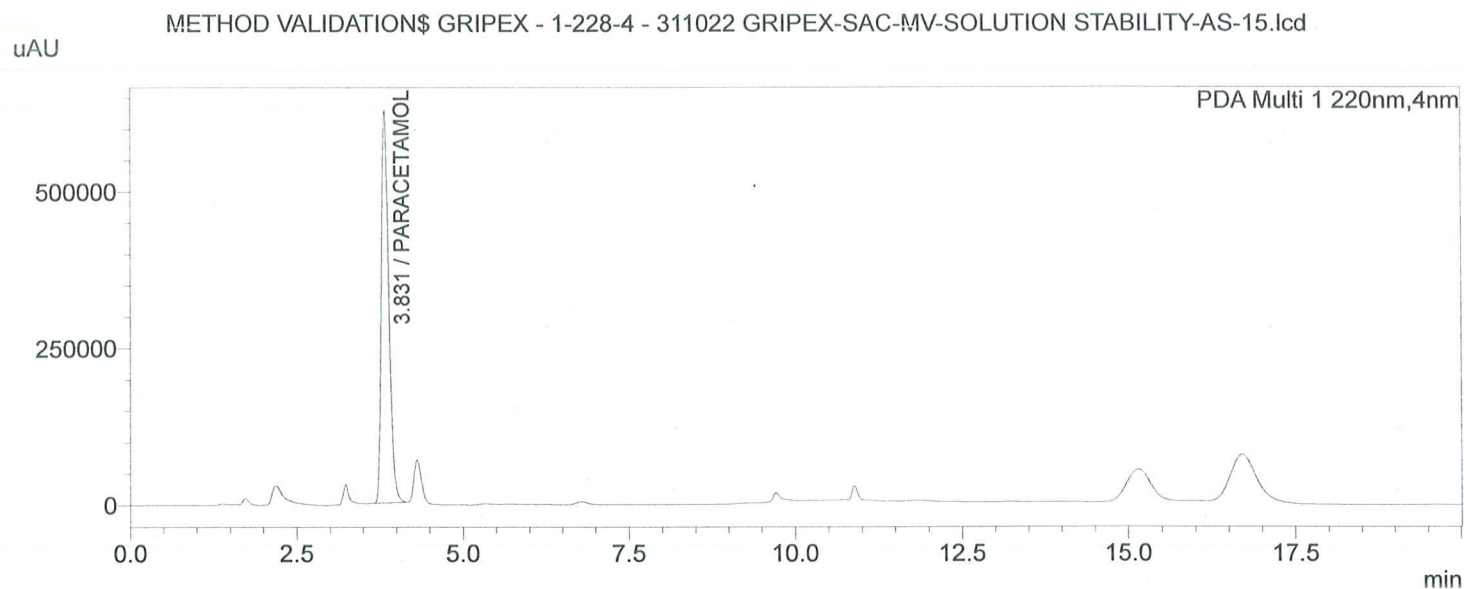
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-2Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-15.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 10/31/2022 10:18:41 PM  
Date Processed : 11/11/2022 3:34:47 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.831     | 4925345 | 100.000 | 4774    | 1.262    | --         | --       | PARACETAMOL |
| Total |           | 4925345 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

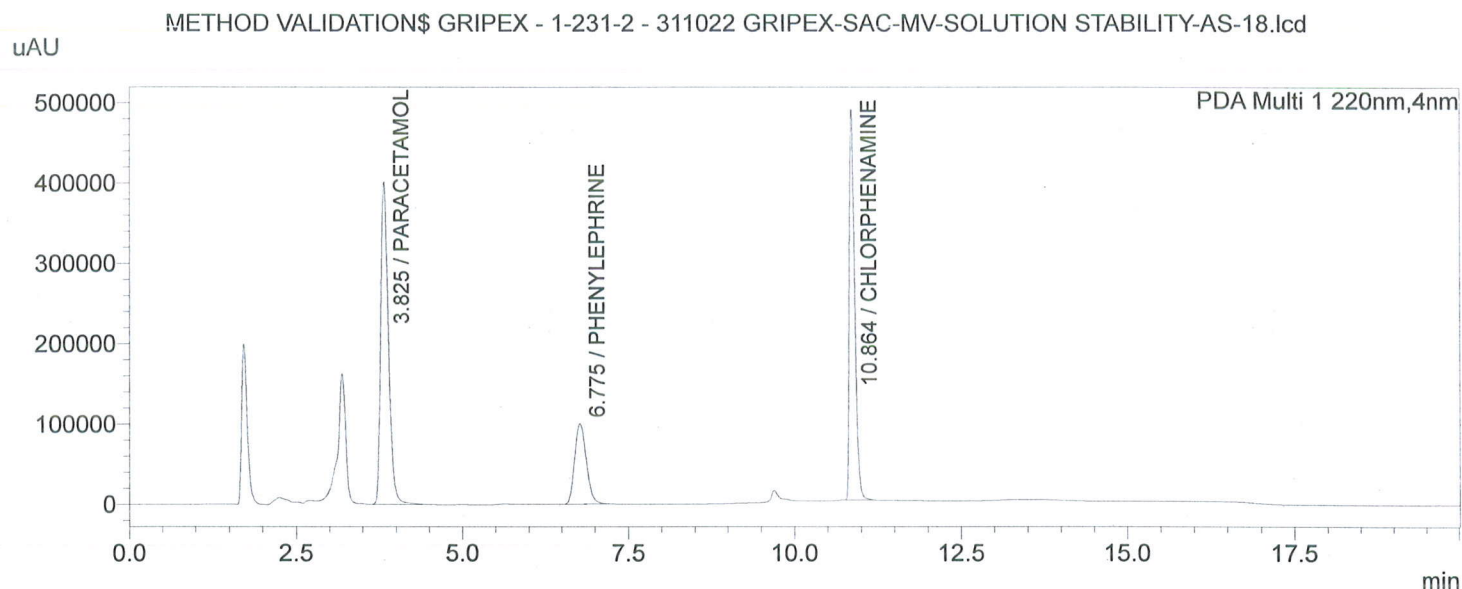
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENYL+CPM-SST-AS-4Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-18.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 10/31/2022 11:35:30 PM  
Date Processed : 11/11/2022 1:17:31 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.825     | 3227028 | 44.868  | 4725    | 1.272    | --         | --       | PARACETAMOL    |
| 2     | 6.775     | 1220297 | 16.967  | 6729    | 1.185    | 10.67      | --       | PHENYLEPHRINE  |
| 3     | 10.864    | 2744905 | 38.165  | 70841   | 1.405    | 16.56      | --       | CHLORPHENAMINE |
| Total |           | 7192230 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

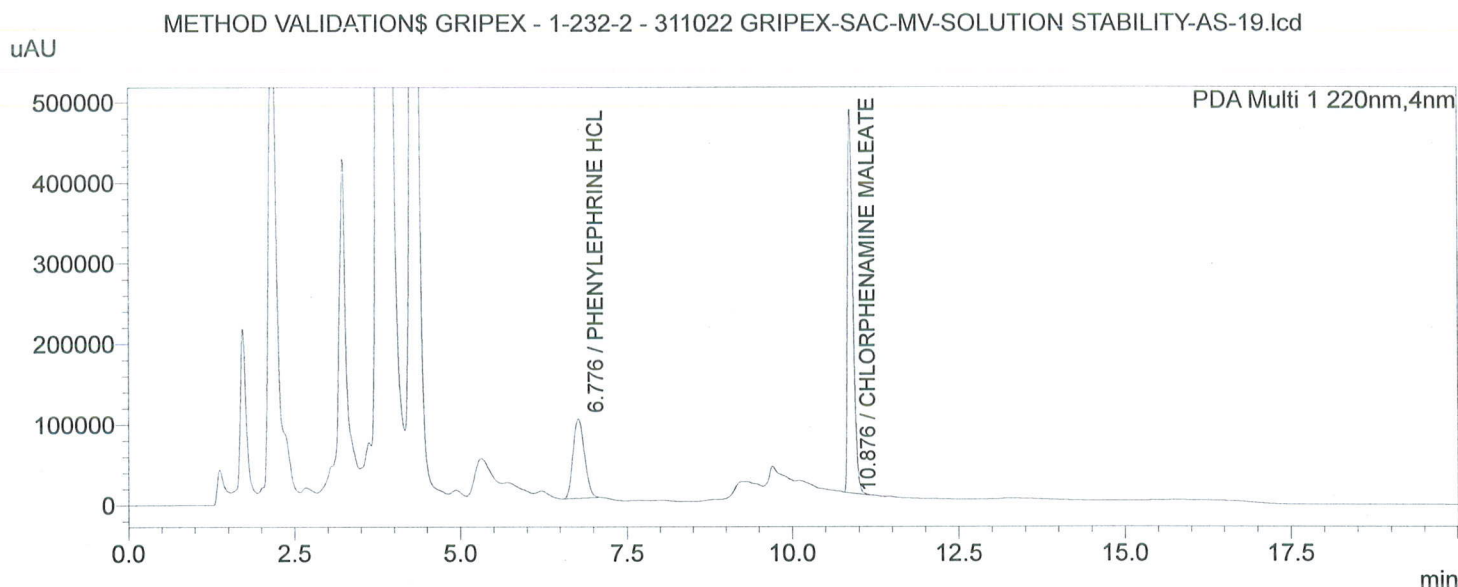
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-4Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-19.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 10/31/2022 11:56:06 PM  
Date Processed : 11/11/2022 3:23:52 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.776     | 1165174 | 30.385  | 6936    | 1.148    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.876    | 2669563 | 69.615  | 66846   | 1.395    | 16.61      | --       | CHLORPHENAMINE MALE |
| Total |           | 3834737 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

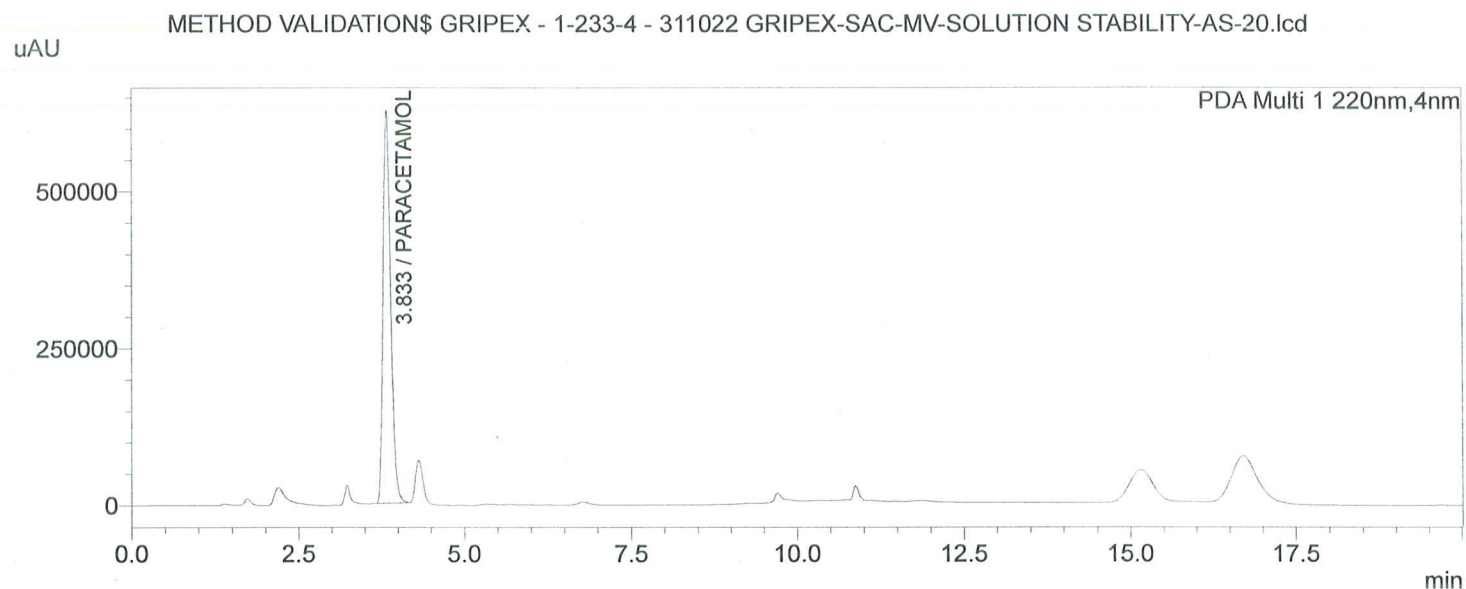
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-4Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-20.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 12:16:41 AM  
Date Processed : 11/11/2022 3:34:49 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.833     | 4928358 | 100.000 | 4796    | 1.262    | --         | --       | PARACETAMOL |
| Total |           | 4928358 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date:



# Safetab Life Science

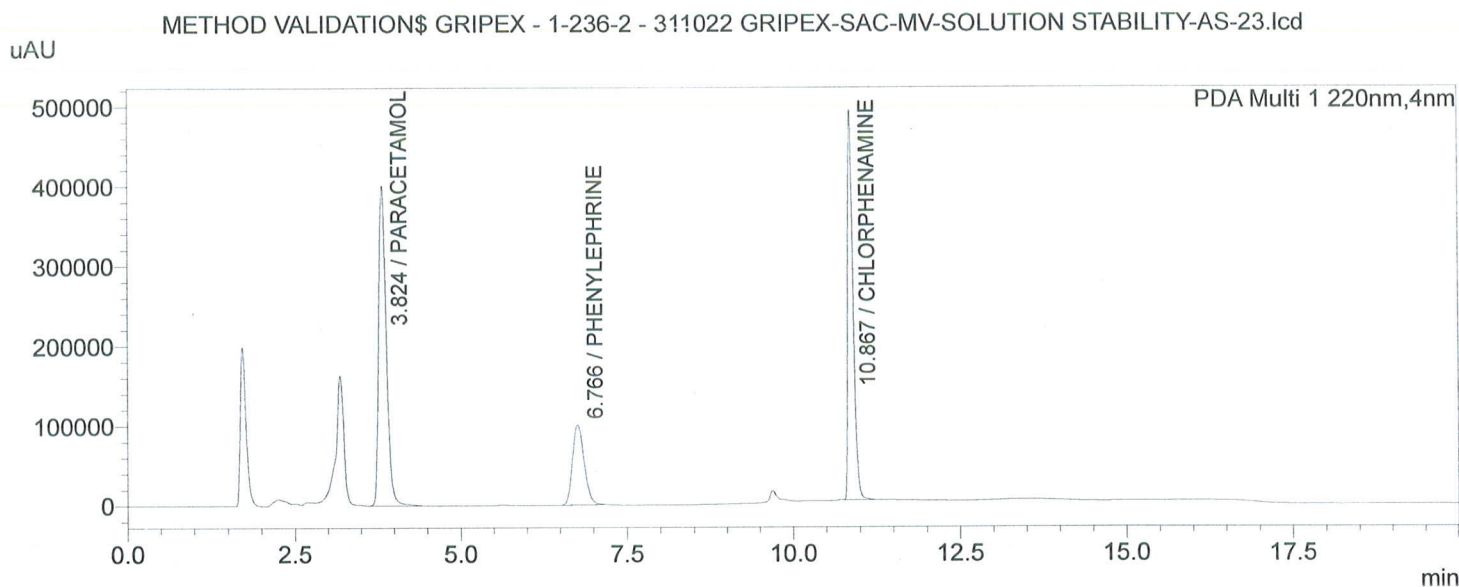
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENYL+CPM-SST-AS-6Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-23.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/11/2022 1:33:26 AM  
Date Processed : 11/11/2022 1:17:34 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.824     | 3226423 | 44.850  | 4711    | 1.272    | --         | --       | PARACETAMOL    |
| 2     | 6.766     | 1217218 | 16.920  | 6740    | 1.185    | 10.65      | --       | PHENYLEPHRINE  |
| 3     | 10.867    | 2750153 | 38.230  | 66900   | 1.399    | 16.48      | --       | CHLORPHENAMINE |
| Total |           | 7193794 | 100.000 |         |          |            |          |                |

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Date :

Checked By

Date :





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Puducherry- 605 107

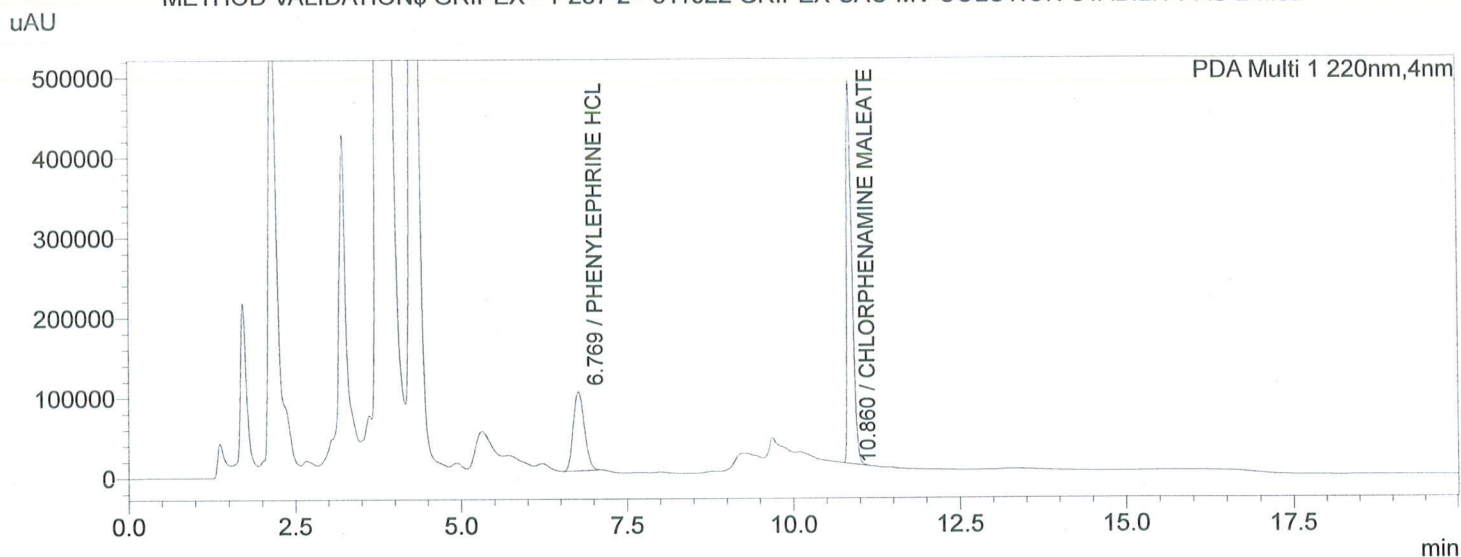
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-6Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-24.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 1:54:00 AM  
Date Processed : 11/11/2022 3:23:54 PM

### <Chromatogram>

METHOD VALIDATIONS\$ GRIPEX - 1-237-2 - 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-24.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.769     | 1162951 | 30.415  | 6948    | 1.152    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.860    | 2660606 | 69.585  | 68960   | 1.405    | 16.69      | --       | CHLORPHENAMINE MALE |
| Total |           | 3823558 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

Puducherry- 605 107

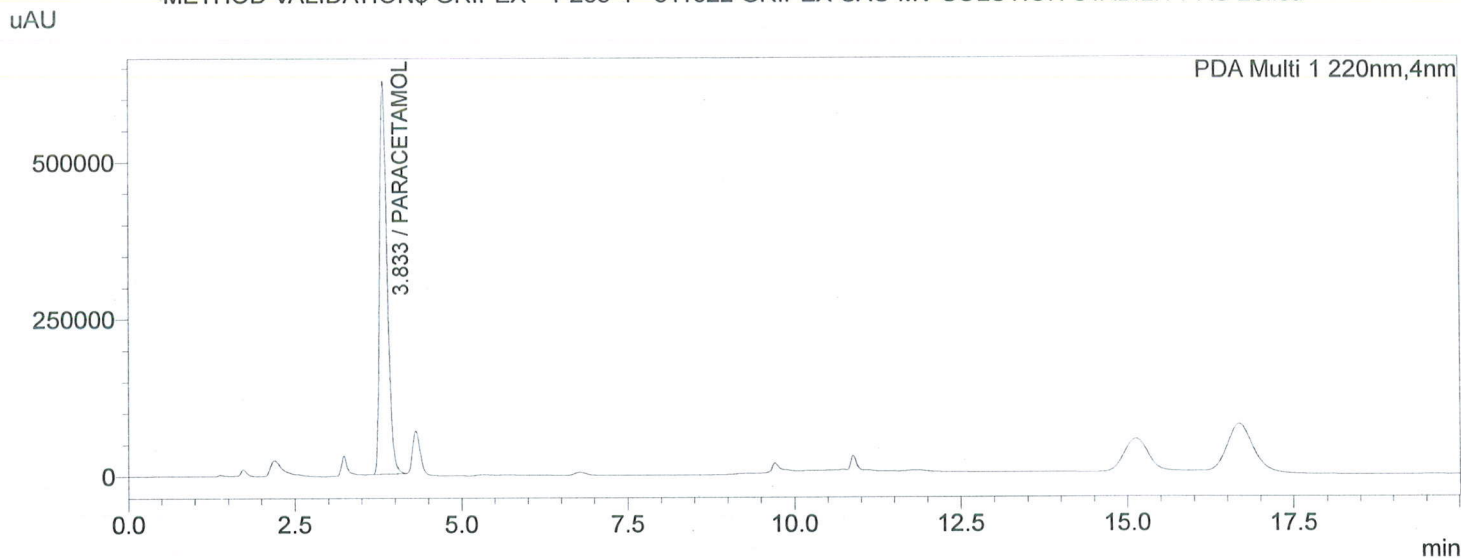
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-6Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-25.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/11/2022 2:14:35 AM  
Date Processed : 11/11/2022 3:34:51 PM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-238-4 - 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-25.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.833     | 4930168 | 100.000 | 4795    | 1.264    | --         | --       | PARACETAMOL |
| Total |           | 4930168 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

Puducherry- 605 107

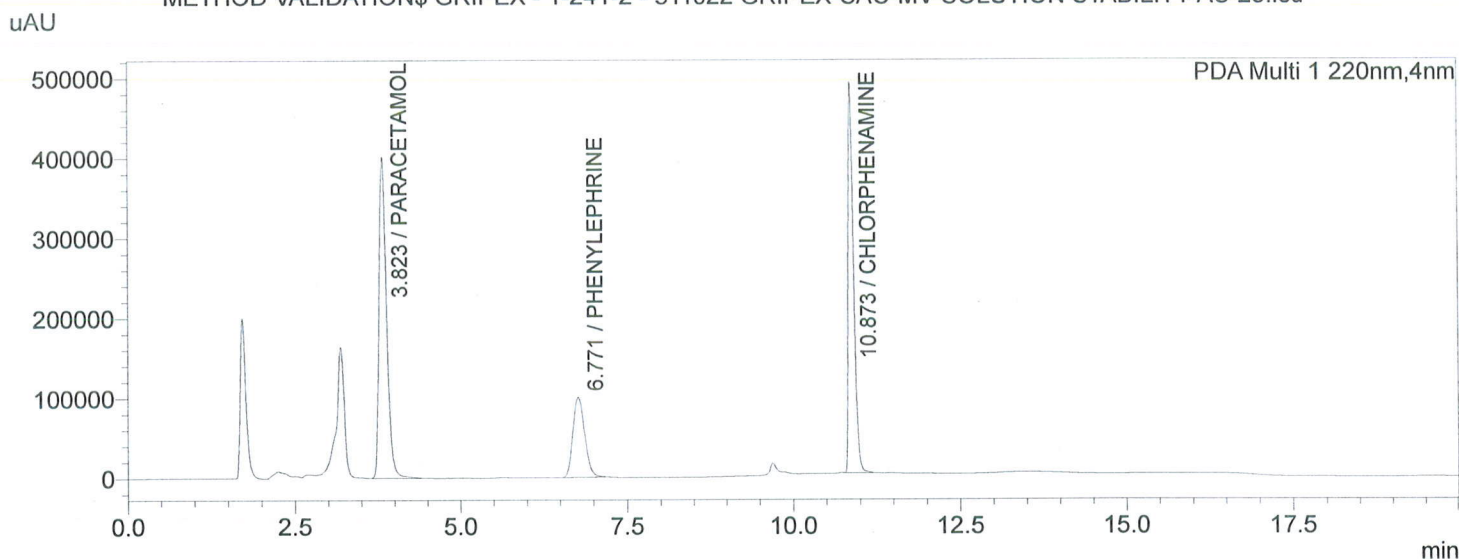
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENYL+CPM-SST-AS-8Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-28.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 3:31:18 AM  
Date Processed : 11/11/2022 1:17:37 PM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-241-2 - 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-28.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.823     | 3226648 | 44.833  | 4719    | 1.275    | --         | --       | PARACETAMOL    |
| 2     | 6.771     | 1219763 | 16.948  | 6737    | 1.188    | 10.67      | --       | PHENYLEPHRINE  |
| 3     | 10.873    | 2750671 | 38.219  | 69166   | 1.415    | 16.56      | --       | CHLORPHENAMINE |
| Total |           | 7197082 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

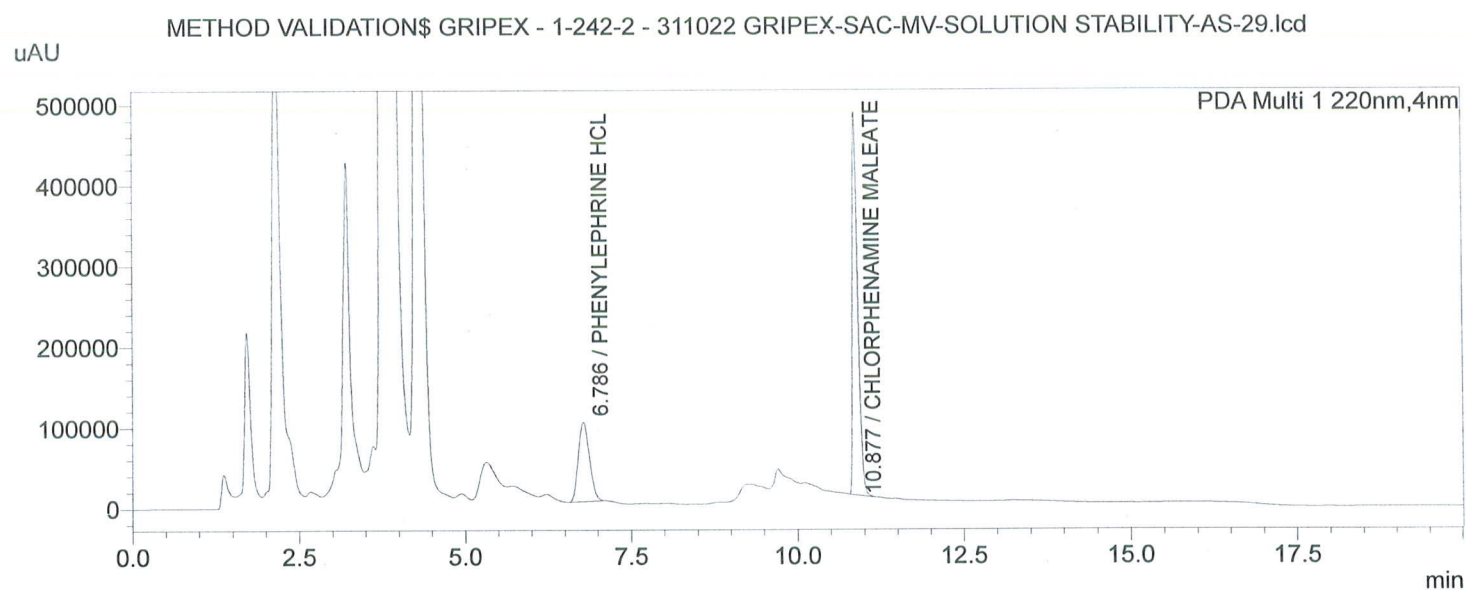
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-8Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-29.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 3:51:53 AM  
Date Processed : 11/11/2022 3:23:57 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.786     | 1161638 | 30.370  | 6987    | 1.146    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.877    | 2663302 | 69.630  | 66797   | 1.393    | 16.59      | --       | CHLORPHENAMINE MALE |
| Total |           | 3824940 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

*[Signature]*  
11/11/22

Checked By

Date :

*[Signature]*  
11/11/2022





# Safetab Life Science

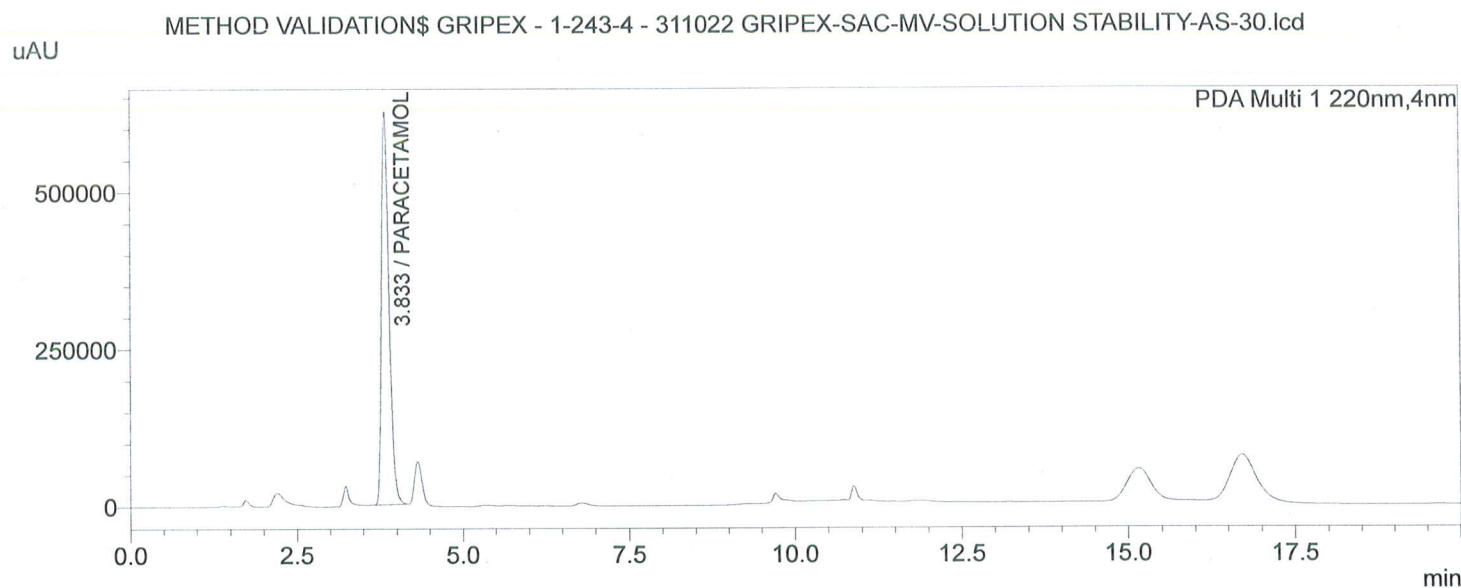
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-8Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-30.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 4:12:27 AM  
Date Processed : 11/11/2022 3:34:54 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.833     | 4932849 | 100.000 | 4780    | 1.264    | --         | --       | PARACETAMOL |
| Total |           | 4932849 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

Puducherry- 605 107

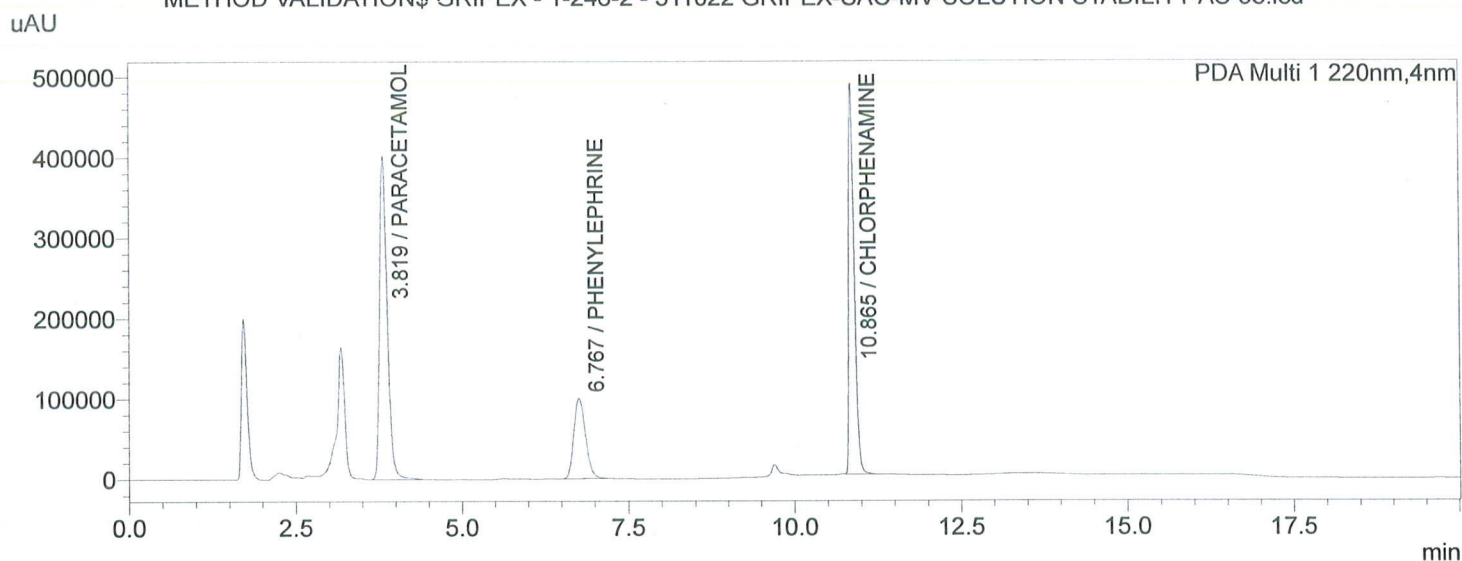
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENY+CPM-SST-AS-10Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-33.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 5:29:13 AM  
Date Processed : 11/11/2022 1:17:40 PM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-246-2 - 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-33.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.819     | 3223569 | 44.886  | 4678    | 1.277    | --         | --       | PARACETAMOL    |
| 2     | 6.767     | 1217414 | 16.952  | 6712    | 1.184    | 10.65      | --       | PHENYLEPHRINE  |
| 3     | 10.865    | 2740710 | 38.162  | 66563   | 1.406    | 16.43      | --       | CHLORPHENAMINE |
| Total |           | 7181693 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

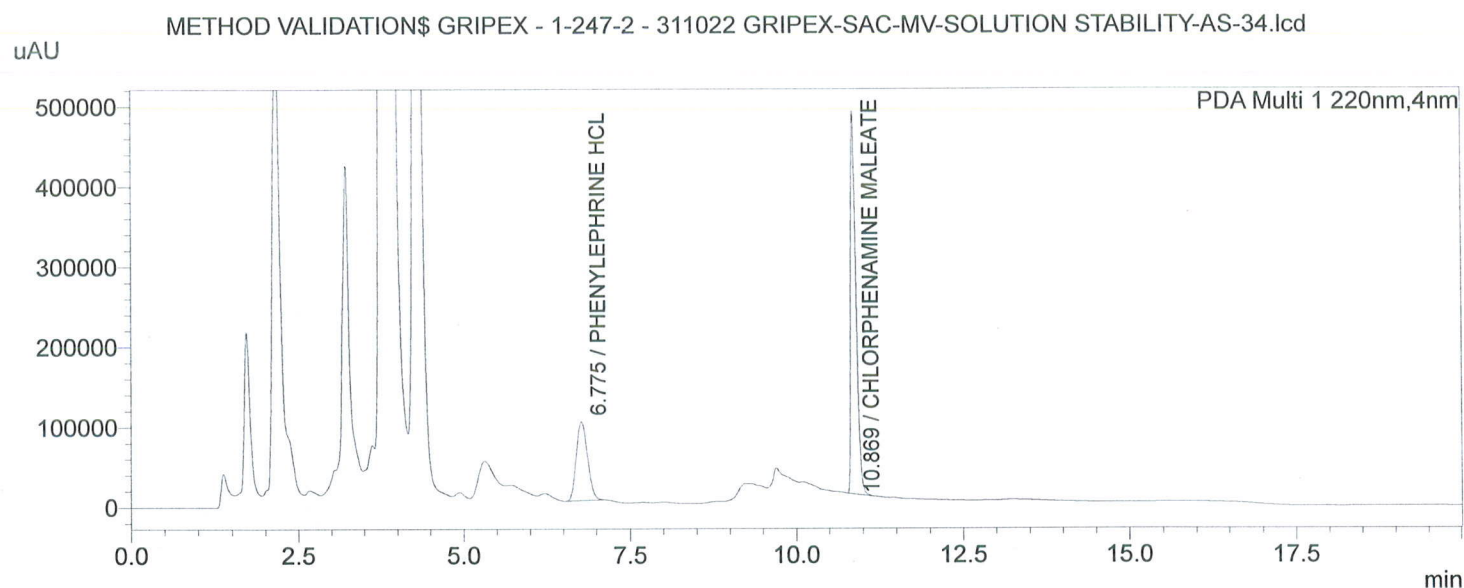
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-10Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-34.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 5:49:47 AM  
Date Processed : 11/11/2022 3:24:01 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.775     | 1161012 | 30.321  | 6980    | 1.149    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.869    | 2668062 | 69.679  | 68170   | 1.396    | 16.68      | --       | CHLORPHENAMINE MALE |
| Total |           | 3829074 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

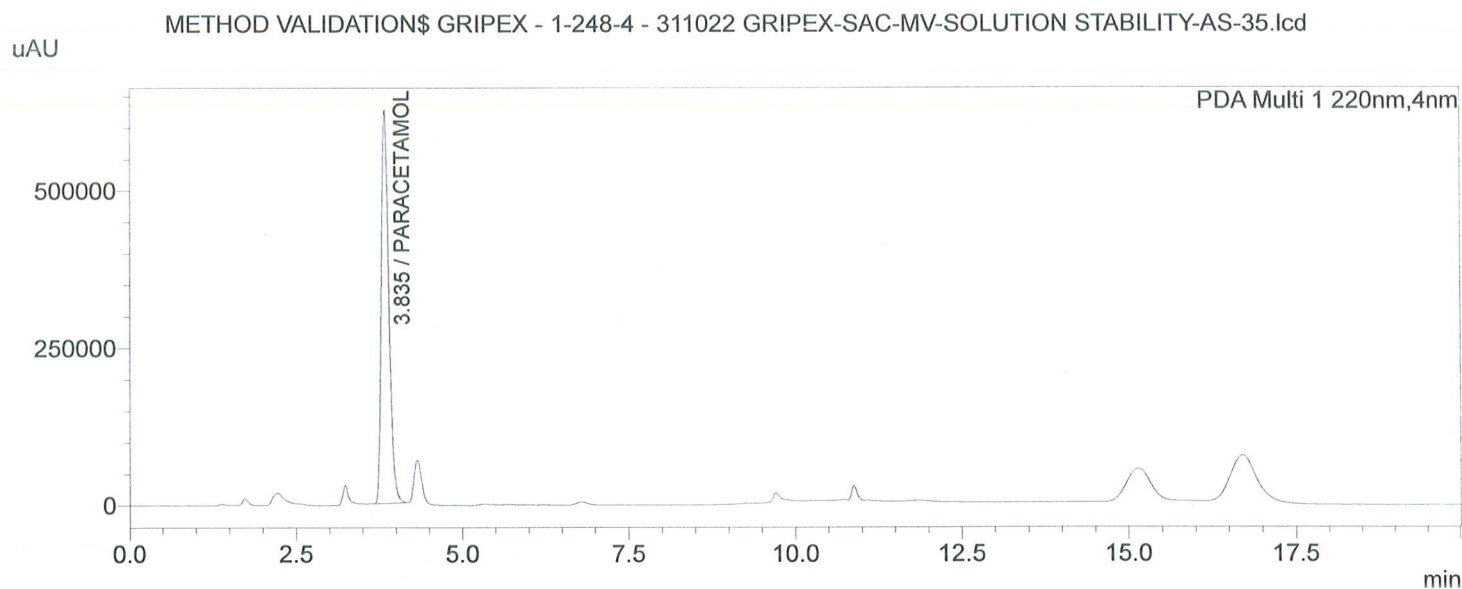
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-10Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-35.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 6:10:23 AM  
Date Processed : 11/11/2022 3:34:57 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.835     | 4929737 | 100.000 | 4800    | 1.265    | --         | --       | PARACETAMOL |
| Total |           | 4929737 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

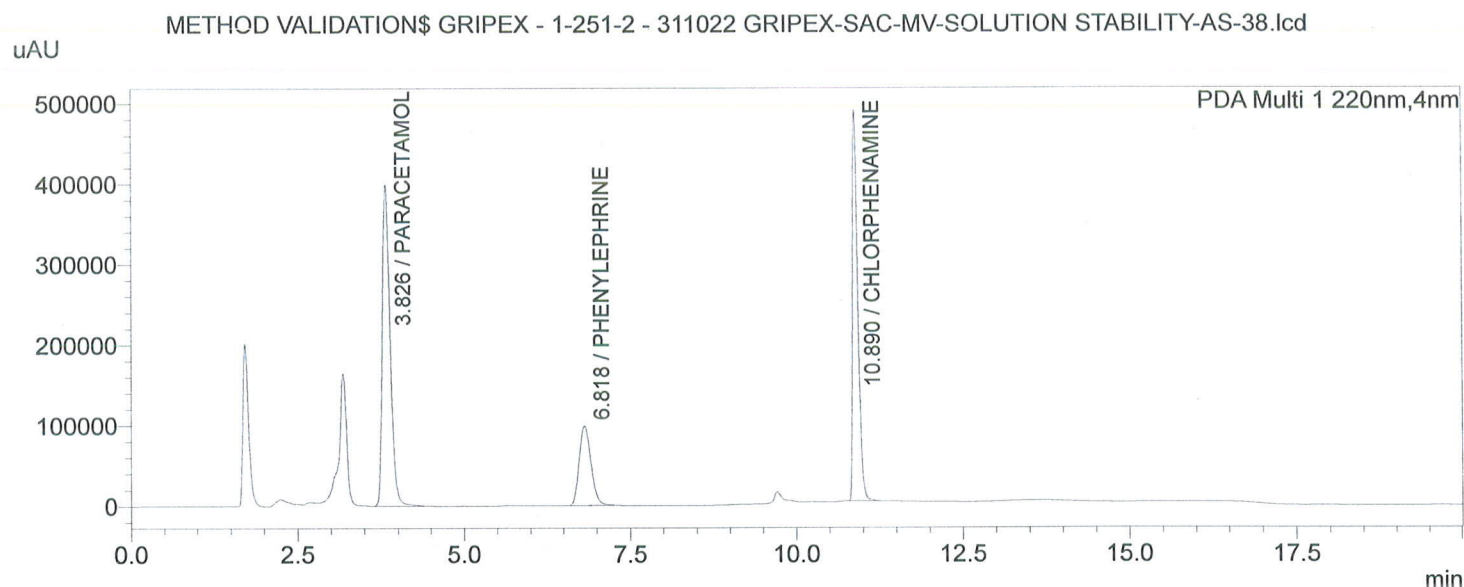
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENY+CPM-SST-AS-12Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-38.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 7:27:07 AM  
Date Processed : 11/11/2022 1:17:44 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.826     | 3220281 | 44.836  | 4671    | 1.269    | --         | --       | PARACETAMOL    |
| 2     | 6.818     | 1220624 | 16.995  | 6624    | 1.184    | 10.70      | --       | PHENYLEPHRINE  |
| 3     | 10.890    | 2741408 | 38.169  | 67488   | 1.396    | 16.20      | --       | CHLORPHENAMINE |
| Total |           | 7182314 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

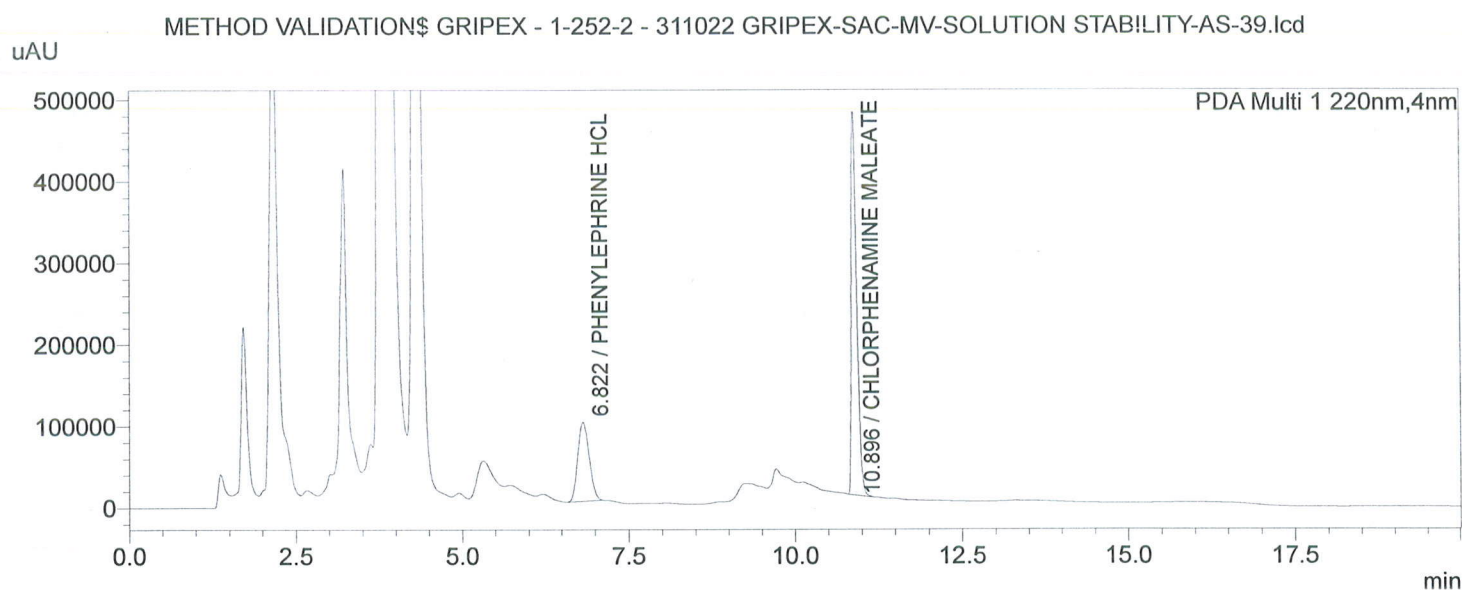
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-12Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-39.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 7:47:43 AM  
Date Processed : 11/11/2022 3:24:04 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.822     | 1153456 | 30.215  | 6852    | 1.134    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.896    | 2664088 | 69.785  | 69940   | 1.399    | 16.48      | --       | CHLORPHENAMINE MALE |
| Total |           | 3817544 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

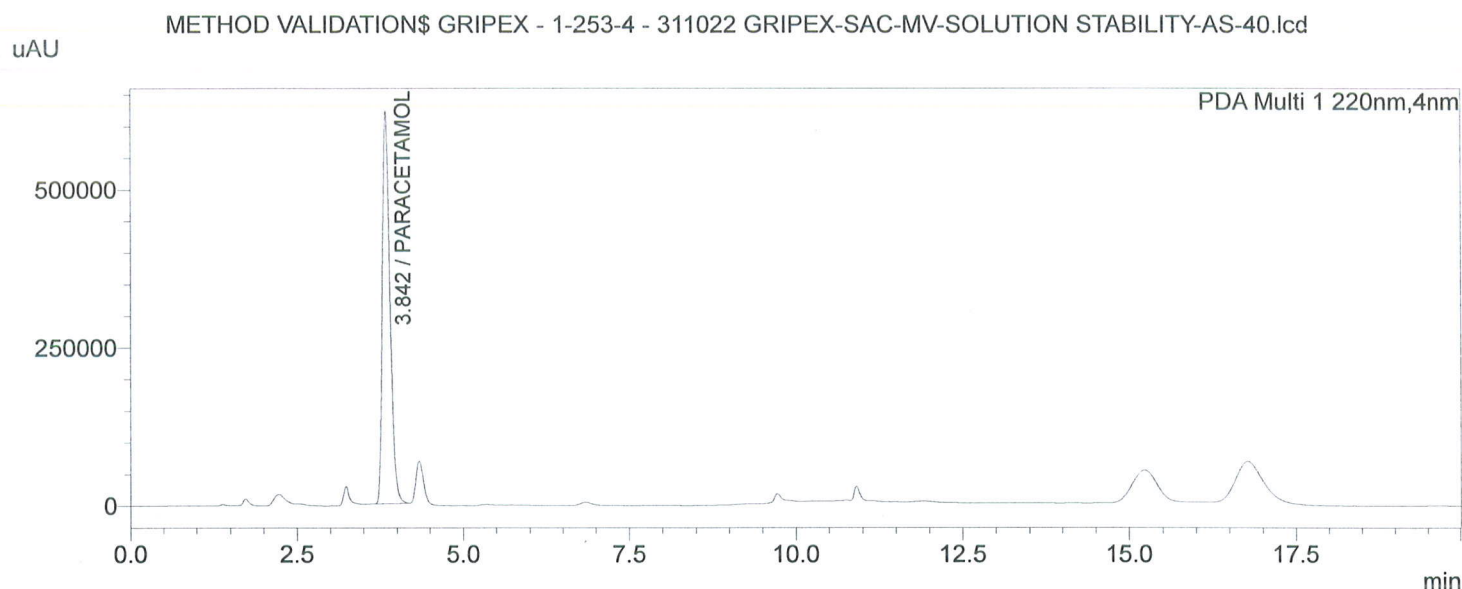
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-12Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-40.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 8:08:16 AM  
Date Processed : 11/11/2022 3:35:00 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.842     | 4908573 | 100.000 | 4755    | 1.259    | --         | --       | PARACETAMOL |
| Total |           | 4908573 | 100.000 |         |          |            |          |             |

Analysed By

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Checked By

Date :



# Safetab Life Science

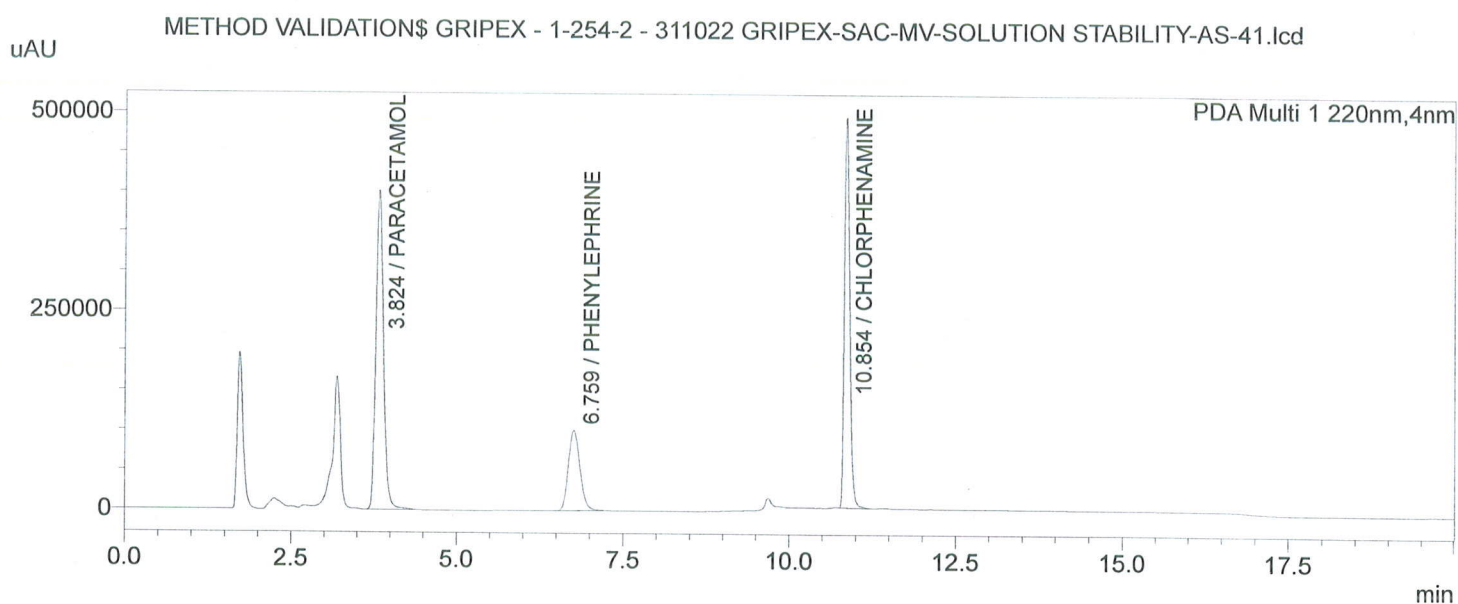
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENY+CPM-SST-AS-16Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-41.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 12:11:06 PM  
Date Processed : 11/11/2022 1:17:46 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.824     | 3234620 | 44.827  | 4724    | 1.276    | --         | --       | PARACETAMOL    |
| 2     | 6.759     | 1219779 | 16.904  | 6785    | 1.186    | 10.66      | --       | PHENYLEPHRINE  |
| 3     | 10.854    | 2761349 | 38.268  | 66935   | 1.403    | 16.51      | --       | CHLORPHENAMINE |
| Total |           | 7215748 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

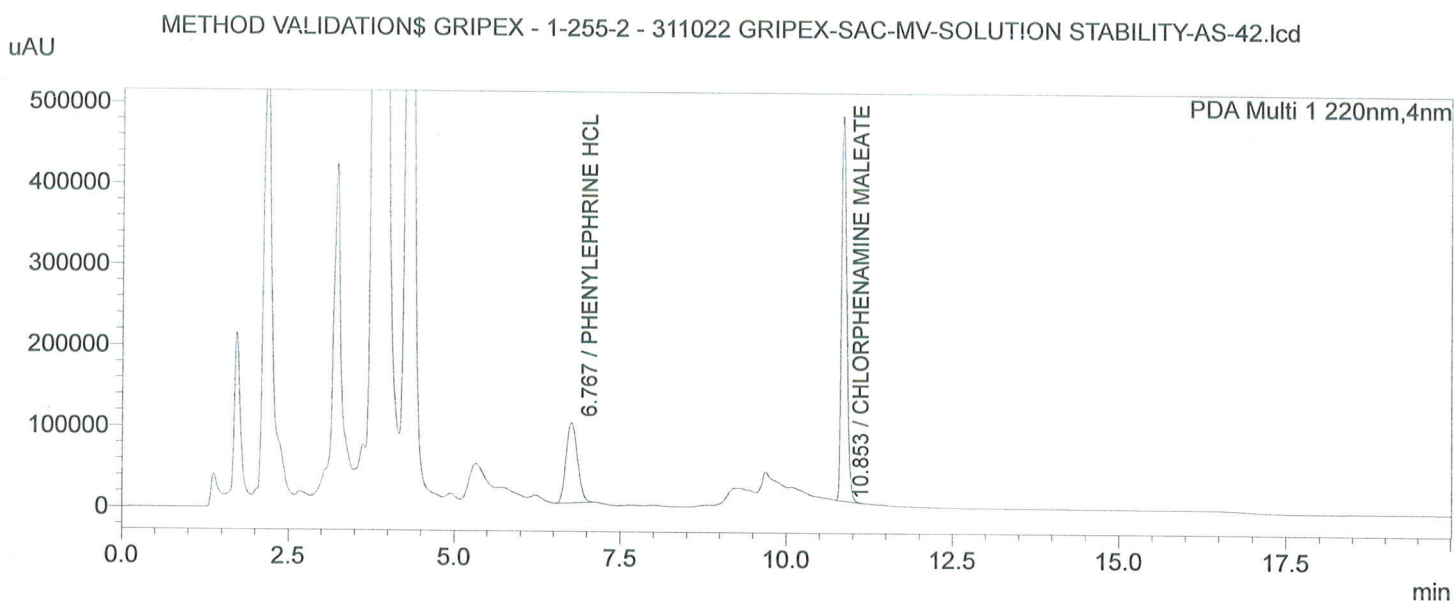
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-16Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-42.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 12:31:41 PM  
Date Processed : 11/11/2022 3:24:07 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.767     | 1161420 | 30.449  | 7024    | 1.152    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.853    | 2652937 | 69.551  | 71323   | 1.400    | 16.83      | --       | CHLORPHENAMINE MALE |
| Total |           | 3814356 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

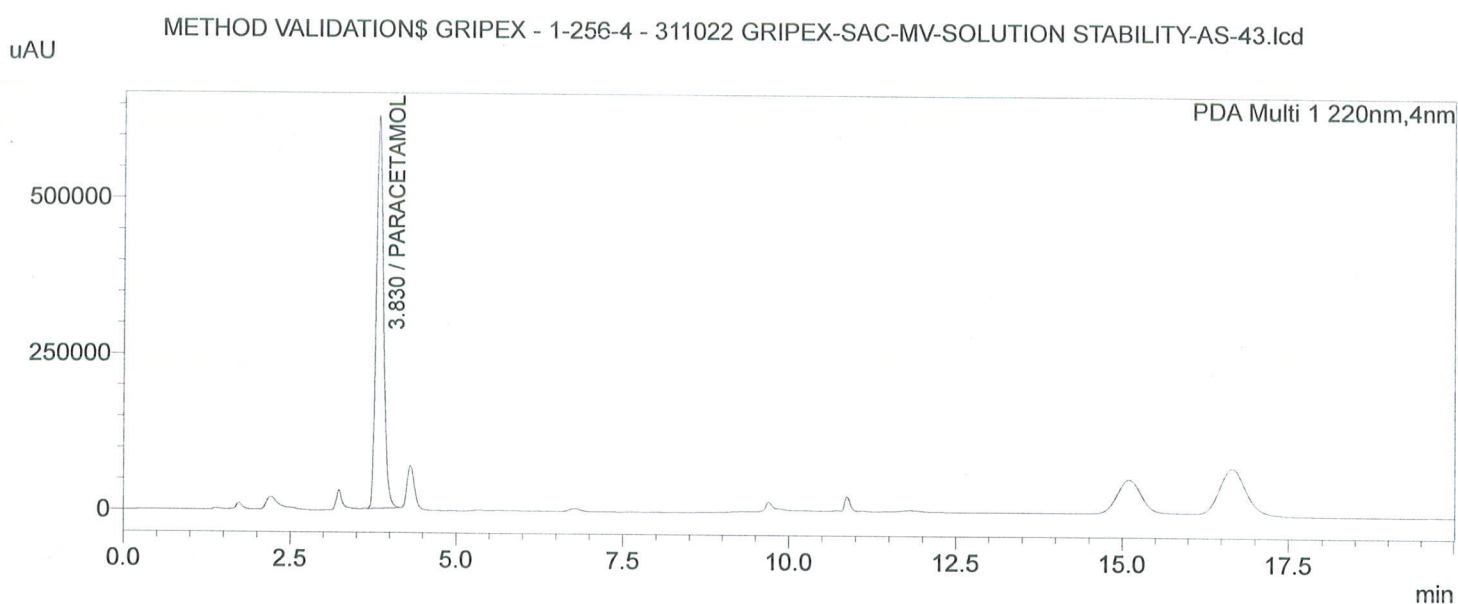
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-16Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-43.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/11/2022 12:52:16 PM  
Date Processed : 11/11/2022 3:35:02 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.830     | 4947677 | 100.000 | 4764    | 1.265    | --         | --       | PARACETAMOL |
| Total |           | 4947677 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

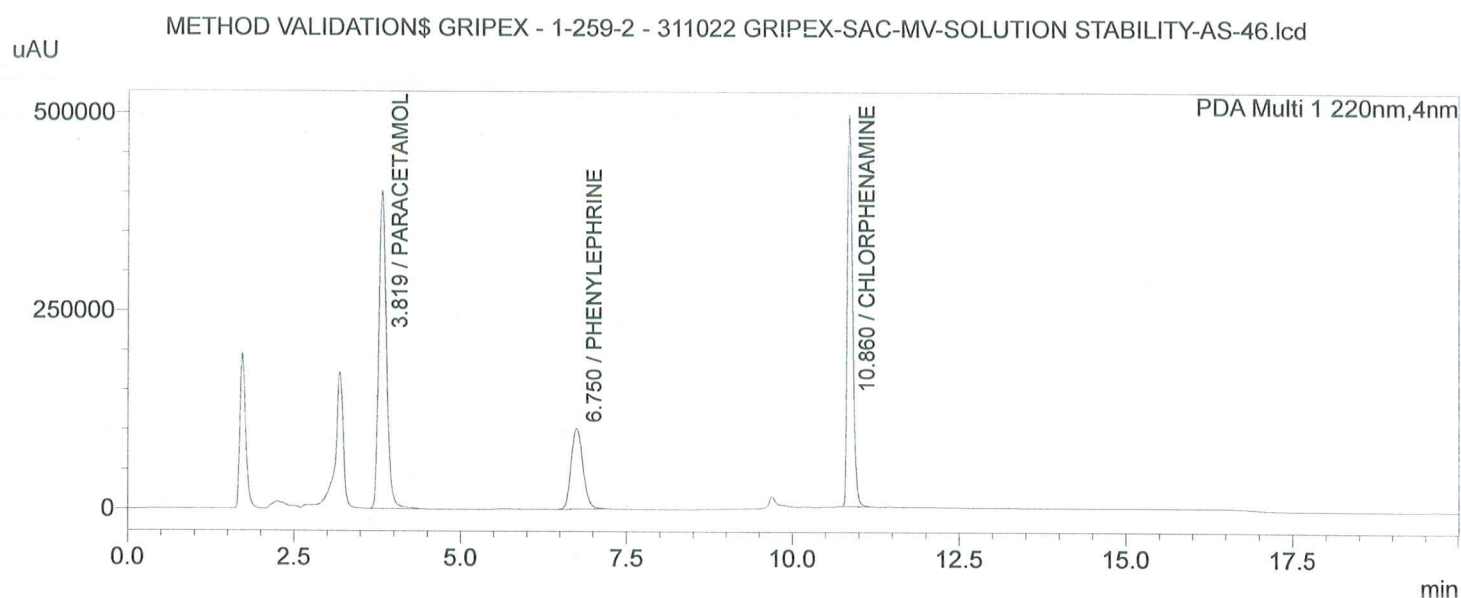
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENY+CPM-SST-AS-20Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-46.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 4:19:19 PM  
Date Processed : 11/11/2022 1:17:49 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plots | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.819     | 3239548 | 44.859  | 4641    | 1.280    | --         | --       | PARACETAMOL    |
| 2     | 6.750     | 1225065 | 16.964  | 6809    | 1.189    | 10.63      | --       | PHENYLEPHRINE  |
| 3     | 10.860    | 2757052 | 38.178  | 69227   | 1.411    | 16.70      | --       | CHLORPHENAMINE |
| Total |           | 7221665 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

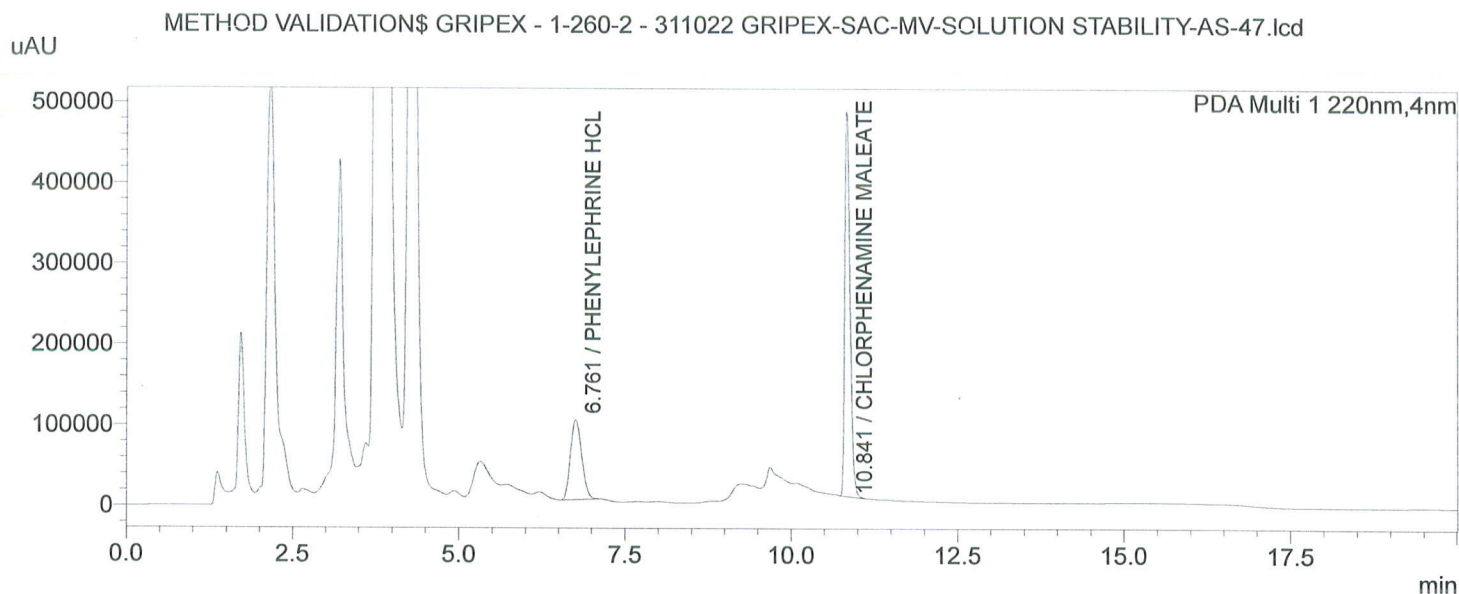
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-20Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-47.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 4:39:54 PM  
Date Processed : 11/11/2022 3:24:10 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plale | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.761     | 1161276 | 30.444  | 7010    | 1.150    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.841    | 2653169 | 69.556  | 70847   | 1.403    | 16.79      | --       | CHLORPHENAMINE MALE |
| Total |           | 3814445 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

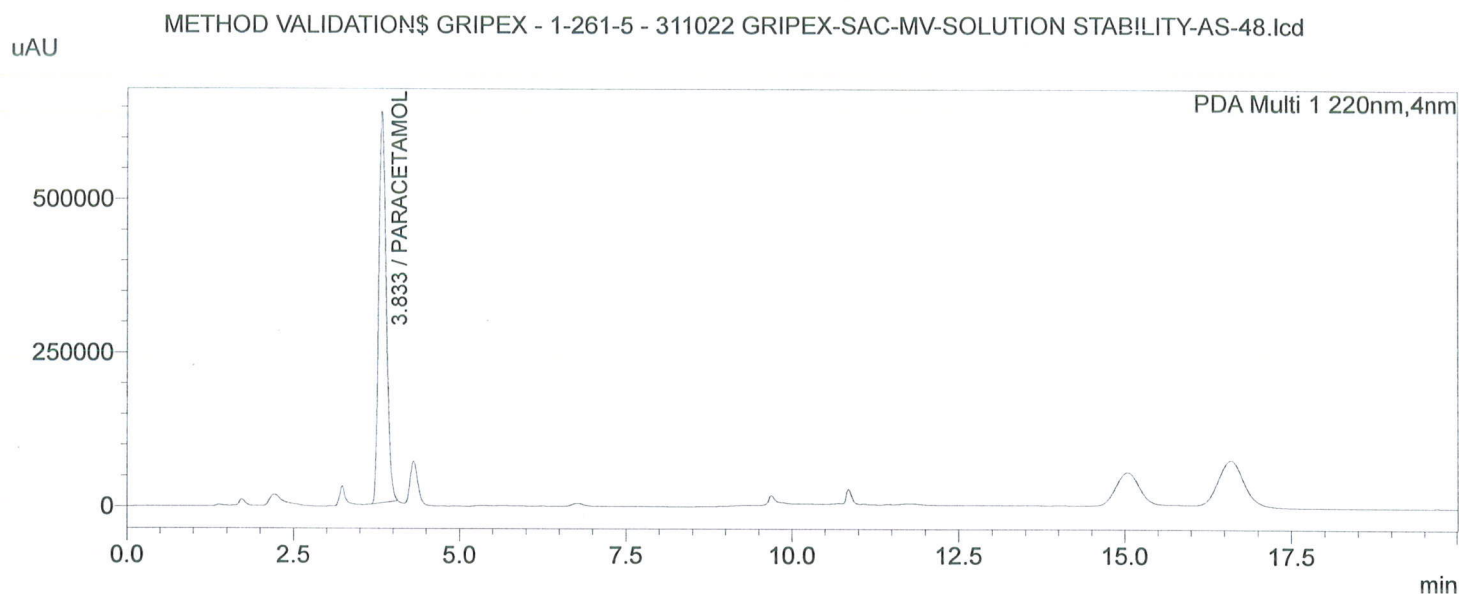
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-20Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-48.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 5:00:28 PM  
Date Processed : 11/11/2022 5:04:21 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plale | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.833     | 4982290 | 100.000 | 4805    | 1.244    | --         | --       | PARACETAMOL |
| Total |           | 4982290 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

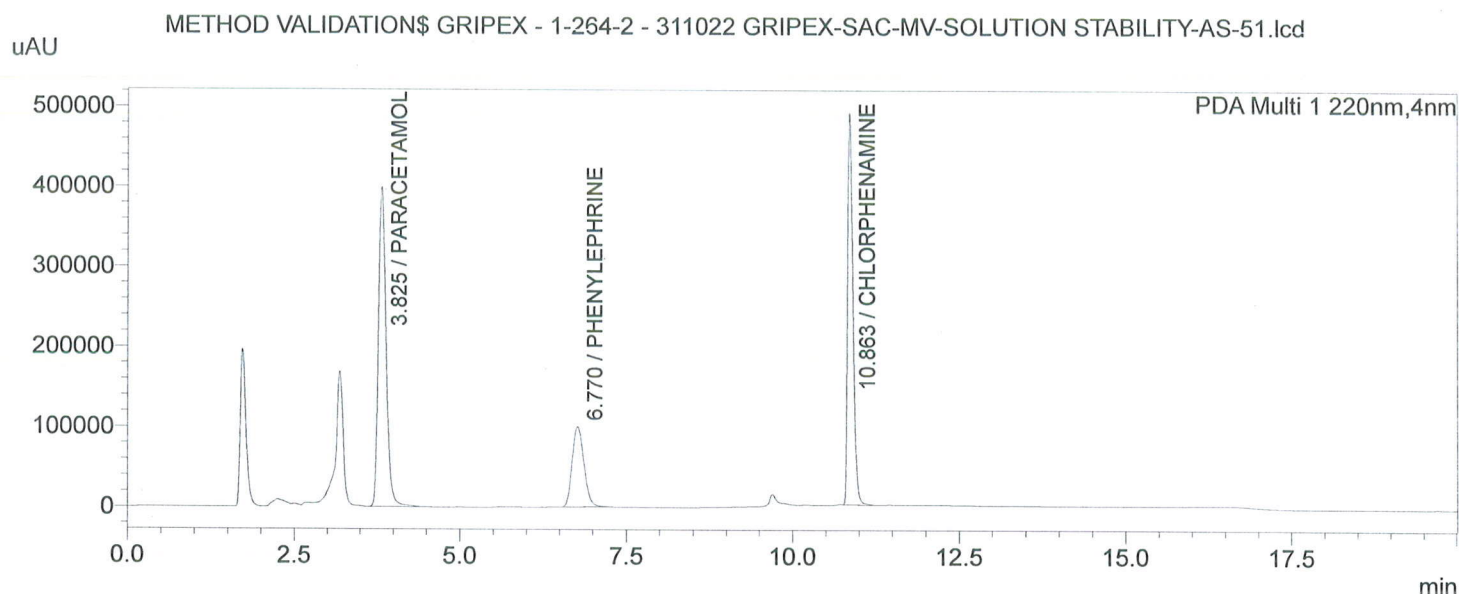
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENY+CPM-SST-AS-24Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-51.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 8:17:13 PM  
Date Processed : 11/11/2022 1:17:52 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.825     | 3233798 | 44.800  | 4678    | 1.274    | --         | --       | PARACETAMOL    |
| 2     | 6.770     | 1227808 | 17.010  | 6684    | 1.189    | 10.61      | --       | PHENYLEPHRINE  |
| 3     | 10.863    | 2756651 | 38.190  | 70325   | 1.409    | 16.53      | --       | CHLORPHENAMINE |
| Total |           | 7218257 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

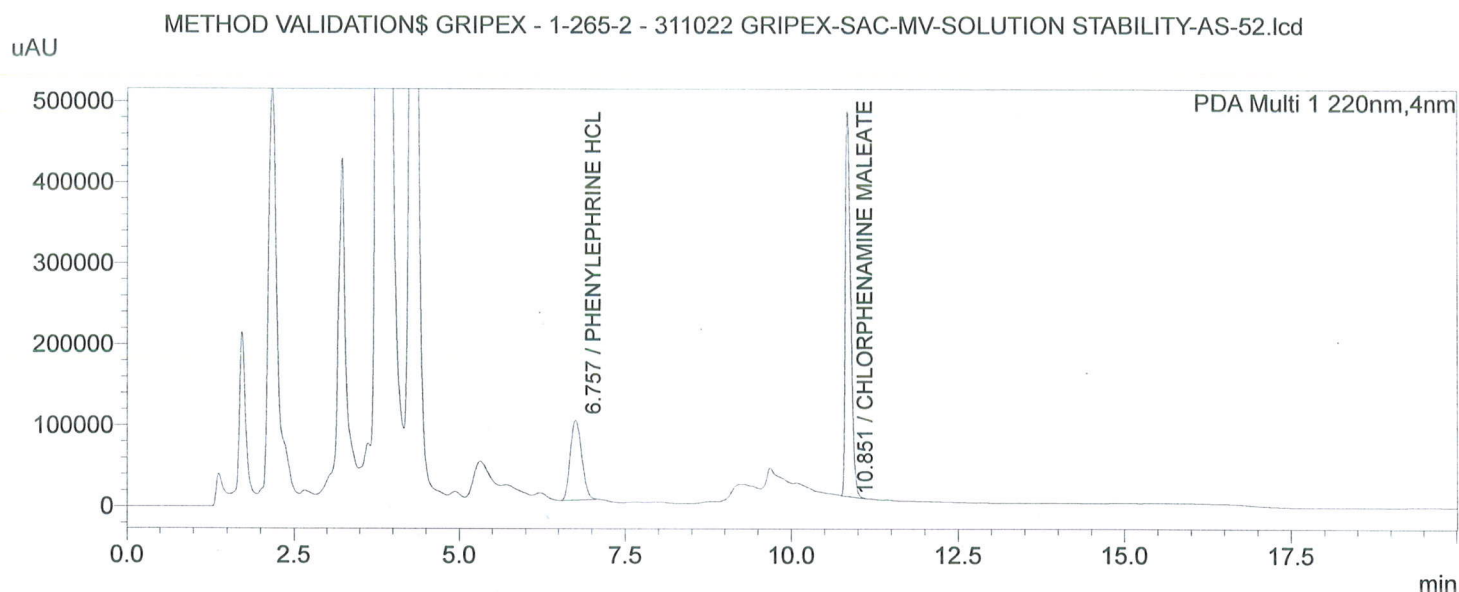
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-24Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-52.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 8:37:48 PM  
Date Processed : 11/11/2022 3:24:13 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.757     | 1162495 | 30.481  | 6940    | 1.153    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.851    | 2651393 | 69.519  | 69310   | 1.402    | 16.73      | --       | CHLORPHENAMINE MALE |
| Total |           | 3813888 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

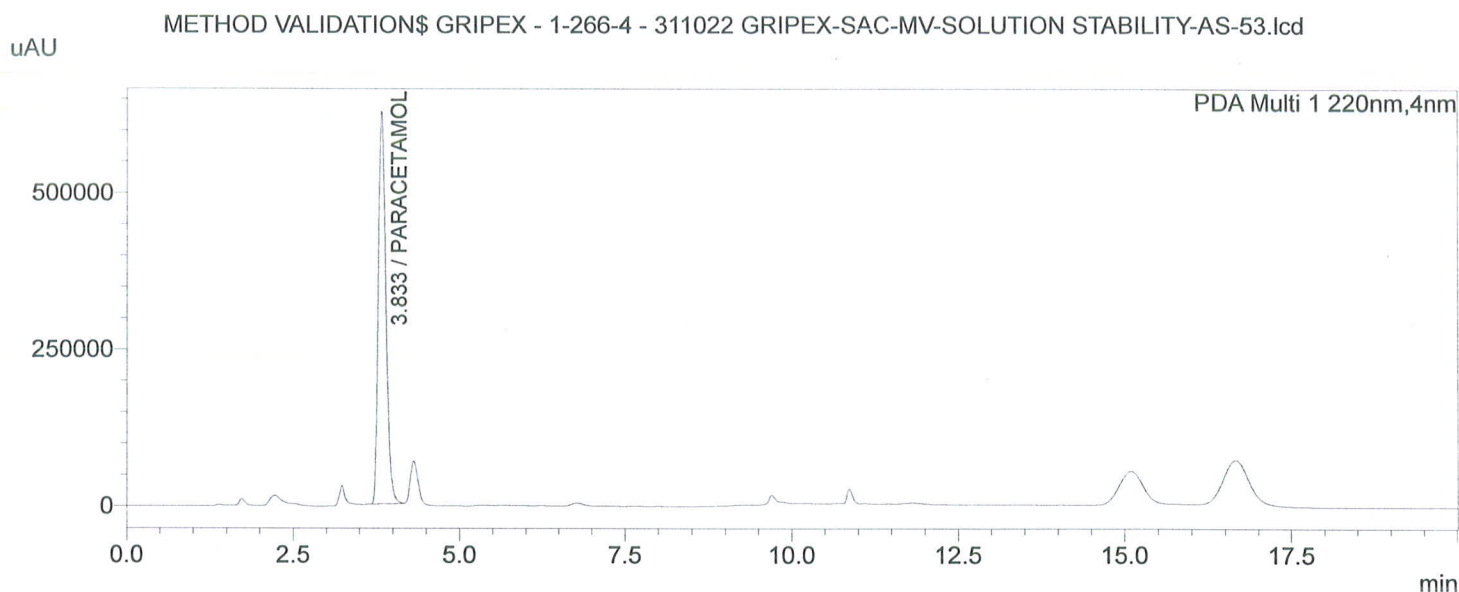
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-24Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-53.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/1/2022 8:58:24 PM  
Date Processed : 11/11/2022 3:35:08 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R. Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|-----------|-------------|
| 1     | 3.833     | 4966235 | 100.000 | 4749    | 1.261    | --         | --        | PARACETAMOL |
| Total |           | 4966235 | 100.000 |         |          |            |           |             |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

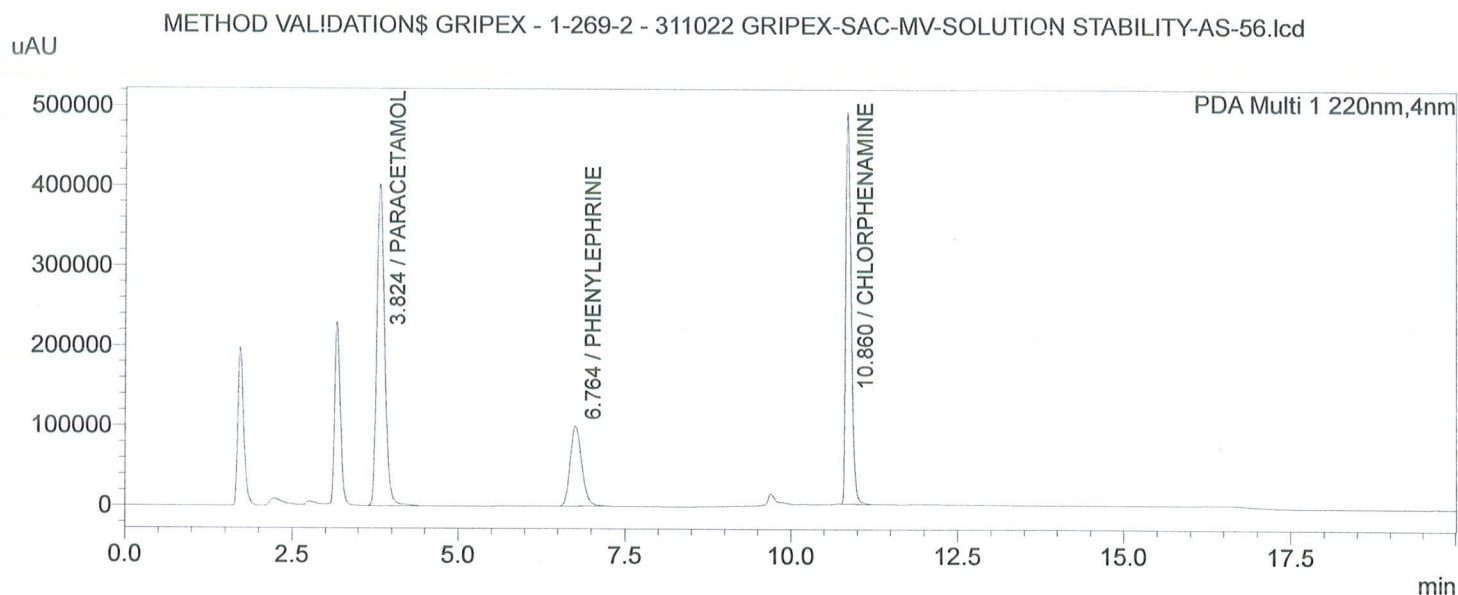
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENY+CPM-SST-AS-28Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-56.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 12:15:09 AM  
Date Processed : 11/11/2022 1:17:55 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.824     | 3231066 | 44.848  | 4730    | 1.279    | --         | --       | PARACETAMOL    |
| 2     | 6.764     | 1225894 | 17.016  | 6680    | 1.190    | 10.62      | --       | PHENYLEPHRINE  |
| 3     | 10.860    | 2747570 | 38.137  | 68649   | 1.426    | 16.49      | --       | CHLORPHENAMINE |
| Total |           | 7204530 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

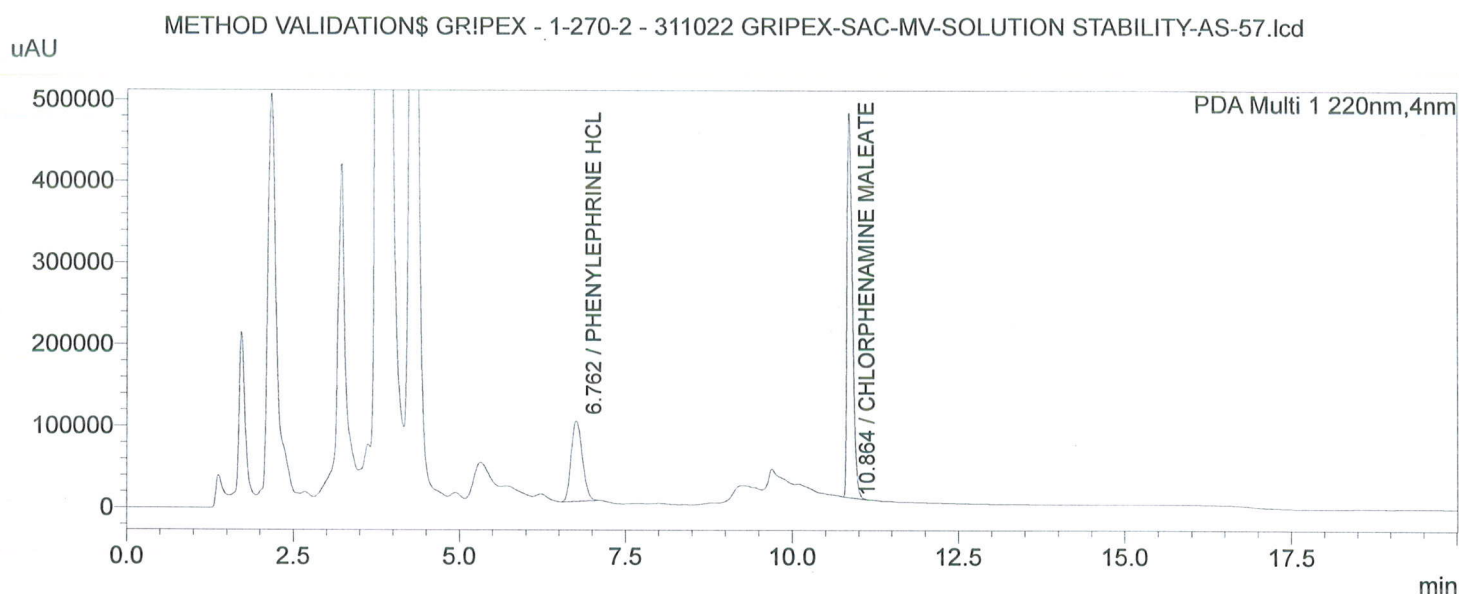
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-28Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-57.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 12:35:44 AM  
Date Processed : 11/11/2022 3:24:16 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plale | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.762     | 1161262 | 30.383  | 7002    | 1.145    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.864    | 2660799 | 69.617  | 65940   | 1.386    | 16.66      | --       | CHLORPHENAMINE MALE |
| Total |           | 3822061 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

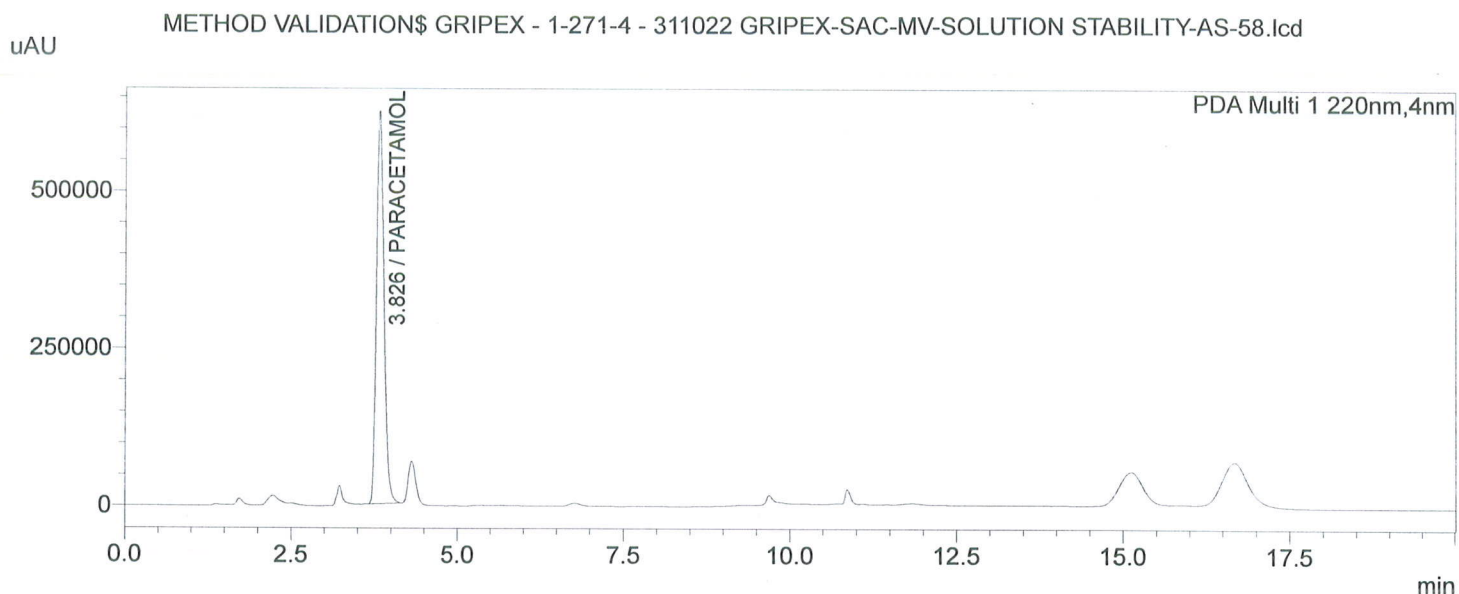
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-28Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-58.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 12:56:18 AM  
Date Processed : 11/11/2022 3:35:10 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.826     | 4936853 | 100.000 | 4742    | 1.264    | --         | --       | PARACETAMOL |
| Total |           | 4936853 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

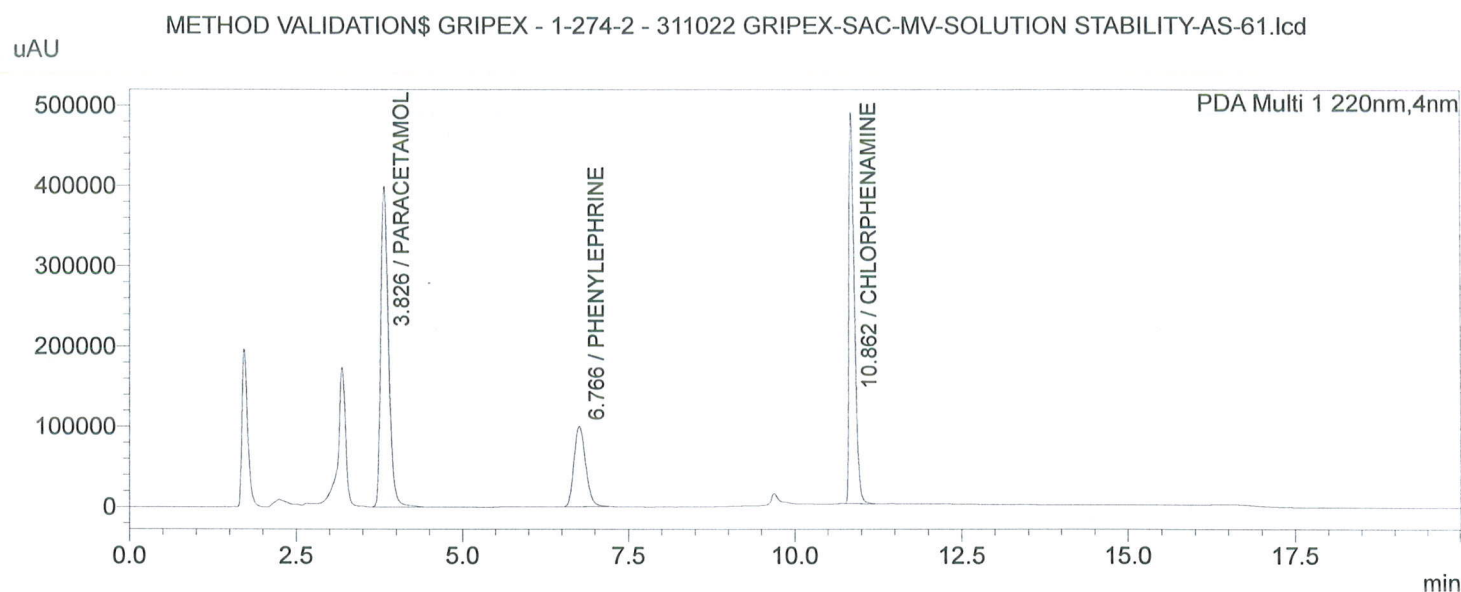
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENY+CPM-SST-AS-32Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-61.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 4:13:02 AM  
Date Processed : 11/11/2022 1:17:57 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plale | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.826     | 3233265 | 44.804  | 4659    | 1.277    | --         | --       | PARACETAMOL    |
| 2     | 6.766     | 1226790 | 17.000  | 6656    | 1.190    | 10.57      | --       | PHENYLEPHRINE  |
| 3     | 10.862    | 2756336 | 38.195  | 68811   | 1.414    | 16.47      | --       | CHLORPHENAMINE |
| Total |           | 7216391 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

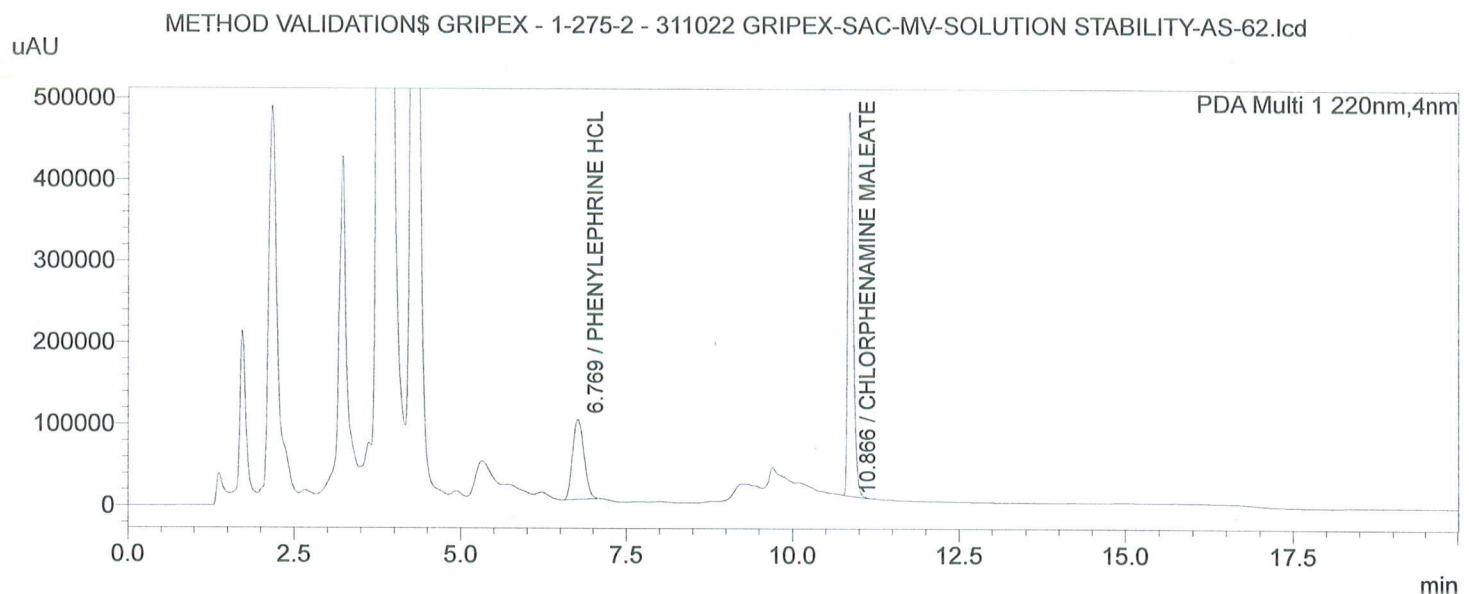
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-32Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-62.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 4:33:36 AM  
Date Processed : 11/11/2022 3:24:19 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.769     | 1162011 | 30.414  | 6895    | 1.151    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.866    | 2658650 | 69.586  | 66072   | 1.396    | 16.55      | --       | CHLORPHENAMINE MALE |
| Total |           | 3820660 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

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Date :



# Safetab Life Science

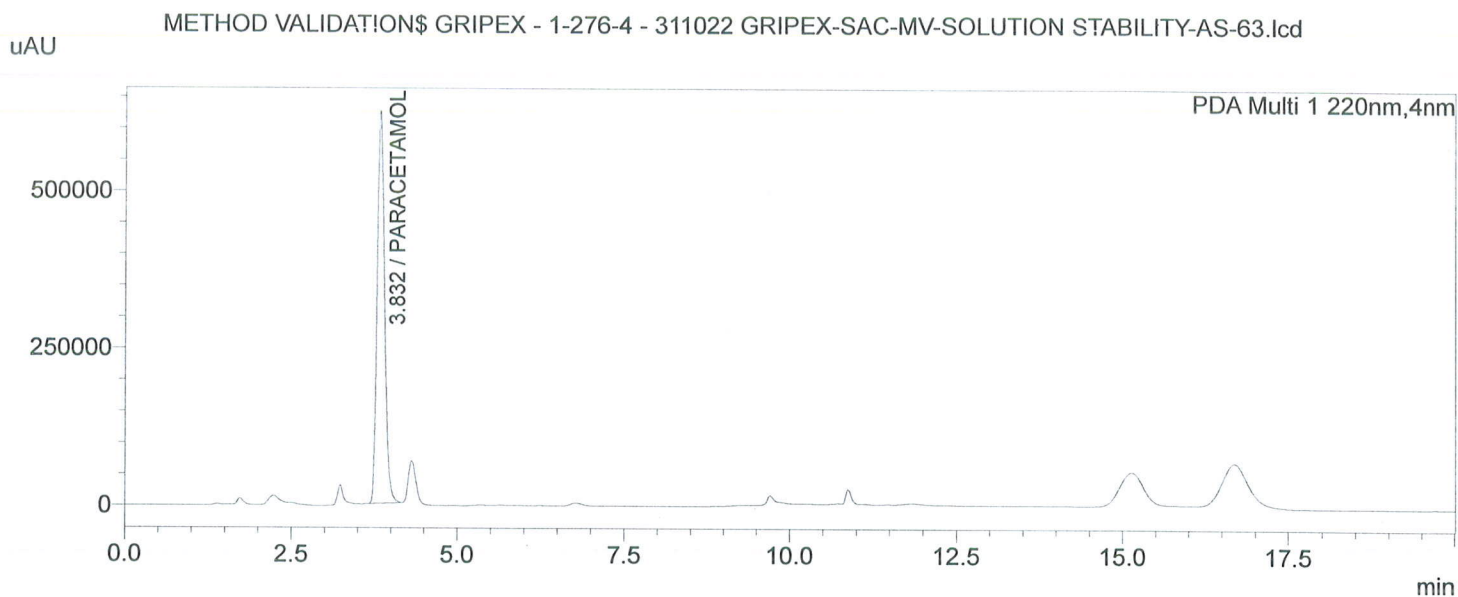
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-32Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-63.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 4:54:10 AM  
Date Processed : 11/11/2022 3:35:13 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.832     | 4958588 | 100.000 | 4707    | 1.265    | --         | --       | PARACETAMOL |
| Total |           | 4958588 | 100.000 |         |          |            |          |             |

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Date :

Checked By

Date :





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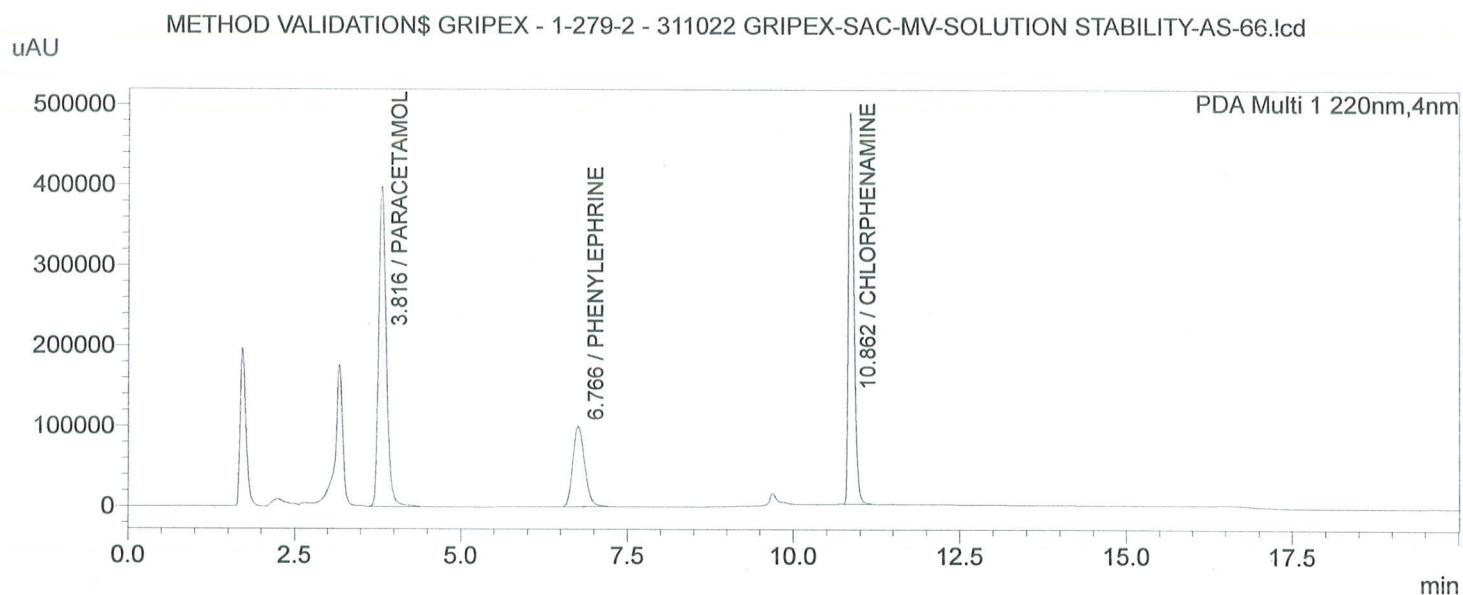
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENY+CPM-SST-AS-36Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-66.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 8:11:05 AM  
Date Processed : 11/11/2022 1:18:00 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.816     | 3224184 | 44.771  | 4628    | 1.279    | --         | --       | PARACETAMOL    |
| 2     | 6.766     | 1221998 | 16.969  | 6650    | 1.189    | 10.61      | --       | PHENYLEPHRINE  |
| 3     | 10.862    | 2755310 | 38.260  | 68544   | 1.421    | 16.46      | --       | CHLORPHENAMINE |
| Total |           | 7201492 | 100.000 |         |          |            |          |                |

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Checked By

Date :



# Safetab Life Science

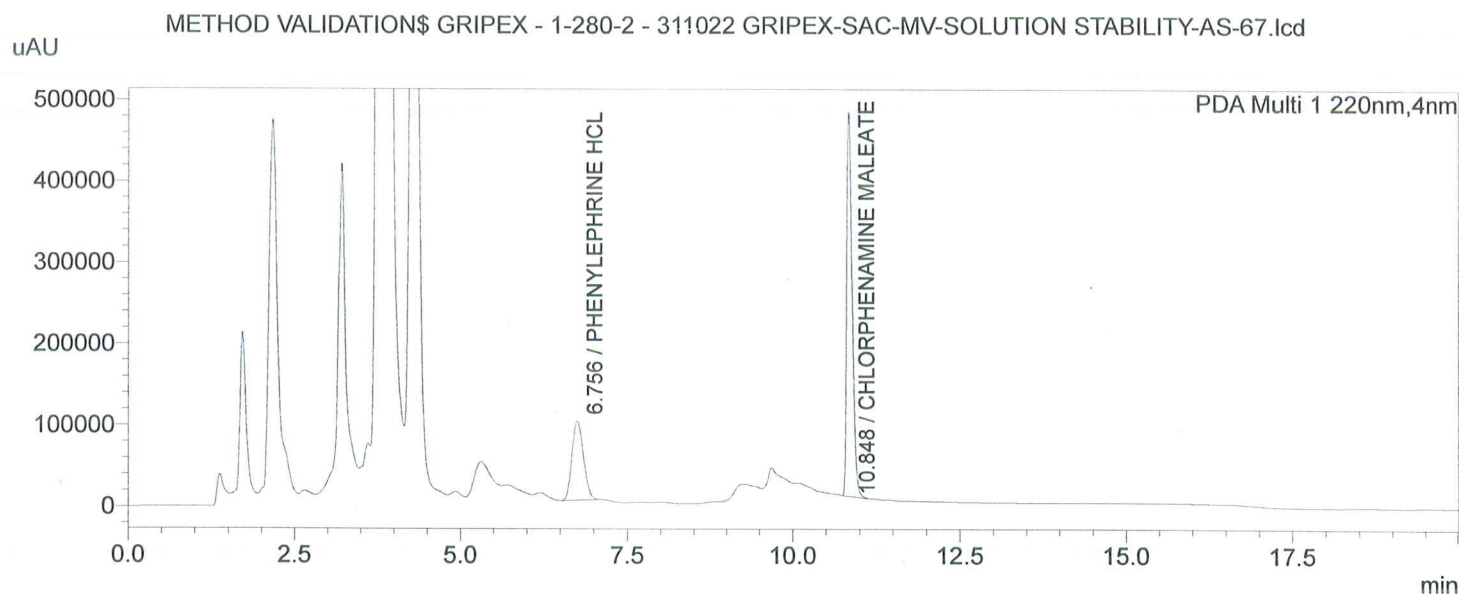
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-36Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-67.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 8:31:39 AM  
Date Processed : 11/11/2022 3:24:22 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.756     | 1159390 | 30.469  | 6846    | 1.151    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.848    | 2645749 | 69.531  | 67683   | 1.402    | 16.59      | --       | CHLORPHENAMINE MALE |
| Total |           | 3805138 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

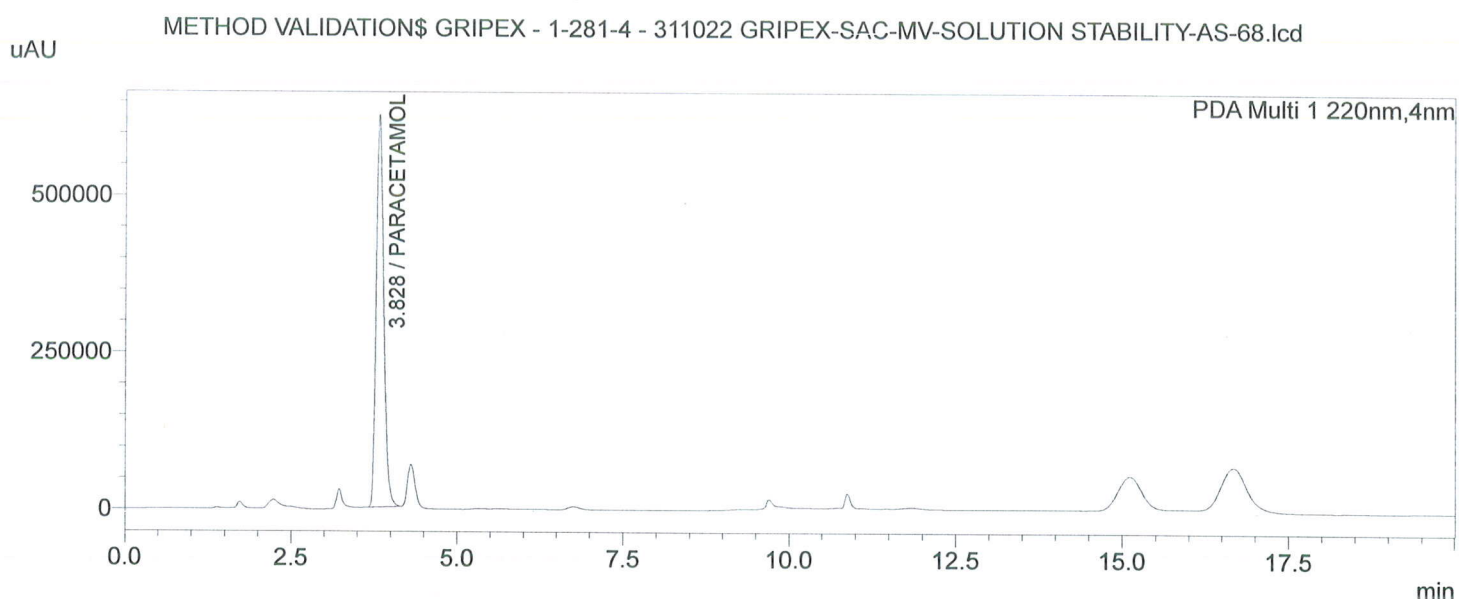
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-36Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-68.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 8:52:14 AM  
Date Processed : 11/11/2022 3:35:15 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.828     | 4947666 | 100.000 | 4723    | 1.267    | --         | --       | PARACETAMOL |
| Total |           | 4947666 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

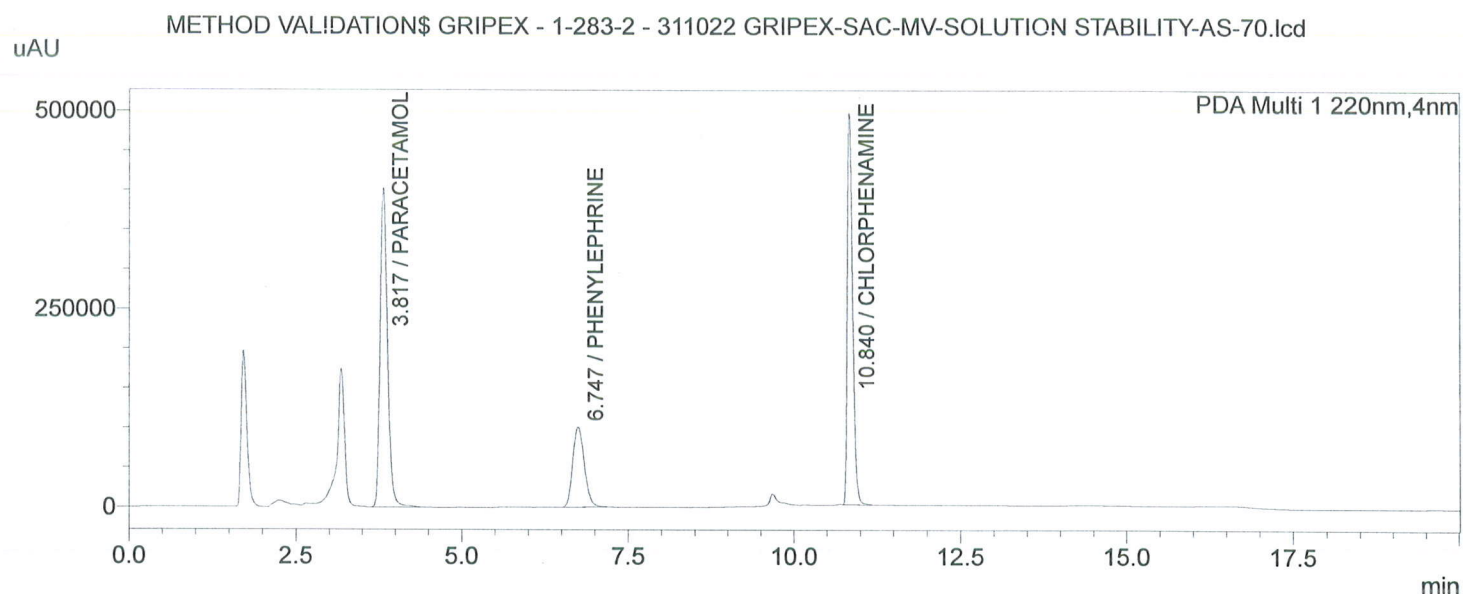
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENY+CPM-SST-AS-40Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-70.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 11:59:58 AM  
Date Processed : 11/11/2022 1:18:03 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plots | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.817     | 3225424 | 44.800  | 4709    | 1.268    | --         | --       | PARACETAMOL    |
| 2     | 6.747     | 1222884 | 16.985  | 6761    | 1.184    | 10.64      | --       | PHENYLEPHRINE  |
| 3     | 10.840    | 2751333 | 38.215  | 69905   | 1.410    | 16.63      | --       | CHLORPHENAMINE |
| Total |           | 7199640 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

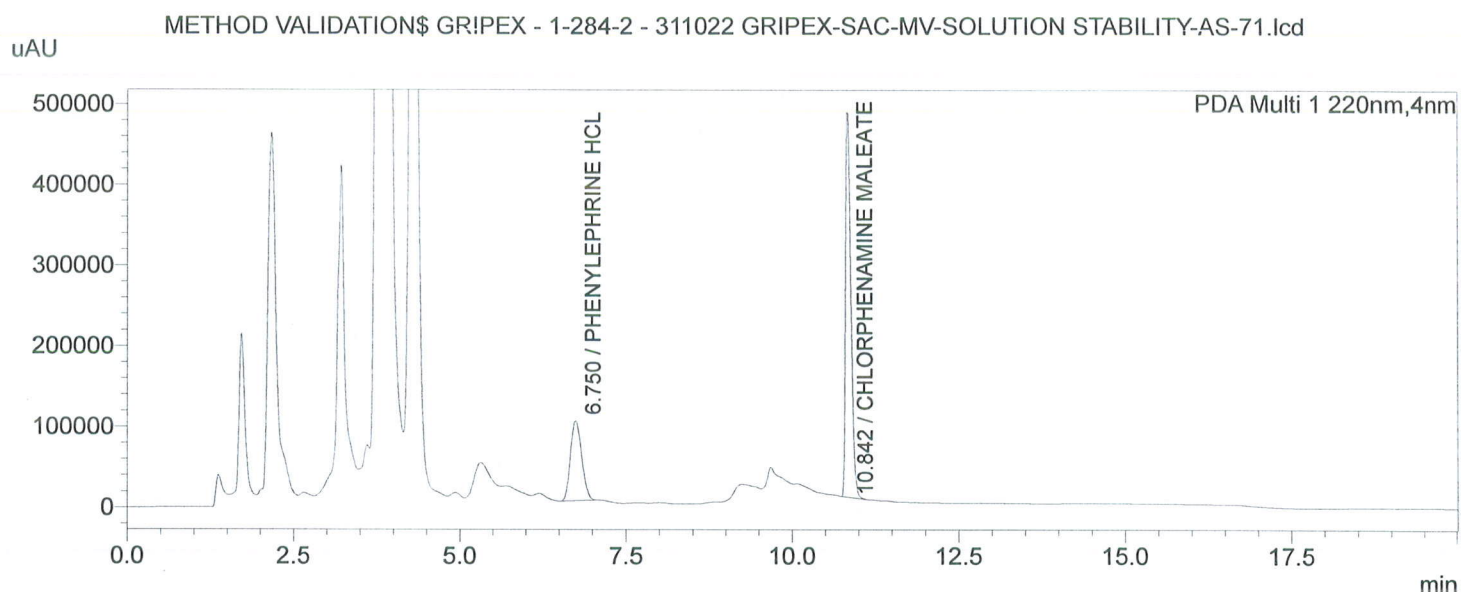
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-40Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-71.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 12:20:33 PM  
Date Processed : 11/11/2022 3:24:25 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plale | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.750     | 1161765 | 30.361  | 7005    | 1.147    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.842    | 2664706 | 69.639  | 70993   | 1.402    | 16.86      | --       | CHLORPHENAMINE MALE |
| Total |           | 3826472 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

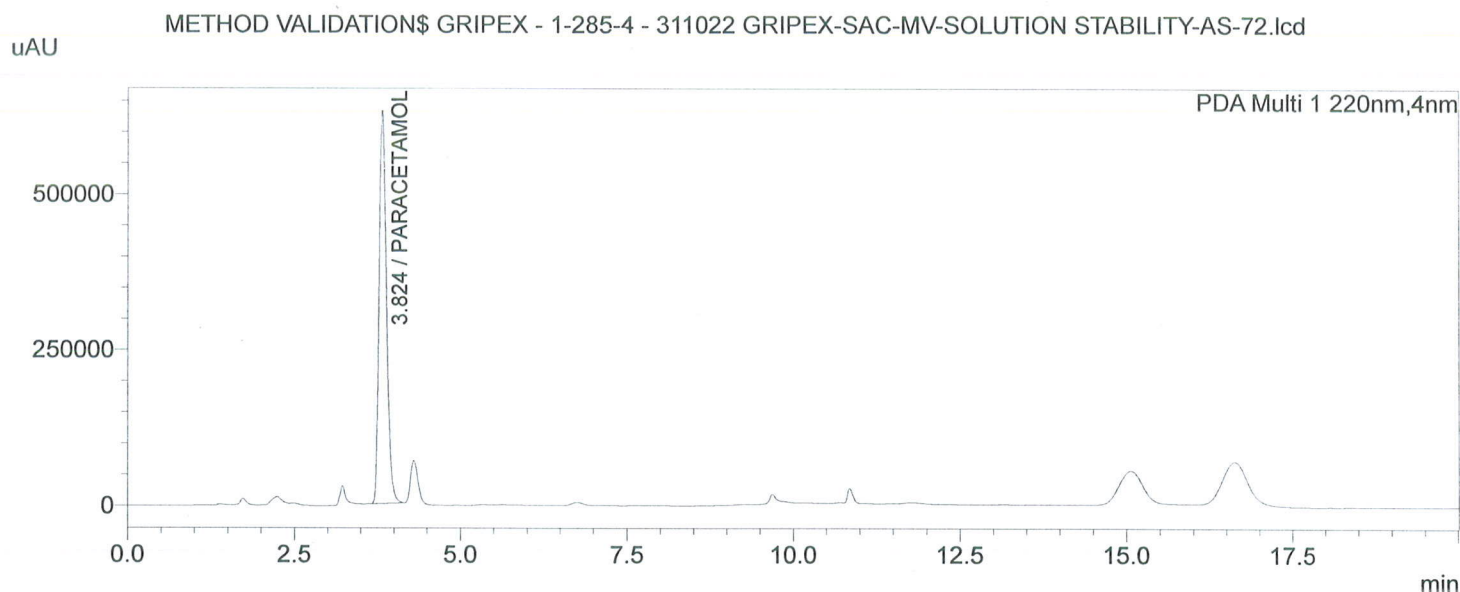
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-40Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-72.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 12:41:08 PM  
Date Processed : 11/11/2022 3:35:18 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.824     | 4959520 | 100.000 | 4799    | 1.257    | --         | --       | PARACETAMOL |
| Total |           | 4959520 | 100.000 |         |          |            |          |             |

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Date :

Checked By

Date :





# Safetab Life Science

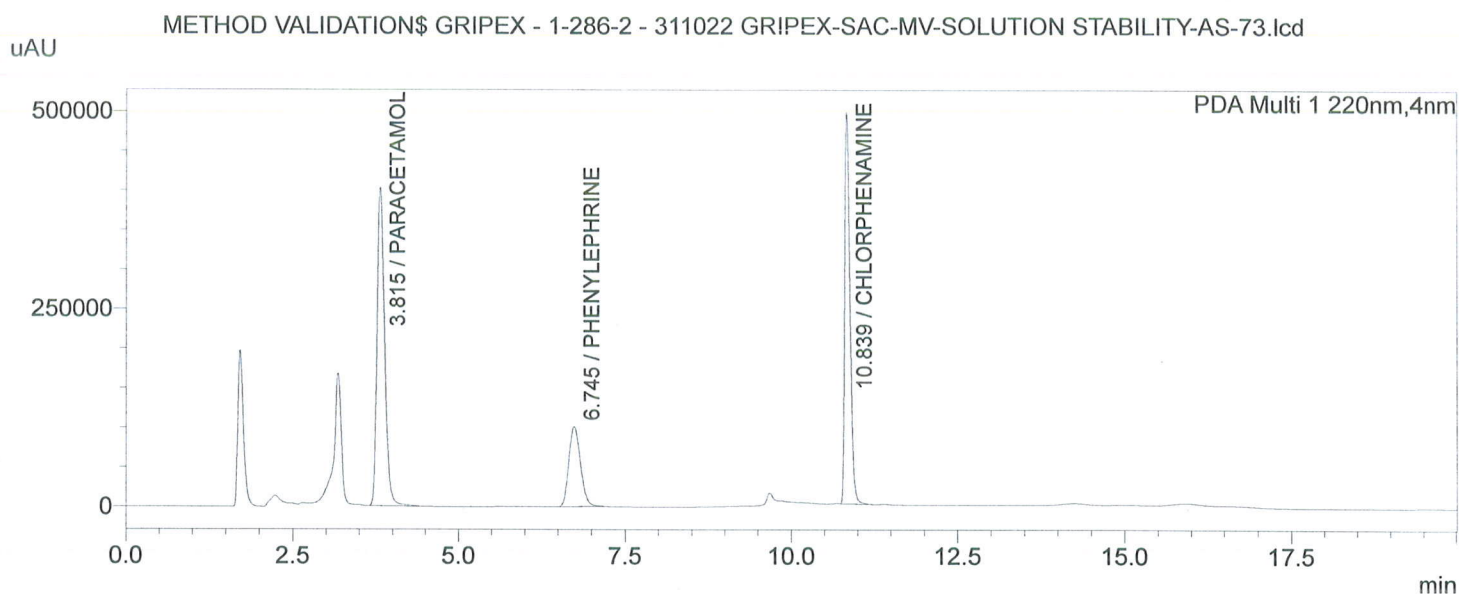
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : PARA+PHENY+CPM-SST-AS-44Hrs-STD  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-73.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-2  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 3:55:37 PM  
Date Processed : 11/11/2022 1:18:06 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plale | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.815     | 3224404 | 44.767  | 4720    | 1.267    | --         | --       | PARACETAMOL    |
| 2     | 6.745     | 1224314 | 16.998  | 6777    | 1.185    | 10.66      | --       | PHENYLEPHRINE  |
| 3     | 10.839    | 2753930 | 38.235  | 69424   | 1.414    | 16.63      | --       | CHLORPHENAMINE |
| Total |           | 7202647 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

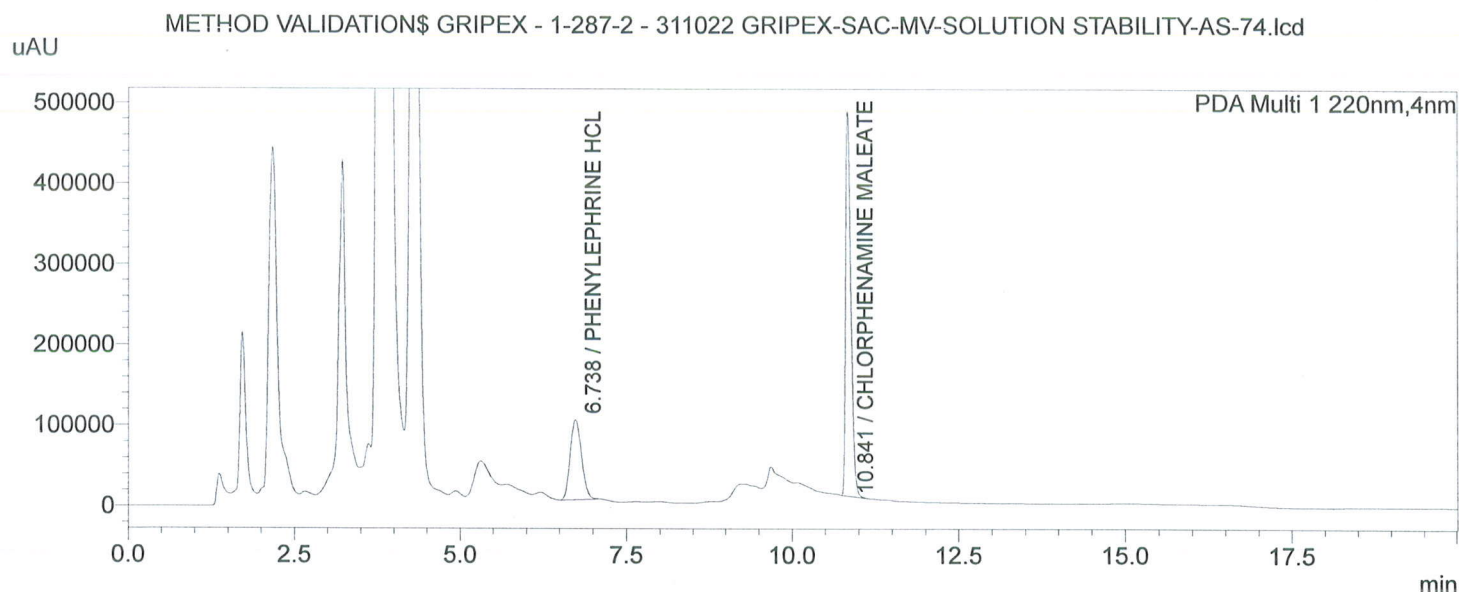
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-44Hrs-SOL-A  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-74.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-3  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 4:16:12 PM  
Date Processed : 11/11/2022 3:24:29 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plots | T.Factor | Resolution | R.R.Time | Name                   |
|-------|-----------|---------|---------|---------|----------|------------|----------|------------------------|
| 1     | 6.738     | 1162439 | 30.469  | 6998    | 1.151    | --         | --       | PHENYLEPHRINE HCL      |
| 2     | 10.841    | 2652746 | 69.531  | 70556   | 1.404    | 16.90      | --       | CHLORPHENAMINE MALEATE |
| Total |           | 3815186 | 100.000 |         |          |            |          |                        |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

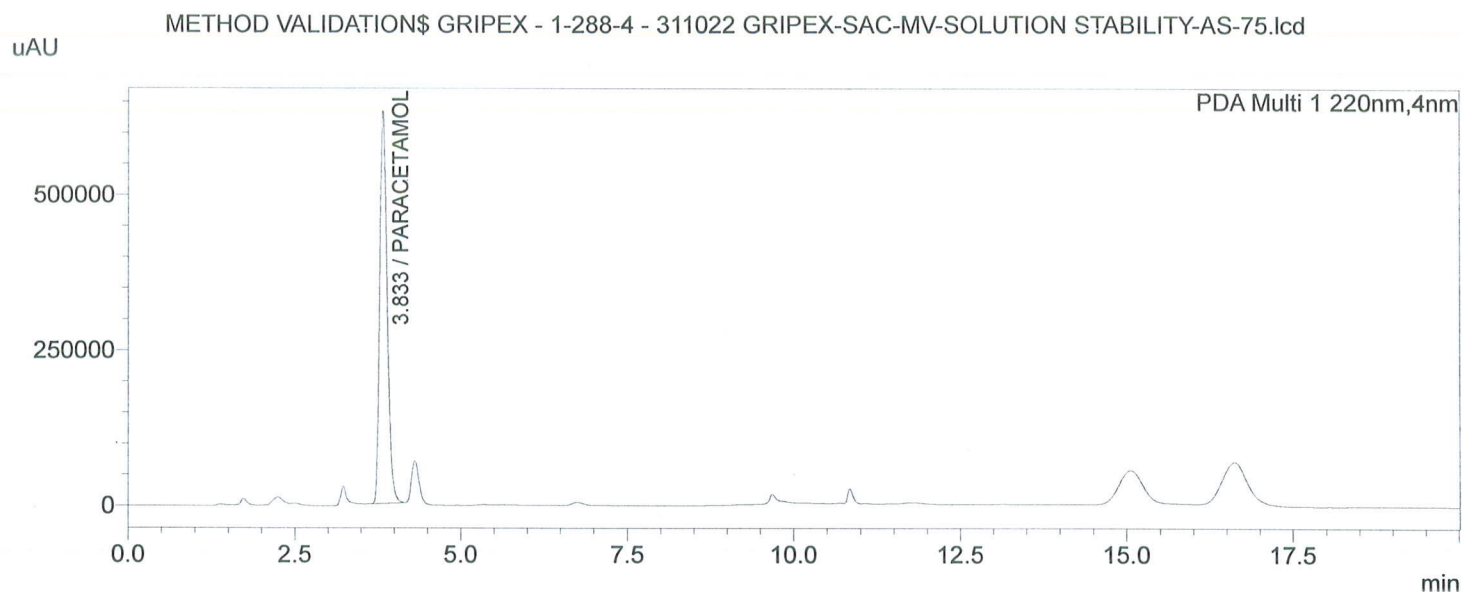
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SOLUTION STABILITY-AS  
Sample ID : GRIPEX-MV-S.STB-AS-44Hrs-SOL-B  
Data Filename : 311022 GRIPEX-SAC-MV-SOLUTION STABILITY-AS-75.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 311022 GRIPEX-SAC-MV-AS-SOLUTION STABILITY.lcb  
Vial # : 3-4  
Injection Volume : 50 uL  
Date Acquired : 11/2/2022 4:36:47 PM  
Date Processed : 11/11/2022 3:35:21 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.833     | 4966015 | 100.000 | 4794    | 1.254    | --         | --       | PARACETAMOL |
| Total |           | 4966015 | 100.000 |         |          |            |          |             |

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Puducherry- 605 107

## Quality control Department

### =====BATCH TABLE=====

| Vial# | Tray | Inj. Vol. | Sample Name                                  | Sample ID | Batch Table | Method File            | Data File                          | Report Format      |
|-------|------|-----------|----------------------------------------------|-----------|-------------|------------------------|------------------------------------|--------------------|
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-01.lcd | system\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENYL+CPM-SST-AS-STD-01   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-02.lcd | system\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENYL+CPM-SST-AS-STD-02   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-03.lcd | system\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENYL+CPM-SST-AS-STD-03   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-04.lcd | system\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENYL+CPM-SST-AS-STD-04   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-05.lcd | system\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENYL+CPM-SST-AS-STD-05   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-06.lcd | system\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-SST-INIT-AS-SOL-A-01  |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-07.lcd | system\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-SST-INIT-AS-SOL-A-02  |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-08.lcd | system\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-SST-INIT-AS-SOL-B-01  |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-09.lcd | system\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-SST-INIT-AS-SOL-B-02  |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-10.lcd | system\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           |             | GRPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-11.lcd | system\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-12.lcd | system\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENYL+CPM-SST-AS-2Hrs-STD |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-13.lcd | system\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-2Hrs-SOL-A   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-14.lcd | system\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-2Hrs-SOL-B   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-15.lcd | system\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           |             | GRPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-16.lcd | system\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-17.lcd | system\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENYL+CPM-SST-AS-4Hrs-STD |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-18.lcd | system\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-4Hrs-SOL-A   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-19.lcd | system\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-4Hrs-SOL-B   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-20.lcd | system\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           |             | GRPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-21.lcd | system\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-22.lcd | system\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENYL+CPM-SST-AS-6Hrs-STD |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-23.lcd | system\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-6Hrs-SOL-A   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-24.lcd | system\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-6Hrs-SOL-B   |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-25.lcd | system\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           |             | GRPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-26.lcd | system\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-27.lcd | system\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENYL+CPM-SST-AS-8Hrs-STD |           |             | GRPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-28.lcd | system\DEFAULT.isr |



| Vial# | Tray | Inj. Vol. | Sample Name                                  | Sample ID | Method File             | Data File                          | Report Format     |
|-------|------|-----------|----------------------------------------------|-----------|-------------------------|------------------------------------|-------------------|
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-8Hrs-SOL-A   |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-29.lcd | ystem\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-8Hrs-SOL-B   |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-30.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           | GRIPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-31.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-32.lcd | ystem\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENV+CPM-SST-AS-10Hrs-STD |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-33.lcd | ystem\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-10Hrs-SOL-A  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-34.lcd | ystem\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-10Hrs-SOL-B  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-35.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           | GRIPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-36.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-37.lcd | ystem\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENV+CPM-SST-AS-12Hrs-STD |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-38.lcd | ystem\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-12Hrs-SOL-A  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-39.lcd | ystem\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-12Hrs-SOL-B  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-40.lcd | ystem\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENV+CPM-SST-AS-16Hrs-STD |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-41.lcd | ystem\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-16Hrs-SOL-A  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-42.lcd | ystem\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-16Hrs-SOL-B  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-43.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           | GRIPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-44.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-45.lcd | ystem\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENV+CPM-SST-AS-20Hrs-STD |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-46.lcd | ystem\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-20Hrs-SOL-A  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-47.lcd | ystem\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-20Hrs-SOL-B  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-48.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           | GRIPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-49.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-50.lcd | ystem\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENV+CPM-SST-AS-24Hrs-STD |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-51.lcd | ystem\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-24Hrs-SOL-A  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-52.lcd | ystem\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-24Hrs-SOL-B  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-53.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           | GRIPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-54.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-55.lcd | ystem\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENV+CPM-SST-AS-28Hrs-STD |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-56.lcd | ystem\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-28Hrs-SOL-A  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-57.lcd | ystem\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-28Hrs-SOL-B  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-58.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           | GRIPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-59.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-60.lcd | ystem\DEFAULT.isr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENV+CPM-SST-AS-32Hrs-STD |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-61.lcd | ystem\DEFAULT.isr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-32Hrs-SOL-A  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-62.lcd | ystem\DEFAULT.isr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-32Hrs-SOL-B  |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-63.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA STABILIZE                       |           | GRIPEX-AS-stabilize.lcm | IC-MV-SOLUTION STABILITY-AS-64.lcd | ystem\DEFAULT.isr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           | GRIPEX-AS.lcm           | IC-MV-SOLUTION STABILITY-AS-65.lcd | ystem\DEFAULT.isr |



| Vial# | Tray | Inj. Vol. | Sample Name                                  | Sample ID | Method File        | Data File                           | Report Format        |
|-------|------|-----------|----------------------------------------------|-----------|--------------------|-------------------------------------|----------------------|
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENV+CPM-SST-AS-36Hrs-STD |           | GRIPEX-AS.lcm      | \\C-MV-SOLUTION STABILITY-AS-66.lcd | \\system\DEFAULT.lsr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-36Hrs-SOL-A  |           | GRIPEX-AS.lcm      | \\C-MV-SOLUTION STABILITY-AS-67.lcd | \\system\DEFAULT.lsr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-36Hrs-SOL-B  |           | GRIPEX-AS.lcm      | \\C-MV-SOLUTION STABILITY-AS-68.lcd | \\system\DEFAULT.lsr |
| 1     | 3    | 50.0      | SOLUTION STA BLANK-AS                        |           | GRIPEX-AS.lcm      | \\C-MV-SOLUTION STABILITY-AS-69.lcd | \\system\DEFAULT.lsr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENV+CPM-SST-AS-40Hrs-STD |           | GRIPEX-AS.lcm      | \\C-MV-SOLUTION STABILITY-AS-70.lcd | \\system\DEFAULT.lsr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-40Hrs-SOL-A  |           | GRIPEX-AS.lcm      | \\C-MV-SOLUTION STABILITY-AS-71.lcd | \\system\DEFAULT.lsr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-40Hrs-SOL-B  |           | GRIPEX-AS.lcm      | \\C-MV-SOLUTION STABILITY-AS-72.lcd | \\system\DEFAULT.lsr |
| 2     | 3    | 50.0      | SOLUTION STA PARA+PHENV+CPM-SST-AS-44Hrs-STD |           | GRIPEX-AS.lcm      | \\C-MV-SOLUTION STABILITY-AS-73.lcd | \\system\DEFAULT.lsr |
| 3     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-44Hrs-SOL-A  |           | GRIPEX-AS.lcm      | \\C-MV-SOLUTION STABILITY-AS-74.lcd | \\system\DEFAULT.lsr |
| 4     | 3    | 50.0      | SOLUTION STA GRIPEX-MV-S.STB-AS-44Hrs-SOL-B  |           | GRIPEX-AS.lcm      | \\C-MV-SOLUTION STABILITY-AS-75.lcd | \\system\DEFAULT.lsr |
| 1     | 3    | 50.0      | SOLUTION STA SHUT                            |           | HUTDOWN METHOD.lcm | \\C-MV-SOLUTION STABILITY-AS-76.lcd | \\system\DEFAULT.lsr |

Analysed By  
Date :



Checked By  
Date :





**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

|                            |                |
|----------------------------|----------------|
| <b>Name of the Product</b> | GRIPEX SACHETS |
| <b>Batch No</b>            | ST/T/S-1322    |

Stability of Analytical Solution:

Std. Stock Soln. A:

Acc. Weigh of Paracetamol and 40.30g of Chlorpheniramine maleate (wts) in 100ml volumetric flask added 70ml of diluent. Sonicate to dissolve and make up to volume with diluent.

Std. Stock Soln. B:

Acc. Weigh of phenylephrine HCl (wts) in 100ml volumetric flask added 70ml of diluent. Sonicated for dissolve and make up to the volume with same diluent.

Std. Preparation:

Each 5ml of Stock soln A & B to 50ml with diluent

Sample Preparation:

4501.10gm sample in 500ml volumetric flask added about 300ml of diluent and Sonicated for dissolve. And make up to the volume with diluent. Filter the solution using 0.45 µm PTFE filter (sol'n). To dilute 5ml of this solution to 100ml with diluent.

|                                                                                                   |                 |              |        |
|---------------------------------------------------------------------------------------------------|-----------------|--------------|--------|
| Analyzed by :  | Date : 31/10/22 | Checked by : | Date : |
|---------------------------------------------------------------------------------------------------|-----------------|--------------|--------|



**Safetab Life Science ,**  
Puducherry - 605 107

**QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

**Title**

**ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS**

|                       |                                     |                     |                    |
|-----------------------|-------------------------------------|---------------------|--------------------|
| <b>Product Name :</b> | <b>GRIPEX</b>                       | <b>Batch size :</b> | <b>500 SACHETS</b> |
| <b>Batch Number :</b> | <b>ST/T/S-1322</b>                  | <b>Mfg.Date :</b>   | <b>Sep-22</b>      |
| <b>Parameter :</b>    | <b>INTERFERENCE FROM DEGRADANTS</b> | <b>Exp.Date :</b>   | <b>To be fixed</b> |

Each 4500 mg of Sachet contains:

Paracetamol BP ----- 650mg

Chlorphenamine Maleate BP ----- 20mg

Phenylephrine Hydrochloride BP ----- 10mg

**ASSAY OF PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE AND CHLORPHENAMINE MALEATE**

|                       |              |                     |                 |                |              |                       |       |
|-----------------------|--------------|---------------------|-----------------|----------------|--------------|-----------------------|-------|
| <b>Instrument ID:</b> | ST/QC/EQ/039 | <b>Balance ID :</b> | ST/QC/EQ/041&30 | <b>WS No.:</b> | ST/WS/22/011 | <b>% Purity (aib)</b> | 100.0 |
|                       |              |                     |                 | <b>WS No.:</b> | IAARI/WS/344 | <b>% Purity (aib)</b> | 98.9  |
|                       |              |                     |                 | <b>WS No.:</b> | ST/WS/22/039 | <b>% Purity (aib)</b> | 99.7  |

|                                 |       |            |     |            |   |            |    |
|---------------------------------|-------|------------|-----|------------|---|------------|----|
| <b>Paracetamol Std. Dil:</b>    | 65.97 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| <b>Std. conc (in ppm)-65.97</b> | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                                  |       |            |     |            |   |            |    |
|----------------------------------|-------|------------|-----|------------|---|------------|----|
| <b>Phenylephrine Std. Dil:</b>   | 40.49 | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| <b>Std. conc (in ppm)-20.245</b> | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                                 |       |            |     |            |   |            |    |
|---------------------------------|-------|------------|-----|------------|---|------------|----|
| <b>Chlorphenamine Std:</b>      | 40.13 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| <b>Std. conc (in ppm)-40.13</b> | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                         |            |            |     |            |   |            |     |
|-------------------------|------------|------------|-----|------------|---|------------|-----|
| <b>Test dilution .:</b> | One Sachet | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
|                         | 1          | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

| S.No | Sample Name                         | Peak name         | Assay % | Degradation in % | Peak purity |
|------|-------------------------------------|-------------------|---------|------------------|-------------|
| 1    | Assuch sample<br>(Method precision) | Paracetamol       | 99.1    | NA               | 1.000       |
|      |                                     | Phenylephrine Hcl | 97.3    | NA               | 1.000       |
|      |                                     | Chlorphenamine    | 101.2   | NA               | 1.000       |
| 2    | Acid degradation                    | Paracetamol       | 93.8    | 5.3              | 1.000       |
|      |                                     | Phenylephrine Hcl | 64.4    | 32.9             | 1.000       |
|      |                                     | Chlorphenamine    | 94.7    | 6.5              | 1.000       |
| 3    | Alkali degradation                  | Paracetamol       | 92.3    | 6.8              | 1.000       |
|      |                                     | Phenylephrine Hcl | 62.2    | 35.1             | 1.000       |
|      |                                     | Chlorphenamine    | 96.5    | 4.7              | 0.999       |
| 4    | Peroxide Degradation                | Paracetamol       | 93.9    | 5.2              | 1.000       |
|      |                                     | Phenylephrine Hcl | 96.6    | 0.7              | 1.000       |
|      |                                     | Chlorphenamine    | 90.0    | 11.2             | 1.000       |

**Results :**

- 1) There is No any interference due to degradants with analyte in stressed samples.
- 2) Peak purity was passes According to Lab solution.

**Acceptance criteria:**

- 1) There should not be any interference due to degradants with analyte in stressed samples.
- 2) The desired degradation should be 10-30% in acid, alkali and peroxide degradation, (if possible).
- 3) If about 10% and 30% degradation is not achieved by applying above harsher stressed condition, same shall be documented .
- 4) Peak purity should not be less than 0.950 according to Lab solution.

**Analysed by :**

C. ALBIN JOSE

**Date :**

10-11-2022

**Checked by :**

**Date :**

*[Signature]*  
10/11/2022





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                               |            |             |
|--------------|-----------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                        | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                   | Mfg. Date  | Sep-22      |
| Stage        | INTERFERENCE FROM DEGRADANTS-ACID DEGRADATION | Exp. Date  | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                |              |             |                  |         |              |                |       |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID: | ST/QC/EQ/041&030 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|

|                            |              |            |     |            |   |            |     |
|----------------------------|--------------|------------|-----|------------|---|------------|-----|
| Standard dilution.:        | 65.97        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50  |
| Std.conc (in ppm)-65.97    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
| Test conc(in ppm)-65.18922 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

Conversion factor : 1.0000

Labeled claim : 650 mg

Average weight : 4500 mg

|                      |         |         |         |         |         |         |       |          |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Paracetamol          | 5227452 | 5315468 | 5326120 | 5316446 | 5310656 | 5299228 | 40515 | 0.765    |
| With Bracketing std. |         |         |         |         |         | 5299228 | 40515 | 0.765    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4513.10                   | 4912191     | 609.74               | 93.8         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|         |              |                |      |
|---------|--------------|----------------|------|
| WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
|---------|--------------|----------------|------|

|                             |              |            |     |            |   |            |    |
|-----------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:         | 40.49        | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-20.245    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:             | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc (in ppm)-20.05823 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

Conversion factor : 1.0000

Labeled claim : 10 mg

|                      |         |         |         |         |         |         |        |          |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
| Phenylephrine HCL    | 1215872 | 1238018 | 1237298 | 1237587 | 1233420 | 1232439 | 9443   | 0.766    |
| With Bracketing std. |         |         |         |         |         | 1232439 | 9442.8 | 0.766    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4513.10                   | 794956      | 6.44                 | 64.4         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|         |              |                |      |
|---------|--------------|----------------|------|
| WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
|---------|--------------|----------------|------|

|                            |              |            |     |            |   |            |    |
|----------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:        | 40.13        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-40.13    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc(in ppm)-40.11644 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

Conversion factor : 1.0000

Labeled claim : 20 mg

|                        |         |         |         |         |         |         |       |          |
|------------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Chlorphenamine maleate | 2742921 | 2773527 | 2771631 | 2766508 | 2769113 | 2764740 | 12480 | 0.451    |
| With Bracketing std.   |         |         |         |         |         | 2764740 | 12480 | 0.451    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4513.10                   | 2624059     | 18.93                | 94.7         |

Assay limit :90.0% to 110.0%

Calculation formula :

|                     |                                                                          |
|---------------------|--------------------------------------------------------------------------|
| Assay in mg /Sachet | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt |
|                     | Standard area x sample dilution x 100                                    |

|            |                          |
|------------|--------------------------|
| Assay in % | Assay in mg/Sachet x 100 |
|            | Labeled claim            |

Analysed by : C.ALBIN JOSE

Date : 10-11-2022

Checked by :

Date :





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                                 |            |             |
|--------------|-------------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                          | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                     | Mfg.Date   | Sep-22      |
| Stage        | INTERFERENCE FROM DEGRADANTS-ALKALI DEGRADATION | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                            |              |            |             |                  |         |            |              |                |       |
|----------------------------|--------------|------------|-------------|------------------|---------|------------|--------------|----------------|-------|
| Instrument ID:             | ST/QC/EQ/039 |            | Balance ID: | ST/QC/EQ/041&030 |         | WS No.:    | ST/WS/22/011 | % Purity (aib) | 100.0 |
| Standard dilution.:        | 65.97        | mg to ---> | 100         | ml to --->       | 5       | ml to ---> | 50           |                |       |
| Std.conc (in ppm)-65.97    | 1            | ml to ---> | 1           | ml to --->       | 1       | ml to ---> | 1            |                |       |
|                            |              |            |             |                  |         |            |              |                |       |
| Test dilution .:           | Granule/Pow. | mg to ---> | 500         | ml to --->       | 5       | ml to ---> | 100          |                |       |
| Test conc(in ppm)-65.09388 | 1            | ml to ---> | 1           | ml to --->       | 1       | ml to ---> | 1            |                |       |
| Conversion factor :        | 1.0000       | mg         |             |                  |         |            |              |                |       |
| Labeled claim :            | 650          |            |             |                  |         |            |              |                |       |
| Average weight :           | 4500         |            |             |                  |         |            |              |                |       |
| System suitability         | 1            | 2          | 3           | 4                | 5       | MEAN       | S.D          | RSD in %       |       |
| Paracetamol                | 5227452      | 5315468    | 5326120     | 5316446          | 5310656 | 5299228    | 40515        | 0.765          |       |
| With Bracketing std.       |              |            |             |                  |         | 5299228    | 40515        | 0.765          |       |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4506.50                   | 4823630     | 599.63               | 92.3         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|                            |              |            |         |            |         |            |              |                |      |
|----------------------------|--------------|------------|---------|------------|---------|------------|--------------|----------------|------|
|                            |              |            |         |            |         | WS No.:    | IAARI/WS/344 | % Purity (aib) | 99.9 |
| Standard dilution.:        | 40.49        | mg to ---> | 200     | ml to ---> | 5       | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-20.245   | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500     | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Test conc (in ppm)-20.0288 | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Conversion factor :        | 1.0000       |            |         |            |         |            |              |                |      |
| Labeled claim :            | 10           | mg         |         |            |         |            |              |                |      |
| System suitability         | 1            | 2          | 3       | 4          | 5       | MEAN       | S.D          | RSD in %       |      |
| Phenylephrine HCL          | 1215872      | 1238018    | 1237298 | 1237587    | 1233420 | 1232439    | 9443         | 0.766          |      |
| With Bracketing std.       |              |            |         |            |         | 1232439    | 9442.8       | 0.766          |      |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4506.50                   | 766363      | 6.22                 | 62.2         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|                            |              |            |         |            |         |            |              |                |      |
|----------------------------|--------------|------------|---------|------------|---------|------------|--------------|----------------|------|
|                            |              |            |         |            |         | WS No.:    | ST/WS/22/039 | % Purity (aib) | 99.7 |
| Standard dilution.:        | 40.13        | mg to ---> | 100     | ml to ---> | 5       | ml to ---> | 50           |                |      |
| Std.conc (in ppm)-40.13    | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500     | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Test conc(in ppm)-40.05777 | 1            | ml to ---> | 1       | ml to ---> | 1       | ml to ---> | 1            |                |      |
| Conversion factor :        | 1.0000       |            |         |            |         |            |              |                |      |
| Labeled claim :            | 20           | mg         |         |            |         |            |              |                |      |
| System suitability         | 1            | 2          | 3       | 4          | 5       | MEAN       | S.D          | RSD in %       |      |
| Chlorphenamine maleate     | 2742921      | 2773527    | 2771631 | 2766508    | 2769113 | 2764740    | 12480        | 0.451          |      |
| With Bracketing std.       |              |            |         |            |         | 2764740    | 12480        | 0.451          |      |

| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
|--------------------|---------------------------|-------------|----------------------|--------------|
| 1                  | 4506.50                   | 2670451     | 19.29                | 96.5         |

Assay limit :90.0% to 110.0%

Calculation formula :

Assay in mg /Sachet =  $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$

Assay in %

Assay in mg/Sachet x 100  
Labeled claim

Analysed by : C.ALBIN JOSE  
Date : 10-11-2022

Checked by :  
Date : 10/11/2022





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                                   |            |             |
|--------------|---------------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                            | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                       | Mfg.Date   | Sep-22      |
| Stage        | INTERFERENCE FROM DEGRADANTS-PEROXIDE DEGRADATION | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains;  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                |              |             |                  |         |              |                |       |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID: | ST/QC/EQ/041&030 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|

|                            |              |            |     |            |   |            |     |
|----------------------------|--------------|------------|-----|------------|---|------------|-----|
| Standard dilution.:        | 65.97        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50  |
| Std.conc (in ppm)-65.97    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
| Test conc(in ppm)-65.14444 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

|                     |        |    |
|---------------------|--------|----|
| Conversion factor : | 1.0000 |    |
| Labeled claim :     | 650    | mg |
| Average weight :    | 4500   | mg |

|                      |         |         |         |         |         |         |       |          |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Paracetamol          | 5227452 | 5315468 | 5326120 | 5316446 | 5310656 | 5299228 | 40515 | 0.765    |
| With Bracketing std. |         |         |         |         |         | 5299228 | 40515 | 0.765    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4510.00                   | 4914110     | 610.40               | 93.9         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|         |              |                |      |
|---------|--------------|----------------|------|
| WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
|---------|--------------|----------------|------|

|                            |              |            |     |            |   |            |    |
|----------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:        | 40.49        | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-20.245   | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc (in ppm)-20.0444 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                     |        |    |
|---------------------|--------|----|
| Conversion factor : | 1.0000 |    |
| Labeled claim :     | 10     | mg |

|                      |         |         |         |         |         |         |        |          |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
| Phenylephrine HCL    | 1215872 | 1238018 | 1237298 | 1237587 | 1233420 | 1232439 | 9443   | 0.766    |
| With Bracketing std. |         |         |         |         |         | 1232439 | 9442.8 | 0.766    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4510.00                   | 1192348     | 9.66                 | 96.6         |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|         |              |                |      |
|---------|--------------|----------------|------|
| WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
|---------|--------------|----------------|------|

|                            |              |            |     |            |   |            |    |
|----------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:        | 40.13        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-40.13    | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:            | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc(in ppm)-40.08888 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                     |        |    |
|---------------------|--------|----|
| Conversion factor : | 1.0000 |    |
| Labeled claim :     | 20     | mg |

|                        |         |         |         |         |         |         |       |          |
|------------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Chlorphenamine maleate | 2742921 | 2773527 | 2771631 | 2766508 | 2769113 | 2764740 | 12480 | 0.451    |
| With Bracketing std.   |         |         |         |         |         | 2764740 | 12480 | 0.451    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4510.00                   | 2494045     | 18.01                | 90.0         |

Assay limit :90.0% to 110.0%

Calculation formula :

Assay in mg /Sachet  $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$

Assay in %  $\frac{\text{Assay in mg/Sachet} \times 100}{\text{Labeled claim}}$

Analysed by : C.ALBIN JOSE  
Date : 10-11-2022

Checked by :  
Date : 10/11/2022



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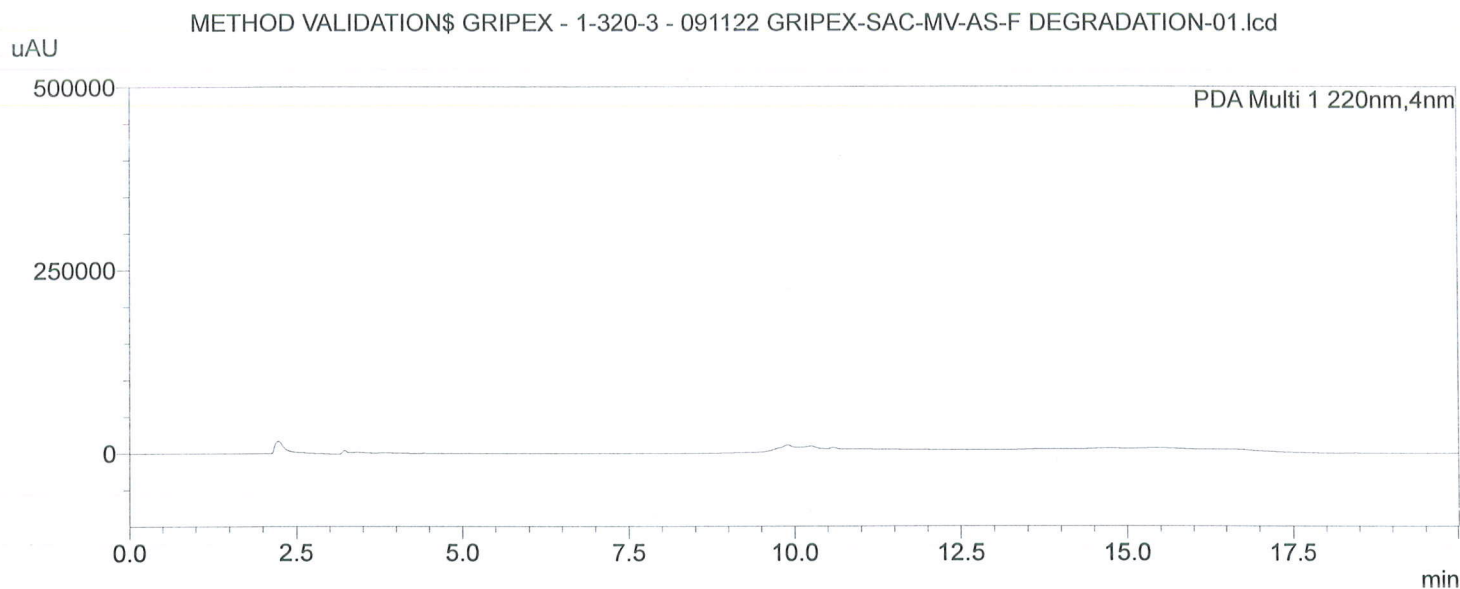
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : BLANK-AS  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-01.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-37  
Injection Volume : 50 uL  
Date Acquired : 11/9/2022 6:28:26 PM  
Date Processed : 11/10/2022 9:52:27 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :





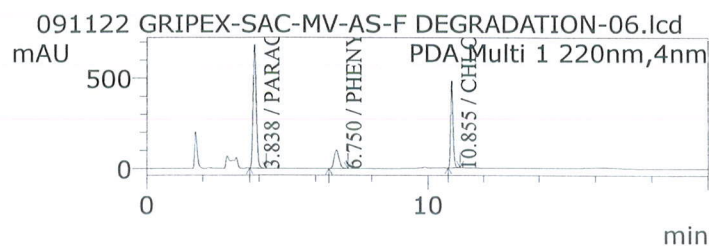
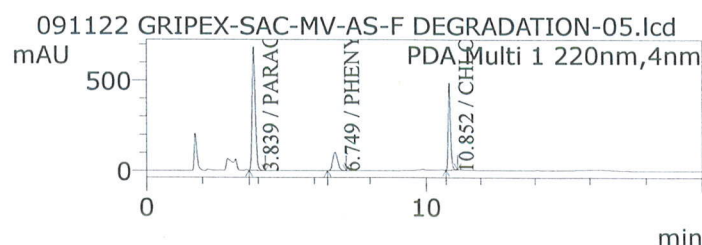
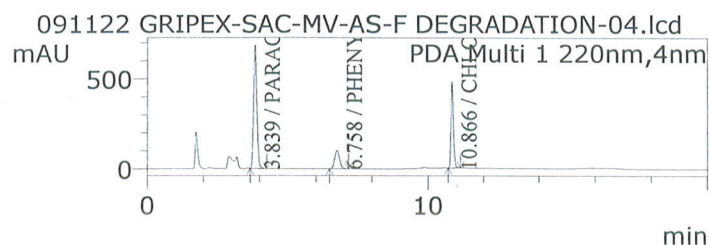
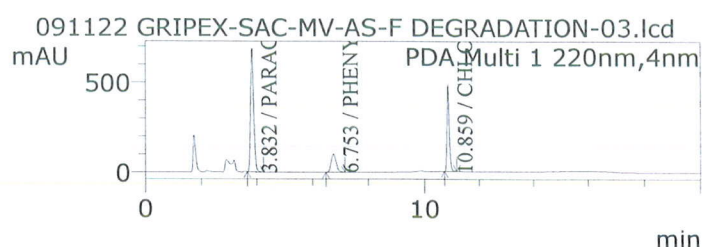
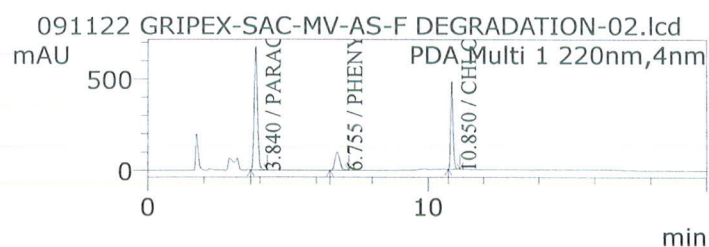
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : PARA+CPM+PHENYL-STD-01  
Tray# : 3  
Vial# : 38  
Injection Volume : 50  
Data File : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-02.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/9/2022 6:49:01 PM  
Date Processed : 11/10/2022 9:52:31 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID              | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------|--------|---------|----------|----------|
| 38    | DATION-02.lcd | PARA+CPM+PHENYL-STD-01 | 3.840  | 5227452 | 4865     | 1.240    |
| 38    | DATION-03.lcd | PARA+CPM+PHENYL-STD-02 | 3.832  | 5315468 | 4893     | 1.240    |
| 38    | DATION-04.lcd | PARA+CPM+PHENYL-STD-03 | 3.839  | 5326120 | 4847     | 1.242    |
| 38    | DATION-05.lcd | PARA+CPM+PHENYL-STD-04 | 3.839  | 5316446 | 4840     | 1.242    |
| 38    | DATION-06.lcd | PARA+CPM+PHENYL-STD-05 | 3.838  | 5310656 | 4856     | 1.244    |
|       | Average       |                        | 3.837  | 5299228 | 4860     | 1.241    |
|       | %RSD          |                        | 0.088  | 0.765   | 0.425    | 0.145    |

## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID              | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------|--------|---------|----------|----------|
| 38    | DATION-02.lcd | PARA+CPM+PHENYL-STD-01 | 6.755  | 1215872 | 6573     | 1.141    |
| 38    | DATION-03.lcd | PARA+CPM+PHENYL-STD-02 | 6.753  | 1238018 | 6539     | 1.140    |
| 38    | DATION-04.lcd | PARA+CPM+PHENYL-STD-03 | 6.758  | 1237298 | 6579     | 1.142    |
| 38    | DATION-05.lcd | PARA+CPM+PHENYL-STD-04 | 6.749  | 1237587 | 6596     | 1.143    |
| 38    | DATION-06.lcd | PARA+CPM+PHENYL-STD-05 | 6.750  | 1233420 | 6624     | 1.146    |
|       | Average       |                        | 6.753  | 1232439 | 6582     | 1.142    |
|       | %RSD          |                        | 0.052  | 0.766   | 0.479    | 0.214    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID              | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|------------------------|--------|---------|----------|----------|
| 38    | DATION-02.lcd | PARA+CPM+PHENYL-STD-01 | 10.850 | 2742921 | 66053    | 1.298    |
| 38    | DATION-03.lcd | PARA+CPM+PHENYL-STD-02 | 10.859 | 2773527 | 65388    | 1.304    |
| 38    | DATION-04.lcd | PARA+CPM+PHENYL-STD-03 | 10.866 | 2771631 | 63702    | 1.303    |
| 38    | DATION-05.lcd | PARA+CPM+PHENYL-STD-04 | 10.852 | 2766508 | 66208    | 1.305    |
| 38    | DATION-06.lcd | PARA+CPM+PHENYL-STD-05 | 10.855 | 2769113 | 63306    | 1.309    |
|       | Average       |                        | 10.856 | 2764740 | 64932    | 1.304    |
|       | %RSD          |                        | 0.057  | 0.451   | 2.073    | 0.293    |

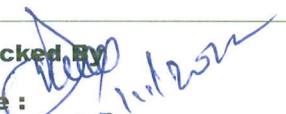
Analysed By

Date :


  
10/11/22

Checked By

Date :


  
10/11/22





# Safetab Life Science

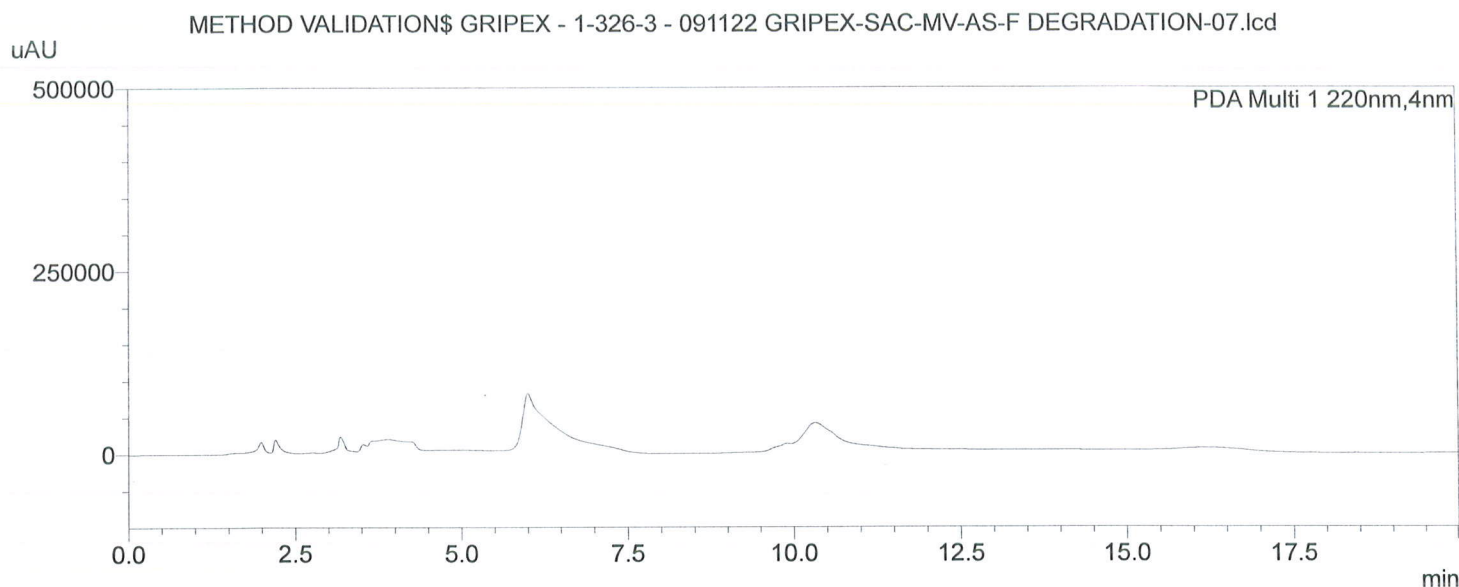
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : BLANK-AS  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-07.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-39  
Injection Volume : 50 uL  
Date Acquired : 11/9/2022 8:31:57 PM  
Date Processed : 11/10/2022 9:52:42 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



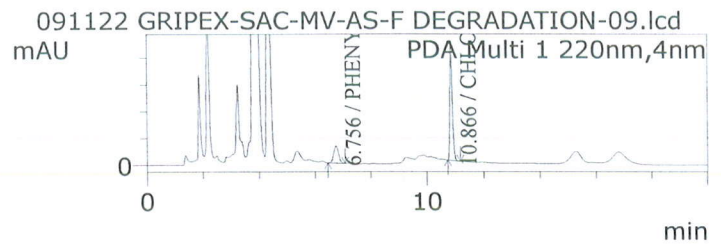
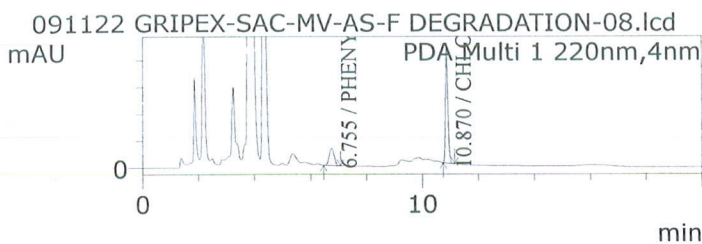
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Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-ACID DEGRA-SOL-A-01  
Tray# : 3  
Vial# : 40  
Injection Volume : 50  
Data File : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-08.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/9/2022 8:52:32 PM  
Date Processed : 11/10/2022 10:07:32 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

| Vial# | Title         | Sample ID                     | R.Time | Area   | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|--------|----------|----------|
| 40    | DATION-08.lcd | GRIPEX-MV-ACID DEGRA-SOL-A-01 | 6.755  | 796502 | 6459     | 1.049    |
| 40    | DATION-09.lcd | GRIPEX-MV-ACID DEGRA-SOL-A-02 | 6.756  | 793410 | 6489     | 1.049    |
|       | Average       |                               | 6.755  | 794956 | 6474     | 1.049    |
|       | %RSD          |                               | 0.004  | 0.275  | 0.325    | 0.049    |

ID#2 Compound Name: CHLORPHENAMINE MALEATE

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 40    | DATION-08.lcd | GRIPEX-MV-ACID DEGRA-SOL-A-01 | 10.870 | 2617780 | 62270    | 1.239    |
| 40    | DATION-09.lcd | GRIPEX-MV-ACID DEGRA-SOL-A-02 | 10.866 | 2630339 | 60850    | 1.256    |
|       | Average       |                               | 10.868 | 2624059 | 61560    | 1.248    |
|       | %RSD          |                               | 0.022  | 0.338   | 1.631    | 0.967    |

Analysed By

Date :

Checked By

Date :





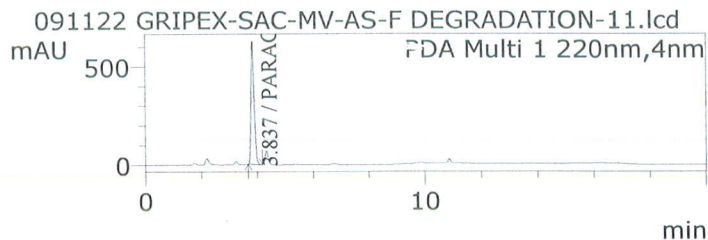
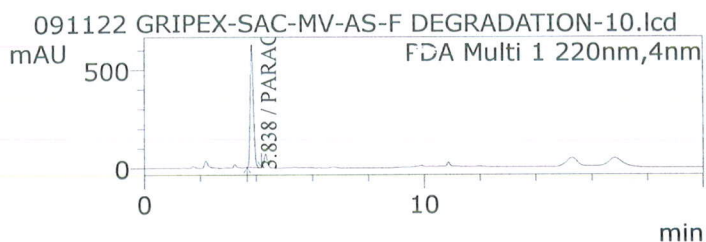
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-ACID DEGRA-SOL-B-01  
Tray# : 3  
Vial# : 41  
Injection Volume : 50  
Data File : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-10.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/9/2022 9:33:41 PM  
Date Processed : 11/10/2022 10:10:32 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                     | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|-------------------------------|--------|---------|----------|----------|
| 41    | DATION-10.lcd | GRIPEX-MV-ACID DEGRA-SOL-B-01 | 3.838  | 4908826 | 4791     | 1.248    |
| 41    | DATION-11.lcd | GRIPEX-MV-ACID DEGRA-SOL-B-02 | 3.837  | 4915557 | 4790     | 1.244    |
|       | Average       |                               | 3.838  | 4912191 | 4790     | 1.246    |
|       | %RSD          |                               | 0.021  | 0.097   | 0.010    | 0.257    |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

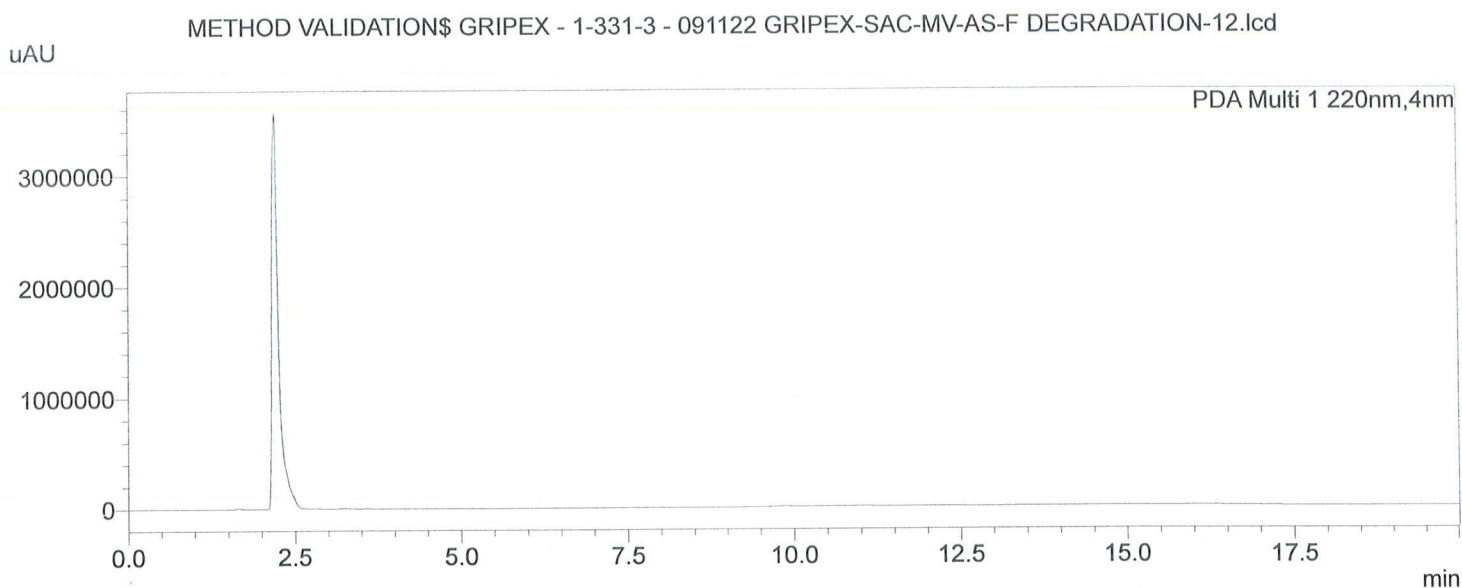
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : BLANK-AS  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-12.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-42  
Injection Volume : 50 uL  
Date Acquired : 11/9/2022 10:14:51 PM  
Date Processed : 11/10/2022 9:52:47 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plake | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :





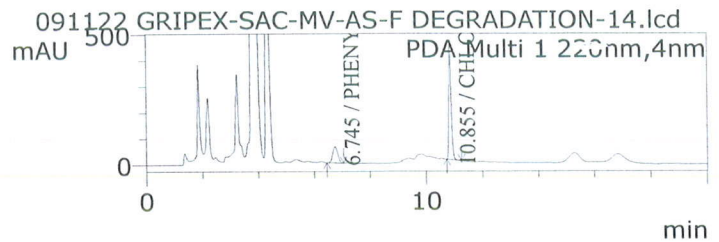
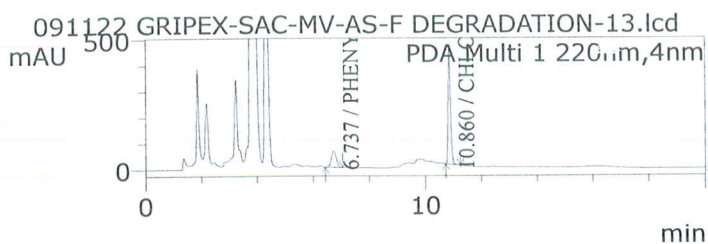
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-ALKALI DEGRA-SOL-A-01  
Tray# : 3  
Vial# : 43  
Injection Volume : 50  
Data File : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-13.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/9/2022 10:35:25 PM  
Date Processed : 11/10/2022 10:08:18 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE HCL

| Vial# | Title         | Sample ID                       | R.Time | Area   | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|--------|----------|----------|
| 43    | DATION-13.lcd | GRIPEX-MV-ALKALI DEGRA-SOL-A-01 | 6.737  | 764302 | 6521     | 1.054    |
| 43    | DATION-14.lcd | GRIPEX-MV-ALKALI DEGRA-SOL-A-02 | 6.745  | 768425 | 6516     | 1.050    |
|       | Average       |                                 | 6.741  | 766363 | 6519     | 1.052    |
|       | %RSD          |                                 | 0.079  | 0.380  | 0.047    | 0.275    |

ID#2 Compound Name: CHLORPHENAMINE MALEATE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 43    | DATION-13.lcd | GRIPEX-MV-ALKALI DEGRA-SOL-A-01 | 10.860 | 2672910 | 63573    | 1.279    |
| 43    | DATION-14.lcd | GRIPEX-MV-ALKALI DEGRA-SOL-A-02 | 10.855 | 2667991 | 61847    | 1.274    |
|       | Average       |                                 | 10.858 | 2670451 | 62710    | 1.276    |
|       | %RSD          |                                 | 0.029  | 0.130   | 1.947    | 0.289    |

Analysed By

Date :

Checked By

Date :



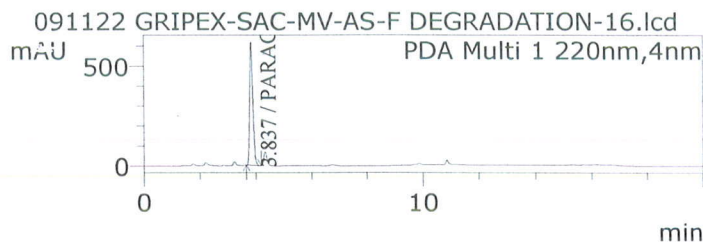
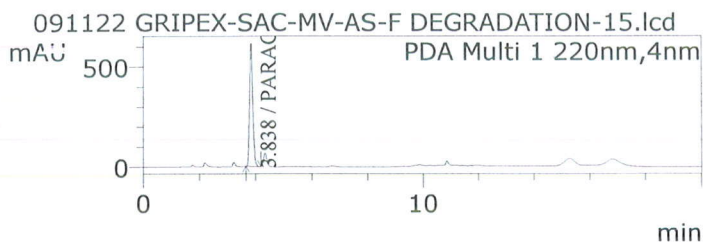
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-ALKALI DEGRA-SOL-B-01  
Tray# : 3  
Vial# : 44  
Injection Volume : 50  
Data File : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-15.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/9/2022 11:16:37 PM  
Date Processed : 11/10/2022 10:10:37 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 44    | DATION-15.lcd | GRIPEX-MV-ALKALI DEGRA-SOL-B-01 | 3.838  | 4823268 | 4781     | 1.251    |
| 44    | DATION-16.lcd | GRIPEX-MV-ALKALI DEGRA-SOL-B-02 | 3.837  | 4823991 | 4797     | 1.249    |
|       | Average       |                                 | 3.838  | 4823630 | 4789     | 1.250    |
|       | %RSD          |                                 | 0.018  | 0.011   | 0.239    | 0.151    |

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Date :

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Date :





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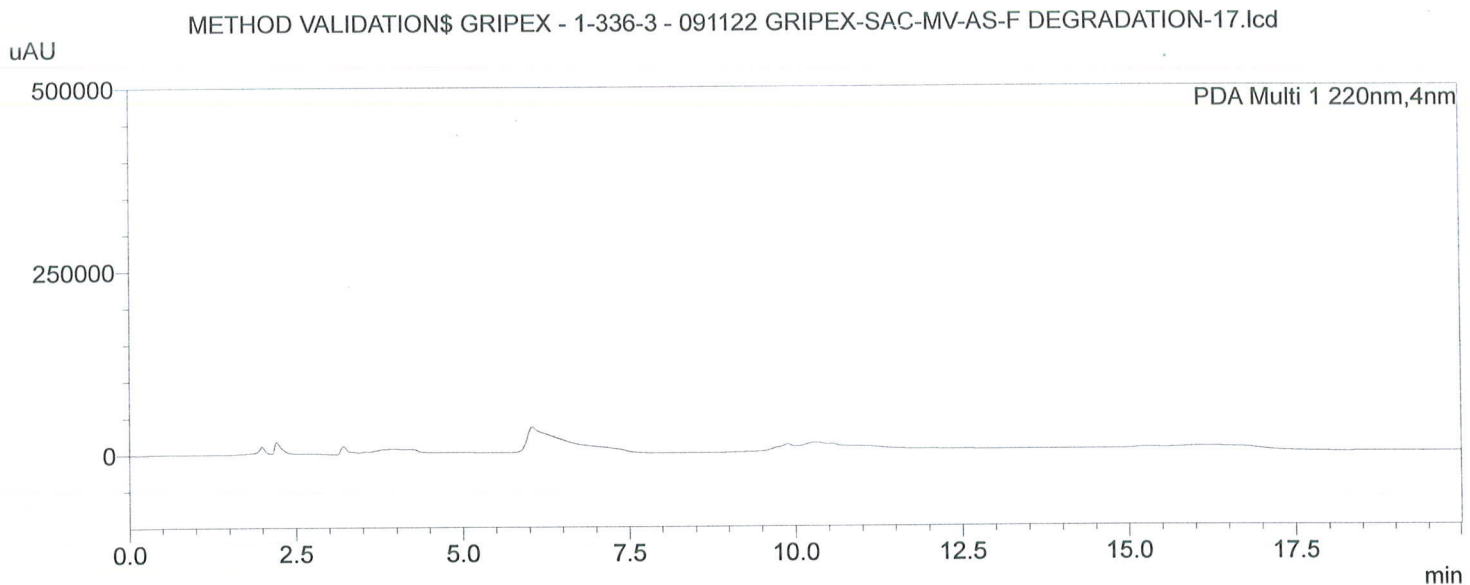
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : BLANK-AS  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-17.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-45  
Injection Volume : 50 uL  
Date Acquired : 11/9/2022 11:57:53 PM  
Date Processed : 11/10/2022 9:52:45 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plake | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

Checked By

Date :



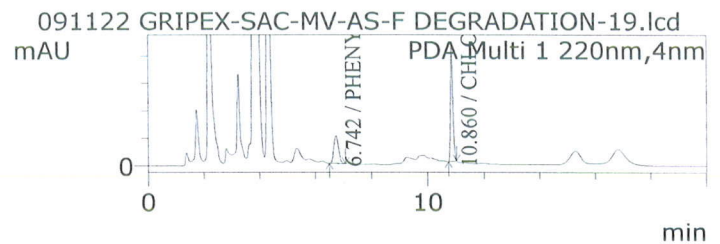
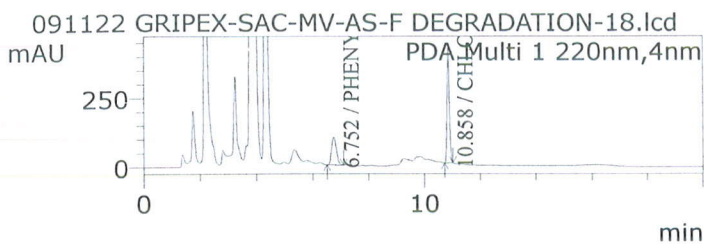
# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-PEROXI DEGRA-SOL-A-01  
Tray# : 3  
Vial# : 46  
Injection Volume : 50  
Data File : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-18.lcd  
Method File : GRIPEX-AS-A\_p.lcm  
Batch File : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/10/2022 12:18:29 AM  
Date Processed : 11/10/2022 11:31:06 AM



<< PDA >>

ID#1 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 46    | DATION-18.lcd | GRIPEX-MV-PEROXI DEGRA-SOL-A-01 | 6.752  | 1192466 | 6926     | 1.137    |
| 46    | DATION-19.lcd | GRIPEX-MV-PEROXI DEGRA-SOL-A-02 | 6.742  | 1192231 | 6912     | 1.138    |
|       | Average       |                                 | 6.747  | 1192348 | 6919     | 1.138    |
|       | %RSD          |                                 | 0.103  | 0.014   | 0.140    | 0.062    |

ID#2 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 46    | DATION-18.lcd | GRIPEX-MV-PEROXI DEGRA-SOL-A-01 | 10.858 | 2492416 | 63587    | 1.249    |
| 46    | DATION-19.lcd | GRIPEX-MV-PEROXI DEGRA-SOL-A-02 | 10.860 | 2495674 | 64595    | 1.265    |
|       | Average       |                                 | 10.859 | 2494045 | 64091    | 1.257    |
|       | %RSD          |                                 | 0.014  | 0.092   | 1.113    | 0.887    |

Analysed By

Date :

Checked By

Date :





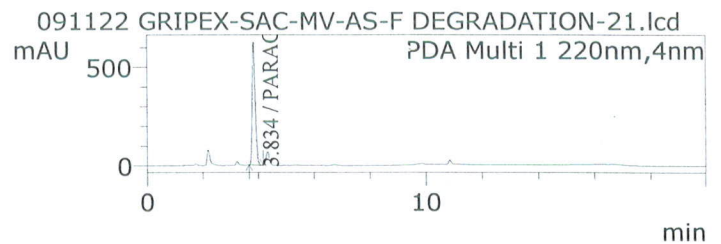
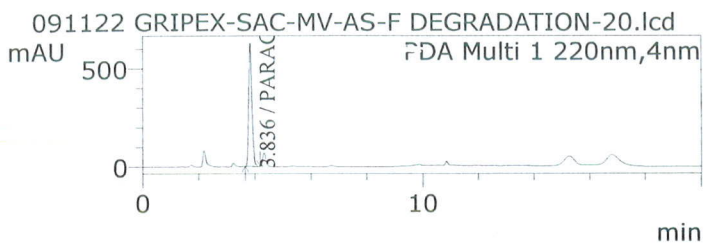
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Puducherry- 605 107

## Quality control Department

### Sample Information

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-PEROXI DEGRA-SOL-B-01  
Tray# : 3  
Vial# : 47  
Injection Volume : 50  
Data File : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-20.lcd  
Method File : GRIPEX-AS-B\_p.lcm  
Batch File : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 11/10/2022 12:59:41 AM  
Date Processed : 11/10/2022 10:10:42 AM



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 47    | DATION-20.lcd | GRIPEX-MV-PEROXI DEGRA-SOL-B-01 | 3.836  | 4922507 | 4794     | 1.241    |
| 47    | DATION-21.lcd | GRIPEX-MV-PEROXI DEGRA-SOL-B-02 | 3.834  | 4905713 | 4813     | 1.239    |
|       | Average       |                                 | 3.835  | 4914110 | 4803     | 1.240    |
|       | %RSD          |                                 | 0.034  | 0.242   | 0.284    | 0.108    |

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Date :

Checked By

Date :



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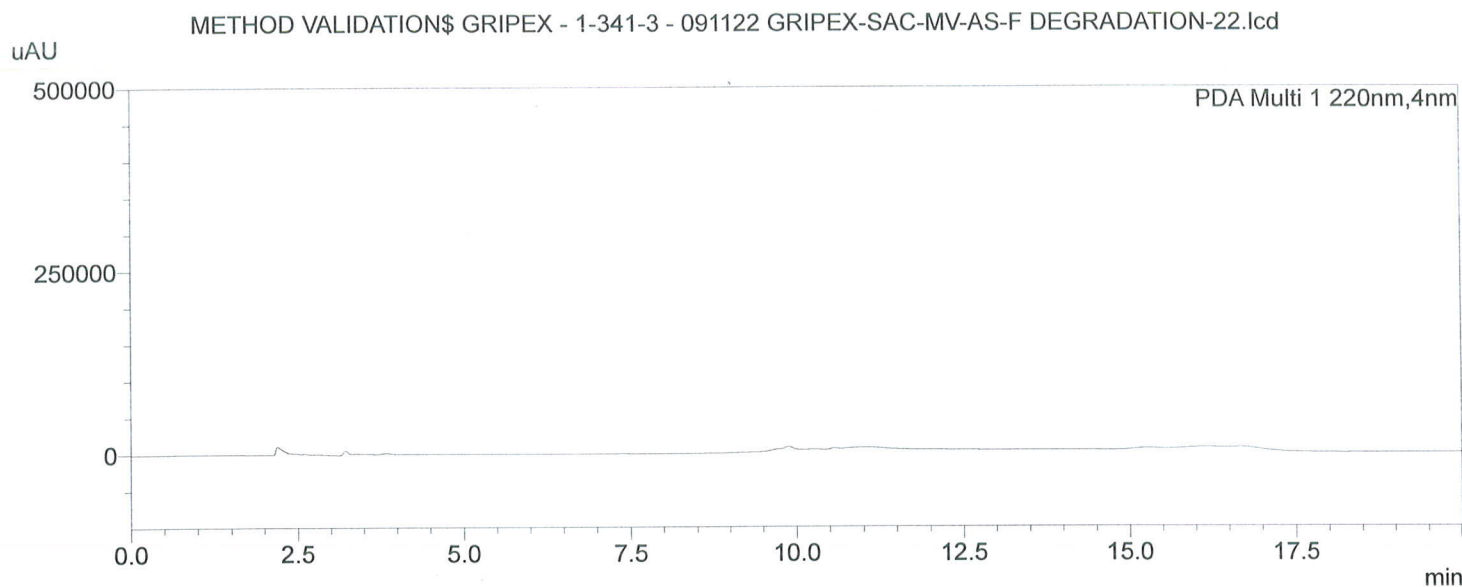
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : BLANK-AS  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-22.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-37  
Injection Volume : 50 uL  
Date Acquired : 11/10/2022 1:40:53 AM  
Date Processed : 11/10/2022 9:52:49 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

*[Signature]*  
10/11/22

Checked By

Date :

*[Signature]*  
10/11/22



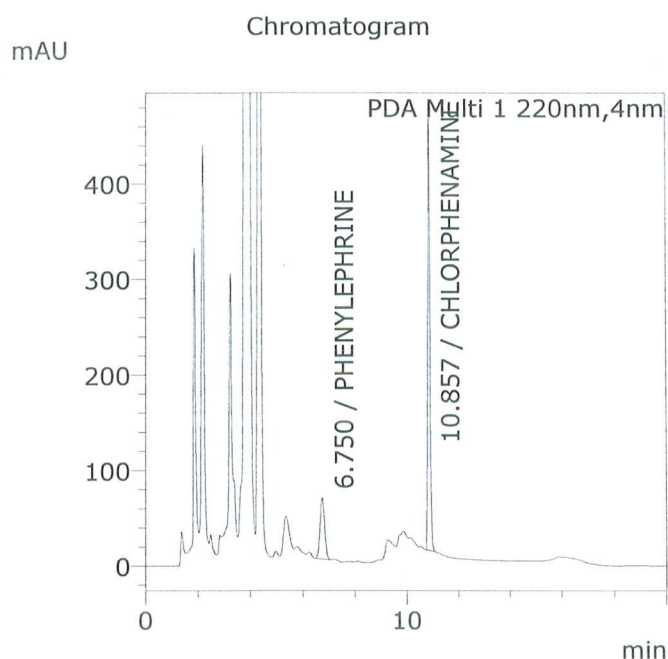


## Quality control Department

### <Sample Information>

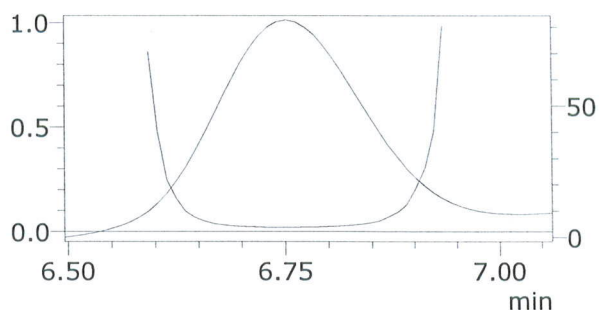
Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-ACID DEGRA-SOL-A  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-23.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-40  
Injection Volume : 50 uL  
Date Acquired : 11/10/2022 2:01:31 AM  
Date Processed : 11/10/2022 10:42:29 AM

### <Chromatogram>



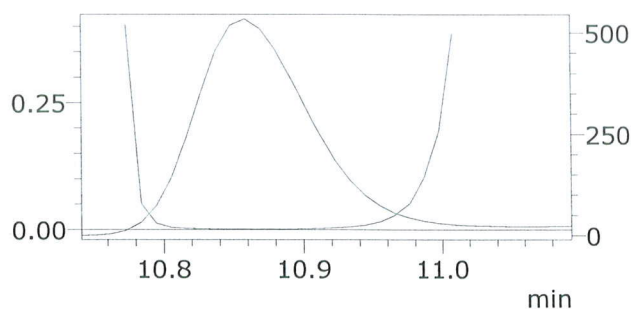
#### PeakPurity

ID# : 1  
Retention Time : 6.750 min  
Compound Name : PHENYLEPHRINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.980501  
Minimum peak purity index : 19499

ID# : 2  
Retention Time : 10.857 min  
Compound Name : CHLORPHENAMINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.998932  
Minimum peak purity index : 1067

<Peak purity table>

| Peak Table    |           |                   |                        |                |
|---------------|-----------|-------------------|------------------------|----------------|
| PDA Ch1 220nm |           |                   |                        |                |
| Peak#         | Ret. Time | Peak Purity Index | Single Point Threshold | Name           |
| 1             | 6.750     | 1.000000          | 0.980501               | PHENYLEPHRINE  |
| 2             | 10.857    | 1.000000          | 0.998932               | CHLORPHENAMINE |
| Total         |           |                   |                        |                |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

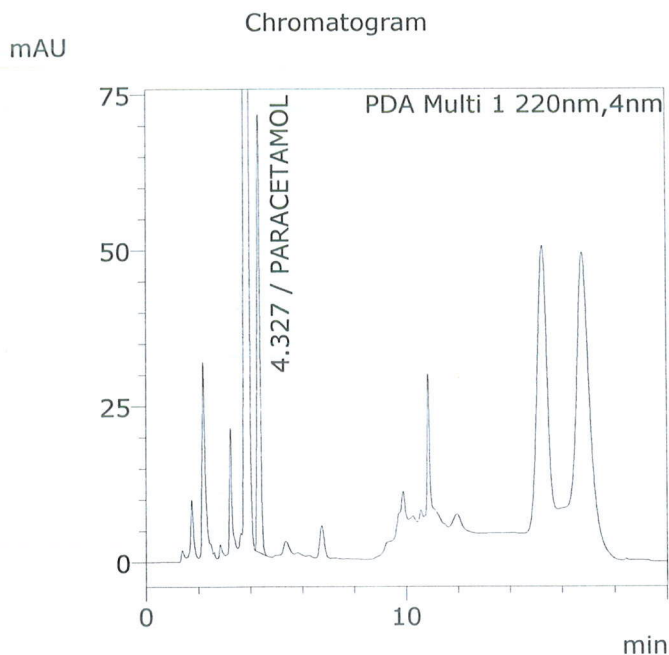
Puducherry- 605 107

## Quality control Department

### <Sample Information>

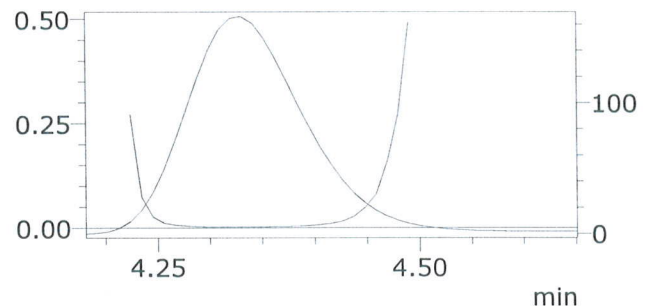
Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-ACID DEGRA-SOL-B  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-24.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-41  
Injection Volume : 50 uL  
Date Acquired : 11/10/2022 2:22:07 AM  
Date Processed : 11/10/2022 10:44:14 AM

### <Chromatogram>



### PeakPurity

ID# : 1  
Retention Time : 4.327 min  
Compound Name : PARACETAMOL



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.998025  
Minimum peak purity index : 1974

### <Peak purity table>

Peak Table

PDA Ch1 220nm

| Peak# | Ret. Time | Peak Purity Index | Single Point Threshold | Name        |
|-------|-----------|-------------------|------------------------|-------------|
| 1     | 4.327     | 1.000000          | 0.998025               | PARACETAMOL |
| Total |           |                   |                        |             |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

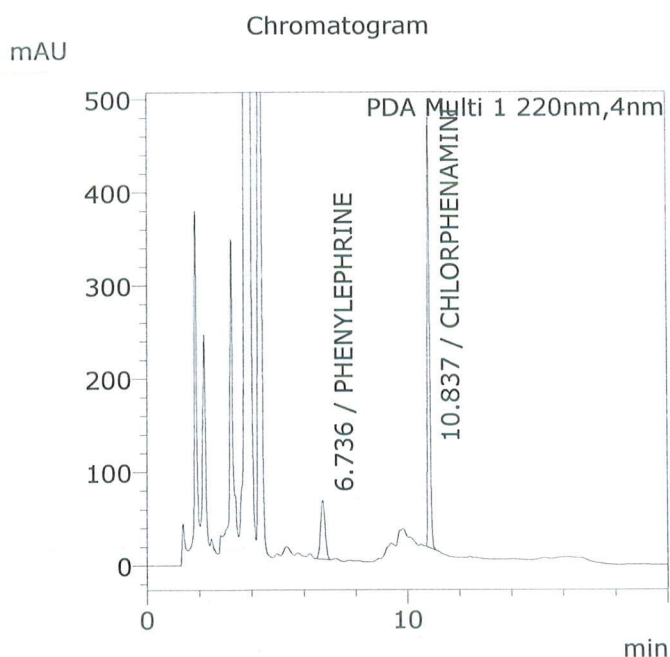
Puducherry- 605 107

## Quality control Department

### <Sample Information>

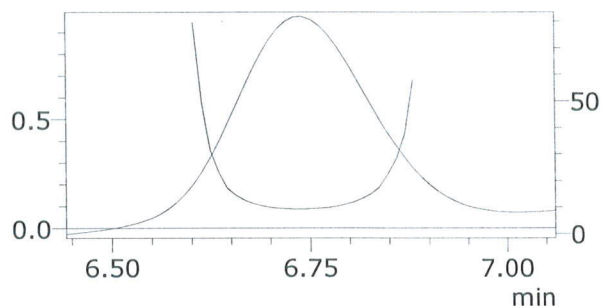
Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-ALKALI DEGRA-SOL-A  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-25.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-43  
Injection Volume : 50 uL  
Date Acquired : 11/10/2022 2:42:42 AM  
Date Processed : 11/10/2022 10:46:50 AM

### <Chromatogram>



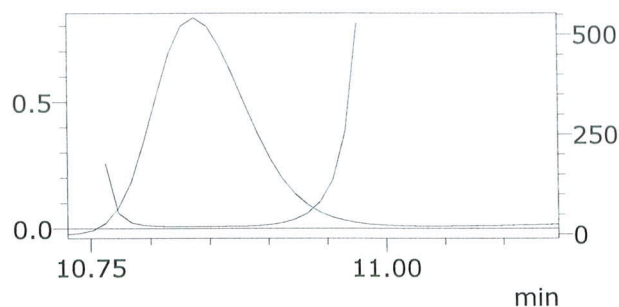
#### PeakPurity

ID# : 1  
Retention Time : 6.736 min  
Compound Name : PHENYLEPHRINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.913445  
Minimum peak purity index : 86554

ID# : 2  
Retention Time : 10.837 min  
Compound Name : CHLORPHENAMINE



Impurity : Not Detected  
Peak purity index : 0.999999  
Single point threshold : 0.992606  
Minimum peak purity index : 7393



<Peak purity table>

Peak Table

PDA Ch1 220nm

| Peak # | Ret. Time | Peak Purity Index | Single Point Threshold | Name           |
|--------|-----------|-------------------|------------------------|----------------|
| 1      | 6.736     | 1.000000          | 0.913445               | PHENYLEPHRINE  |
| 2      | 10.837    | 0.999999          | 0.992606               | CHLORPHENAMINE |
| Total  |           |                   |                        |                |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

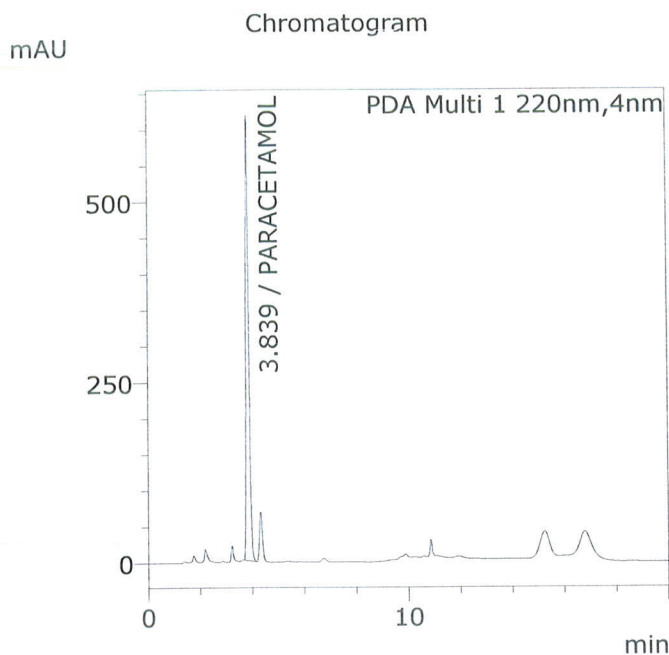
Puducherry- 605 107

## Quality control Department

### <Sample Information>

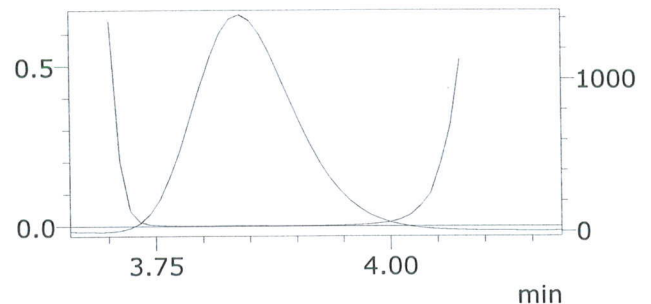
Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-ALKALI DEGRA-SOL-B  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-26.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-44  
Injection Volume : 50 uL  
Date Acquired : 11/10/2022 3:03:18 AM  
Date Processed : 11/10/2022 10:48:12 AM

### <Chromatogram>



### PeakPurity

ID# : 1  
Retention Time : 3.839 min  
Compound Name : PARACETAMOL



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.999176  
Minimum peak purity index : 824

### <Peak purity table>

Peak Table

PDA Ch1 220nm

| Peak# | Ret. Time | Peak Purity Index | Single Point Threshold | Name        |
|-------|-----------|-------------------|------------------------|-------------|
| 1     | 3.839     | 1.000000          | 0.999176               | PARACETAMOL |
| Total |           |                   |                        |             |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

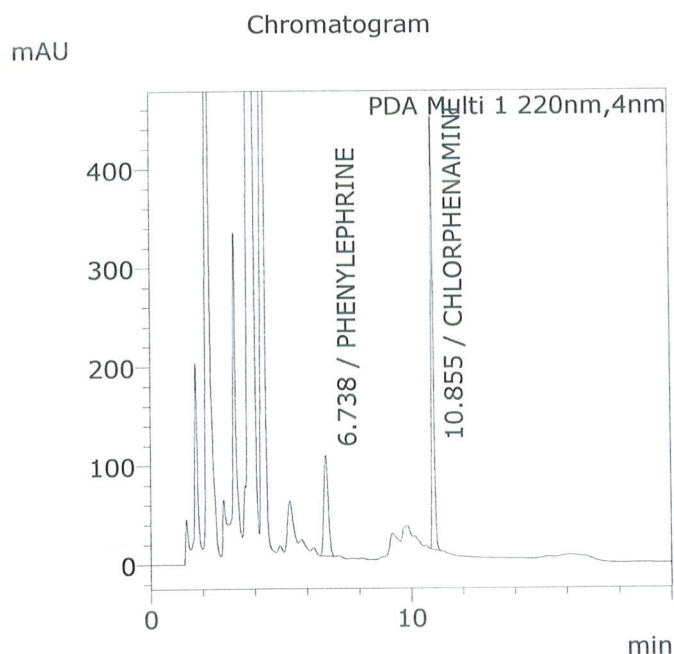
Puducherry- 605 107

## Quality control Department

### <Sample Information>

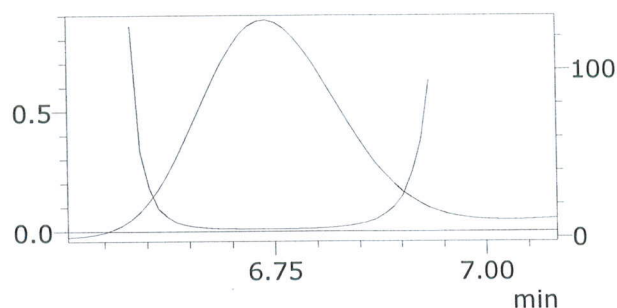
Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-PEROXI DEGRA-SOL-A  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-27.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-46  
Injection Volume : 50 uL  
Date Acquired : 11/10/2022 3:23:54 AM  
Date Processed : 11/10/2022 10:49:55 AM

### <Chromatogram>



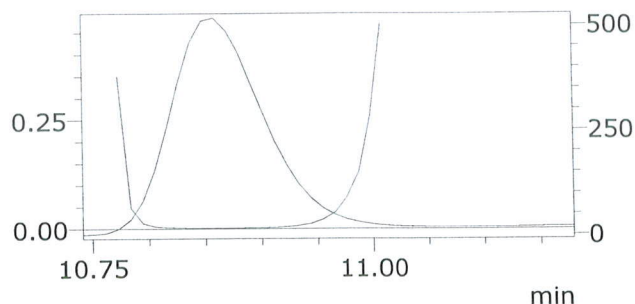
#### PeakPurity

ID# : 1  
Retention Time : 6.738 min  
Compound Name : PHENYLEPHRINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.990317  
Minimum peak purity index : 9682

ID# : 2  
Retention Time : 10.855 min  
Compound Name : CHLORPHENAMINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.998701  
Minimum peak purity index : 1299

<Peak purity table>

Peak Table

PDA Ch1 220nm

| Peak# | Ret. Time | Peak Purity Index | Single Point Threshold | Name           |
|-------|-----------|-------------------|------------------------|----------------|
| 1     | 6.738     | 1.000000          | 0.990317               | PHENYLEPHRINE  |
| 2     | 10.855    | 1.000000          | 0.998701               | CHLORPHENAMINE |
| Total |           |                   |                        |                |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

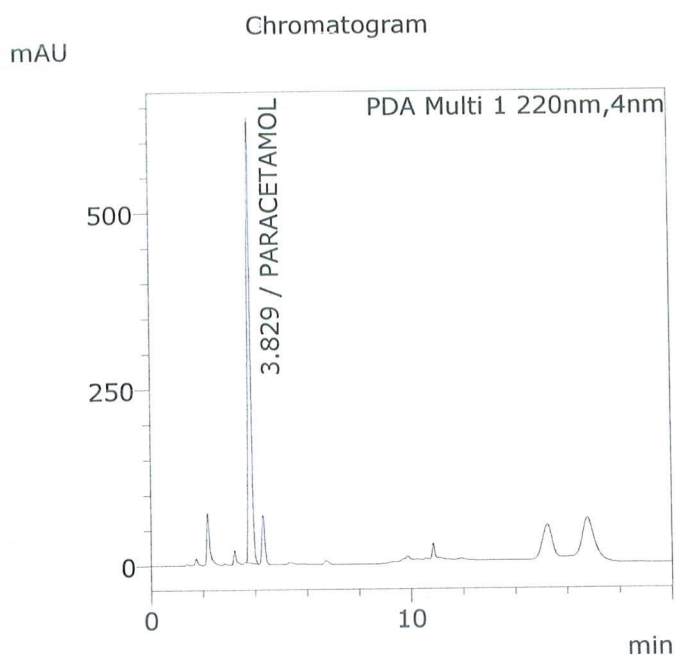
Puducherry- 605 107

## Quality control Department

### <Sample Information>

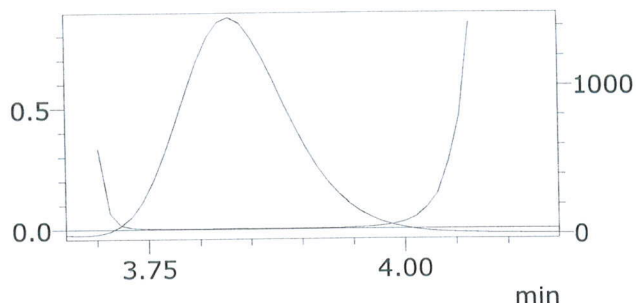
Acquired by : C.Albin Jose  
Sample Name : DEGRADATION-AS  
Sample ID : GRIPEX-MV-PEROXI DEGRA-SOL-B  
Data Filename : 091122 GRIPEX-SAC-MV-AS-F DEGRADATION-28.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 091122 GRIPEX-SAC-MV-AS-FORCED DEGRADATION.lcb  
Vial # : 3-47  
Injection Volume : 50 uL  
Date Acquired : 11/10/2022 3:44:30 AM  
Date Processed : 11/10/2022 10:51:37 AM

### <Chromatogram>



### PeakPurity

ID# : 1  
Retention Time : 3.829 min  
Compound Name : PARACETAMOL



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.998928  
Minimum peak purity index : 1071

### <Peak purity table>

Peak Table

PDA Ch1 220nm

| Peak# | Ret. Time | Peak Purity Index | Single Point Threshold | Name        |
|-------|-----------|-------------------|------------------------|-------------|
| 1     | 3.829     | 1.000000          | 0.998928               | PARACETAMOL |
| Total |           |                   |                        |             |

Analysed By

Date :

Checked By

Date :



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Puducherry- 605 107

Quality control Department

## =====BATCH TABLE=====

Batch Table

| Vial# | Tray | Inj. Vol. | Sample Name | Sample ID                       | Method File   | Data File                        | Report Format      |
|-------|------|-----------|-------------|---------------------------------|---------------|----------------------------------|--------------------|
| 37    | 3    | 50.0      | DEGRADATION | BLANK-AS                        | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-01.lcd | system\DEFAULT.isr |
| 38    | 3    | 50.0      | DEGRADATION | PARA+CPM+PHENYL-STD-01          | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-02.lcd | system\DEFAULT.isr |
| 38    | 3    | 50.0      | DEGRADATION | PARA+CPM+PHENYL-STD-02          | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-03.lcd | system\DEFAULT.isr |
| 38    | 3    | 50.0      | DEGRADATION | PARA+CPM+PHENYL-STD-03          | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-04.lcd | system\DEFAULT.isr |
| 38    | 3    | 50.0      | DEGRADATION | PARA+CPM+PHENYL-STD-04          | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-05.lcd | system\DEFAULT.isr |
| 38    | 3    | 50.0      | DEGRADATION | PARA+CPM+PHENYL-STD-05          | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-06.lcd | system\DEFAULT.isr |
| 39    | 3    | 50.0      | DEGRADATION | BLANK-AS                        | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-07.lcd | system\DEFAULT.isr |
| 40    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ACID DEGRA-SOL-A-01   | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-08.lcd | system\DEFAULT.isr |
| 40    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ACID DEGRA-SOL-A-02   | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-09.lcd | system\DEFAULT.isr |
| 41    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ACID DEGRA-SOL-B-01   | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-10.lcd | system\DEFAULT.isr |
| 41    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ACID DEGRA-SOL-B-02   | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-11.lcd | system\DEFAULT.isr |
| 42    | 3    | 50.0      | DEGRADATION | BLANK-AS                        | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-12.lcd | system\DEFAULT.isr |
| 43    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ALKALI DEGRA-SOL-A-01 | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-13.lcd | system\DEFAULT.isr |
| 43    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ALKALI DEGRA-SOL-A-02 | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-14.lcd | system\DEFAULT.isr |
| 44    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ALKALI DEGRA-SOL-B-01 | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-15.lcd | system\DEFAULT.isr |
| 44    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ALKALI DEGRA-SOL-B-02 | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-16.lcd | system\DEFAULT.isr |
| 45    | 3    | 50.0      | DEGRADATION | BLANK-AS                        | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-17.lcd | system\DEFAULT.isr |
| 46    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-PEROXI DEGRA-SOL-A-01 | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-18.lcd | system\DEFAULT.isr |
| 46    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-PEROXI DEGRA-SOL-A-02 | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-19.lcd | system\DEFAULT.isr |
| 47    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-PEROXI DEGRA-SOL-B-01 | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-20.lcd | system\DEFAULT.isr |
| 47    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-PEROXI DEGRA-SOL-B-02 | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-21.lcd | system\DEFAULT.isr |
| 37    | 3    | 50.0      | DEGRADATION | BLANK-AS                        | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-22.lcd | system\DEFAULT.isr |
| 40    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ACID DEGRA-SOL-A      | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-23.lcd | system\DEFAULT.isr |
| 41    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ACID DEGRA-SOL-B      | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-24.lcd | system\DEFAULT.isr |
| 43    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ALKALI DEGRA-SOL-A    | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-25.lcd | system\DEFAULT.isr |
| 44    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-ALKALI DEGRA-SOL-B    | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-26.lcd | system\DEFAULT.isr |
| 46    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-PEROXI DEGRA-SOL-A    | GRIPEX-AS.lcm | X-SAC-MV-AS-F DEGRADATION-27.lcd | system\DEFAULT.isr |



| Vial# | Tray | Inj. Vol. | Sample Name | Sample ID                    | Method File        | Data File                        | Report Format      |
|-------|------|-----------|-------------|------------------------------|--------------------|----------------------------------|--------------------|
| 47    | 3    | 50.0      | DEGRADATION | GRIPEX-MV-PEROXI DEGRA-SOL-B | GRIPEX-AS.lcm      | X-SAC-MV-AS-F DEGRADATION-28.lcd | system\DEFAULT.lsr |
| -1    | 3    | 50.0      | DEGRADATION | SHUT                         | HUTDOWN METHOD.lcm | X-SAC-MV-AS-F DEGRADATION-29.lcd | system\DEFAULT.lsr |

Analysed By

Date :

Signature

Checked By

Date :

Signature

Date :

|                     |               |
|---------------------|---------------|
| Name of the Product | GRIPEX SACHET |
| Batch No            | ST/T/S-1322   |

## Forced Degradation

### Std Preparation:

#### Solution A:

65.92mg Paracetamol and 40.13mg cpm in total volume. Then add total of solvent solvent to dissolve and make up to volume with solvent.

#### Sol B:

40.49mg of phenylephrine HCl in total of volume. Then add total of solvent solvent to dissolve and make up to volume with solvent.

#### Std Preparation:

Std of each solution A & B in total of volume and make up to volume with solvent.

Analyzed by :

*[Signature]*

Date : 09/11/20

Checked by :

*[Signature]*

Date :

09/11/20



**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

Page - 2

|                     |                |
|---------------------|----------------|
| Name of the Product | GRIPEX Sachets |
| Batch No            | ST/T/S-1322    |

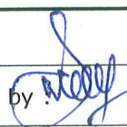
| S. No | TEST / OBSERVATION / LIMIT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | <p><u>Freeed Degradation:</u></p> <p>i) <u>Acid degradation:</u></p> <p>4.5131 gm of sample in 50ml volumetric flask added about 30ml of diluent Sonicate for 5min. Then add 5ml of 5N HCl again Sonicate for 5min. Add cool and neutralize with 5ml of 5N NaOH and makeup to volume with diluent. Filter the solution through 0.45 µm PVDF filter paper (Solution A)</p> <p>5ml of Solution (A) to 100ml volumetric flask and makeup to volume with diluent (Solution B)</p> <p>ii) <u>Alkali Degradation:</u></p> <p>4.5065 gm of sample in 50ml volumetric flask added about 30ml of diluent and Sonicate for 5min to dissolve. Then added 5ml of 5N NaOH again Sonicate for 5min. Cool and neutralize with 5ml of 5N HCl and makeup to volume with diluent. Filter the solution through 0.45 µm PVDF filter paper (Solution A)</p> <p><u>Solution B:</u></p> <p>5ml of Solution above Solution (A) in 100ml volumetric flask and makeup upto volume with diluent.</p> |

Analyzed by :



Date: 09/11/22

Checked by :



Date:

09/11/2022

|                     |                |
|---------------------|----------------|
| Name of the Product | ARIPEX SA CTS. |
| Batch No            | ST/T/S-1322    |

ii) Peroxide Degradation:

4.5700 gm of sample in 500ml volumetric flask added about 300ml of diluent and sonicate for 10 minutes. Then added 5ml of 30% Hydrogen peroxide solution again sonicate for 10 minutes. Cool and makeup to volume with diluent. Filter the solution through 0.45 µm filter paper (solution A)

Solution B:

5ml of above solution (A) in 100ml volumetric flask add makeup to volume with diluent.

Analyzed by :



Date

29/11/22

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Date :





QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|                |             |              |             |
|----------------|-------------|--------------|-------------|
| Product Name : | GRIPEX      | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322 | Mfg.Date :   | Sep-22      |
| Parameter :    | SPECIFICITY | Exp.Date :   | To be fixed |

Each 4500 mg of Sachet contains;  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE

|                |              |              |                 |         |              |                |       |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041&30 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|                |              |              |                 | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9  |
|                |              |              |                 | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7  |

|                          |         |            |     |            |   |            |    |
|--------------------------|---------|------------|-----|------------|---|------------|----|
| Paracetamol Std. Dil:    | 64.93   | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std. conc (in ppm)-64.93 | 1       | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Phenylephrine Std. Dil:  | 39.94   | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| Std. conc (in ppm)-19.97 | 1       | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Chlorphenamine Std:      | 40.28   | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std. conc (in ppm)-40.28 | 1       | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution :          | 4500.90 | mg to ---> | 200 | ml to ---> | 2 | ml to ---> | 50 |
|                          | 1       | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

| S.No. | Sample ID.                                                           | Peak Name              | Retention time | Peak purity    |
|-------|----------------------------------------------------------------------|------------------------|----------------|----------------|
| 1     | Blank                                                                | ***                    | ***            | Not applicable |
| 2     | Standard preparation                                                 | Paracetamol            | 3.801          | 1.000          |
|       |                                                                      | Phenylephrine HCL      | 6.795          | 1.000          |
|       |                                                                      | Chlorphenamine Maleate | 10.886         | 1.000          |
| 3     | Plain placebo                                                        | ***                    | ***            | Not applicable |
| 4     | Chlorphenamine Maleate                                               | Chlorphenamine Maleate | 10.889         | 1.000          |
| 5     | Phenylephrine Hcl                                                    | Phenylephrine HCL      | 6.799          | 1.000          |
| 6     | Paracetamol                                                          | Paracetamol            | 3.811          | 1.000          |
| 7     | Plain placebo with Chlorphenamine Maleate                            | Chlorphenamine Maleate | 10.889         | 1.000          |
| 8     | Plain placebo with Phenylephrine Hcl                                 | Phenylephrine HCL      | 6.781          | 1.000          |
| 9     | Plain placebo with Paracetamol                                       | Paracetamol            | 3.808          | 0.999          |
| 10    | Plain placebo with Chlorphenamine, Phenylephrine Hcl and Paracetamol | Paracetamol            | 3.811          | 1.000          |
|       |                                                                      | Phenylephrine HCL      | 6.741          | 1.000          |
|       |                                                                      | Chlorphenamine Maleate | 10.878         | 1.000          |
| 11    | Test preparation-Sol-A                                               | Phenylephrine HCL      | 6.760          | 1.000          |
|       |                                                                      | Chlorphenamine Maleate | 10.890         | 1.000          |
| 12    | Test preparation-Sol-B                                               | Paracetamol            | 3.811          | 0.999          |

Results :

- 1) Blank peaks, Placebo peaks are not interfere with Paracetamol, Phenylephrine Hydrochloride and Chlorphenamine Maleate peak in test preparation.
- 2) Peak purity passes within specified limits.

Acceptance criteria:

- 1) Should No significant interference from blank, placebo and impurity peaks.
- 2) Peak purity should not be less than 0.950 according to Lab solution software.

Analysed by :

C. ALBIN JOSE

Date :

28-10-2022

Checked by :

Date :

28/10/2022



# Safetab Life Science

Puducherry- 605 107

## Quality control Department

### <Sample Information>

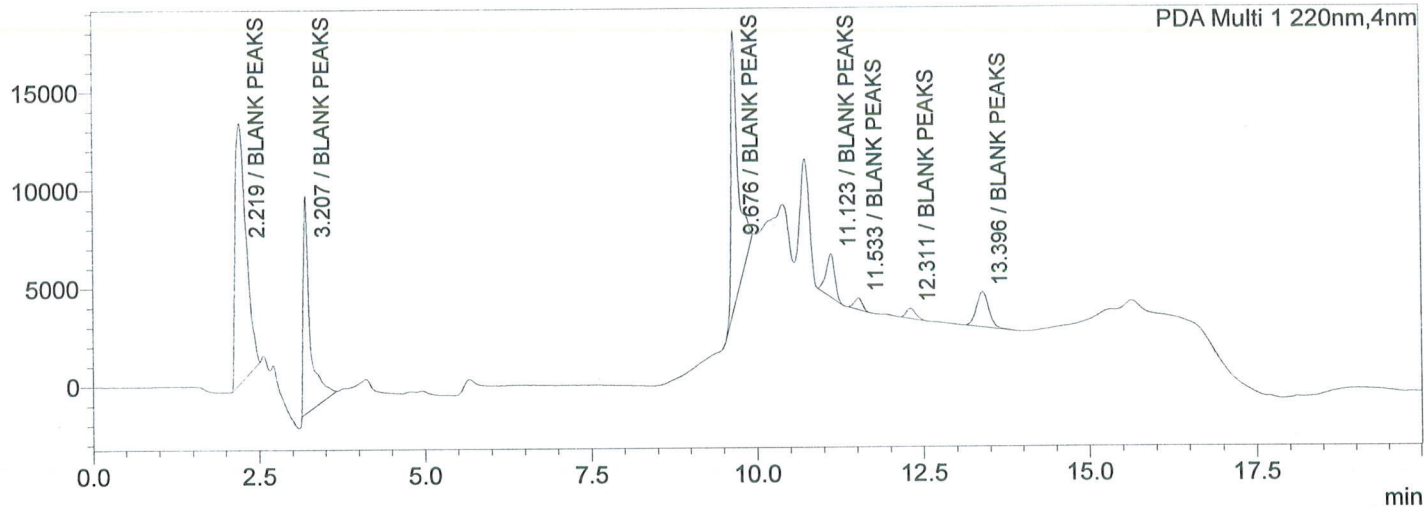
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : BLANK-AS  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-01.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-1  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 2:34:01 PM  
Date Processed : 10/28/2022 10:34:10 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-64-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-01.lcd

uAU

PDA Multi 1 220nm,4nm



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area   | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|--------|---------|---------|----------|------------|----------|-------------|
| 1     | 2.219     | 151153 | 38.750  | 869     | 1.704    | --         | --       | BLANK PEAKS |
| 2     | 3.207     | 79973  | 20.502  | 6737    | 2.884    | 4.33       | --       | BLANK PEAKS |
| 3     | 9.676     | 106363 | 27.267  | 42411   | 1.871    | 37.58      | --       | BLANK PEAKS |
| 4     | 11.123    | 19811  | 5.079   | 30844   | 0.877    | 6.56       | --       | BLANK PEAKS |
| 5     | 11.533    | 4740   | 1.215   | 37786   | 0.973    | 1.67       | --       | BLANK PEAKS |
| 6     | 12.311    | 5046   | 1.294   | 31989   | 1.277    | 3.04       | --       | BLANK PEAKS |
| 7     | 13.396    | 22989  | 5.893   | 24028   | 1.062    | 3.49       | --       | BLANK PEAKS |
| Total |           | 390074 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :





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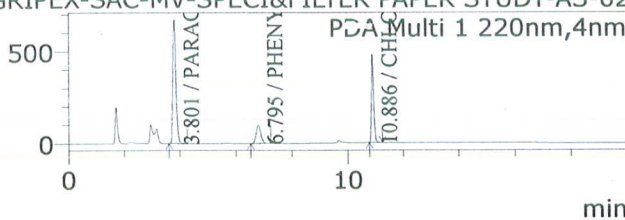
Puducherry- 605 107

## Quality control Department

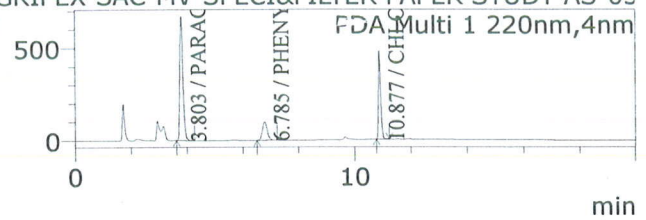
### Sample Information

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PARA+CPM+PNENYL-SPECI-AS-STD-01  
Tray# : 1  
Vial# : 2  
Injection Volume : 50  
Data File : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-02.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/27/2022 2:54:37 PM  
Date Processed : 10/28/2022 10:27:37 AM

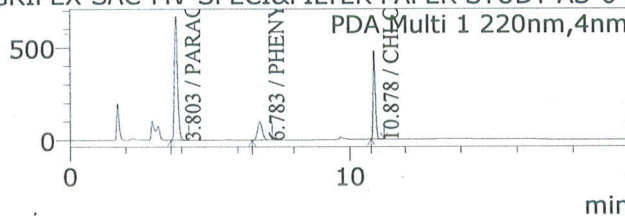
022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-02  
mAU



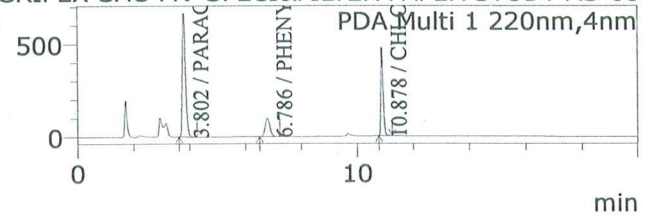
022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-03  
mAU



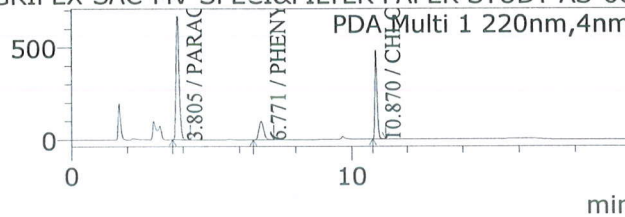
022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-04  
mAU



022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-05  
mAU



022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-06  
mAU



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 2     | JDY-AS-02.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-01 | 3.801  | 5134323 | 4957     | 1.257    |
| 2     | JDY-AS-03.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-02 | 3.803  | 5136054 | 4957     | 1.259    |
| 2     | JDY-AS-04.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-03 | 3.803  | 5137189 | 4945     | 1.262    |
| 2     | JDY-AS-05.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-04 | 3.802  | 5137500 | 4912     | 1.257    |
| 2     | JDY-AS-06.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-05 | 3.805  | 5136455 | 4936     | 1.260    |
|       | Average       |                                 | 3.803  | 5136304 | 4941     | 1.259    |
|       | %RSD          |                                 | 0.033  | 0.024   | 0.376    | 0.169    |

## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 2     | JDY-AS-02.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-01 | 6.795  | 1178545 | 7082     | 1.168    |
| 2     | JDY-AS-03.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-02 | 6.785  | 1178543 | 7053     | 1.169    |
| 2     | JDY-AS-04.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-03 | 6.783  | 1177657 | 7038     | 1.170    |
| 2     | JDY-AS-05.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-04 | 6.786  | 1178028 | 7025     | 1.170    |
| 2     | JDY-AS-06.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-05 | 6.771  | 1182528 | 6990     | 1.172    |
|       | Average       |                                 | 6.784  | 1179060 | 7038     | 1.170    |
|       | %RSD          |                                 | 0.127  | 0.167   | 0.484    | 0.124    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                       | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------------|--------|---------|----------|----------|
| 2     | JDY-AS-02.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-01 | 10.886 | 2709593 | 66197    | 1.375    |
| 2     | JDY-AS-03.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-02 | 10.877 | 2707952 | 66251    | 1.369    |
| 2     | JDY-AS-04.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-03 | 10.878 | 2708503 | 66094    | 1.371    |
| 2     | JDY-AS-05.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-04 | 10.878 | 2715046 | 65816    | 1.374    |
| 2     | JDY-AS-06.lcd | PARA+CPM+PNENYL-SPECI-AS-STD-05 | 10.870 | 2709152 | 67334    | 1.378    |
|       | Average       |                                 | 10.878 | 2710049 | 66338    | 1.374    |
|       | %RSD          |                                 | 0.053  | 0.106   | 0.876    | 0.237    |

Analysed By

Date :

Checked By

Date :





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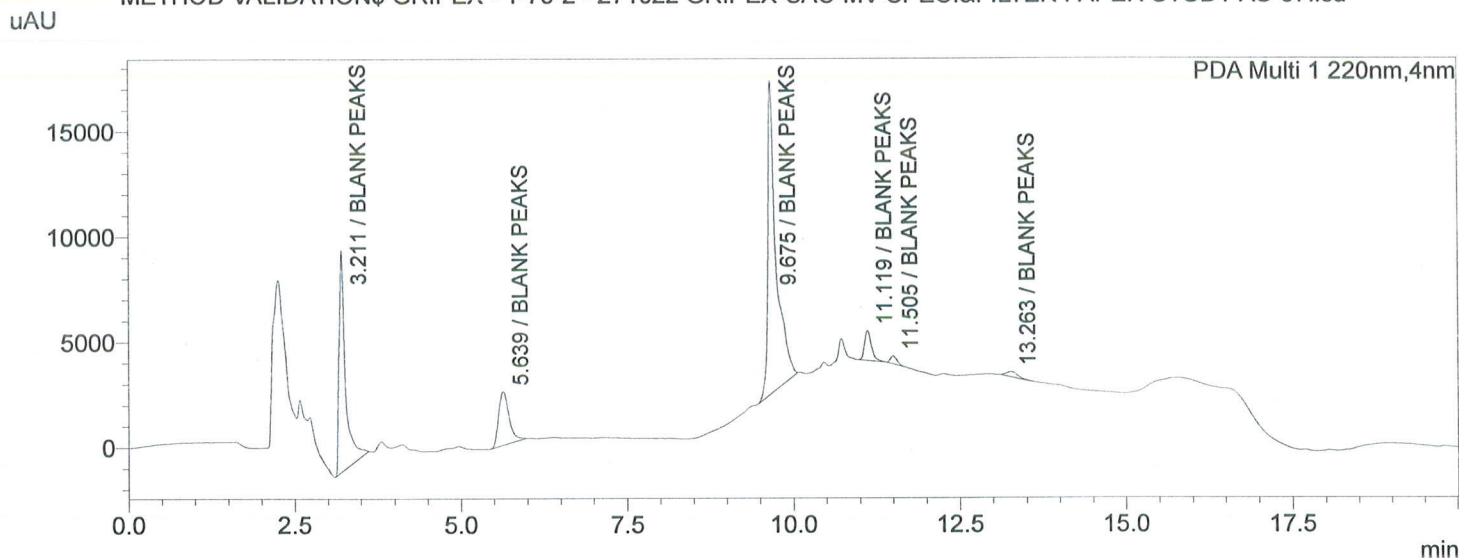
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : BLANK-AS  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-07.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-3  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 4:37:33 PM  
Date Processed : 10/28/2022 10:35:57 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-70-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-07.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area   | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|--------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.211     | 70226  | 28.809  | 5843    | 2.198    | --         | --       | BLANK PEAKS |
| 2     | 5.639     | 27926  | 11.456  | 5934    | 1.373    | 10.54      | --       | BLANK PEAKS |
| 3     | 9.675     | 130219 | 53.420  | 35935   | 1.895    | 16.24      | --       | BLANK PEAKS |
| 4     | 11.119    | 9972   | 4.091   | 48736   | 1.394    | 7.12       | --       | BLANK PEAKS |
| 5     | 11.505    | 2448   | 1.004   | 55219   | 1.392    | 1.94       | --       | BLANK PEAKS |
| 6     | 13.263    | 2973   | 1.220   | 26964   | 1.386    | 6.78       | --       | BLANK PEAKS |
| Total |           | 243763 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :



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Puducherry- 605 107

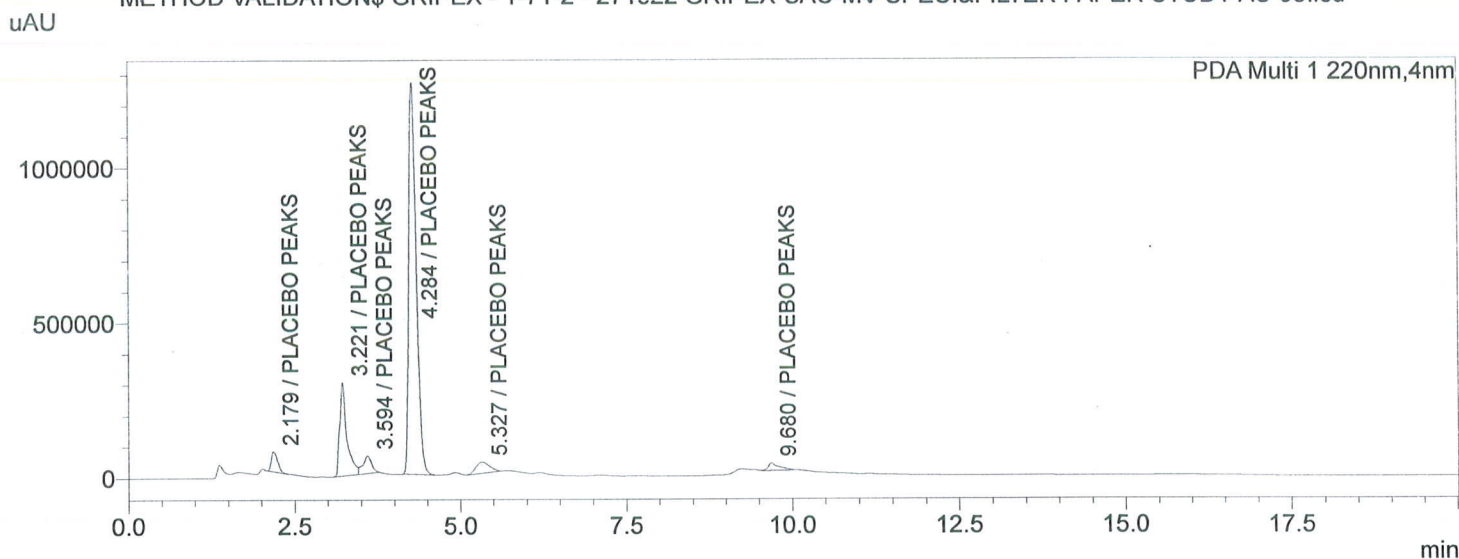
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PLAIN PLACEBO  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-08.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-4  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 4:58:09 PM  
Date Processed : 10/28/2022 11:32:07 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-71-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-08.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area     | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name          |
|-------|-----------|----------|---------|---------|----------|------------|----------|---------------|
| 1     | 2.179     | 420322   | 3.036   | 2094    | 1.490    | --         | --       | PLACEBO PEAKS |
| 2     | 3.221     | 2220014  | 16.034  | 4726    | --       | 5.52       | --       | PLACEBO PEAKS |
| 3     | 3.594     | 524831   | 3.790   | 3013    | --       | 1.66       | --       | PLACEBO PEAKS |
| 4     | 4.284     | 9885525  | 71.396  | 5984    | 1.262    | 2.85       | --       | PLACEBO PEAKS |
| 5     | 5.327     | 519780   | 3.754   | 2750    | 1.174    | 3.32       | --       | PLACEBO PEAKS |
| 6     | 9.680     | 275577   | 1.990   | 20804   | 2.058    | 12.90      | --       | PLACEBO PEAKS |
| Total |           | 13846049 | 100.000 |         |          |            |          |               |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

Puducherry- 605 107

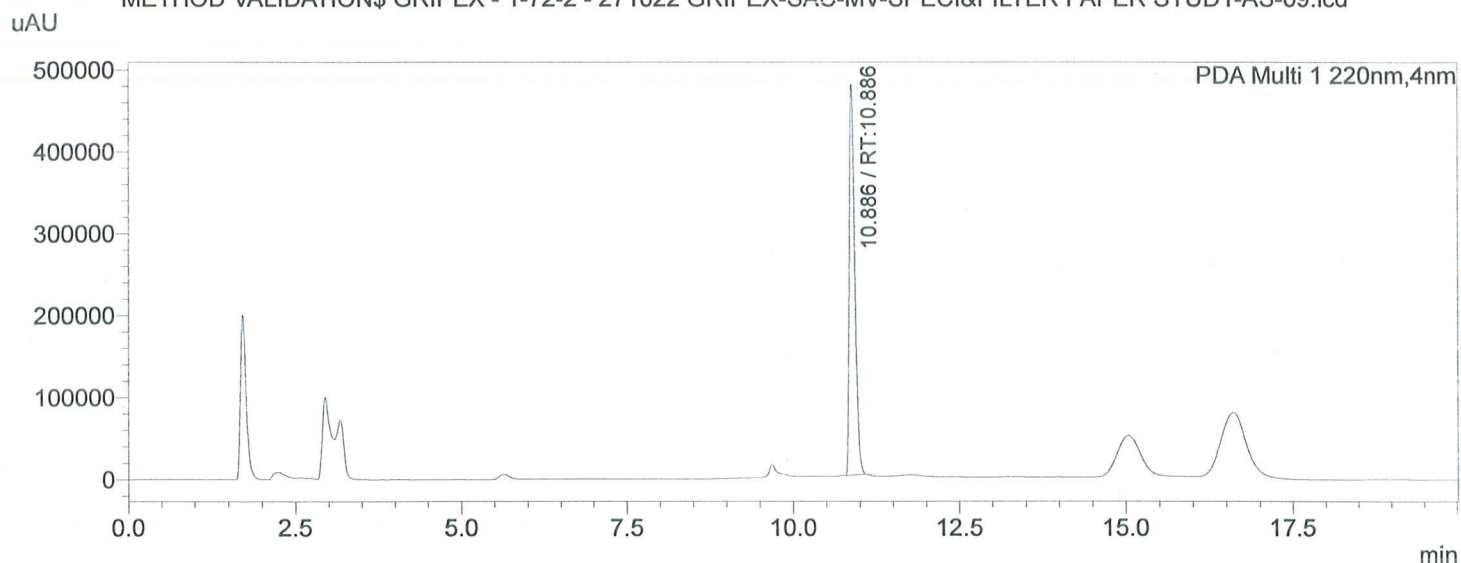
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : CHLORPHENAMINE-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-09.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-5  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 5:18:44 PM  
Date Processed : 10/28/2022 11:35:52 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-72-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-09.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name      |
|-------|-----------|---------|---------|---------|----------|------------|----------|-----------|
| 1     | 10.886    | 2711396 | 100.000 | 64840   | 1.381    | --         | --       | RT:10.886 |
| Total |           | 2711396 | 100.000 |         |          |            |          |           |

Analysed By

Date :

Checked By

Date :



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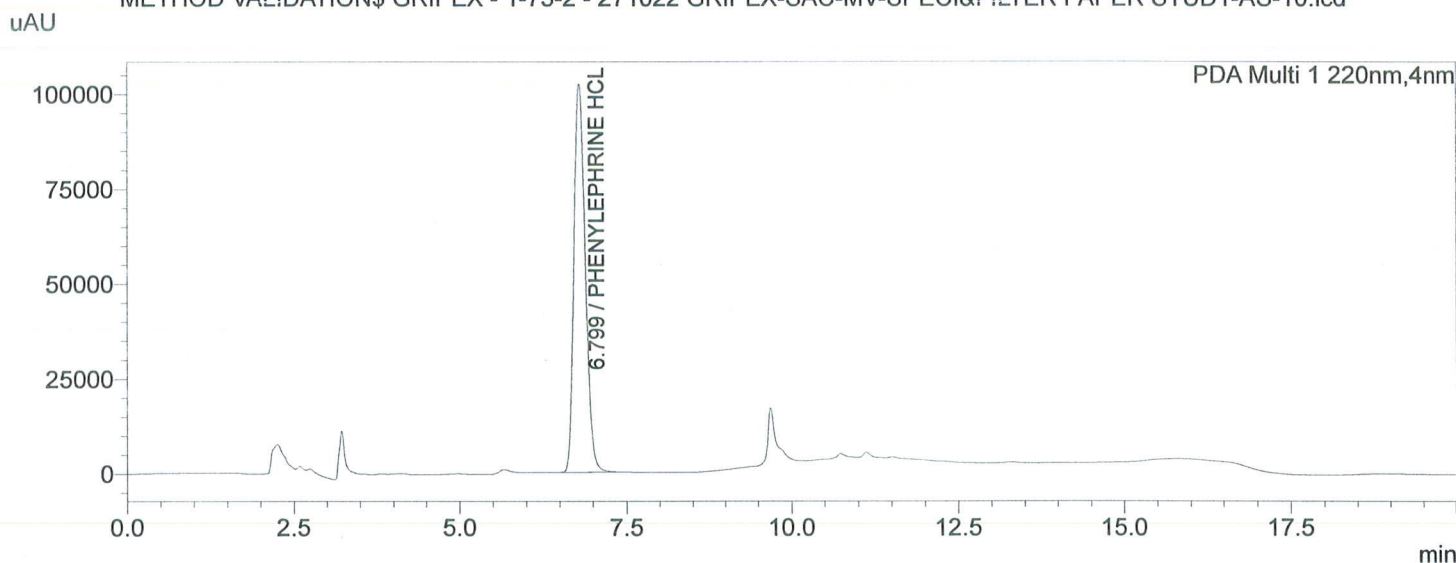
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PHENYLEPHRINE HCL-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-10.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-6  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 5:39:19 PM  
Date Processed : 10/28/2022 11:37:12 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-73-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-10.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name              |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------------|
| 1     | 6.799     | 1213589 | 100.000 | 7082    | 1.178    | --         | --       | PHENYLEPHRINE HCL |
| Total |           | 1213589 | 100.000 |         |          |            |          |                   |

Analysed By

Date :

Checked By

Date :





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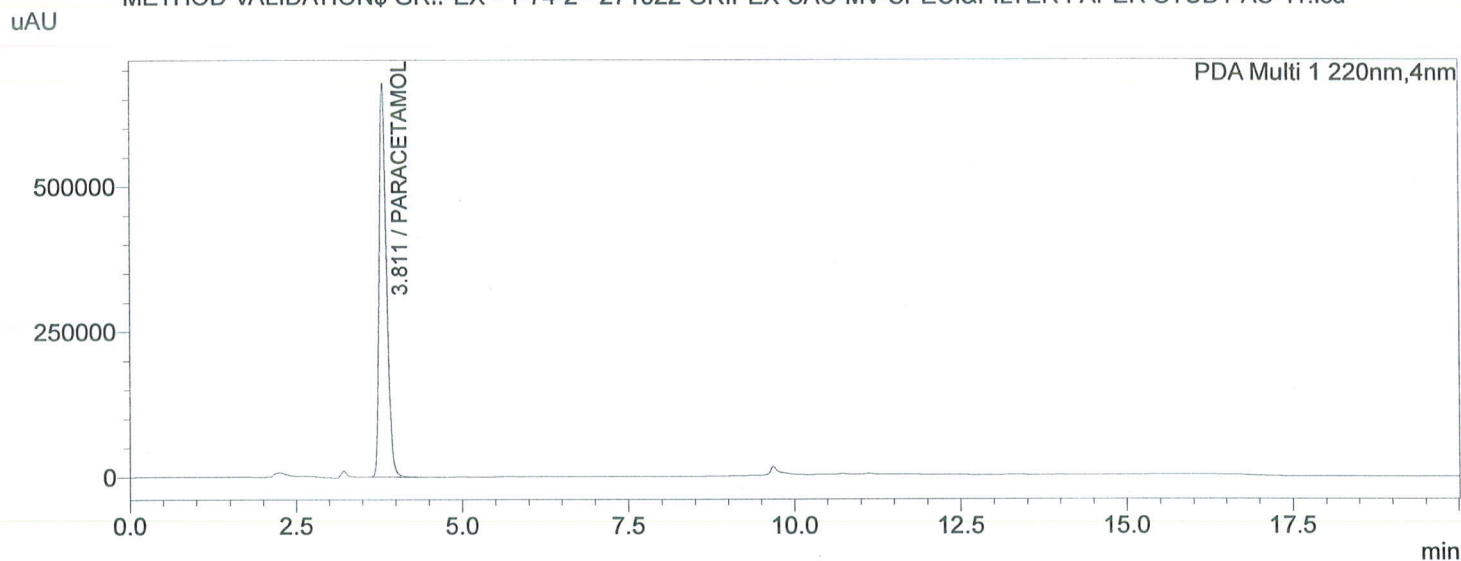
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PARACETAMOL-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-11.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-7  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 5:59:55 PM  
Date Processed : 10/28/2022 11:38:32 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-74-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-11.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.811     | 5233672 | 100.000 | 4912    | 1.254    | --         | --       | PARACETAMOL |
| Total |           | 5233672 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

Puducherry- 605 107

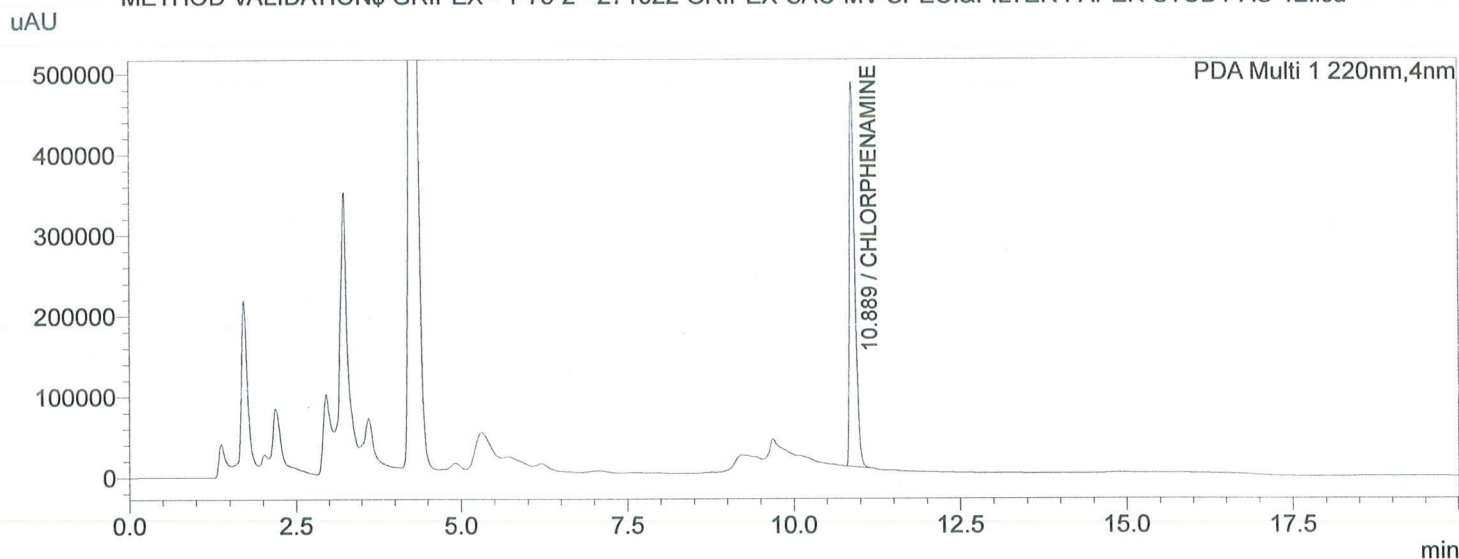
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PLACEBO+CHLORPHENAMINE STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-12.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-8  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 6:20:31 PM  
Date Processed : 10/28/2022 11:50:29 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-75-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-12.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 10.889    | 2690452 | 100.000 | 65979   | 1.368    | --         | --       | CHLORPHENAMINE |
| Total |           | 2690452 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date:



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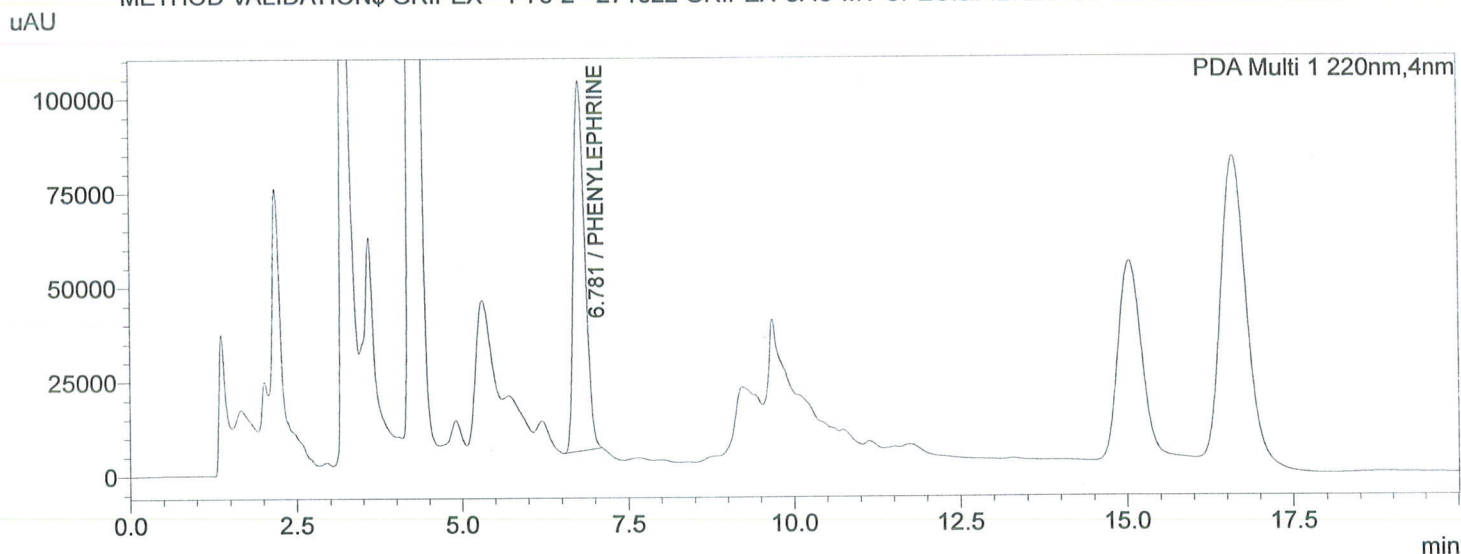
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PLACEBO+PHENYLEPHRINE HCL-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-13.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-9  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 6:41:07 PM  
Date Processed : 10/28/2022 11:52:15 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-76-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-13.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name          |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------|
| 1     | 6.781     | 1148676 | 100.000 | 7108    | 1.153    | --         | --       | PHENYLEPHRINE |
| Total |           | 1148676 | 100.000 |         |          |            |          |               |

Analysed By

Date :

Checked By

Date :





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Puducherry- 605 107

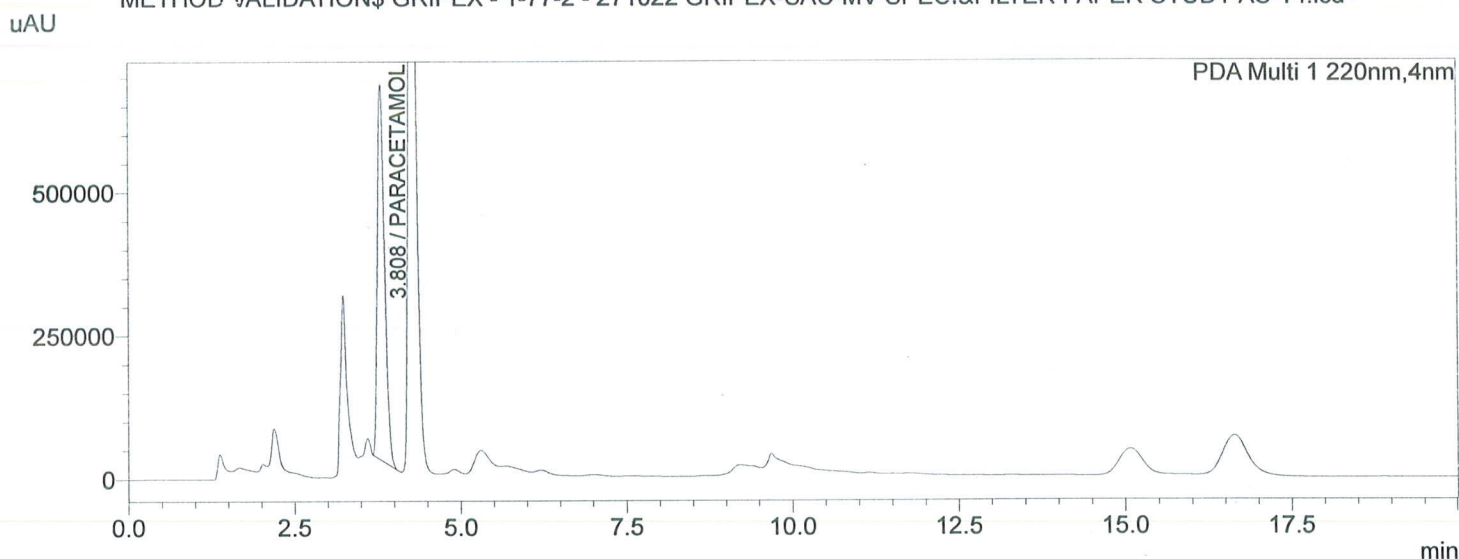
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PLACEBO+PARACETAMOL-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-14.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-10  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 7:01:42 PM  
Date Processed : 10/28/2022 11:56:38 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-77-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-14.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.808     | 4873651 | 100.000 | 5057    | 1.251    | --         | --       | PARACETAMOL |
| Total |           | 4873651 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

Puducherry- 605 107

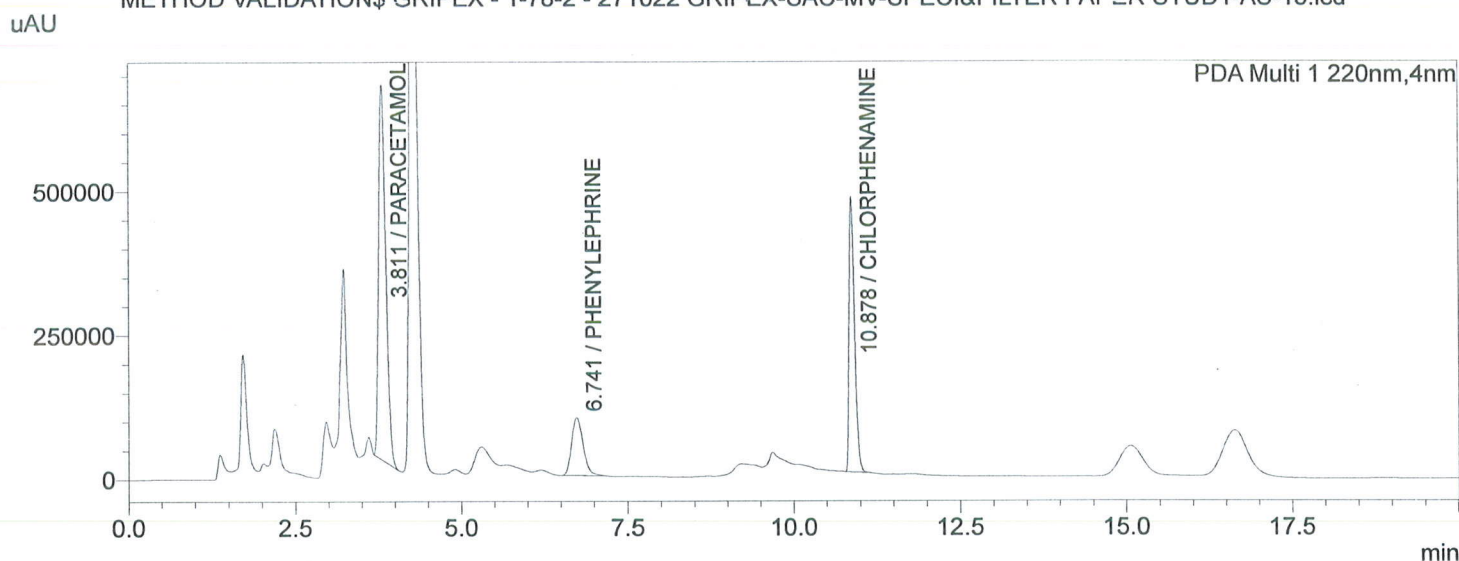
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PLACEBO+CPM+PHENYL+PARA-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-15.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-11  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 7:22:18 PM  
Date Processed : 10/28/2022 11:59:37 AM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-78-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-15.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|---------|----------|------------|----------|----------------|
| 1     | 3.811     | 4839860 | 55.433  | 5097    | 1.252    | --         | --       | PARACETAMOL    |
| 2     | 6.741     | 1195083 | 13.688  | 7067    | 1.217    | 10.97      | --       | PHENYLEPHRINE  |
| 3     | 10.878    | 2696032 | 30.879  | 65518   | 1.356    | 16.86      | --       | CHLORPHENAMINE |
| Total |           | 8730975 | 100.000 |         |          |            |          |                |

Analysed By

Date :

Checked By

Date :



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Puducherry- 605 107

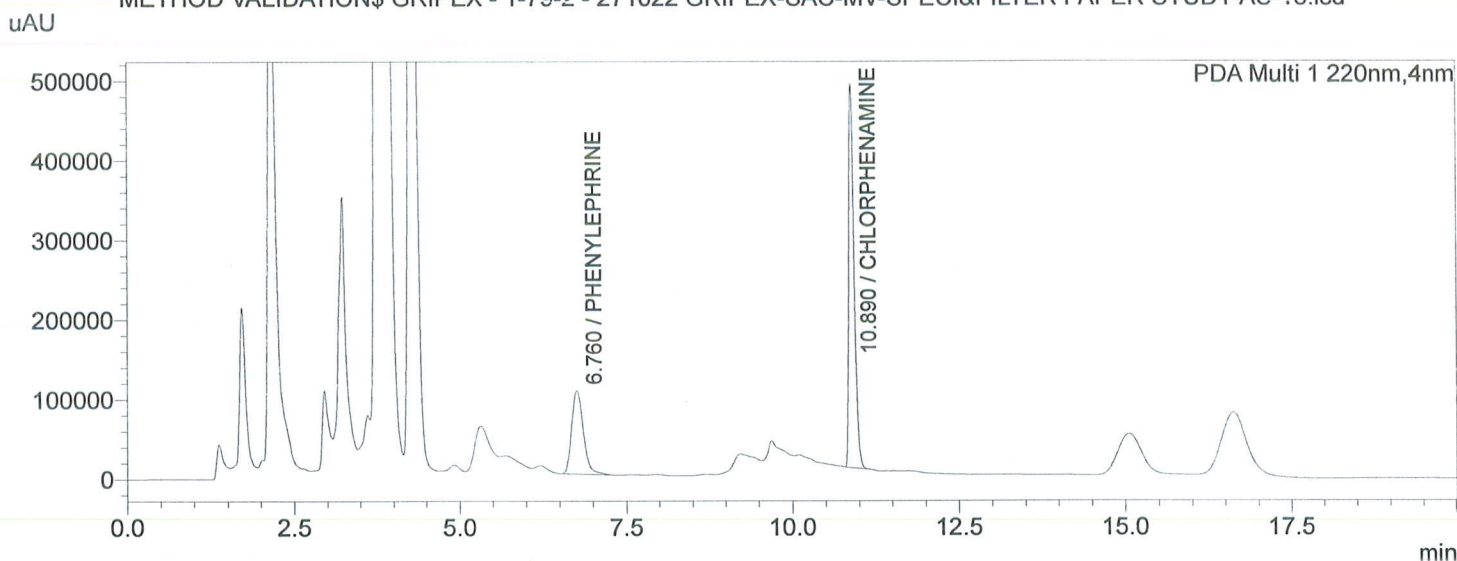
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : TEST PREPARATION-SOLUTION-A  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-16.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-12  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 7:42:53 PM  
Date Processed : 10/28/2022 12:01:37 PM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-79-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-16.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plates | T.Factor | Resolution | R.R.Time | Name           |
|-------|-----------|---------|---------|----------|----------|------------|----------|----------------|
| 1     | 6.760     | 1265209 | 32.117  | 6997     | 1.223    | --         | --       | PHENYLEPHRINE  |
| 2     | 10.890    | 2674169 | 67.883  | 67917    | 1.352    | 16.84      | --       | CHLORPHENAMINE |
| Total |           | 3939378 | 100.000 |          |          |            |          |                |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

Puducherry- 605 107

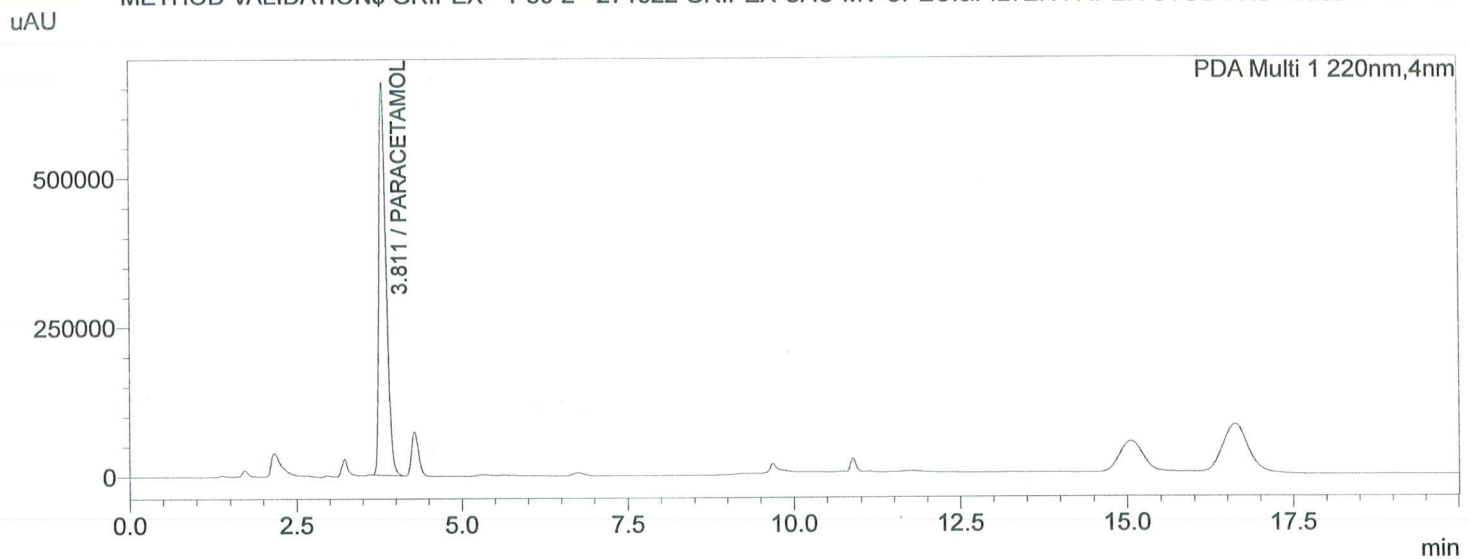
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : TEST PREPARATION-SOLUTION-B  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-17.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-13  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 8:03:28 PM  
Date Processed : 10/28/2022 12:07:26 PM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-80-2 - 271022 GR!PEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-17.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.811     | 4981942 | 100.000 | 5032    | 1.253    | --         | --       | PARACETAMOL |
| Total |           | 4981942 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

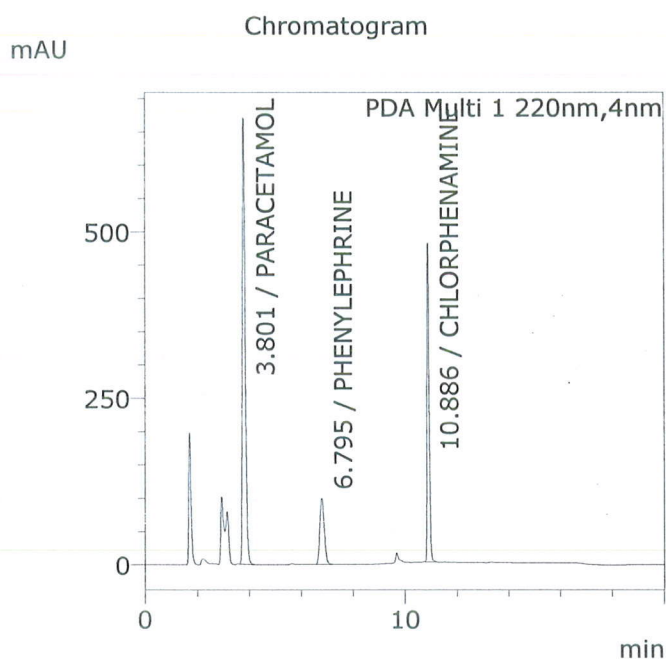
Puducherry- 605 107

## Quality control Department

### <Sample Information>

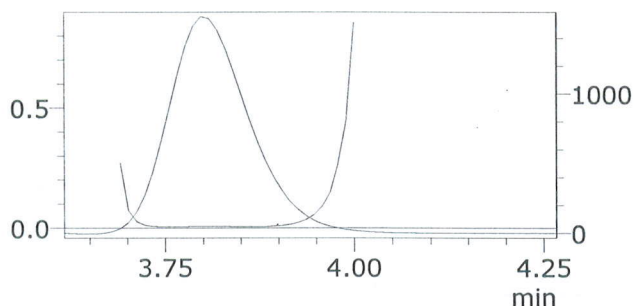
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PARA+CPM+PNENYL-SPECI-AS-STD-01  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-02.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-2  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 2:54:37 PM  
Date Processed : 10/28/2022 10:27:37 AM

### <Chromatogram>



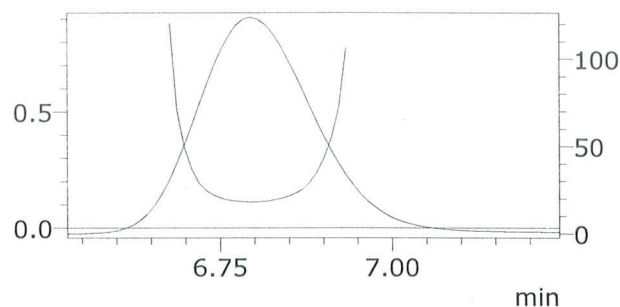
#### PeakPurity

ID# : 1  
Retention Time : 3.801 min  
Compound Name : PARACETAMOL



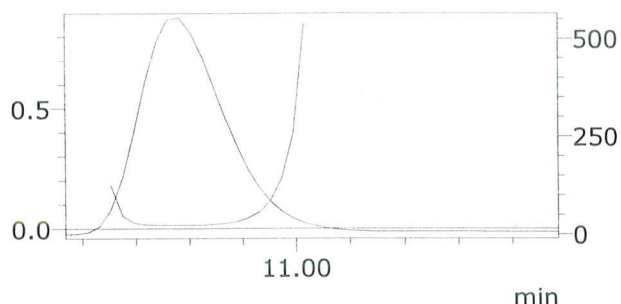
Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.995568  
Minimum peak purity index : 4432

ID# : 2  
Retention Time : 6.795 min  
Compound Name : PHENYLEPHRINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.888906  
Minimum peak purity index : 111094

ID# : 3  
 Retention Time : 10.886 min  
 Compound Name : CHLORPHENAMINE



Impurity : Not Detected  
 Peak purity index : 1.000000  
 Single point threshold : 0.986055  
 Minimum peak purity index : 13944

<Peak purity table>

Peak Table

PDA Ch1 220nm

| Peak# | Ret. Time | Peak Purity Index | Single Point Threshold | Name           |
|-------|-----------|-------------------|------------------------|----------------|
| 1     | 3.801     | 1.000000          | 0.995568               | PARACETAMOL    |
| 2     | 6.795     | 1.000000          | 0.888906               | PHENYLEPHRINE  |
| 3     | 10.886    | 1.000000          | 0.986055               | CHLORPHENAMINE |
| Total |           |                   |                        |                |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

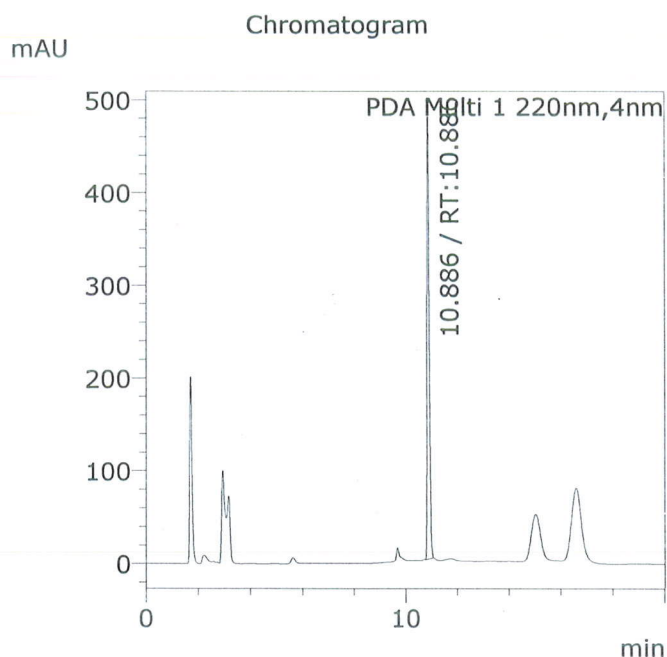
Puducherry- 605 107

## Quality control Department

### <Sample Information>

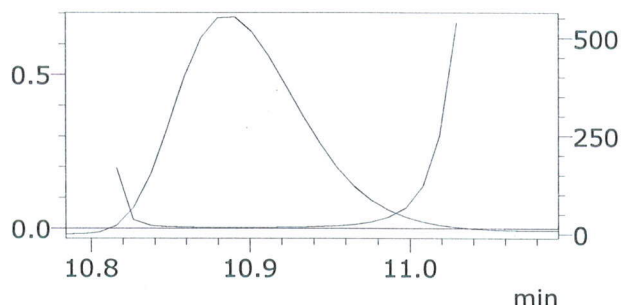
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : CHLORPHENAMINE-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-09.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-5  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 5:18:44 PM  
Date Processed : 10/28/2022 11:35:52 AM

### <Chromatogram>



### PeakPurity

ID# : 1  
Retention Time : 10.886 min  
Compound Name : RT:10.886



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.997150  
Minimum peak purity index : 2849

### <Peak purity table>

| PDA Ch1 220nm |           | Peak Table        |                        |           |
|---------------|-----------|-------------------|------------------------|-----------|
| Peak#         | Ret. Time | Peak Purity Index | Single Point Threshold | Name      |
| 1             | 10.886    | 1.000000          | 0.997150               | RT:10.886 |
| Total         |           |                   |                        |           |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

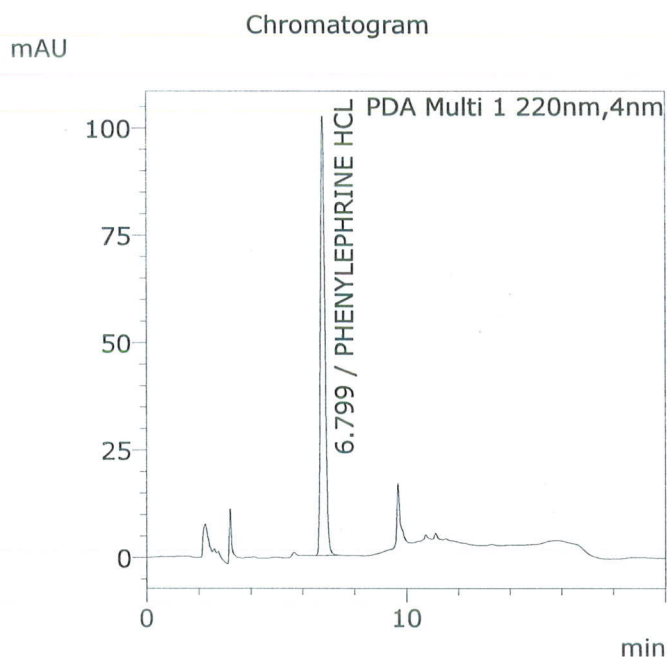
Puducherry- 605 107

## Quality control Department

### <Sample Information>

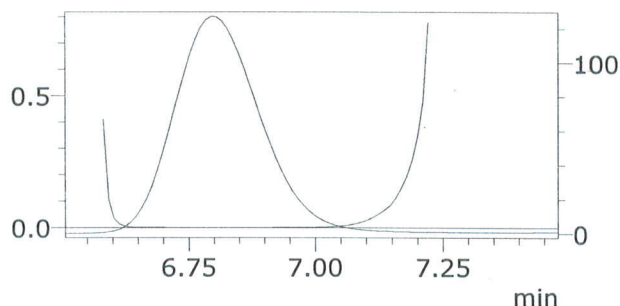
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PHENYLEPHRINE HCL-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-10.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-6  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 5:39:19 PM  
Date Processed : 10/28/2022 11:37:12 AM

### <Chromatogram>



### PeakPurity

ID# : 1  
Retention Time : 6.799 min  
Compound Name : PHENYLEPHRINE HCL



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.999983  
Minimum peak purity index : 17

### <Peak purity table>

Peak Table

PDA Ch1 220nm

| Peak# | Ret. Time | Peak Purity Index | Single Point Threshold | Name              |
|-------|-----------|-------------------|------------------------|-------------------|
| 1     | 6.799     | 1.000000          | 0.999983               | PHENYLEPHRINE HCL |
| Total |           |                   |                        |                   |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

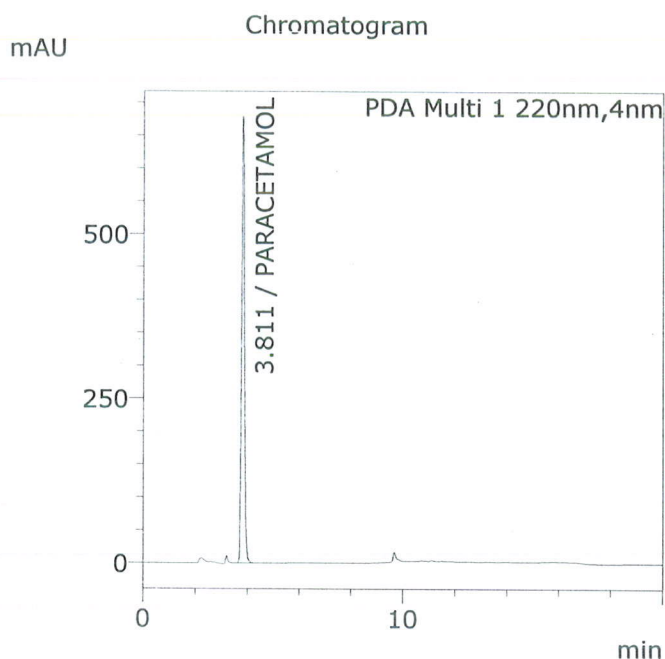
Puducherry- 605 107

## Quality control Department

### <Sample Information>

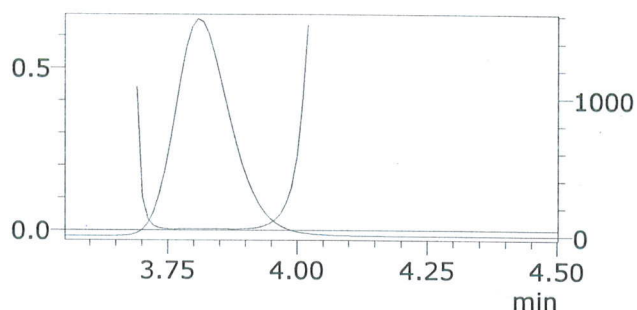
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PARACETAMOL-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-11.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-7  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 5:59:55 PM  
Date Processed : 10/28/2022 11:38:32 AM

### <Chromatogram>



### PeakPurity

ID# : 1  
Retention Time : 3.811 min  
Compound Name : PARACETAMOL



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.997174  
Minimum peak purity index : 2825

### <Peak purity table>

| PDA Ch1 220nm |           | Peak Table        |                        |             |
|---------------|-----------|-------------------|------------------------|-------------|
| Peak#         | Ret. Time | Peak Purity Index | Single Point Threshold | Name        |
| 1             | 3.811     | 1.000000          | 0.997174               | PARACETAMOL |
| Total         |           |                   |                        |             |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

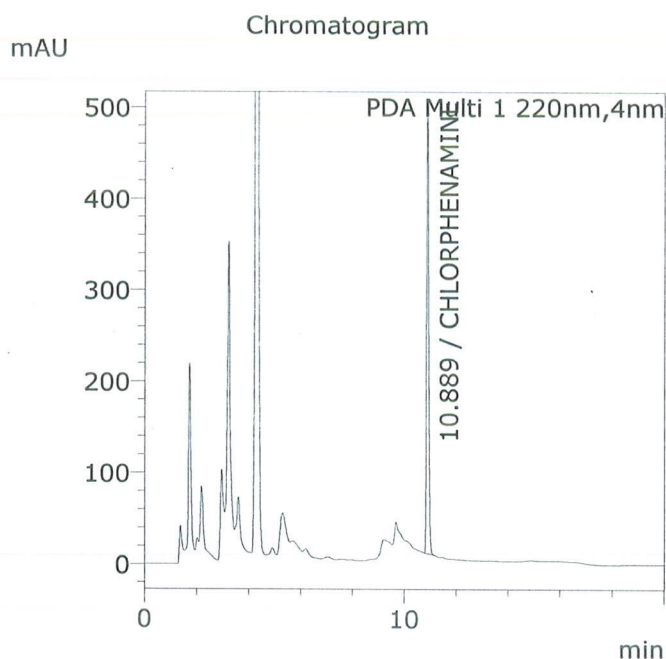
Puducherry- 605 107

## Quality control Department

### <Sample Information>

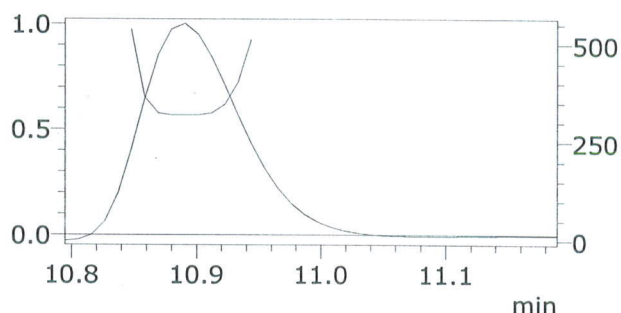
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PLACEBO+CHLORPHENAMINE STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-12.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-8  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 6:20:31 PM  
Date Processed : 10/28/2022 11:50:29 AM

### <Chromatogram>



### PeakPurity

ID# : 1  
Retention Time : 10.889 min  
Compound Name : CHLORPHENAMINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.432131  
Minimum peak purity index : 567868

### <Peak purity table>

| PDA Ch1 220nm |           | Peak Table        |                        |                |
|---------------|-----------|-------------------|------------------------|----------------|
| Peak#         | Ret. Time | Peak Purity Index | Single Point Threshold | Name           |
| 1             | 10.889    | 1.000000          | 0.432131               | CHLORPHENAMINE |
| Total         |           |                   |                        |                |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

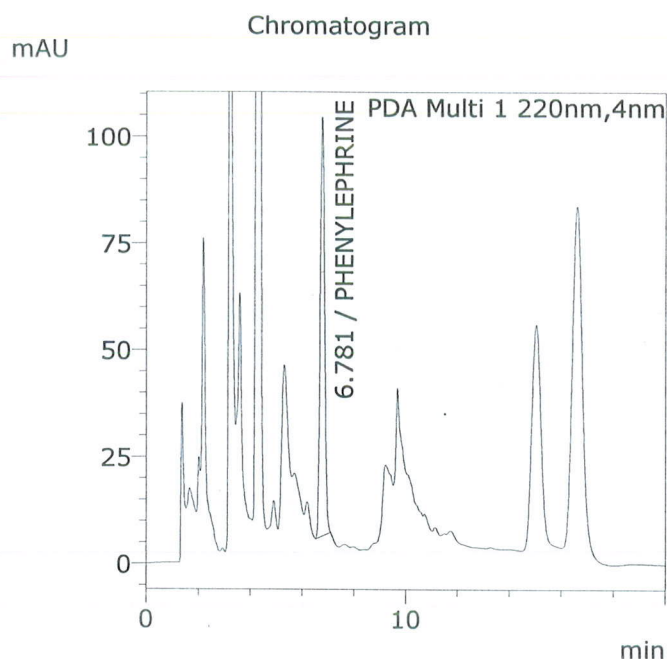
Puducherry- 605 107

## Quality control Department

### <Sample Information>

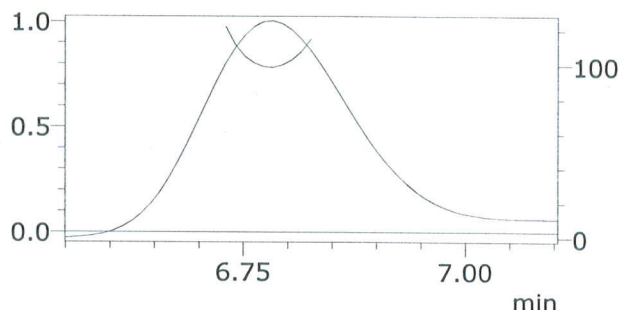
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PLACEBO+PHENYLEPHRINE HCL-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-13.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-9  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 6:41:07 PM  
Date Processed : 10/28/2022 11:52:15 AM

### <Chromatogram>



### PeakPurity

ID# : 1  
Retention Time : 6.781 min  
Compound Name : PHENYLEPHRINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.216219  
Minimum peak purity index : 783781

### <Peak purity table>

| PDA Ch1 220nm |           | Peak Table        |                        |               |
|---------------|-----------|-------------------|------------------------|---------------|
| Peak#         | Ret. Time | Peak Purity Index | Single Point Threshold | Name          |
| 1             | 6.781     | 1.000000          | 0.216219               | PHENYLEPHRINE |
| Total         |           |                   |                        |               |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

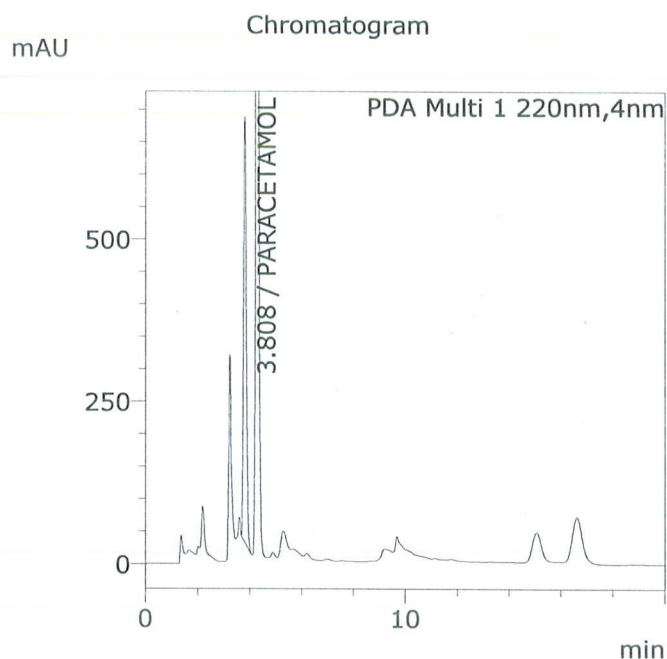
Puducherry- 605 107

## Quality control Department

### <Sample Information>

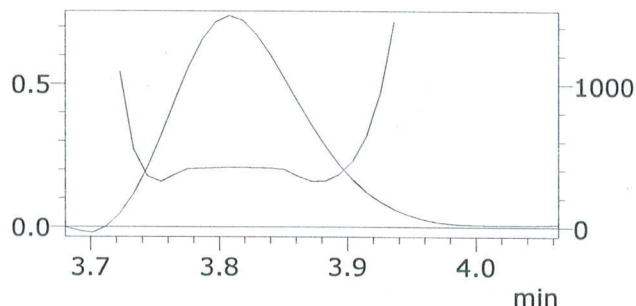
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PLACEBO+PARACETAMOL-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-14.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-10  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 7:01:42 PM  
Date Processed : 10/28/2022 11:56:38 AM

### <Chromatogram>



### PeakPurity

ID# : 1  
Retention Time : 3.808 min  
Compound Name : PARACETAMOL



Impurity : Not Detected  
Peak purity index : 0.999999  
Single point threshold : 0.841980  
Minimum peak purity index : 158018

### <Peak purity table>

| PDA Ch1 220nm |           | Peak Table        |                        |             |
|---------------|-----------|-------------------|------------------------|-------------|
| Peak#         | Ret. Time | Peak Purity Index | Single Point Threshold | Name        |
| 1             | 3.808     | 0.999999          | 0.841980               | PARACETAMOL |
| Total         |           |                   |                        |             |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

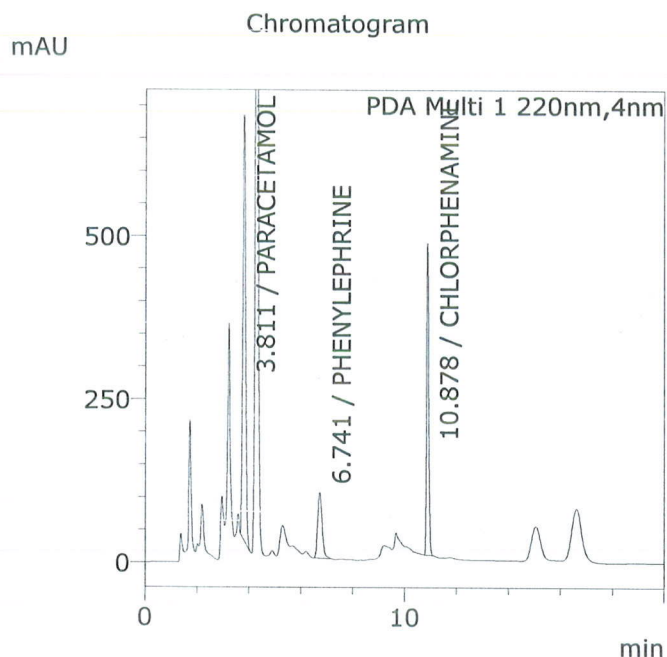
Puducherry- 605 107

## Quality control Department

### <Sample Information>

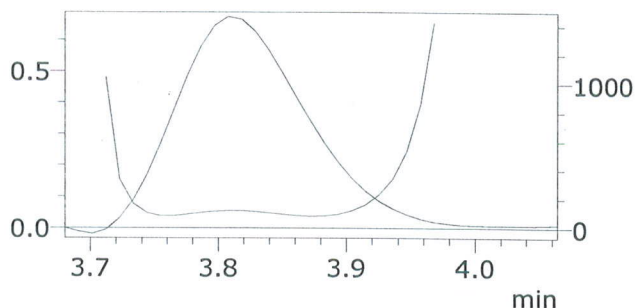
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : PLACEBO+CPM+PHENYL+PARA-STD  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-15.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-11  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 7:22:18 PM  
Date Processed : 10/28/2022 11:59:37 AM

### <Chromatogram>



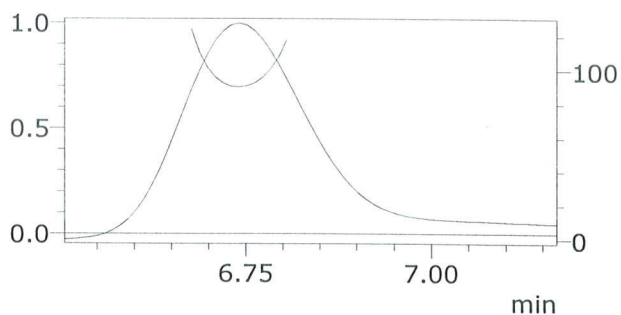
#### PeakPurity

ID# : 1  
Retention Time : 3.811 min  
Compound Name : PARACETAMOL



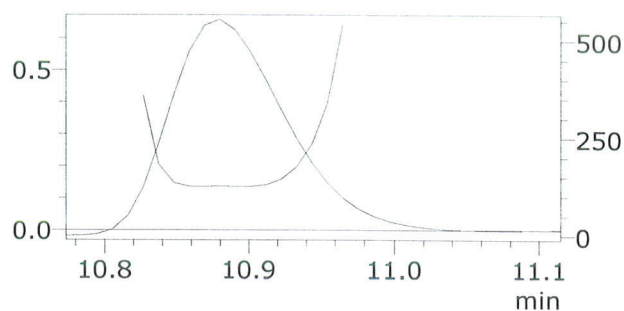
Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.962624  
Minimum peak purity index : 37375

ID# : 2  
Retention Time : 6.741 min  
Compound Name : PHENYLEPHRINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.304249  
Minimum peak purity index : 695750

ID# : 3  
Retention Time : 10.878 min  
Compound Name : CHLORPHENAMINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.864675  
Minimum peak purity index : 135325

<Peak purity table>

Peak Table

PDA Ch1 220nm

| Peak# | Ret. Time | Peak Purity Index | Single Point Threshold | Name           |
|-------|-----------|-------------------|------------------------|----------------|
| 1     | 3.811     | 1.000000          | 0.962624               | PARACETAMOL    |
| 2     | 6.741     | 1.000000          | 0.304249               | PHENYLEPHRINE  |
| 3     | 10.878    | 1.000000          | 0.864675               | CHLORPHENAMINE |
| Total |           |                   |                        |                |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

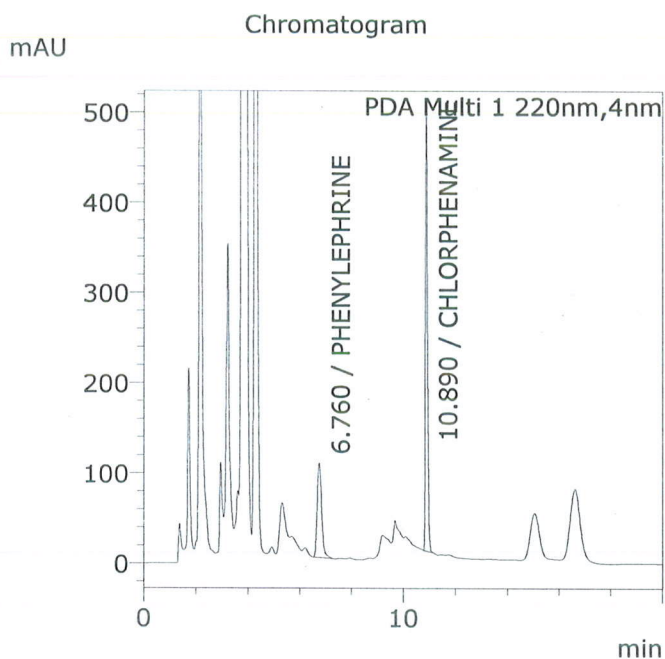
Puducherry- 605 107

## Quality control Department

### <Sample Information>

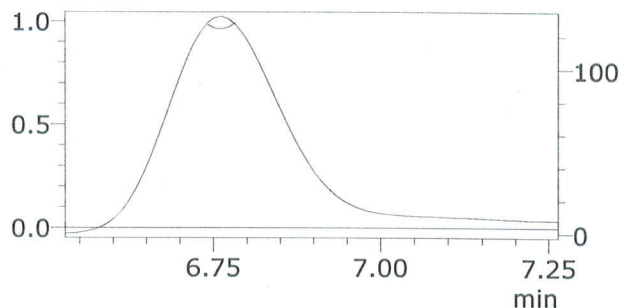
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : TEST PREPARATION-SOLUTION-A  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-16.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-12  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 7:42:53 PM  
Date Processed : 10/28/2022 12:01:37 PM

### <Chromatogram>



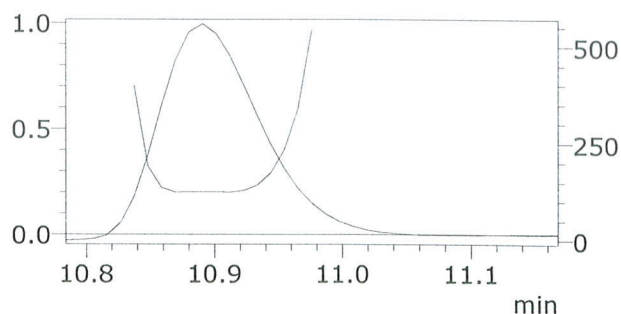
#### PeakPurity

ID# : 1  
Retention Time : 6.760 min  
Compound Name : PHENYLEPHRINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.037126  
Minimum peak purity index : 962874

ID# : 2  
Retention Time : 10.890 min  
Compound Name : CHLORPHENAMINE



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.800910  
Minimum peak purity index : 199090



# <Peak purity table>

Peak Table

PDA Ch1 220nm

| Peak# | Ret. Time | Peak Purity Index | Single Point Threshold | Name           |
|-------|-----------|-------------------|------------------------|----------------|
| 1     | 6.760     | 1.000000          | 0.037126               | PHENYLEPHRINE  |
| 2     | 10.890    | 1.000000          | 0.800910               | CHLORPHENAMINE |
| Total |           |                   |                        |                |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

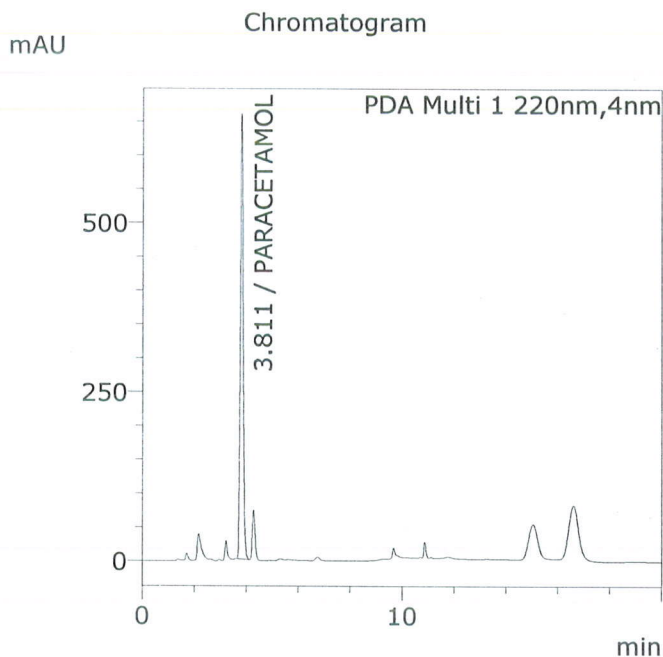
Puducherry- 605 107

## Quality control Department

### <Sample Information>

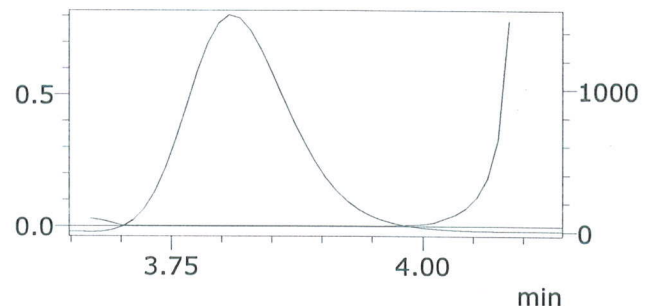
Acquired by : C.Albin Jose  
Sample Name : SPECIFICITY-AS  
Sample ID : TEST PREPARATION-SOLUTION-B  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-17.lcd  
Method Filename : GRIPEX-AS.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-13  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 8:03:28 PM  
Date Processed : 10/28/2022 12:07:26 PM

### <Chromatogram>



PeakPurity

ID# : 1  
Retention Time : 3.811 min  
Compound Name : PARACETAMOL



Impurity : Not Detected  
Peak purity index : 1.000000  
Single point threshold : 0.999836  
Minimum peak purity index : 164

### <Peak purity table>

| PDA Ch1 220nm |           | Peak Table        |                        |             |
|---------------|-----------|-------------------|------------------------|-------------|
| Peak#         | Ret. Time | Peak Purity Index | Single Point Threshold | Name        |
| 1             | 3.811     | 1.000000          | 0.999836               | PARACETAMOL |
| Total         |           |                   |                        |             |

Analysed By

Date :

*[Signature]*  
22/10/22

Checked By

Date :

*[Signature]*  
22/10/22

**Safetab Life Science ,**

Puducherry - 605 107

**QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

**ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS**

|                |                    |              |             |
|----------------|--------------------|--------------|-------------|
| Product Name : | GRIPEX             | Batch size : | 500 SACHETS |
| Batch Number : | ST/T/S-1322        | Mfg.Date :   | Sep-22      |
| Parameter :    | FILTER PAPER STUDY | Exp.Date :   | To be fixed |

Each 4500 mg of Sachet contains:

Paracetamol BP ----- 650mg

Chlorphenamine Maleate BP ----- 20mg

Phenylephrine Hydrochloride BP ----- 10mg

**ASSAY OF PARACETAMOL , PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE**

|                |              |              |                 |         |              |                |       |
|----------------|--------------|--------------|-----------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID : | ST/QC/EQ/041&30 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|                |              |              |                 | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9  |
|                |              |              |                 | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7  |

|                         |       |            |     |            |   |            |    |
|-------------------------|-------|------------|-----|------------|---|------------|----|
| Paracetamol Std.Dil:    | 64.93 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-64.93 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                         |       |            |     |            |   |            |    |
|-------------------------|-------|------------|-----|------------|---|------------|----|
| Phenylephrine Std.Dil:  | 39.94 | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-19.97 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                         |       |            |     |            |   |            |    |
|-------------------------|-------|------------|-----|------------|---|------------|----|
| Chlorphenamine Std:     | 40.28 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-40.28 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                  |            |            |     |            |   |            |     |
|------------------|------------|------------|-----|------------|---|------------|-----|
| Test dilution .: | One Sachet | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
|                  | 1          | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

| S.No | Sample Name                           | Paracetamol assay in % | % Difference from unfiltered sample | Phenylephrine assay in % | % Difference from unfiltered sample | Chlorphenamine assay in % | % Difference from unfiltered sample |
|------|---------------------------------------|------------------------|-------------------------------------|--------------------------|-------------------------------------|---------------------------|-------------------------------------|
| 1    | Unfiltered sample (Centrifuged)       | 96.8                   | Not applicable                      | 103.4                    | Not applicable                      | 99.2                      | Not applicable                      |
| 2    | Filter set-1<br>(0.45µ PVDF membrane) | 96.6                   | 0.21                                | 103.4                    | 0.00                                | 98.7                      | 0.51                                |
| 3    | Filter set-1<br>(0.45µ PVDF membrane) | 95.7                   | 1.15                                | 103.2                    | 0.19                                | 98.8                      | 0.40                                |
| 4    | Filter set-1<br>(0.45µ PVDF membrane) | 96.3                   | 0.52                                | 103.5                    | -0.10                               | 98.7                      | 0.51                                |

**Results :**

The % difference on filtered sample (0.45µ PVDF membrane) within limit against that of unfiltered.

**Acceptance criteria:**The % difference on filter solution should not differ  $\pm 2.0$  against that of unfiltered.

Analysed by :

C.ALBIN JOSE

Date :

28-10-2022

Checked by :

Date :

28/10/22





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                               |            |             |
|--------------|-------------------------------|------------|-------------|
| Product Name | GRIPEX                        | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                   | Mfg.Date   | Sep-22      |
| Stage        | UNFILTERED CENTRIFUGED SAMPLE | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                |              |             |                  |         |              |                |       |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID: | ST/QC/EQ/041&030 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|

|                         |       |            |     |            |   |            |    |
|-------------------------|-------|------------|-----|------------|---|------------|----|
| Standard dilution.:     | 64.93 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-64.93 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                          |              |            |     |            |   |            |     |
|--------------------------|--------------|------------|-----|------------|---|------------|-----|
| Test dilution.:          | Granule/Pow. | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
| Test conc(in ppm)-65.013 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

Conversion factor : 1.0000

Labeled claim : 650 mg

Average weight : 4500 mg

|                      |         |         |         |         |         |         |       |          |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Paracetamol          | 5164203 | 5149828 | 5177505 | 5168936 | 5192359 | 5170566 | 15782 | 0.305    |
| With Bracketing std. |         |         |         |         |         | 5170566 | 15782 | 0.305    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 5011140     | 629.15               | 96.8         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|  |  |  |  |  |  |         |              |                |      |
|--|--|--|--|--|--|---------|--------------|----------------|------|
|  |  |  |  |  |  | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
|--|--|--|--|--|--|---------|--------------|----------------|------|

|                         |       |            |     |            |   |            |    |
|-------------------------|-------|------------|-----|------------|---|------------|----|
| Standard dilution.:     | 39.94 | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-19.97 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                           |              |            |     |            |   |            |   |
|---------------------------|--------------|------------|-----|------------|---|------------|---|
| Test dilution.:           | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1 |
| Test conc (in ppm)-20.004 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1 |

Conversion factor : 1.0000

Labeled claim : 10 mg

|                      |         |         |         |         |         |         |        |          |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
| Phenylephrine HCL    | 1181397 | 1184282 | 1188082 | 1186671 | 1191624 | 1186411 | 3864   | 0.326    |
| With Bracketing std. |         |         |         |         |         | 1186411 | 3863.5 | 0.326    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 1243073     | 10.34                | 103.4        |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|  |  |  |  |  |  |         |              |                |      |
|--|--|--|--|--|--|---------|--------------|----------------|------|
|  |  |  |  |  |  | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
|--|--|--|--|--|--|---------|--------------|----------------|------|

|                         |       |            |     |            |   |            |    |
|-------------------------|-------|------------|-----|------------|---|------------|----|
| Standard dilution.:     | 40.28 | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-40.28 | 1     | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                          |              |            |     |            |   |            |   |
|--------------------------|--------------|------------|-----|------------|---|------------|---|
| Test dilution.:          | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1 |
| Test conc(in ppm)-40.008 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1 |

Conversion factor : 1.0000

Labeled claim : 20 mg

|                        |         |         |         |         |         |         |      |          |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
| Chlorphenamine maleate | 2712924 | 2727748 | 2724712 | 2724245 | 2736812 | 2725288 | 8561 | 0.314    |
| With Bracketing std.   |         |         |         |         |         | 2725288 | 8561 | 0.314    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 2692335     | 19.83                | 99.2         |

Assay limit :90.0% to 110.0%

Calculation formula :

Assay in mg /Sachet  $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$

Assay in %  $\frac{\text{Assay in mg/Sachet} \times 100}{\text{Labeled claim}}$

Analysed by : C.ALBIN JOSE

Date : 28-10-2022

Checked by :

Date :

28/10/2022





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                              |            |             |
|--------------|----------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                       | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                  | Mfg.Date   | Sep-22      |
| Stage        | FILTERED SET- 1 (0.45µ PVDF membrane filter) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                |              |             |                  |         |              |                |       |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID: | ST/QC/EQ/041&030 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|

|                          |              |            |     |            |   |            |     |
|--------------------------|--------------|------------|-----|------------|---|------------|-----|
| Standard dilution.:      | 64.93        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50  |
| Std.conc (in ppm)-64.93  | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |
| Test dilution.:          | Granule/Pow. | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
| Test conc(in ppm)-65.013 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

|                     |         |
|---------------------|---------|
| Conversion factor : | 1.0000  |
| Labeled claim :     | 650 mg  |
| Average weight :    | 4500 mg |

|                      |         |         |         |         |         |         |       |          |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Paracetamol          | 5164203 | 5149828 | 5177505 | 5168936 | 5192359 | 5170566 | 15782 | 0.305    |
| With Bracketing std. |         |         |         |         |         | 5170566 | 15782 | 0.305    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 5000255     | 627.79               | 96.6         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|  |  |  |  |  |  |         |              |                |      |
|--|--|--|--|--|--|---------|--------------|----------------|------|
|  |  |  |  |  |  | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
|--|--|--|--|--|--|---------|--------------|----------------|------|

|                           |              |            |     |            |   |            |    |
|---------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:       | 39.94        | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-19.97   | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:           | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc (in ppm)-20.004 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 10 mg  |

|                      |         |         |         |         |         |         |        |          |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
| Phenylephrine HCL    | 1181397 | 1184282 | 1188082 | 1186671 | 1191624 | 1186411 | 3864   | 0.326    |
| With Bracketing std. |         |         |         |         |         | 1186411 | 3863.5 | 0.326    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 1242670     | 10.34                | 103.4        |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|  |  |  |  |  |  |         |              |                |      |
|--|--|--|--|--|--|---------|--------------|----------------|------|
|  |  |  |  |  |  | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
|--|--|--|--|--|--|---------|--------------|----------------|------|

|                          |              |            |     |            |   |            |    |
|--------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:      | 40.28        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-40.28  | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:          | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc(in ppm)-40.008 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 20 mg  |

|                        |         |         |         |         |         |         |      |          |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
| Chlorphenamine maleate | 2712924 | 2727748 | 2724712 | 2724245 | 2736812 | 2725288 | 8561 | 0.314    |
| With Bracketing std.   |         |         |         |         |         | 2725288 | 8561 | 0.314    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 2679408     | 19.74                | 98.7         |

Assay limit :90.0% to 110.0%

Calculation formula :

|                     |                                                                                                                   |
|---------------------|-------------------------------------------------------------------------------------------------------------------|
| Assay in mg /Sachet | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt<br>Standard area x sample dilution x 100 |
|---------------------|-------------------------------------------------------------------------------------------------------------------|

|            |                                           |
|------------|-------------------------------------------|
| Assay in % | Assay in mg/Sachet x 100<br>Labeled claim |
|------------|-------------------------------------------|

Analysed by : C.ALBIN JOSE  
Date : 28-10-2022

Checked by :  
Date : 28/10/2022





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                              |            |             |
|--------------|----------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                       | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                  | Mfg.Date   | Sep-22      |
| Stage        | FILTERED SET- 2 (0.45µ PVDF membrane filter) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                |              |             |                  |         |              |                |       |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID: | ST/QC/EQ/041&030 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|

|                          |              |            |     |            |   |            |     |
|--------------------------|--------------|------------|-----|------------|---|------------|-----|
| Standard dilution.:      | 64.93        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50  |
| Std.conc (in ppm)-64.93  | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |
| Test dilution.:          | Granule/Pow. | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
| Test conc(in ppm)-65.013 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

|                     |         |
|---------------------|---------|
| Conversion factor : | 1.0000  |
| Labeled claim :     | 650 mg  |
| Average weight :    | 4500 mg |

|                      |         |         |         |         |         |         |       |          |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Paracetamol          | 5164203 | 5149828 | 5177505 | 5168936 | 5192359 | 5170566 | 15782 | 0.305    |
| With Bracketing std. |         |         |         |         |         | 5170566 | 15782 | 0.305    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 4955143     | 622.12               | 95.7         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|  |  |  |  |  |  |         |              |                |      |
|--|--|--|--|--|--|---------|--------------|----------------|------|
|  |  |  |  |  |  | WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
|--|--|--|--|--|--|---------|--------------|----------------|------|

|                           |              |            |     |            |   |            |    |
|---------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:       | 39.94        | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-19.97   | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:           | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc (in ppm)-20.004 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 10 mg  |

|                      |         |         |         |         |         |         |        |          |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
| Phenylephrine HCL    | 1181397 | 1184282 | 1188082 | 1186671 | 1191624 | 1186411 | 3864   | 0.326    |
| With Bracketing std. |         |         |         |         |         | 1186411 | 3863.5 | 0.326    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 1240536     | 10.32                | 103.2        |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|  |  |  |  |  |  |         |              |                |      |
|--|--|--|--|--|--|---------|--------------|----------------|------|
|  |  |  |  |  |  | WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
|--|--|--|--|--|--|---------|--------------|----------------|------|

|                          |              |            |     |            |   |            |    |
|--------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:      | 40.28        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-40.28  | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:          | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc(in ppm)-40.008 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 20 mg  |

|                        |         |         |         |         |         |         |      |          |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
| Chlorphenamine maleate | 2712924 | 2727748 | 2724712 | 2724245 | 2736812 | 2725288 | 8561 | 0.314    |
| With Bracketing std.   |         |         |         |         |         | 2725288 | 8561 | 0.314    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 2682916     | 19.76                | 98.8         |

Assay limit :90.0% to 110.0%

Calculation formula :

|                     |                                                                          |
|---------------------|--------------------------------------------------------------------------|
| Assay in mg /Sachet | Sample area x Std.dilution x Purity %(aib) x conversion factor x Avg. wt |
|                     | Standard area x sample dilution x 100                                    |

|            |                          |
|------------|--------------------------|
| Assay in % | Assay in mg/Sachet x 100 |
|            | Labeled claim            |

Analysed by : C.ALBIN JOSE  
Date : 28-10-2022

Checked by :  
Date : 28/10/2022





Safetab Life Science  
Puducherry - 605 107

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title ASSAY OF PARACETAMOL, PHENYLEPHRINE HCL AND CHLORPHENAMINE MALEATE IN GRIPEX SACHETS

|              |                                              |            |             |
|--------------|----------------------------------------------|------------|-------------|
| Product Name | GRIPEX                                       | Batch size | 500 SACHETS |
| Batch Number | ST/T/S-1322                                  | Mfg.Date   | Sep-22      |
| Stage        | FILTERED SET- 3 (0.45µ PVDF membrane filter) | Exp.Date   | To be fixed |

Each 4500 mg of Sachet contains:  
Paracetamol BP ----- 650mg  
Chlorphenamine Maleate BP ----- 20mg  
Phenylephrine Hydrochloride BP ----- 10mg

ASSAY OF PARACETAMOL

|                |              |             |                  |         |              |                |       |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|
| Instrument ID: | ST/QC/EQ/039 | Balance ID: | ST/QC/EQ/041&030 | WS No.: | ST/WS/22/011 | % Purity (aib) | 100.0 |
|----------------|--------------|-------------|------------------|---------|--------------|----------------|-------|

|                          |              |            |     |            |   |            |     |
|--------------------------|--------------|------------|-----|------------|---|------------|-----|
| Standard dilution.:      | 64.93        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50  |
| Std.conc (in ppm)-64.93  | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |
| Test dilution.:          | Granule/Pow. | mg to ---> | 500 | ml to ---> | 5 | ml to ---> | 100 |
| Test conc(in ppm)-65.013 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1   |

|                     |         |
|---------------------|---------|
| Conversion factor : | 1.0000  |
| Labeled claim :     | 650 mg  |
| Average weight :    | 4500 mg |

|                      |         |         |         |         |         |         |       |          |
|----------------------|---------|---------|---------|---------|---------|---------|-------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D   | RSD in % |
| Paracetamol          | 5164203 | 5149828 | 5177505 | 5168936 | 5192359 | 5170566 | 15782 | 0.305    |
| With Bracketing std. |         |         |         |         |         | 5170566 | 15782 | 0.305    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 4985379     | 625.92               | 96.3         |

Assay limit :90.0% to 110.0%

ASSAY OF PHENYLEPHRINE HYDROCHLORIDE

|         |              |                |      |
|---------|--------------|----------------|------|
| WS No.: | IAARI/WS/344 | % Purity (aib) | 98.9 |
|---------|--------------|----------------|------|

|                           |              |            |     |            |   |            |    |
|---------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:       | 39.94        | mg to ---> | 200 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-19.97   | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:           | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc (in ppm)-20.004 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 10 mg  |

|                      |         |         |         |         |         |         |        |          |
|----------------------|---------|---------|---------|---------|---------|---------|--------|----------|
| System suitability   | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D    | RSD in % |
| Phenylephrine HCL    | 1181397 | 1184282 | 1188082 | 1186671 | 1191624 | 1186411 | 3864   | 0.326    |
| With Bracketing std. |         |         |         |         |         | 1186411 | 3863.5 | 0.326    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 1243465     | 10.35                | 103.5        |

Assay limit :90.0% to 110.0%

ASSAY OF CHLORPHENAMINE MALEATE

|         |              |                |      |
|---------|--------------|----------------|------|
| WS No.: | ST/WS/22/039 | % Purity (aib) | 99.7 |
|---------|--------------|----------------|------|

|                          |              |            |     |            |   |            |    |
|--------------------------|--------------|------------|-----|------------|---|------------|----|
| Standard dilution.:      | 40.28        | mg to ---> | 100 | ml to ---> | 5 | ml to ---> | 50 |
| Std.conc (in ppm)-40.28  | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |
| Test dilution.:          | Granule/Pow. | mg to ---> | 500 | ml to ---> | 1 | ml to ---> | 1  |
| Test conc(in ppm)-40.008 | 1            | ml to ---> | 1   | ml to ---> | 1 | ml to ---> | 1  |

|                     |        |
|---------------------|--------|
| Conversion factor : | 1.0000 |
| Labeled claim :     | 20 mg  |

|                        |         |         |         |         |         |         |      |          |
|------------------------|---------|---------|---------|---------|---------|---------|------|----------|
| System suitability     | 1       | 2       | 3       | 4       | 5       | MEAN    | S.D  | RSD in % |
| Chlorphenamine maleate | 2712924 | 2727748 | 2724712 | 2724245 | 2736812 | 2725288 | 8561 | 0.314    |
| With Bracketing std.   |         |         |         |         |         | 2725288 | 8561 | 0.314    |

|                    |                           |             |                      |              |
|--------------------|---------------------------|-------------|----------------------|--------------|
| Sample preparation | Sample Weight taken in mg | Sample Area | Content in mg/Sachet | Content in % |
| 1                  | 4500.90                   | 2678642     | 19.73                | 98.7         |

Assay limit :90.0% to 110.0%

Calculation formula :

Assay in mg /Sachet  $\frac{\text{Sample area} \times \text{Std.dilution} \times \text{Purity \% (aib)} \times \text{conversion factor} \times \text{Avg. wt}}{\text{Standard area} \times \text{sample dilution} \times 100}$

Assay in %  $\frac{\text{Assay in mg/Sachet} \times 100}{\text{Labeled claim}}$

Analysed by : C.ALBIN JOSE  
Date : 28-10-2022

Checked by :  
Date : 28/10/2022



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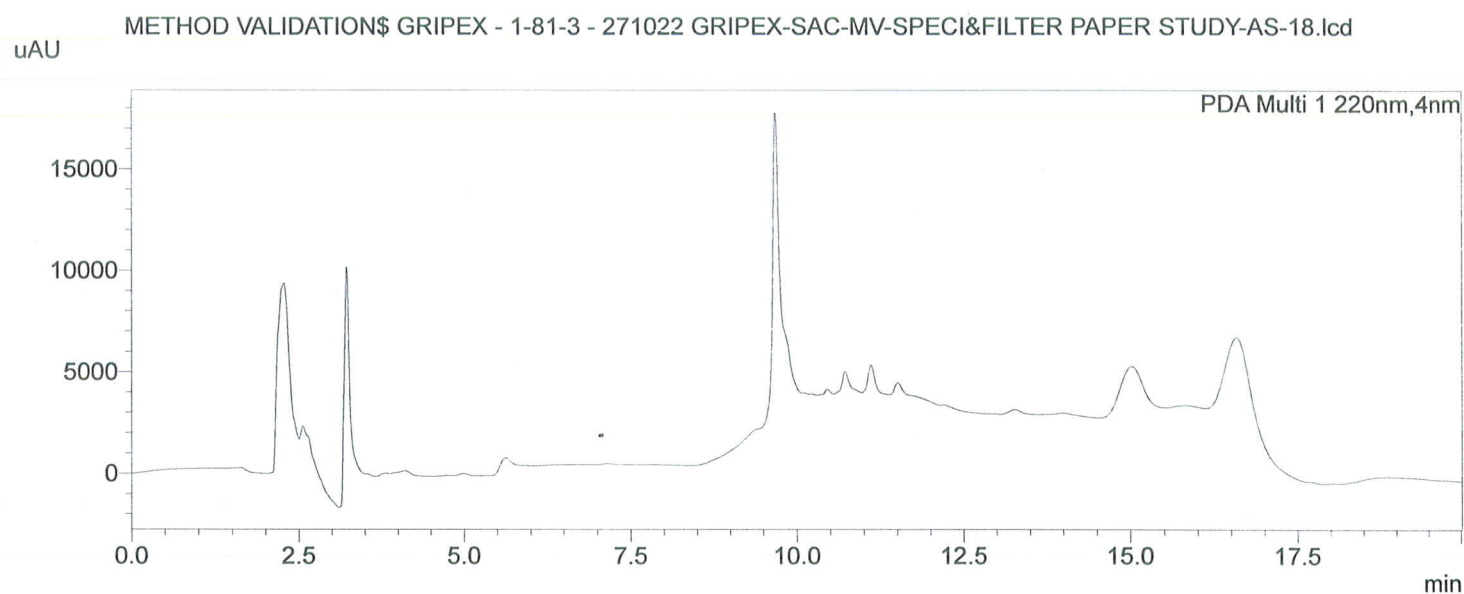
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : FILTER PAPER STUDY-AS  
Sample ID : BLANK-AS  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-18.lcd  
Method Filename : GRIPEX-AS\_p.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-14  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 8:24:04 PM  
Date Processed : 10/28/2022 10:23:11 AM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area | Area% | T.Plate | T.Factor | Resolution | R.R.Time | Name |
|-------|-----------|------|-------|---------|----------|------------|----------|------|
| Total |           |      |       |         |          |            |          |      |

Analysed By

Date :

*[Signature]*  
28/10/22

Checked By

Date :

*[Signature]*  
28/10/22





# Safetab Life Science

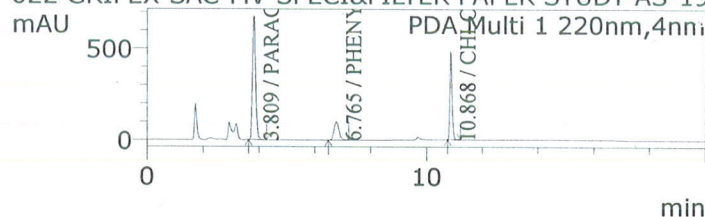
Puducherry- 605 107

## Quality control Department

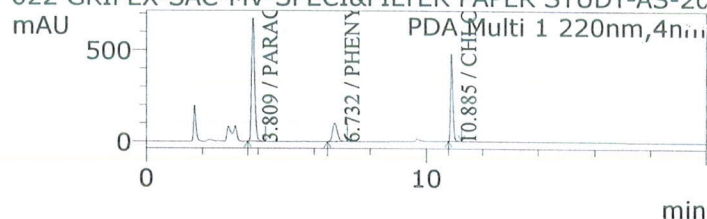
### Sample Information

Acquired by : C.Albin Jose  
Sample Name : FILTER PAPER STUDY-AS  
Sample ID : PARA+CPM+PNENYL-AS-STD-01  
Tray# : 1  
Vial# : 15  
Injection Volume : 50  
Data File : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-19.lcd  
Method File : GRIPEX-AS\_p.lcm  
Batch File : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Report Format File : DEFAULT.lsr  
Date Acquired : 10/27/2022 8:44:39 PM  
Date Processed : 10/28/2022 10:23:09 AM

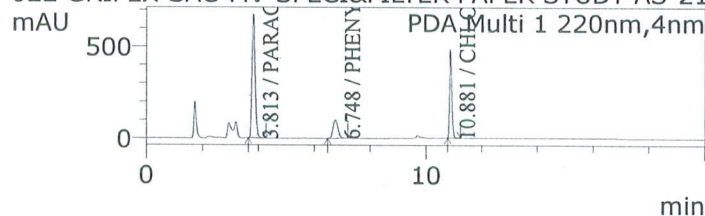
022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-19



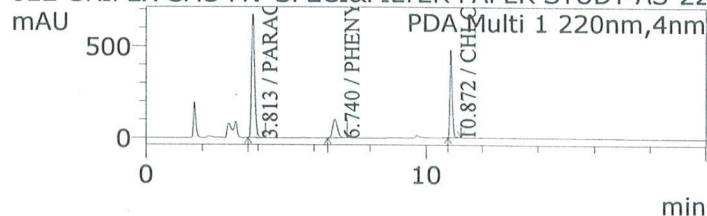
022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-20



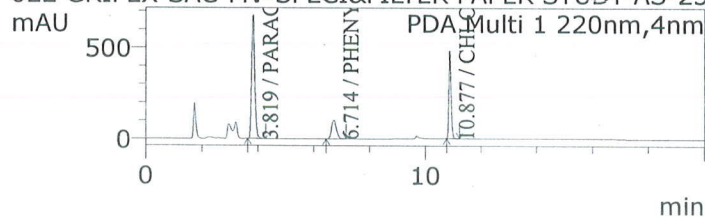
022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-21



022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-22



022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-23



<< PDA >>

ID#1 Compound Name: PARACETAMOL

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 15    | JDY-AS-19.lcd | PARA+CPM+PNENYL-AS-STD-01 | 3.809  | 5164203 | 4941     | 1.252    |
| 15    | JDY-AS-20.lcd | PARA+CPM+PNENYL-AS-STD-02 | 3.809  | 5149828 | 4974     | 1.253    |
| 15    | JDY-AS-21.lcd | PARA+CPM+PNENYL-AS-STD-03 | 3.813  | 5177505 | 4977     | 1.258    |
| 15    | JDY-AS-22.lcd | PARA+CPM+PNENYL-AS-STD-04 | 3.813  | 5168936 | 4990     | 1.258    |
| 15    | JDY-AS-23.lcd | PARA+CPM+PNENYL-AS-STD-05 | 3.819  | 5192359 | 4923     | 1.257    |
|       | Average       |                           | 3.813  | 5170566 | 4961     | 1.256    |
|       | %RSD          |                           | 0.104  | 0.305   | 0.563    | 0.255    |



## ID#2 Compound Name: PHENYLEPHRINE

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 15    | JDY-AS-19.lcd | PARA+CPM+PNENYL-AS-STD-01 | 6.765  | 1181397 | 7067     | 1.162    |
| 15    | JDY-AS-20.lcd | PARA+CPM+PNENYL-AS-STD-02 | 6.732  | 1184282 | 7034     | 1.166    |
| 15    | JDY-AS-21.lcd | PARA+CPM+PNENYL-AS-STD-03 | 6.748  | 1188082 | 7047     | 1.169    |
| 15    | JDY-AS-22.lcd | PARA+CPM+PNENYL-AS-STD-04 | 6.740  | 1186671 | 7067     | 1.170    |
| 15    | JDY-AS-23.lcd | PARA+CPM+PNENYL-AS-STD-05 | 6.714  | 1191624 | 7036     | 1.171    |
|       | Average       |                           | 6.740  | 1186411 | 7050     | 1.168    |
|       | %RSD          |                           | 0.280  | 0.326   | 0.226    | 0.312    |

## ID#3 Compound Name: CHLORPHENAMINE

| Vial# | Title         | Sample ID                 | R.Time | Area    | T. Plate | T.Factor |
|-------|---------------|---------------------------|--------|---------|----------|----------|
| 15    | JDY-AS-19.lcd | PARA+CPM+PNENYL-AS-STD-01 | 10.868 | 2712924 | 66460    | 1.365    |
| 15    | JDY-AS-20.lcd | PARA+CPM+PNENYL-AS-STD-02 | 10.885 | 2727748 | 65357    | 1.385    |
| 15    | JDY-AS-21.lcd | PARA+CPM+PNENYL-AS-STD-03 | 10.881 | 2724712 | 67515    | 1.372    |
| 15    | JDY-AS-22.lcd | PARA+CPM+PNENYL-AS-STD-04 | 10.872 | 2724245 | 67836    | 1.383    |
| 15    | JDY-AS-23.lcd | PARA+CPM+PNENYL-AS-STD-05 | 10.877 | 2736312 | 65410    | 1.377    |
|       | Average       |                           | 10.877 | 2725288 | 66516    | 1.377    |
|       | %RSD          |                           | 0.062  | 0.314   | 1.732    | 0.586    |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

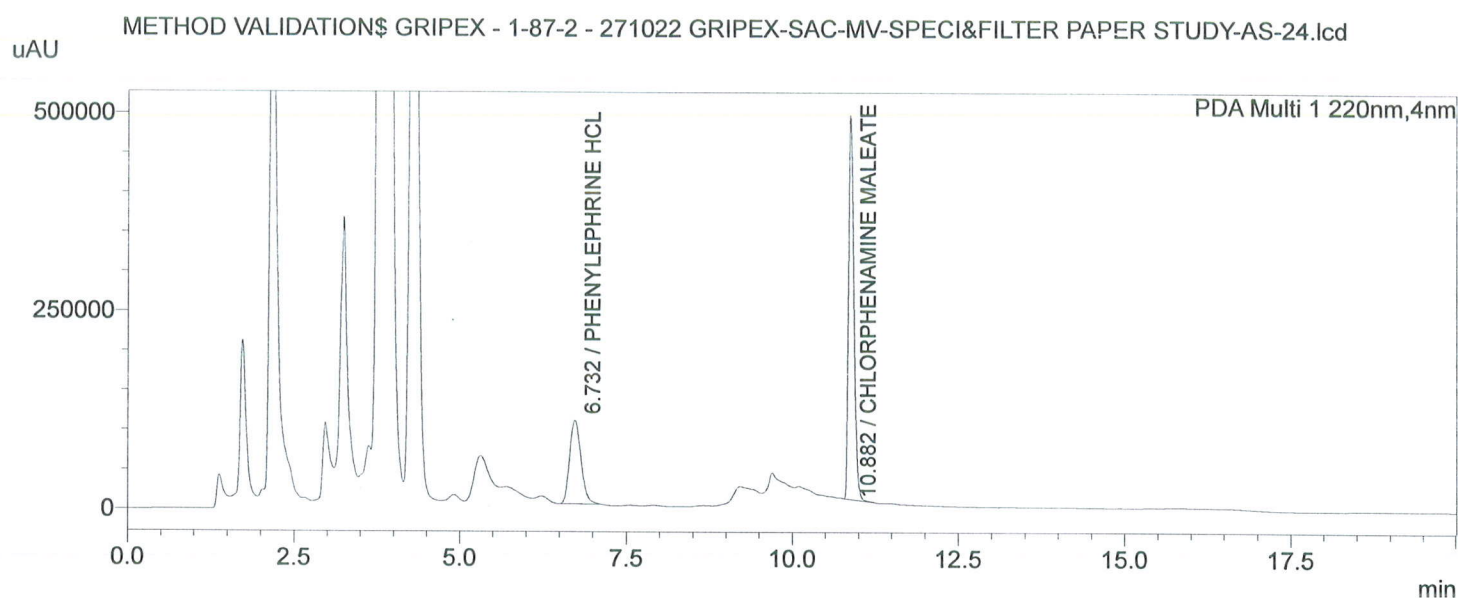
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : FILTER PAPER STUDY-AS  
Sample ID : UNFILTERED CENTRIFUGED SPL-A  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-24.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-16  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 10:27:37 PM  
Date Processed : 10/28/2022 12:09:52 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.732     | 1243073 | 31.587  | 7076    | 1.197    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.882    | 2692335 | 68.413  | 69646   | 1.371    | 17.11      | --       | CHLORPHENAMINE MALE |
| Total |           | 3935407 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

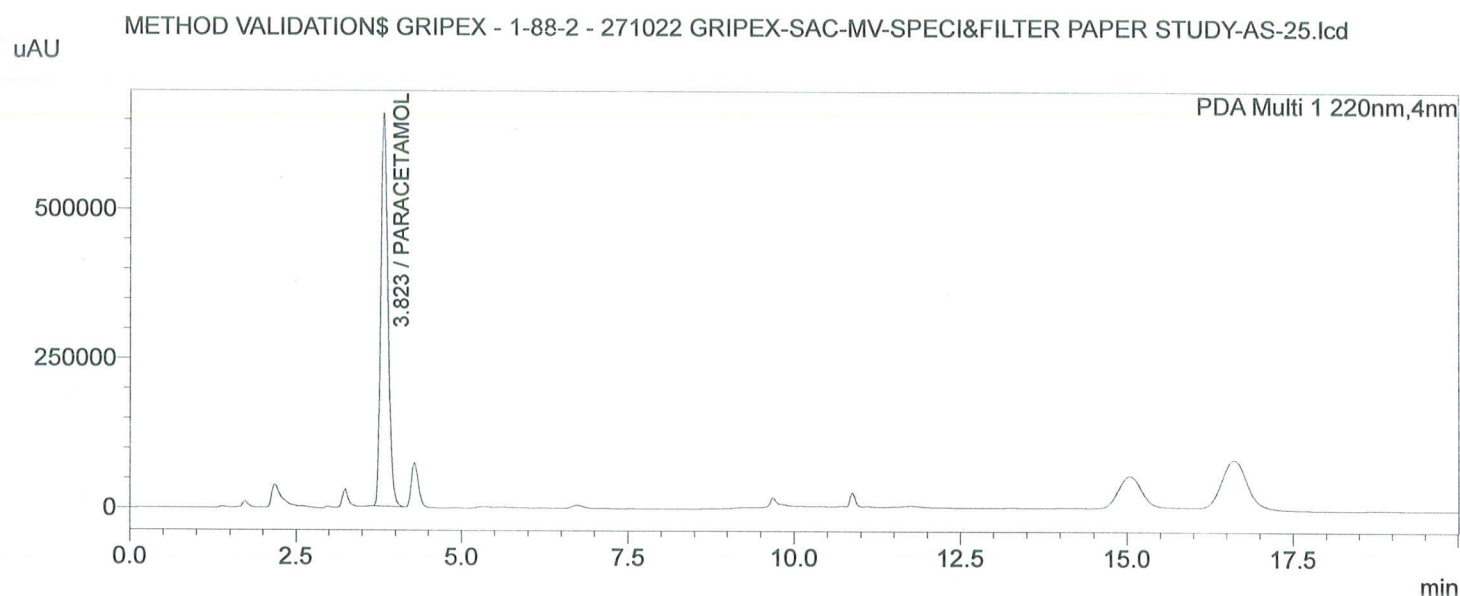
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : FILTER PAPER STUDY-AS  
Sample ID : UNFILTERED CENTRIFUGED SPL-B  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-25.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-17  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 10:48:14 PM  
Date Processed : 10/28/2022 12:10:36 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.823     | 5011140 | 100.000 | 5058    | 1.258    | --         | --       | PARACETAMOL |
| Total |           | 5011140 | 100.000 |         |          |            |          |             |

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Date :

Checked By

Date :





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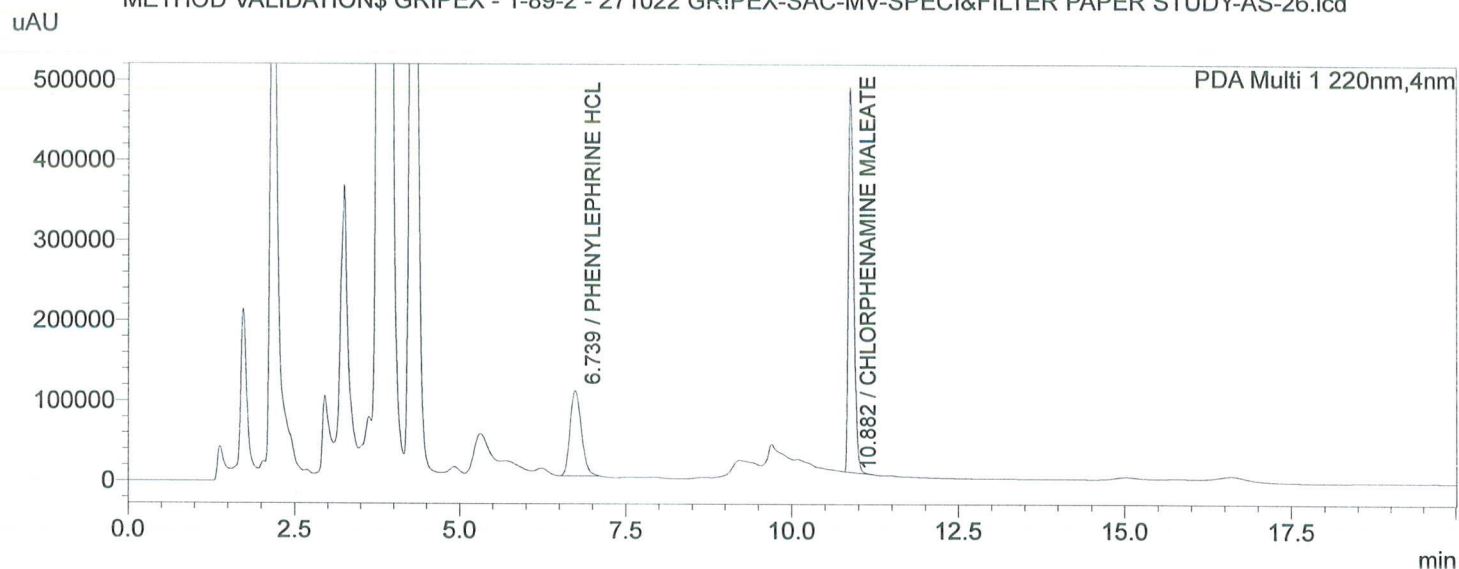
## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : FILTER PAPER STUDY-AS  
Sample ID : FILTER SAMPLE(PVDF) SET-1-SOL-A  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-26.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-18  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 11:08:53 PM  
Date Processed : 10/28/2022 12:09:55 PM

### <Chromatogram>

METHOD VALIDATION\$ GRIPEX - 1-89-2 - 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-26.lcd



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.739     | 1242670 | 31.684  | 7134    | 1.193    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.882    | 2679408 | 68.316  | 69145   | 1.377    | 17.09      | --       | CHLORPHENAMINE MALE |
| Total |           | 3922078 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

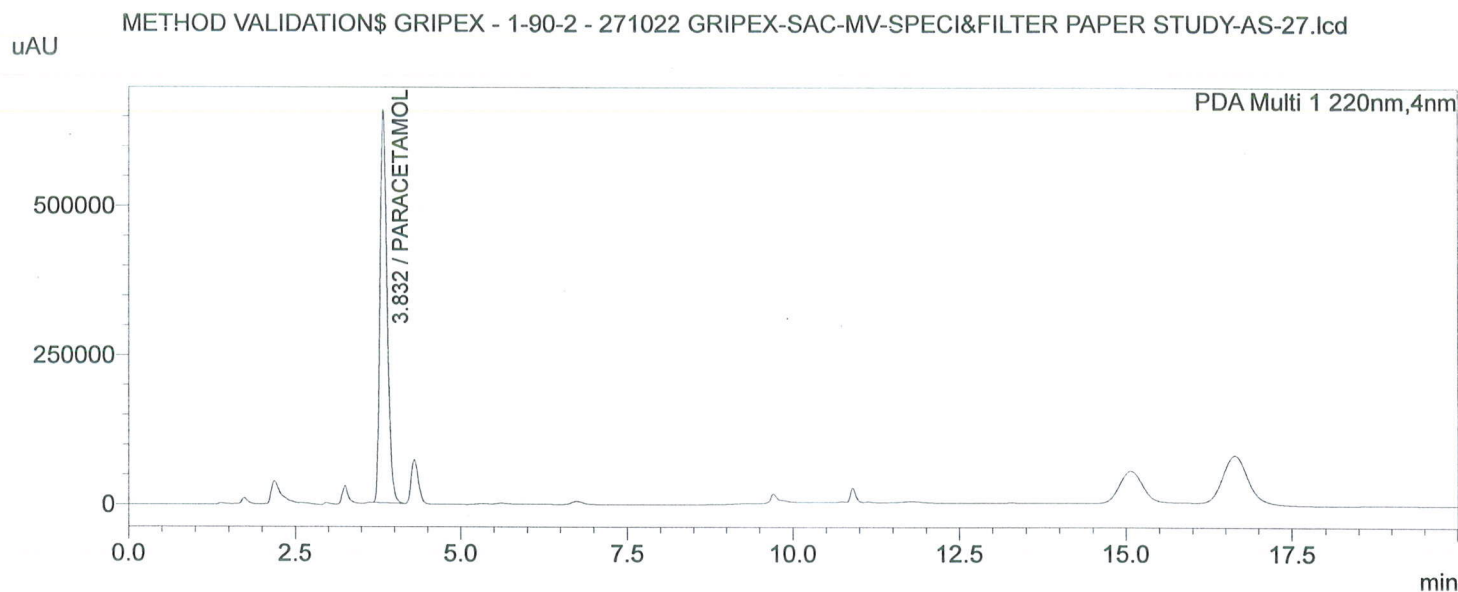
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : FILTER PAPER STUDY-AS  
Sample ID : FILTER SAMPLE(PVDF) SET-1-SOL-B  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-27.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-19  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 11:29:32 PM  
Date Processed : 10/28/2022 12:10:39 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plale | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.832     | 5000255 | 100.000 | 5049    | 1.256    | --         | --       | PARACETAMOL |
| Total |           | 5000255 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

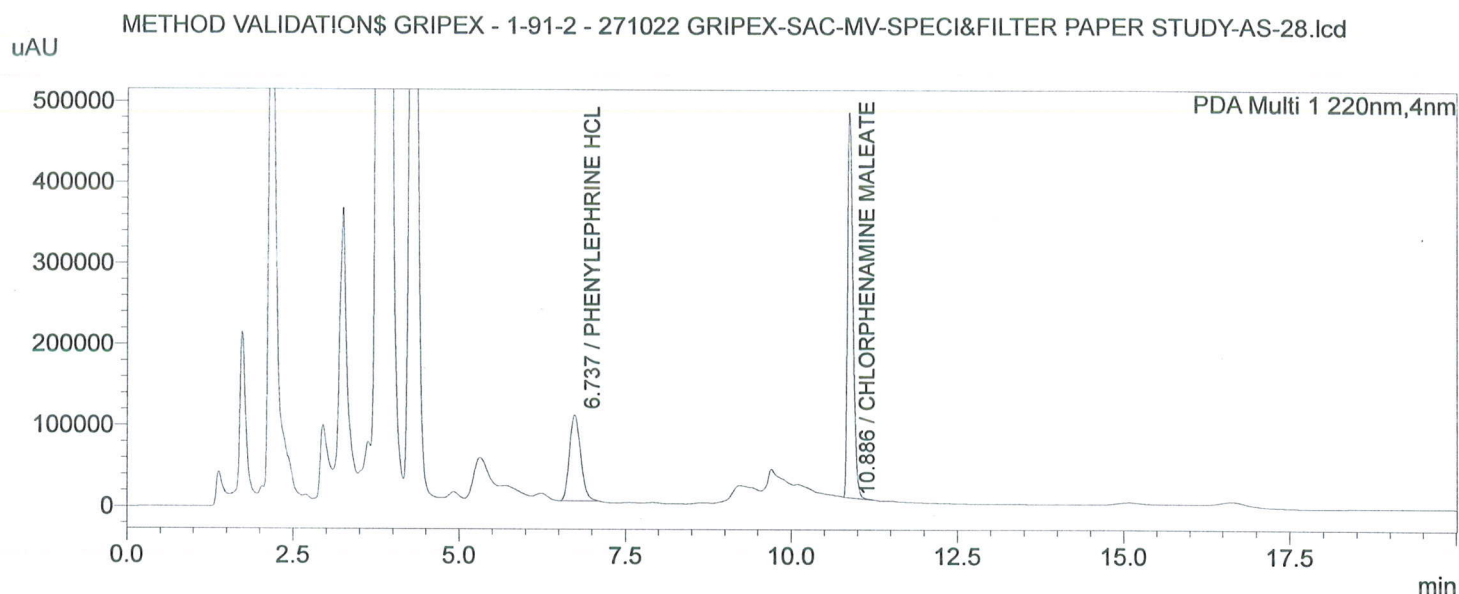
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : FILTER PAPER STUDY-AS  
Sample ID : FILTER SAMPLE(PVDF) SET-2-SOL-A  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-28.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-20  
Injection Volume : 50 uL  
Date Acquired : 10/27/2022 11:50:11 PM  
Date Processed : 10/28/2022 12:09:57 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.737     | 1240536 | 31.618  | 7166    | 1.199    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.886    | 2682916 | 68.382  | 66191   | 1.380    | 17.02      | --       | CHLORPHENAMINE MALE |
| Total |           | 3923452 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

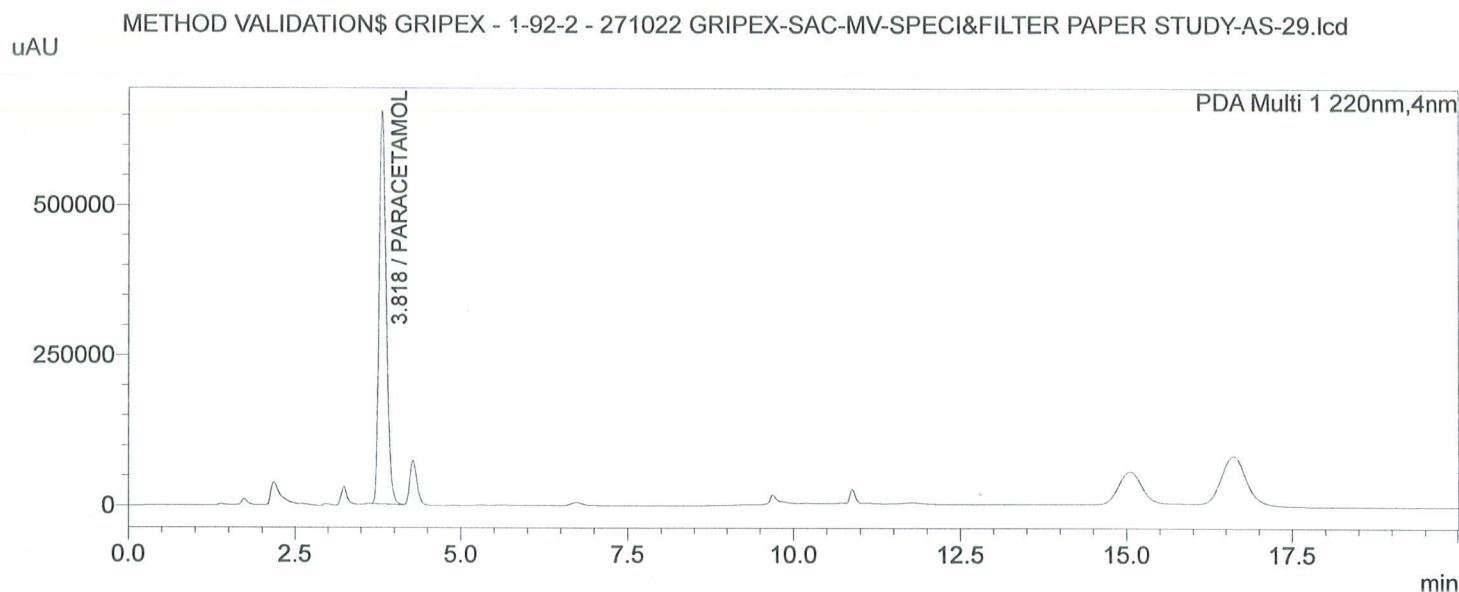
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : FILTER PAPER STUDY-AS  
Sample ID : FILTER SAMPLE(PVDF) SET-2-SOL-B  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-29.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-21  
Injection Volume : 50 uL  
Date Acquired : 10/28/2022 12:10:46 AM  
Date Processed : 10/28/2022 12:10:41 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.818     | 4955143 | 100.000 | 5016    | 1.254    | --         | --       | PARACETAMOL |
| Total |           | 4955143 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

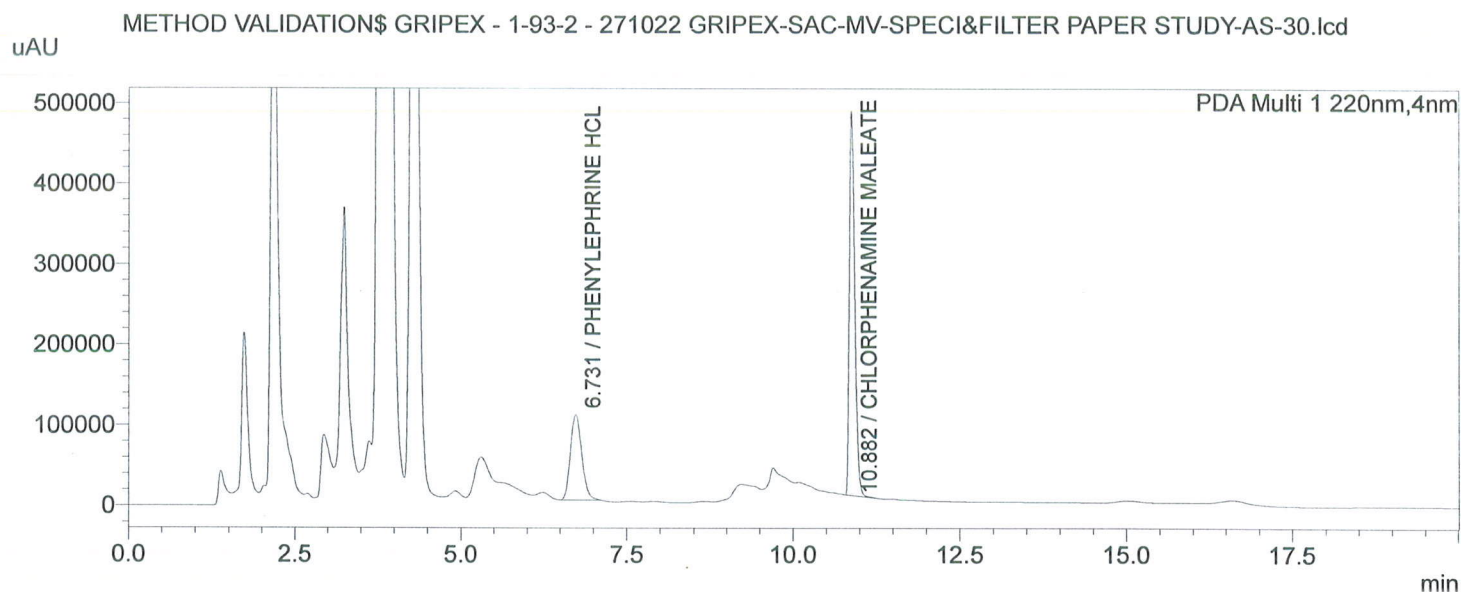
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : FILTER PAPER STUDY-AS  
Sample ID : FILTER SAMPLE(PVDF) SET-3-SOL-A  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-30.lcd  
Method Filename : GRIPEX-AS-A\_p.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-22  
Injection Volume : 50 uL  
Date Acquired : 10/28/2022 12:31:21 AM  
Date Processed : 10/28/2022 12:09:59 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plake | T.Factor | Resolution | R.R.Time | Name                |
|-------|-----------|---------|---------|---------|----------|------------|----------|---------------------|
| 1     | 6.731     | 1243465 | 31.704  | 7124    | 1.206    | --         | --       | PHENYLEPHRINE HCL   |
| 2     | 10.882    | 2678642 | 68.296  | 68565   | 1.382    | 17.11      | --       | CHLORPHENAMINE MALE |
| Total |           | 3922107 | 100.000 |         |          |            |          |                     |

Analysed By

Date :

Checked By

Date :



# Safetab Life Science

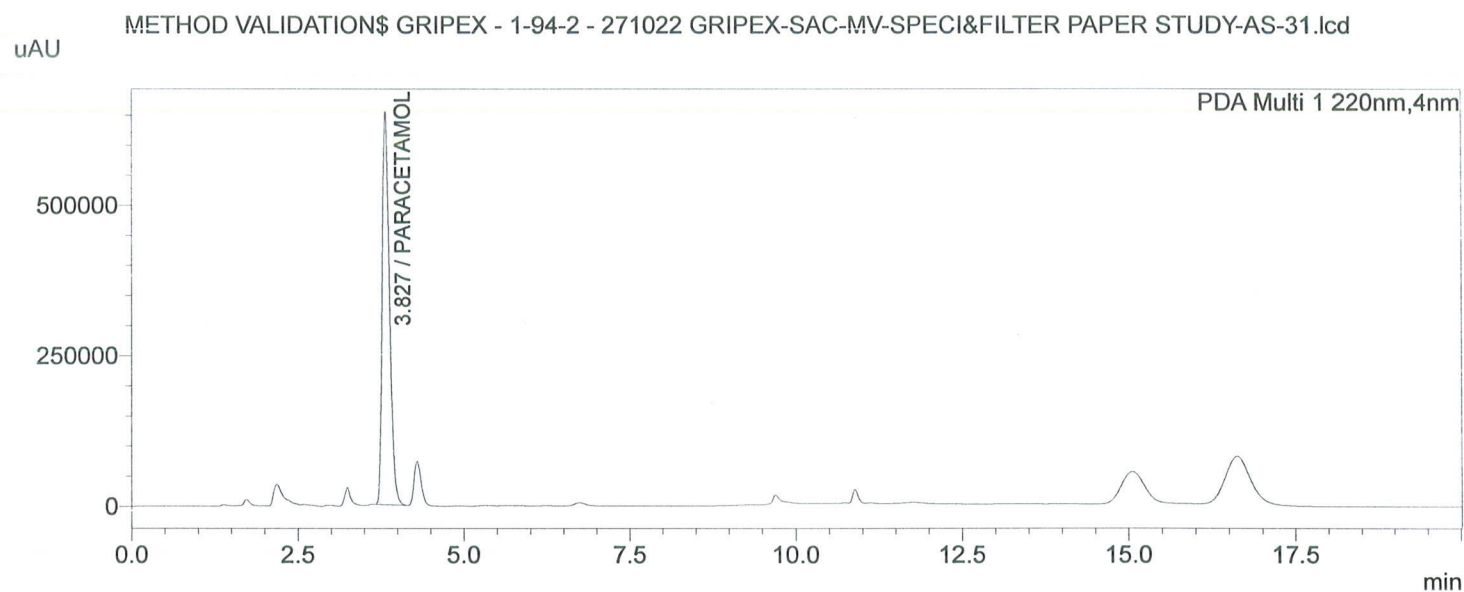
Puducherry- 605 107

## Quality control Department

### <Sample Information>

Acquired by : C.Albin Jose  
Sample Name : FILTER PAPER STUDY-AS  
Sample ID : FILTER SAMPLE(PVDF) SET-3-SOL-B  
Data Filename : 271022 GRIPEX-SAC-MV-SPECI&FILTER PAPER STUDY-AS-31.lcd  
Method Filename : GRIPEX-AS-B\_p.lcm  
Batch Filename : 271022 GRIPEX-SAC-MV-AS-SPECIFICITY& FILTER PAPER STUDY.lcb  
Vial # : 1-23  
Injection Volume : 50  $\mu$ L  
Date Acquired : 10/28/2022 12:51:56 AM  
Date Processed : 10/28/2022 12:10:43 PM

### <Chromatogram>



### <Peak Table>

PDA Ch1 220nm

| Peak# | Ret. Time | Area    | Area%   | T.Plate | T.Factor | Resolution | R.R.Time | Name        |
|-------|-----------|---------|---------|---------|----------|------------|----------|-------------|
| 1     | 3.827     | 4985379 | 100.000 | 4968    | 1.255    | --         | --       | PARACETAMOL |
| Total |           | 4985379 | 100.000 |         |          |            |          |             |

Analysed By

Date :

Checked By

Date :





# Safetab Life Science

Puducherry- 605 107

*Quality control Department*

## =====BATCH TABLE=====

Batch Table

| Vial# | Tray | Inj. Vol. | Sample Name           | Sample ID                           | Method File   | Data File                      | Report Format      |
|-------|------|-----------|-----------------------|-------------------------------------|---------------|--------------------------------|--------------------|
| 1     | 1    | 50.0      | SPECIFICITY-AS        | BLANK-AS                            | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-01.lcd | system\DEFAULT.lsr |
| 2     | 1    | 50.0      | SPECIFICITY-AS        | PARA + CPM + PNENYL-SPECI-AS-STD-01 | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-02.lcd | system\DEFAULT.lsr |
| 2     | 1    | 50.0      | SPECIFICITY-AS        | PARA + CPM + PNENYL-SPECI-AS-STD-02 | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-03.lcd | system\DEFAULT.lsr |
| 2     | 1    | 50.0      | SPECIFICITY-AS        | PARA + CPM + PNENYL-SPECI-AS-STD-03 | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-04.lcd | system\DEFAULT.lsr |
| 2     | 1    | 50.0      | SPECIFICITY-AS        | PARA + CPM + PNENYL-SPECI-AS-STD-04 | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-05.lcd | system\DEFAULT.lsr |
| 2     | 1    | 50.0      | SPECIFICITY-AS        | PARA + CPM + PNENYL-SPECI-AS-STD-05 | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-06.lcd | system\DEFAULT.lsr |
| 3     | 1    | 50.0      | SPECIFICITY-AS        | BLANK-AS                            | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-07.lcd | system\DEFAULT.lsr |
| 4     | 1    | 50.0      | SPECIFICITY-AS        | PLAIN PLACEBO                       | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-08.lcd | system\DEFAULT.lsr |
| 5     | 1    | 50.0      | SPECIFICITY-AS        | CHLORPHENAMINE-STD                  | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-09.lcd | system\DEFAULT.lsr |
| 6     | 1    | 50.0      | SPECIFICITY-AS        | PHENYLEPHRINE HCL-STD               | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-10.lcd | system\DEFAULT.lsr |
| 7     | 1    | 50.0      | SPECIFICITY-AS        | PARACETAMOL-STD                     | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-11.lcd | system\DEFAULT.lsr |
| 8     | 1    | 50.0      | SPECIFICITY-AS        | PLACEBO+CHLORPHENAMINE STD          | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-12.lcd | system\DEFAULT.lsr |
| 9     | 1    | 50.0      | SPECIFICITY-AS        | PLACEBO+PHENYLEPHRINE HCL-STD       | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-13.lcd | system\DEFAULT.lsr |
| 10    | 1    | 50.0      | SPECIFICITY-AS        | PLACEBO+PARACETAMOL-STD             | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-14.lcd | system\DEFAULT.lsr |
| 11    | 1    | 50.0      | SPECIFICITY-AS        | PLACEBO+CPM+PHENYL+PARA-STD         | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-15.lcd | system\DEFAULT.lsr |
| 12    | 1    | 50.0      | SPECIFICITY-AS        | TEST PREPARATION-SOLUTION-A         | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-16.lcd | system\DEFAULT.lsr |
| 13    | 1    | 50.0      | SPECIFICITY-AS        | TEST PREPARATION-SOLUTION-B         | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-17.lcd | system\DEFAULT.lsr |
| 14    | 1    | 50.0      | FILTER PAPER STUDY-AS | BLANK-AS                            | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-18.lcd | system\DEFAULT.lsr |
| 15    | 1    | 50.0      | FILTER PAPER STUDY-AS | PARA + CPM + PNENYL-AS-STD-01       | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-19.lcd | system\DEFAULT.lsr |
| 15    | 1    | 50.0      | FILTER PAPER STUDY-AS | PARA + CPM + PNENYL-AS-STD-02       | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-20.lcd | system\DEFAULT.lsr |
| 15    | 1    | 50.0      | FILTER PAPER STUDY-AS | PARA + CPM + PNENYL-AS-STD-03       | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-21.lcd | system\DEFAULT.lsr |
| 15    | 1    | 50.0      | FILTER PAPER STUDY-AS | PARA + CPM + PNENYL-AS-STD-04       | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-22.lcd | system\DEFAULT.lsr |
| 15    | 1    | 50.0      | FILTER PAPER STUDY-AS | PARA + CPM + PNENYL-AS-STD-05       | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-23.lcd | system\DEFAULT.lsr |
| 16    | 1    | 50.0      | FILTER PAPER STUDY-AS | UNFILTERED CENTRIFUGED SPL-A        | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-24.lcd | system\DEFAULT.lsr |
| 17    | 1    | 50.0      | FILTER PAPER STUDY-AS | UNFILTERED CENTRIFUGED SPL-B        | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-25.lcd | system\DEFAULT.lsr |
| 18    | 1    | 50.0      | FILTER PAPER STUDY-AS | FILTER SAMPLE(PVDF) SET-1-SOL-A     | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-26.lcd | system\DEFAULT.lsr |
| 19    | 1    | 50.0      | FILTER PAPER STUDY-AS | FILTER SAMPLE(PVDF) SET-1-SOL-B     | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-27.lcd | system\DEFAULT.lsr |
| 20    | 1    | 50.0      | FILTER PAPER STUDY-AS | FILTER SAMPLE(PVDF) SET-2-SOL-A     | GRIPEX-AS.lcm | I&FILTER PAPER STUDY-AS-28.lcd | system\DEFAULT.lsr |

| Vial# | Tray | Inj. Vol. | Sample Name           | Sample ID                                           | Method File                                  | Data File          | Report Format |
|-------|------|-----------|-----------------------|-----------------------------------------------------|----------------------------------------------|--------------------|---------------|
| 21    | 1    | 50.0      | FILTER PAPER STUDY-AS | FILTER SAMPLE(PVDF) SET-2-SOL-B                     | GRIPEX-AS.lcm I&FILTER PAPER STUDY-AS-29.lcd | system\DEFAULT.lsr |               |
| 22    | 1    | 50.0      | FILTER PAPER STUDY-AS | FILTER SAMPLE(PVDF) SET-3-SOL-A                     | GRIPEX-AS.lcm I&FILTER PAPER STUDY-AS-30.lcd | system\DEFAULT.lsr |               |
| 23    | 1    | 50.0      | FILTER PAPER STUDY-AS | FILTER SAMPLE(PVDF) SET-3-SOL-B                     | GRIPEX-AS.lcm I&FILTER PAPER STUDY-AS-31.lcd | system\DEFAULT.lsr |               |
| 15    | 1    | 50.0      | FILTER PAPER STUDY-AS | PARA+CPM+PNENYL-AS-BKT-STD                          | GRIPEX-AS.lcm I&FILTER PAPER STUDY-AS-32.lcd | system\DEFAULT.lsr |               |
| -1    | 1    | 50.0      | FILTER PAPER STUDY-AS | SHUT DOWN METHOD.lcm I&FILTER PAPER STUDY-AS-33.lcd | system\DEFAULT.lsr                           | system\DEFAULT.lsr |               |

Analysed By

Date

27/11/2024

Checked By

Date

28/11/2024



SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107  
RECORD OF ANALYSIS

Page - 1

|                     |                |
|---------------------|----------------|
| Name of the Product | GRIPEX SACHETS |
| Batch No            | ST/T/S-1322    |

| S. No | TEST / OBSERVATION / LIMIT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | <p><u>Specimen as filter paper Study:</u></p> <p><u>Std. Stock Solution: A</u></p> <p>64.93mg of paracetamol and 40.28mg of Chlorpheniramine maleate is in 100ml volumetric flask add 70ml of diluent sonicate to dissolve and make up to volume with diluent.</p> <p><u>Std. Stock Solution: B</u></p> <p>39.94mg of phenolphthalein is in 100ml volumetric flask add 120 about 130ml of diluent sonicate to dissolve and make up to volume with diluent.</p> <p><u>Standard Preparation:</u></p> <p>5ml of each standard stock solution to 50ml with diluent.</p> <p><u>Sample Preparation:</u></p> <p>500.9 mg of sample in 500ml volumetric flask added about 300ml of diluent and sonicate for 10 minutes and make up to volume with diluent. Put the solution through 0.45 µm PDA filter (G1A). Take dilute 5ml of this solution to 100ml with diluent (G1.B)</p> |

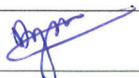
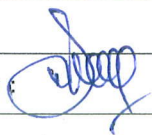
|                                                                                                   |                 |                                                                                                   |                 |
|---------------------------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------------------------|-----------------|
| Analyzed by :  | Date : 27/10/22 | Checked by :  | Date : 28/10/22 |
|---------------------------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------------------------|-----------------|



**SAFETAB LIFE SCIENCE, PUDUCHERRY - 605 107**  
**RECORD OF ANALYSIS**

|                     |             |
|---------------------|-------------|
| Name of the Product | GRIPEX      |
| Batch No            | ST/T/S-1322 |

| S. No | TEST / OBSERVATION / LIMIT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | <p><u>Plain placebo Preparation:</u></p> <p>762.37g of plain placebo in 1000 volumetric flask added about 300ml of diluent sonicate for 10 minutes. And make up to volume with diluent. Filter the solution through 0.45 µm PDA filter.</p> <p><u>Plain placebo + phenylephrine Soln:</u></p> <p>3632.7g of plain placebo and 10.46g of phenylephrine HCl in 5000 volumetric flask added about 300ml of diluent sonicate for 10 min and make up to volume with diluent. Filter the solution through 0.45 µm PDA filter.</p> <p><u>Plain placebo + Chlorpheniramine:</u></p> <p>3825.4g of plain placebo + 20.12g of epm in 5000ml volumetric flask add about 300ml of diluent sonicate for 10 min and make up to volume with diluent. Filter the solution through 0.45 µm PDA filter.</p> |

|                                                                                                  |                |                                                                                                  |                |
|--------------------------------------------------------------------------------------------------|----------------|--------------------------------------------------------------------------------------------------|----------------|
| Analyzed by:  | Date: 27/10/22 | Checked by:  | Date: 27/10/22 |
|--------------------------------------------------------------------------------------------------|----------------|--------------------------------------------------------------------------------------------------|----------------|

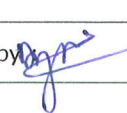
|                     |            |
|---------------------|------------|
| Name of the Product | ARIPIDOL   |
| Batch No            | S1/T/S-132 |

Plan placebo + Paracetamol ..

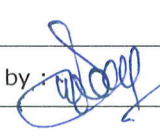
3850.9 mg of Plan place + 680.12g of Paracetamol  
in 500ml of volumetric flask added about 300ml of  
defunct. Some for division and makeup to volume with  
defunct. Further defunct 5ml of gas solvent to 500ml can defunct.  
Filter the solution through 0.45 µm PVDF filter.

Plan place + cpm + Par + phylephrine ..

3828.9 mg of Plan placebo + 80.12g cpm + 10.12g of  
phylephrine + 680.25g of Paracetamol in 500ml of  
volumetric flask added. 300ml of defunct. Some for  
division and makeup to volume with defunct.  
Filter the solution through 0.45 µm PVDF

Analyzed by 

Date 27/10/22

Checked by : 

Date : 27/10/22