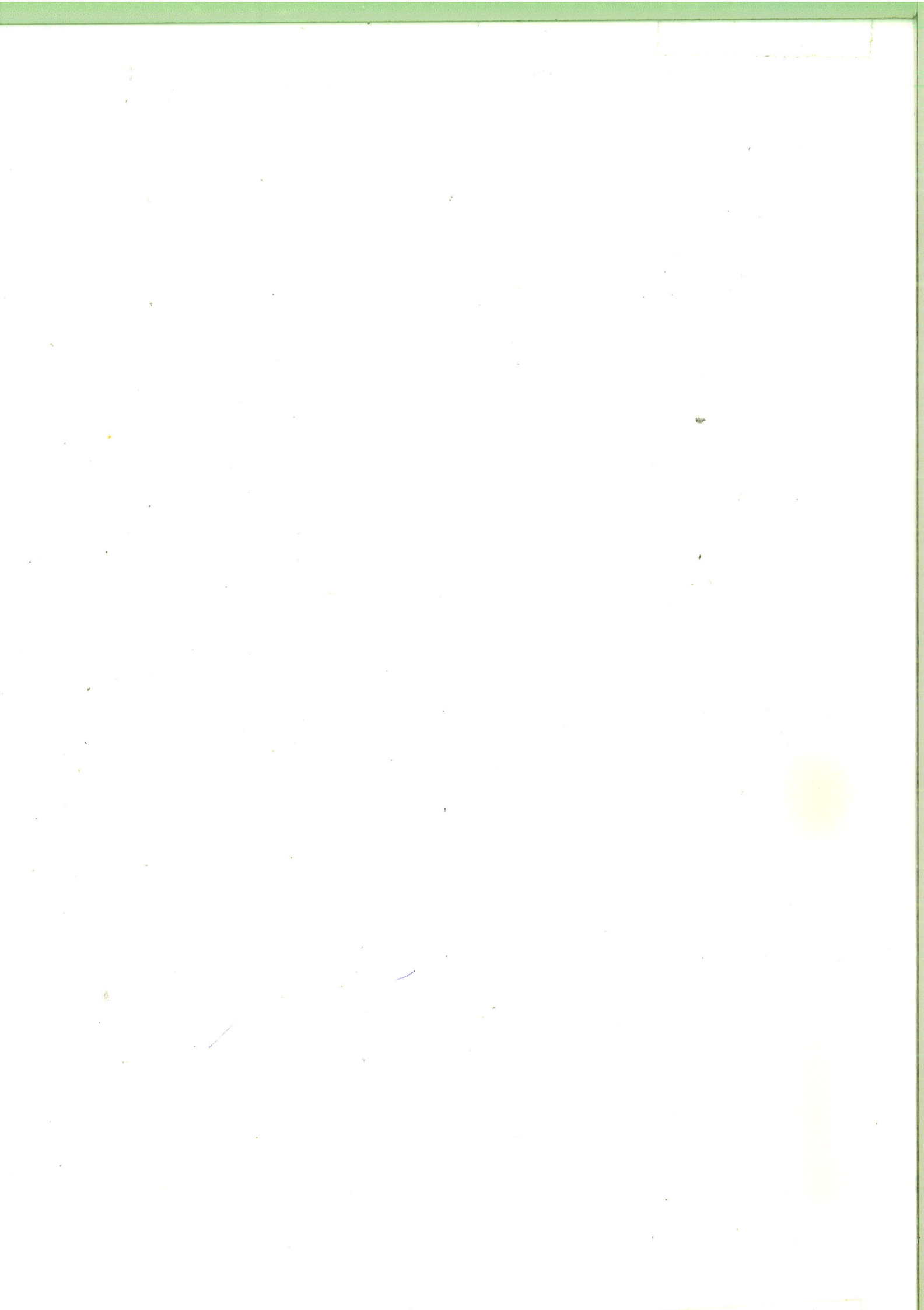




**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

RELATED SUBSTANCES OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Parameter :	LINEARITY and RANGE	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCES OF PARACETAMOL

Instrument ID:	ST/QCLC/005	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
----------------	-------------	--------------	--------------	---------	--------------	----------------	------

Linearity Level-I :	75.14	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-0.30056	2	ml to --->	250	ml to --->	1	ml to --->	1

Linearity Level-II :	75.14	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-1.5028	2	ml to --->	50	ml to --->	1	ml to --->	1

Linearity Level-III :	75.14	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-2.2542	3	ml to --->	50	ml to --->	1	ml to --->	1

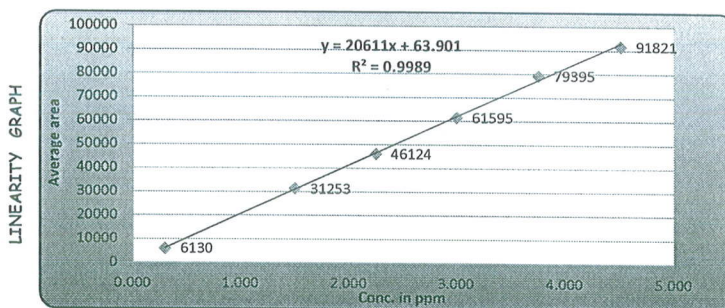
Linearity Level-IV :	75.14	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.0056	4	ml to --->	50	ml to --->	1	ml to --->	1

Linearity Level-V :	75.14	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.757	5	ml to --->	50	ml to --->	1	ml to --->	1

Linearity Level-VI :	75.14	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-4.5084	6	ml to --->	50	ml to --->	1	ml to --->	1

Level"s	I	II	III	IV	V	VI
No. of injections.	10%	50%	75%	100%	125%	150%
1	6171	31248	46207	61661	79436	91785
2	6137	31311	46023	61500	79404	91926
3	6081	31201	46143	61625	79346	91751
Average	6130	31253	46124	61595	79395	91821
RSD%	0.741	0.177	0.203	0.137	0.057	0.101

LEVEL"s	Conc. in ppm (X-axis)	Average area (Y-axis)
I	0.301	6130
II	1.503	31253
III	2.254	46124
IV	3.006	61595
V	3.757	79395
VI	4.508	91821

**Results :**

1) Squared correlation coefficient of Paracetamol

0.998

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 :

E.MEENA

Date :

18-01-2024

Checked By :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCES OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Parameter :	LIMIT OF DETECTION and LIMIT OF QUANTITATION	Exp.Date :	Nov-26

RELATED SUBSTANCES OF PARACETAMOL

Instrument ID:	ST/QCLC/005	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
----------------	-------------	--------------	--------------	---------	--------------	----------------	------

Standard stock soln :	75.14	mg to ---->	100	ml to ---->	5	ml to ---->	100
Std.conc (in ppm)-37.57	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

Level	I	II	III	IV	V	VI
1	6171	31248	46207	61661	79436	91785
2	6137	31311	46023	61500	79404	91926
3	6081	31201	46143	61625	79346	91751
Average	6130	31253	46124	61595	79395	91821

LEVEL	Con.in ppm (X-axis)	Average area (Y-axis)
I	0.301	6130
II	1.503	31253
III	2.254	46124
IV	3.006	61595
V	3.757	79395
VI	4.508	91821

SUMMARY OUTPUT

Regression Statistics

Multiple R	0.999464138
R Square	0.998928563
Adjusted R Square	0.998660704
Standard Error	1156.585065
Observations	6

ANOVA

	df	SS	MS	F	Significance F
Regression	1	4988649727	4988649727	3729.304552	4.30645E-07
Residual	4	5350756.054	1337689.013		
Total	5	4994000483			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	65.21559829	983.0536928	0.066339813	0.950290706	-2664.179015	2794.610212	-2664.179015	2794.610212
X Variable 1	20610.50569	337.5007342	61.06803216	4.30645E-07	19673.45343	21547.55795	19673.45343	21547.55795

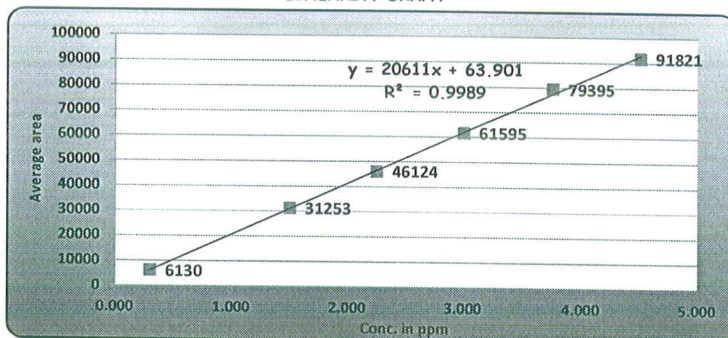
RESIDUAL OUTPUT

Observation	Predicted Y	Residuals
1	6259.909188	-128.2425214
2	31038.68355	214.6497863
3	46525.41752	-401.084188
4	62012.1515	-416.8181624
5	77498.88547	1896.447863
6	92985.61944	-1164.952778

Results:

R2 VALUE	0.9989
CORRELATION COEFFICIENT R	0.9995
Y-INTERCEPT	64
SLOPE	20611
LOD	0.166
LOQ	0.502
STANDARD DEVIATION	1034

LINEARITY GRAPH



CONCENTRATION		%	PPM
OBSERVED	LOD	0.099	0.166
	LOQ	0.301	0.502
DETERMINED	LOD	0.020	0.033
	LOQ	0.040	0.067

Analysed by :

E.MEENA

Date :

18-01-2024

Checked by :

Date :



GENERIC HEALTHCARE PVT. LTD.

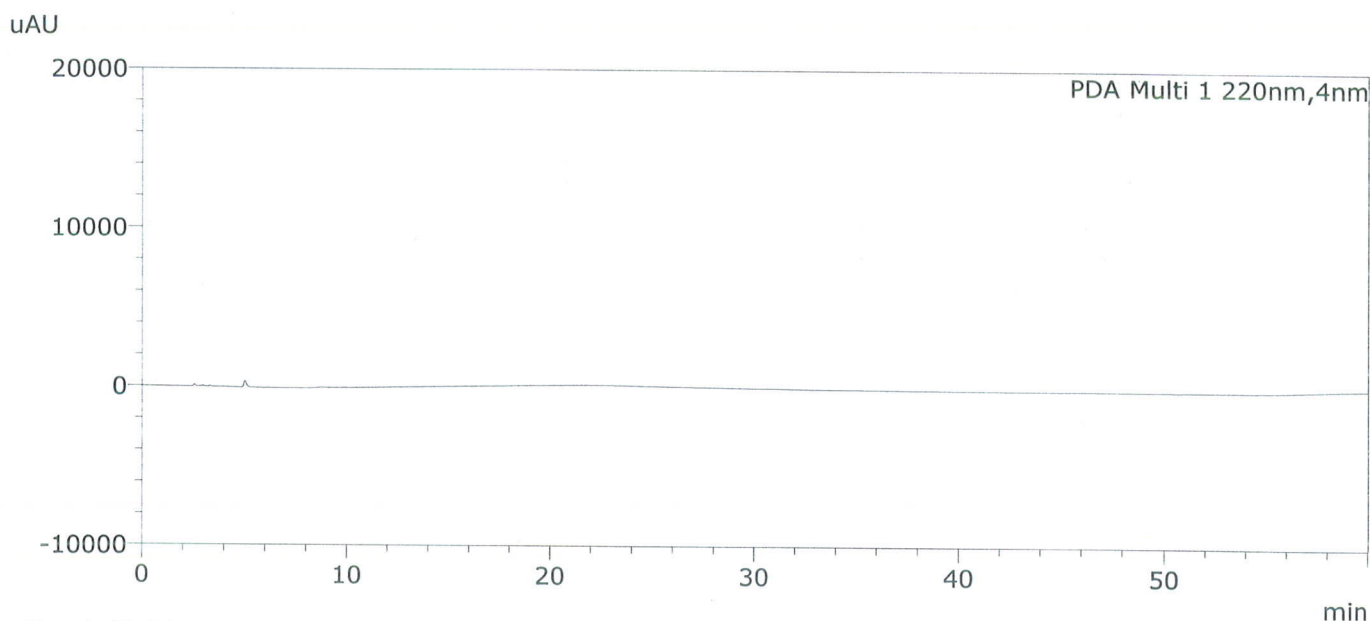
Analysis Report

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Sample Name : LINEARITY-RS
 Sample ID : BLANK-RS
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-09.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 00:28:12
 Date Processed : 18-01-2024 19:40:20

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

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

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

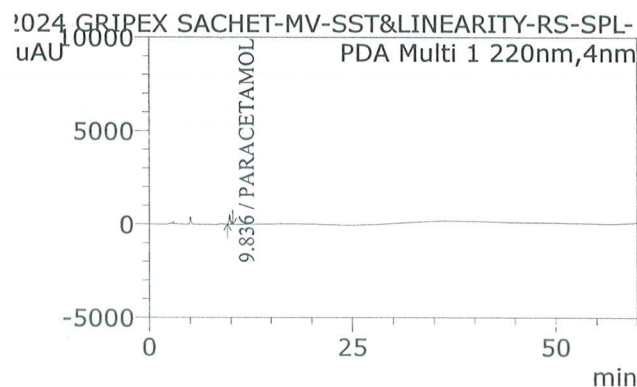
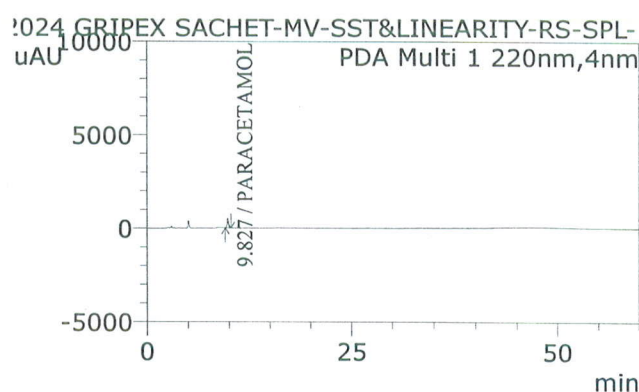
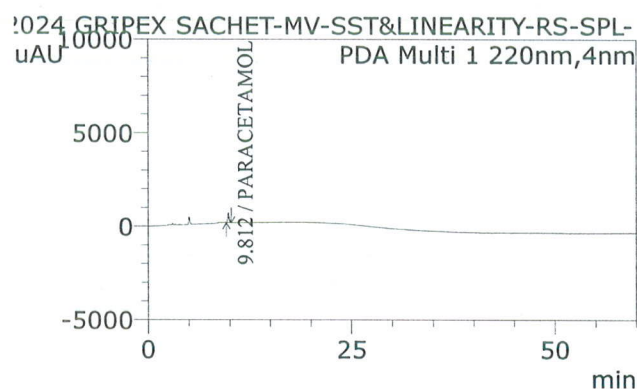
Analysis Report

<Sample Information>

Sample Name : LINEARITY-RS
 Sample ID : PARACETAMOL-LINEARITY-10%-SPL-1
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-10.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 01:43:44
 Date Processed : 18-01-2024 19:40:21

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
5	RS-SPL-10.lcd	PARACETAMOL-LINEARITY-10%-SPL-1	9.81	6171	15129	1.09
5	RS-SPL-11.lcd	PARACETAMOL-LINEARITY-10%-SPL-2	9.83	6137	14987	1.10
5	RS-SPL-12.lcd	PARACETAMOL-LINEARITY-10%-SPL-3	9.84	6081	15133	1.07
Average			9.82	6130	15083	1.09
%RSD			0.122	0.741	0.549	1.132

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

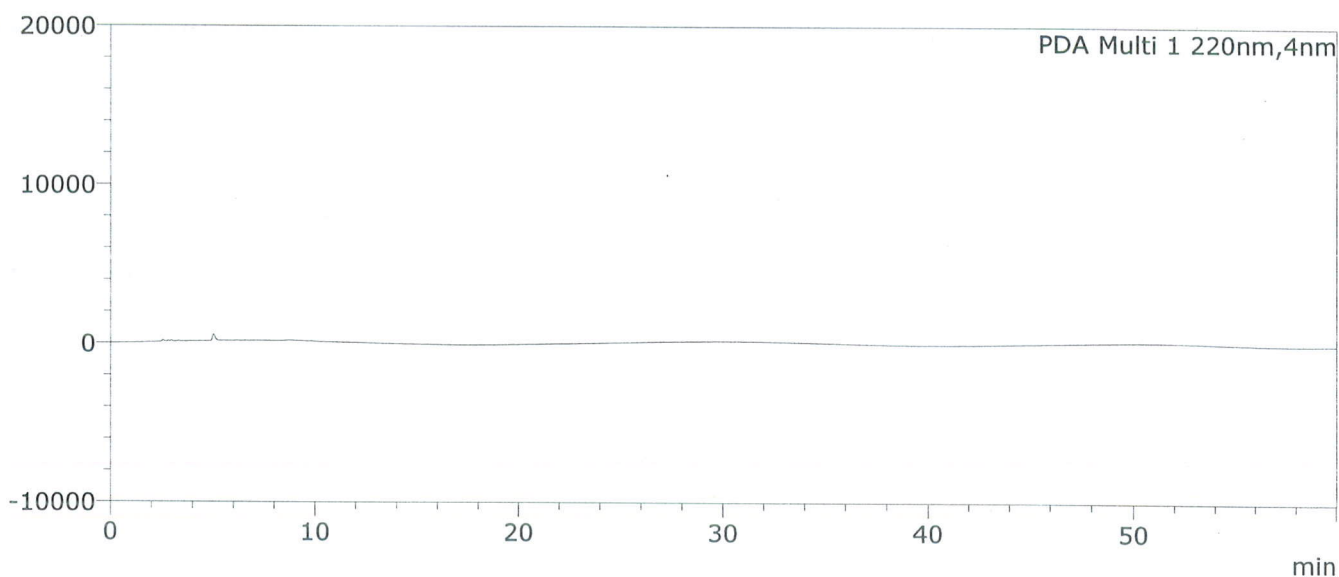
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 Sample ID : BLANK-RS
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-13.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 04:45:38
 Date Processed : 18-01-2024 19:40:21

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

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<Peak Table>

PDA Ch1 220nm

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

18/01/24
 Analysed By

18/01/2024
 Checked By



GENERIC HEALTHCARE PVT. LTD.

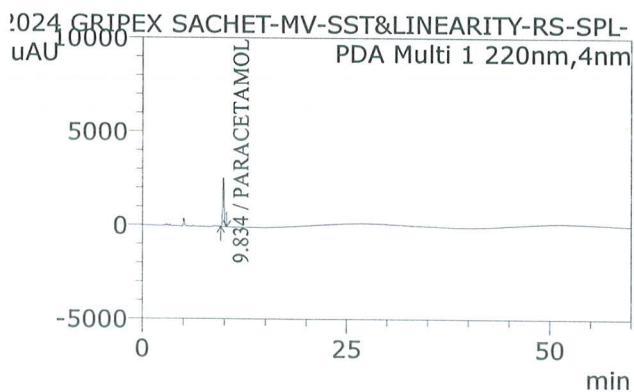
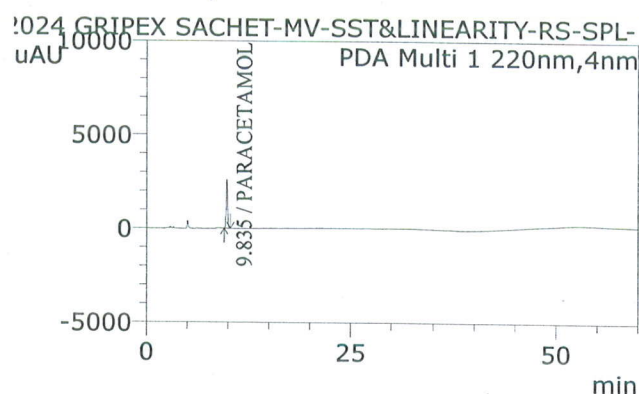
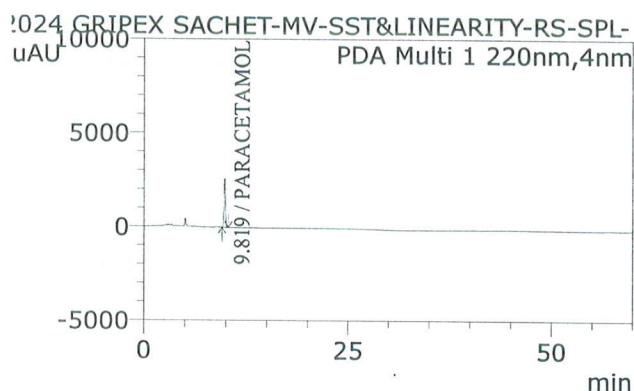
Analysis Report

<Sample Information>

Sample Name : LINEARITY-RS
 Sample ID : PARACETAMOL-LINEARITY-50%-SPL-1
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-14.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-6
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 05:46:29
 Date Processed : 18-01-2024 19:40:21

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
6	RS-SPL-14.lcd	PARACETAMOL-LINEARITY-50%-SPL-1	9.82	31248	14787	1.09
6	RS-SPL-15.lcd	PARACETAMOL-LINEARITY-50%-SPL-2	9.84	31311	14723	1.09
6	RS-SPL-16.lcd	PARACETAMOL-LINEARITY-50%-SPL-3	9.83	31201	14777	1.09
Average			9.83	31253	14762	1.09
%RSD			0.089	0.177	0.236	0.065

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

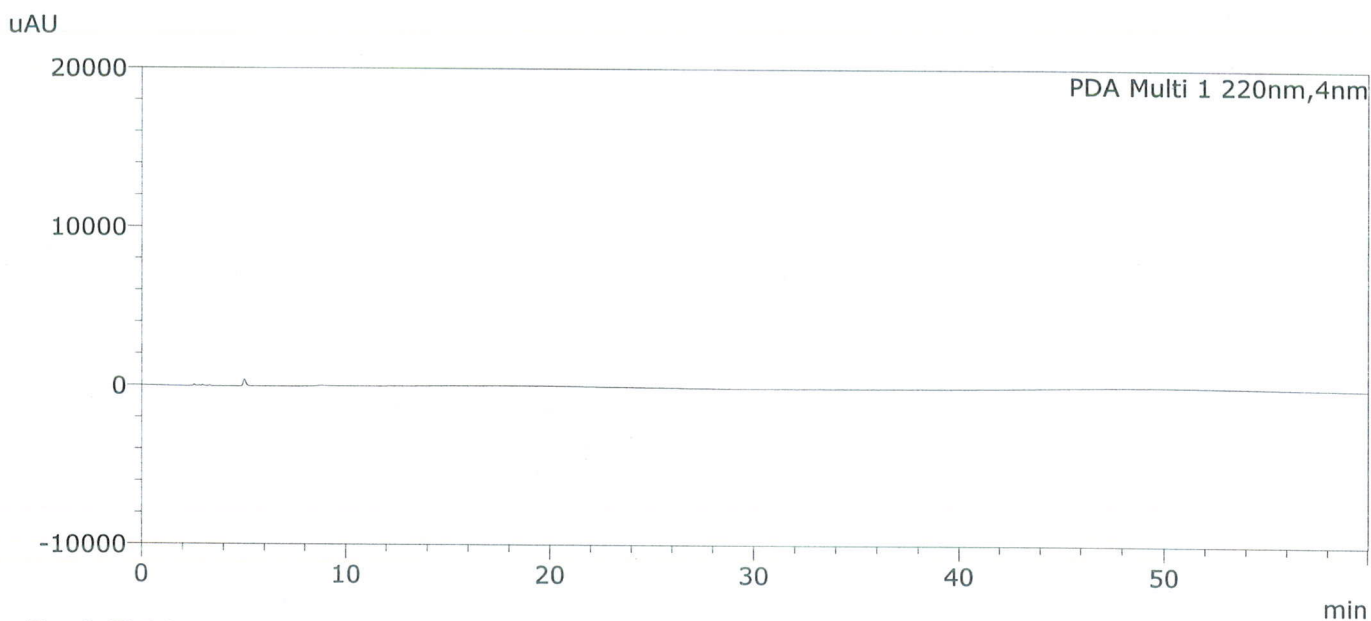
Analysis Report

<Sample Information>

Sample Name : LINEARITY-RS
 Sample ID : BLANK-RS
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-17.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 08:48:23
 Date Processed : 18-01-2024 19:40:22

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

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

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

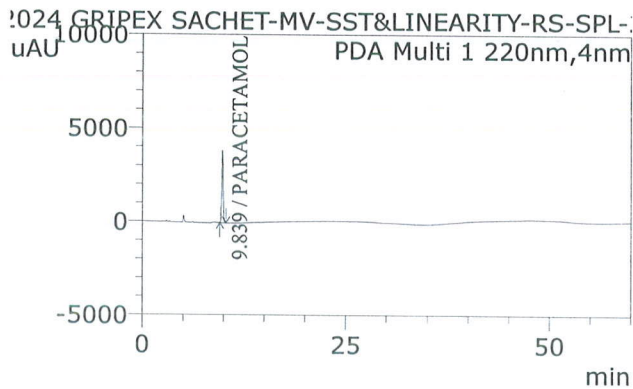
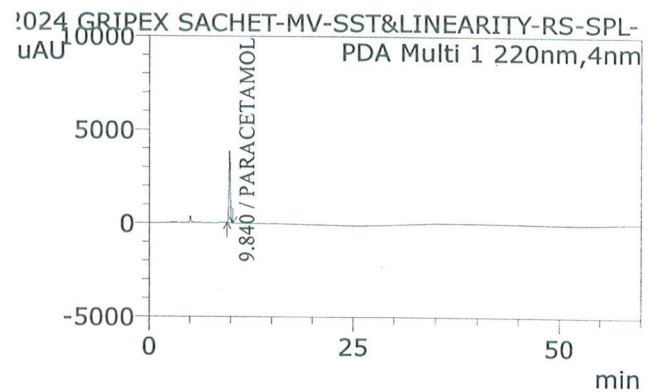
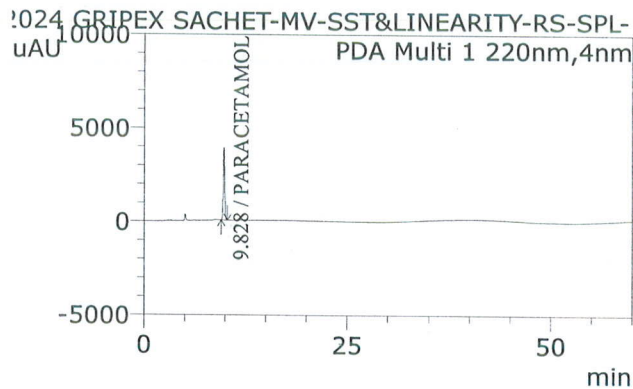
Analysis Report

<Sample Information>

Sample Name : LINEARITY-RS
 Sample ID : PARACETAMOL-LINEARITY-75%-SPL-1
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-18.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-7
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 09:48:55
 Date Processed : 18-01-2024 19:40:23

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
7	RS-SPL-18.lcd	PARACETAMOL-LINEARITY-75%-SPL-1	9.83	46207	14758	1.07
7	RS-SPL-19.lcd	PARACETAMOL-LINEARITY-75%-SPL-2	9.84	46023	14816	1.07
7	RS-SPL-20.lcd	PARACETAMOL-LINEARITY-75%-SPL-3	9.84	46143	14798	1.07
Average			9.84	46124	14791	1.07
%RSD			0.068	0.203	0.200	0.025

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

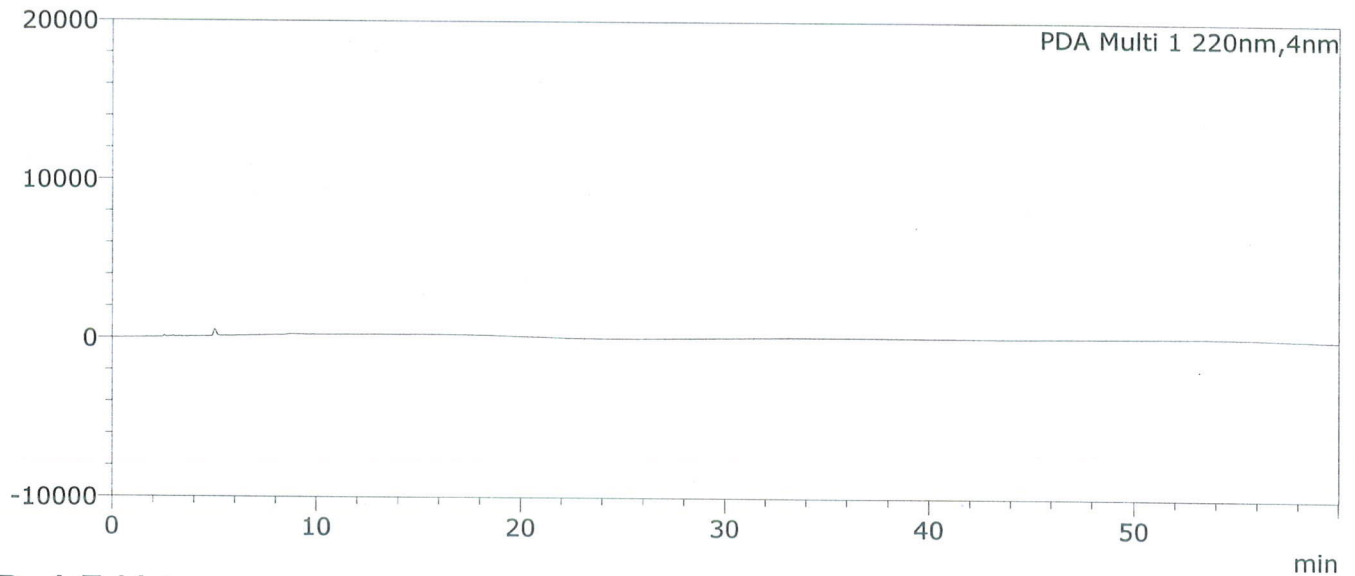
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Sample Name : LINEARITY-RS
 Sample ID : BLANK-RS
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-21.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 12:50:33
 Date Processed : 18-01-2024 19:40:24

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 220nm

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

18/01/24

Analysed By

18/01/2024

Checked By


GENERIC HEALTHCARE PVT. LTD.

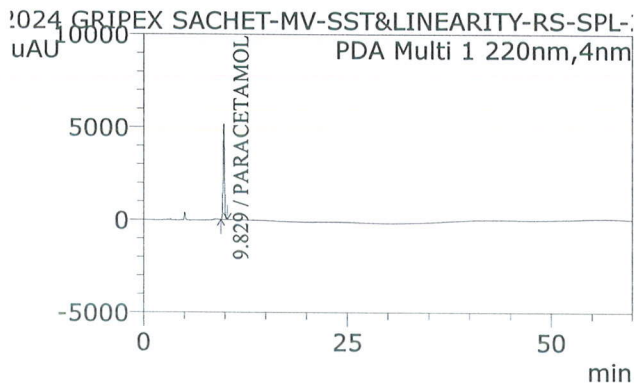
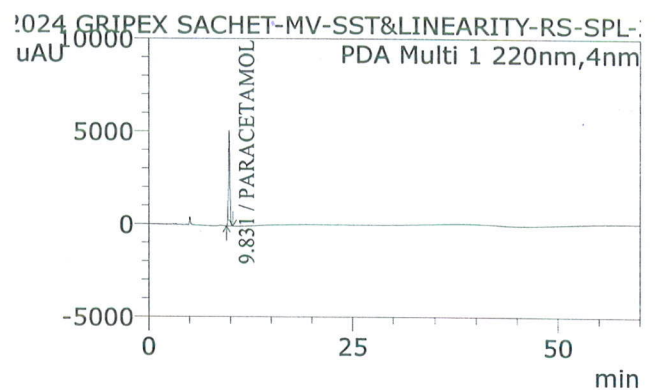
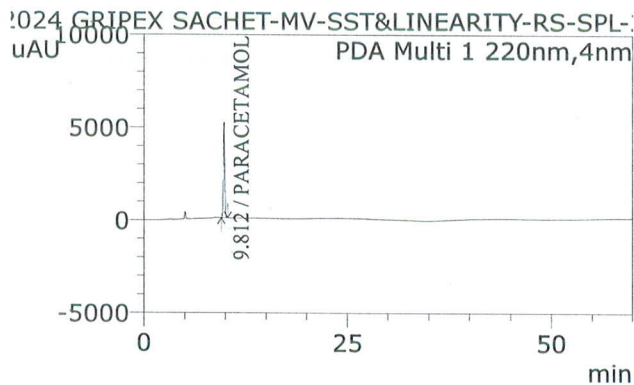
Analysis Report

<Sample Information>

Sample Name : LINEARITY-RS
 Sample ID : PARACETAMOL-LINEARITY100%-SPL-1
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-22.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-8
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 13:51:07
 Date Processed : 18-01-2024 19:40:24

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
8	RS-SPL-22.lcd	PARACETAMOL-LINEARITY100%-SPL-1	9.81	61661	14652	1.07
8	RS-SPL-23.lcd	PARACETAMOL-LINEARITY100%-SPL-2	9.83	61500	14746	1.07
8	RS-SPL-24.lcd	PARACETAMOL-LINEARITY100%-SPL-3	9.83	61625	14721	1.07
Average			9.82	61595	14706	1.07
%RSD			0.109	0.137	0.331	0.167

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

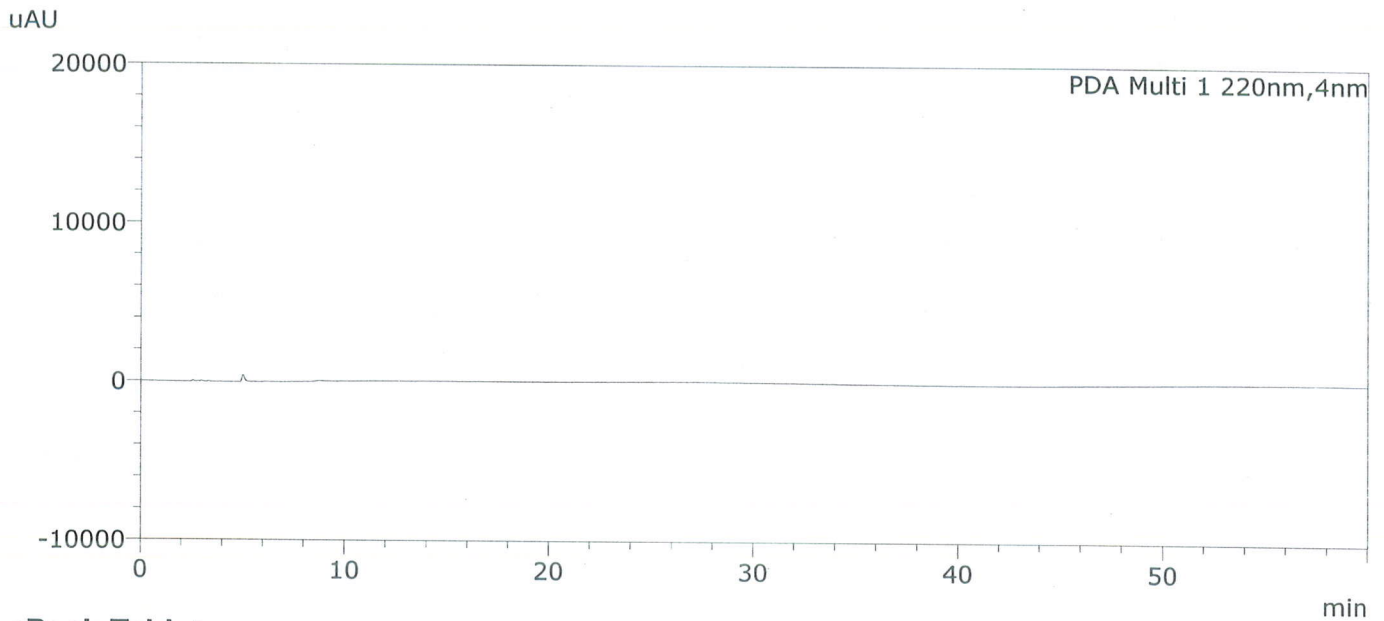
Analysis Report

<Sample Information>

Sample Name : LINEARITY-RS
 Sample ID : BLANK-RS
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-25.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 16:52:47
 Date Processed : 18-01-2024 19:40:25

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

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

18/01/24

Analysed By

18/01/2024

Checked By


GENERIC HEALTHCARE PVT. LTD.

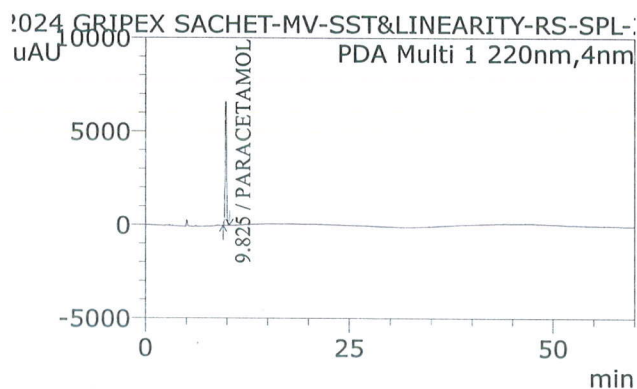
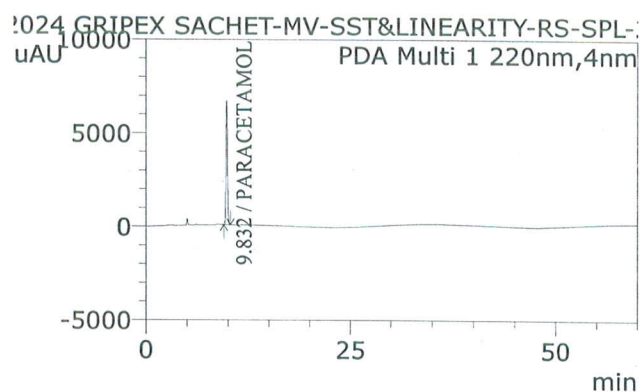
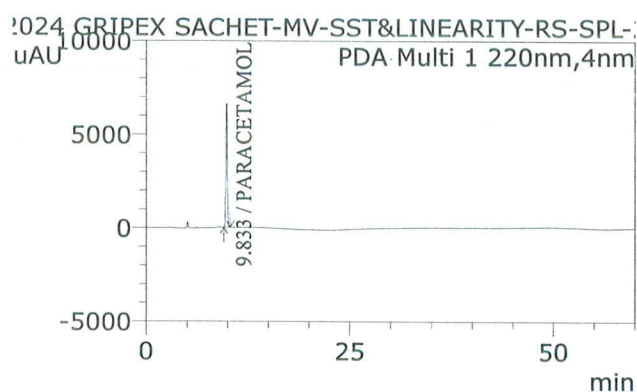
Analysis Report

<Sample Information>

Sample Name : LINEARITY-RS
 Sample ID : PARACETAMOL-LINEARITY125%-SPL-1
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-26.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-9
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 17:53:21
 Date Processed : 18-01-2024 19:40:26

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
9	RS-SPL-26.lcd	PARACETAMOL-LINEARITY125%-SPL-1	9.83	79436	14641	1.07
9	RS-SPL-27.lcd	PARACETAMOL-LINEARITY125%-SPL-2	9.83	79404	14617	1.07
9	RS-SPL-28.lcd	PARACETAMOL-LINEARITY125%-SPL-3	9.82	79346	14663	1.07
Average			9.83	79395	14640	1.07
%RSD			0.045	0.057	0.155	0.061

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

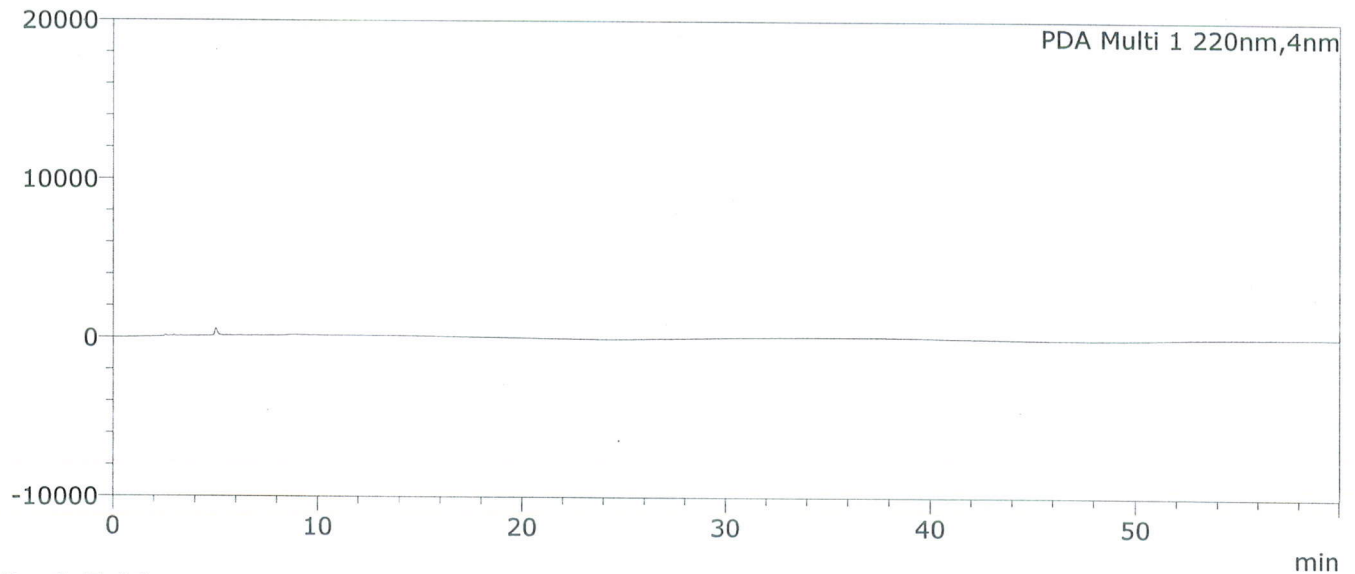
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 Sample ID : BLANK-RS
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-29.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 19:54:46
 Date Processed : 18-01-2024 19:40:26

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 220nm

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

18/01/24

Analysed By

18/01/2024

Checked By


GENERIC HEALTHCARE PVT. LTD.

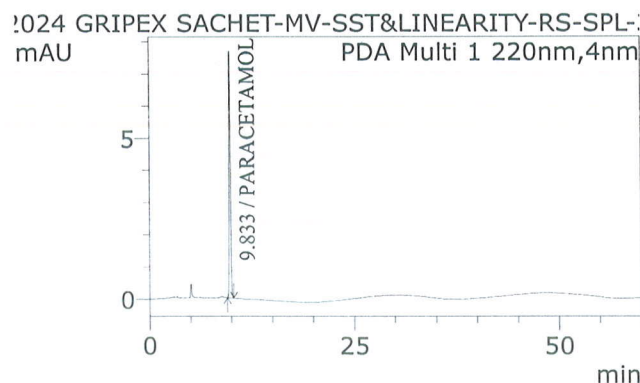
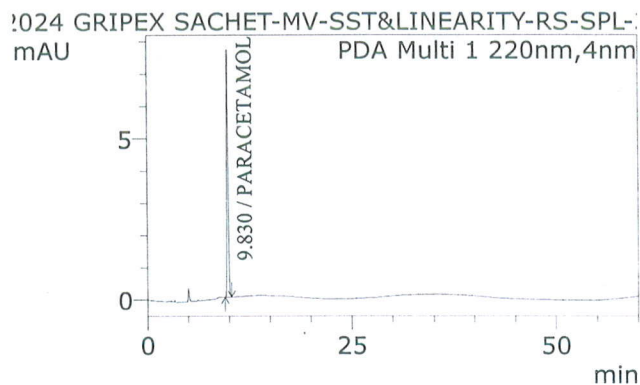
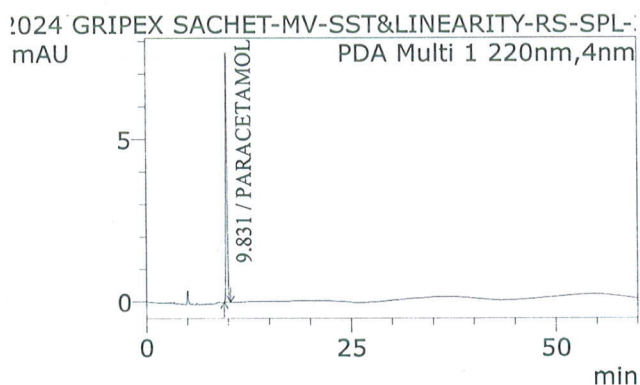
Analysis Report

<Sample Information>

Sample Name : LINEARITY-RS
 Sample ID : PARACETAMOL-LINEARITY150%-SPL-1
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-30.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-10
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 20:55:45
 Date Processed : 18-01-2024 19:40:27

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
10	RS-SPL-30.lcd	PARACETAMOL-LINEARITY150%-SPL-1	9.83	91785	14681	1.07
10	RS-SPL-31.lcd	PARACETAMOL-LINEARITY150%-SPL-2	9.83	91926	14657	1.06
10	RS-SPL-32.lcd	PARACETAMOL-LINEARITY150%-SPL-3	9.83	91751	14614	1.06
	Average		9.83	91820	14651	1.06
	%RSD		0.014	0.101	0.233	0.038

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

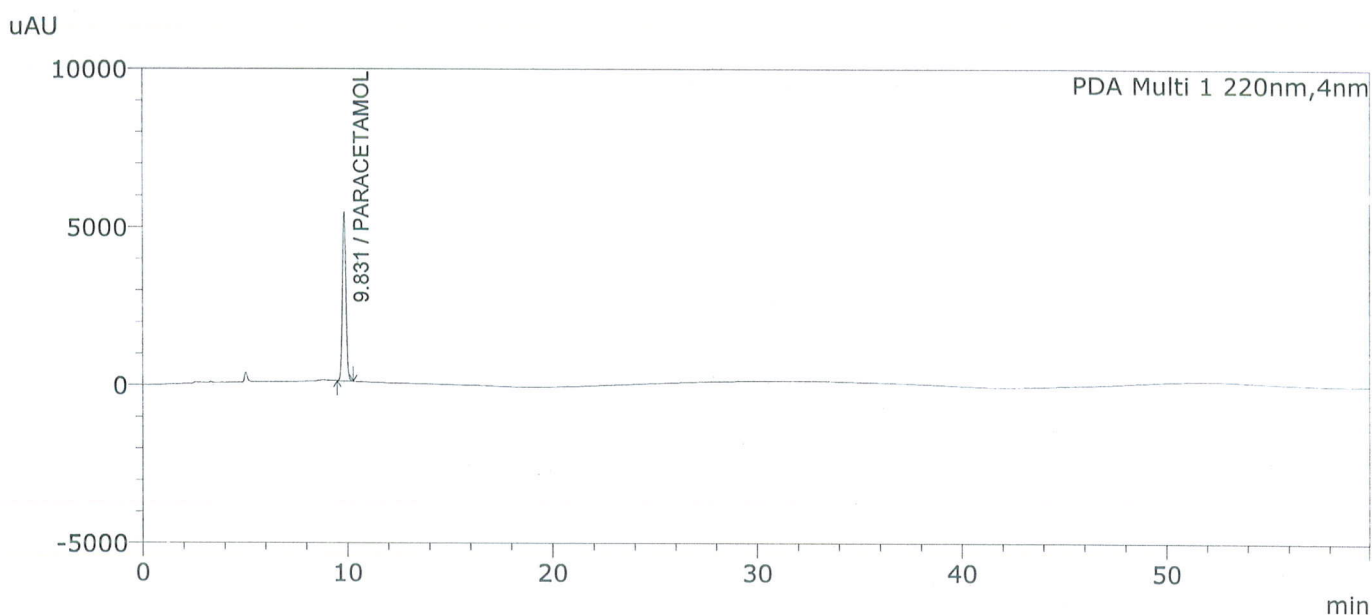
Analysis Report

<Sample Information>

Sample Name : LINEARITY-RS
 Sample ID : PARACETAMOL-RS-STD-BKT
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-33.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 12-01-2024 23:59:09
 Date Processed : 18-01-2024 19:40:27

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	9.83	64157	100.00	14651	1.065	--	--
Total			64157	100.00				

18/01/24
Analysed By

18/01/2024
Checked By



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 11012024.GRIPEX.SACHET-MV-RS-SST&LINEARITY.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	1	SYSTEM SUITABILITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-01.lcd	10.0	QC/CL/23/033
2	1	SYSTEM SUITABILITY-RS	RESOLUTION SOLUTION	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-02.lcd	10.0	QC/CL/23/033
3	1	SYSTEM SUITABILITY-RS	PARACETAMOL-RS-STD-01	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-03.lcd	10.0	QC/CL/23/033
3	1	SYSTEM SUITABILITY-RS	PARACETAMOL-RS-STD-02	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-04.lcd	10.0	QC/CL/23/033
3	1	SYSTEM SUITABILITY-RS	PARACETAMOL-RS-STD-03	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-05.lcd	10.0	QC/CL/23/033
3	1	SYSTEM SUITABILITY-RS	PARACETAMOL-RS-STD-04	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-06.lcd	10.0	QC/CL/23/033
3	1	SYSTEM SUITABILITY-RS	PARACETAMOL-RS-STD-05	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-07.lcd	10.0	QC/CL/23/033
3	1	SYSTEM SUITABILITY-RS	PARACETAMOL-RS-STD-06	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-08.lcd	10.0	QC/CL/23/033
4	1	LINEARITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-09.lcd	10.0	QC/CL/23/033
5	1	LINEARITY-RS	PARACETAMOL-LINEARITY-10%-SPL-1	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-10.lcd	10.0	QC/CL/23/033
5	1	LINEARITY-RS	PARACETAMOL-LINEARITY-10%-SPL-2	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-11.lcd	10.0	QC/CL/23/033
5	1	LINEARITY-RS	PARACETAMOL-LINEARITY-10%-SPL-3	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-12.lcd	10.0	QC/CL/23/033
4	1	LINEARITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-13.lcd	10.0	QC/CL/23/033
6	1	LINEARITY-RS	PARACETAMOL-LINEARITY-50%-SPL-1	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-14.lcd	10.0	QC/CL/23/033
6	1	LINEARITY-RS	PARACETAMOL-LINEARITY-50%-SPL-2	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-15.lcd	10.0	QC/CL/23/033
6	1	LINEARITY-RS	PARACETAMOL-LINEARITY-50%-SPL-3	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-16.lcd	10.0	QC/CL/23/033
4	1	LINEARITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-17.lcd	10.0	QC/CL/23/033
7	1	LINEARITY-RS	PARACETAMOL-LINEARITY-75%-SPL-1	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-18.lcd	10.0	QC/CL/23/033

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
7	1	LINEARITY-RS	PARACETAMOL-LINEARITY-75%-SPL-2	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-19.lcd	10.0	QC/CL/23/033
7	1	LINEARITY-RS	PARACETAMOL-LINEARITY-75%-SPL-3	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-20.lcd	10.0	QC/CL/23/033
4	1	LINEARITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-21.lcd	10.0	QC/CL/23/033
8	1	LINEARITY-RS	PARACETAMOL-LINEARITY100%-SPL-1	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-22.lcd	10.0	QC/CL/23/033
8	1	LINEARITY-RS	PARACETAMOL-LINEARITY100%-SPL-2	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-23.lcd	10.0	QC/CL/23/033
8	1	LINEARITY-RS	PARACETAMOL-LINEARITY100%-SPL-3	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-24.lcd	10.0	QC/CL/23/033
4	1	LINEARITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-25.lcd	10.0	QC/CL/23/033
9	1	LINEARITY-RS	PARACETAMOL-LINEARITY125%-SPL-1	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-26.lcd	10.0	QC/CL/23/033
9	1	LINEARITY-RS	PARACETAMOL-LINEARITY125%-SPL-2	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-27.lcd	10.0	QC/CL/23/033
9	1	LINEARITY-RS	PARACETAMOL-LINEARITY125%-SPL-3	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-28.lcd	10.0	QC/CL/23/033
4	1	LINEARITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-29.lcd	10.0	QC/CL/23/033
10	1	LINEARITY-RS	PARACETAMOL-LINEARITY150%-SPL-1	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-30.lcd	10.0	QC/CL/23/033
10	1	LINEARITY-RS	PARACETAMOL-LINEARITY150%-SPL-2	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-31.lcd	10.0	QC/CL/23/033
10	1	LINEARITY-RS	PARACETAMOL-LINEARITY150%-SPL-3	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-32.lcd	10.0	QC/CL/23/033
3	1	LINEARITY-RS	PARACETAMOL-RS-STD-BKT	METHOD\GRIPEX-RS.lcm	ARITY-RS-SPL-33.lcd	10.0	QC/CL/23/033
-1	1	LINEARITY-RS	SHUTDOWN	HUTDOWN METHOD	ARITY-RS-SPL-34.lcd	10.0	QC/CL/23/033

10/10/24

Analysed By

10/10/24
Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

RELATED SUBSTANCES OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Parameter :	SYSTEM SUITABILITY	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCES OF PARACETAMOL

Instrument ID:	ST/QCLC/005	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution :	60.32	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.016	5	ml to --->	50	ml to --->	1	ml to --->	1

No.of injections	Retention time	Area	Theoretical plate	Tailing factor	Resolution (Ascorbic acid + CPM)	Resolution (CPM + Phenylephrine)	Resolution (Phenylephrine + Paracetamol)
1	9.90	64279	15297	1.06	4.149	3.7	20.917
2	9.89	64374	15262	1.06			
3	9.90	64148	15239	1.06			
4	9.90	64172	15187	1.06			
5	9.90	64219	15119	1.06			
6	9.90	64258	15208	1.07			
Average	9.898	64242	15219	1.06			
RSD %	0.041	0.127	Not applicable	Not applicable			

Results :

- 1) % RSD of area of Paracetamol peak
- 2) Tailing factor for Paracetamol peak
- 3) Theoretical plates for Paracetamol peak
- 4) Resolution between Ascorbic acid and Chlorpheniramine Maleate
- 5) Resolution between Chlorpheniramine Maleate and Phenylephrine Hcl
- 6) Resolution between Phenylephrine Hcl and Paracetamol

0.127

1.06

15219

4.149

3.700

20.917

Acceptance criteria:

- 1) % RSD of area of Paracetamol peak in Six replicate Standard injections should not be more than 5.0.
- 2) Tailing factor for Paracetamol peak in Standard injection should not be more than 2.0.
- 3) Theoretical plate for Paracetamol peak in standard injection should not be less than 2000.
- 4) Resolution between Ascorbic acid and Chlorpheniramine, Chlorpheniramine and Phenylephrine, Phenylephrine Hcl and Paracetamol should not less than 2.0.

Analysed by :

E.MEENA

Date :

18-01-2024

Checked by :

Date :



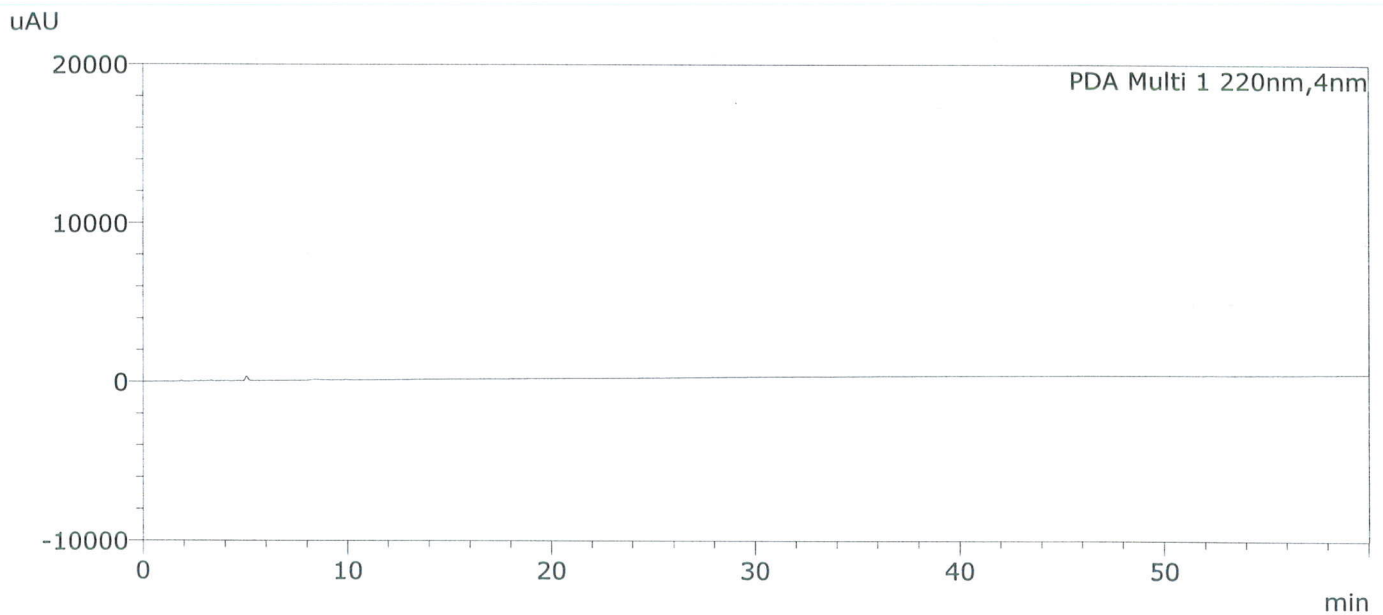
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SYSTEM SUITABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-01.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 11-01-2024 15:31:37
 Date Processed : 18-01-2024 19:40:18
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

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

18/01/24

Analysed By

18/01/2024

Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

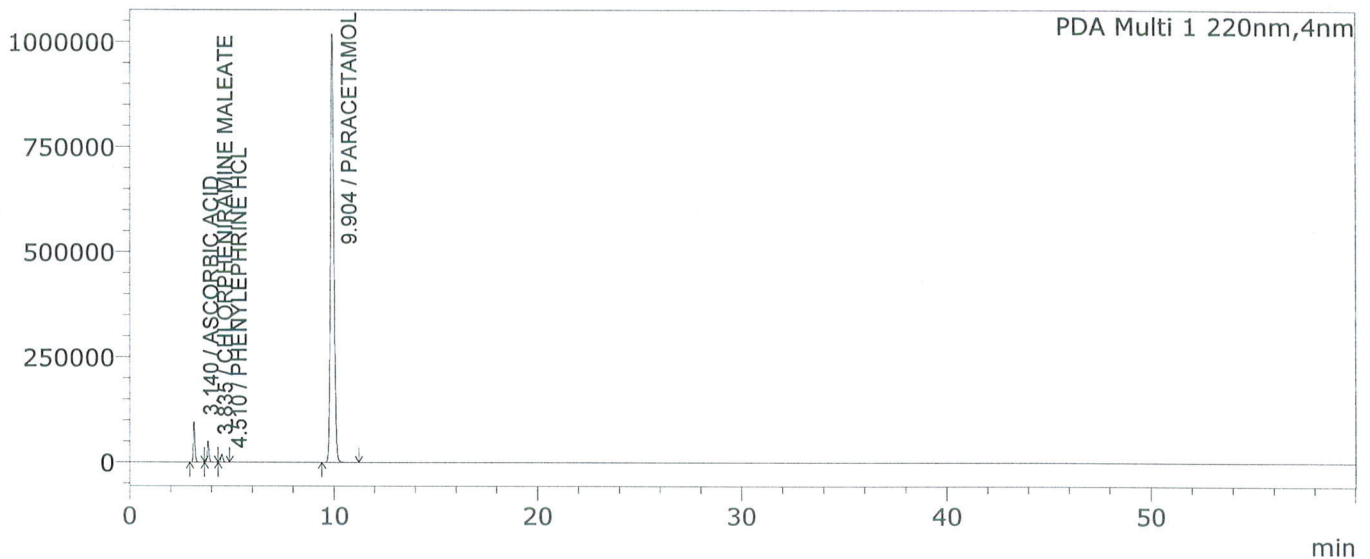
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Sample Name : SYSTEM SUITABILITY-RS
 Sample ID : RESOLUTION SOLUTION
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-02.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 11-01-2024 16:32:10
 Date Processed : 18-01-2024 19:46:47

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>

uAU



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	3.14	544585	4.18	5755	1.264	--	--
2	CHLORPHENIRAMINE MALEATE	3.84	294056	2.26	8170	1.250	4.149	--
3	PHENYLEPHRINE HCL	4.51	132600	1.02	8562	1.177	3.700	--
4	PARACETAMOL	9.90	12061773	92.55	15245	1.101	20.917	--
Total			13033014	100.00				

18/01/24

Analysed By

15/01/2024

Checked By



GENERIC HEALTHCARE PVT. LTD.

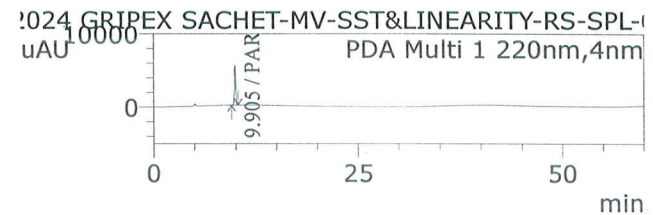
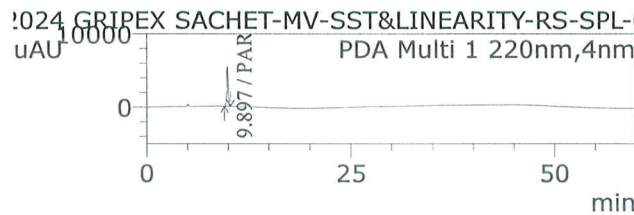
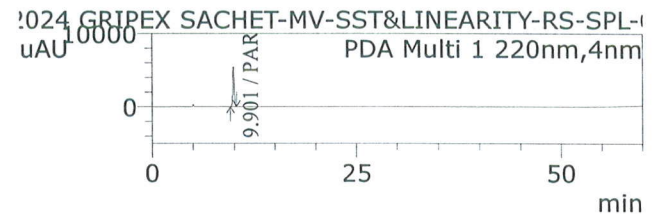
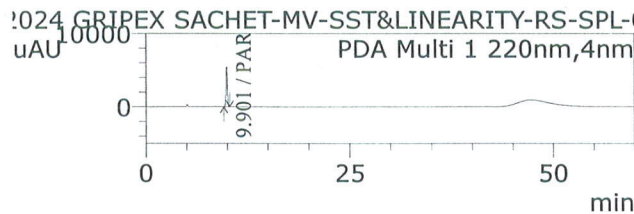
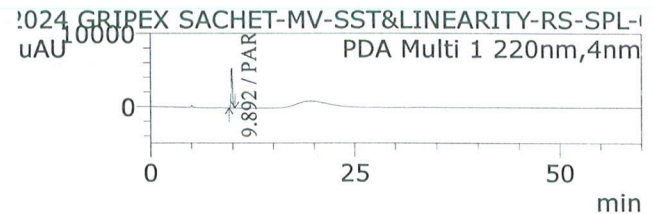
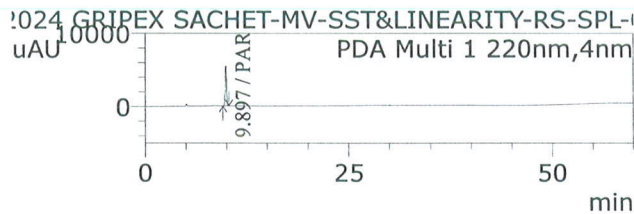
Analysis Report

<Sample Information>

Sample Name : SYSTEM SUITABILITY-RS
 Sample ID : PARACETAMOL-RS-STD-01
 Data Filename : 11012024 GRIPEX SACHET-MV-SST&LINEARITY-RS-SPL-03.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 11012024 GRIPEX SACHET-MV-RS-SST&LINEARITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 11-01-2024 17:32:42
 Date Processed : 18-01-2024 19:40:18

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-03.lcd	PARACETAMOL-RS-STD-01	9.90	64279	15297	1.06
3	RS-SPL-04.lcd	PARACETAMOL-RS-STD-02	9.89	64374	15262	1.06
3	RS-SPL-05.lcd	PARACETAMOL-RS-STD-03	9.90	64148	15239	1.06
3	RS-SPL-06.lcd	PARACETAMOL-RS-STD-04	9.90	64172	15187	1.06
3	RS-SPL-07.lcd	PARACETAMOL-RS-STD-05	9.90	64219	15119	1.06
3	RS-SPL-08.lcd	PARACETAMOL-RS-STD-06	9.90	64258	15208	1.07
Average			9.90	64242	15219	1.06
%RSD			0.044	0.127	0.410	0.273

Analysed By

Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

RELATED SUBSTANCES OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Parameter :	STABILITY OF ANALYTICAL SOLUTION	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCES OF PARACETAMOL

Instrument ID:	ST/QCLC/005	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution :	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Placebo dilution :	348.21	mg to --->	100	ml to --->	1	ml to --->	1
	1	ml to --->	1	ml to --->	1	ml to --->	1

Sample dilution :	415.05	mg to --->	100	ml to --->	1	ml to --->	1
Std.conc (in ppm)-600	1	ml to --->	1	ml to --->	1	ml to --->	1

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	77	0.112
With Bracketing std.	68959						68954	70	0.102

Time interval	Paracetamol area in Standard preparation	Absolute % difference of standard area	Paracetamol area in Sample preparation	Absolute % difference of sample area	Single Maximum unknown impurity peak area in Sample preparation	Absolute % difference of impurity area test preparation
Initial	68953	Not applicable	13463570	Not applicable	Not Detected	Not applicable
14 Hours	68987	-0.05	13463627	0.00	Not Detected	#VALUE!
17 Hours	68816	0.20	13467257	-0.03	Not Detected	#VALUE!
20 Hours	69267	-0.45	13562237	-0.73	Not Detected	#VALUE!
24 Hours	69072	-0.17	13458987	0.03	Not Detected	#VALUE!
28 Hours	69064	-0.16	13468058	-0.03	Not Detected	#VALUE!
38 Hours	68871	0.12	13448568	0.11	Not Detected	#VALUE!
42 Hours	68956	0.00	13457810	0.04	Not Detected	#VALUE!
45 Hours	69041	-0.13	13453311	0.08	Not Detected	#VALUE!
48 Hours	68961	-0.01	13449031	0.11	Not Detected	#VALUE!
Average	68999	-0.07	13469246	-0.05	#DIV/0!	#VALUE!
% RSD	0.180	Not applicable	0.248	Not applicable	#DIV/0!	Not applicable

Results :

Standard solution and Sample Solution Stability Study was performed upto 48 Hrs .

Standard solution and Sample solution was stable upto 48 hrs at room temperature.

Acceptance criteria:The 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 $\pm 10\%$.

Analysed by :

E.MEENA

Date :

18-01-2024

Checked by :

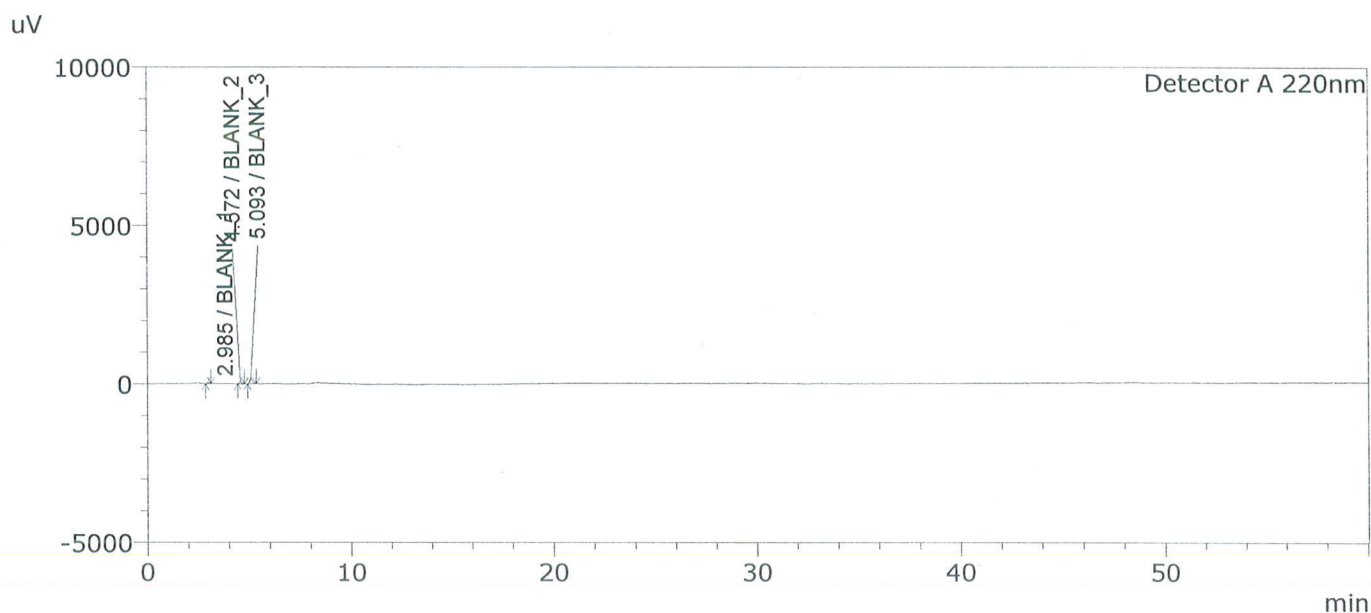
Date :

18/01/2024


GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-01.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/13/2024 5:48:27 PM
 Date Processed : 1/18/2024 3:22:04 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.98	355	15.06	3265	1.120	--	--
2	BLANK_2	4.57	526	22.35	9687	1.374	8.042	--
3	BLANK_3	5.09	1473	62.59	6679	1.476	2.393	--
Total			2353	100.00				

18/01/24
Analysed By

13/01/2024
Checked By



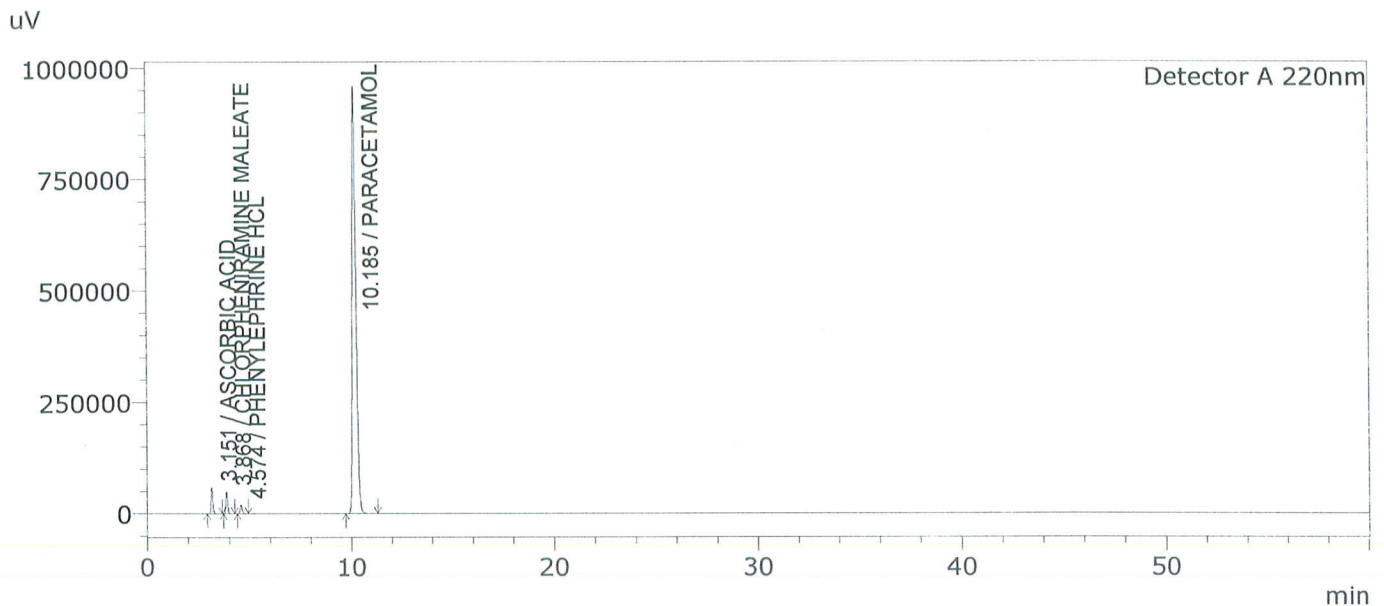
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : RESOLUTION SOLUTION
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-02.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 1/13/2024 6:49:06 PM
 Date Processed : 1/18/2024 3:19:39 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	3.15	343199	2.61	5952	1.300	--	--
2	CHLORPHENIRAMINE MALEATE	3.87	299289	2.27	8269	1.274	4.299	--
3	PHENYLEPHRINE HCL	4.57	140618	1.07	8674	1.235	3.851	--
4	PARACETAMOL	10.19	12379511	94.05	14082	1.193	20.792	--
Total			13162616	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

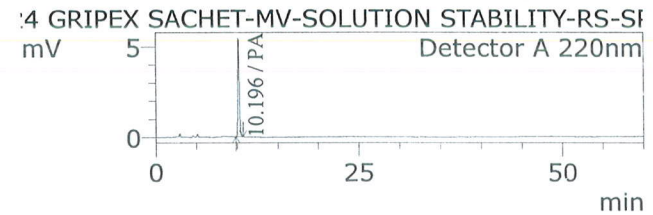
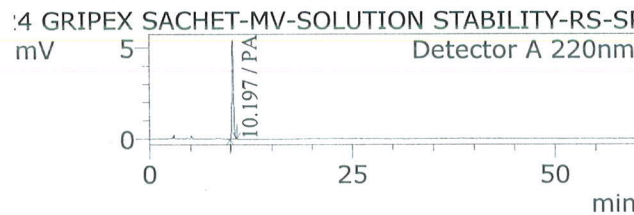
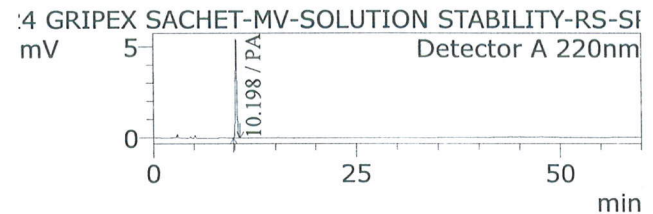
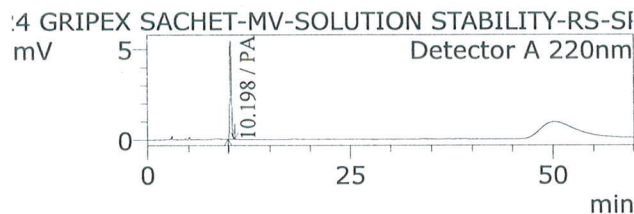
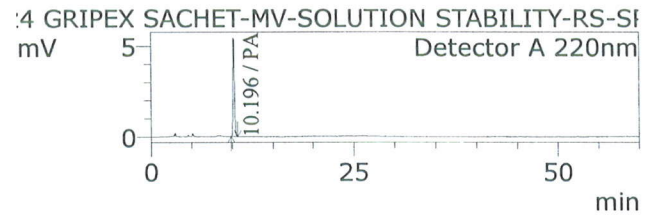
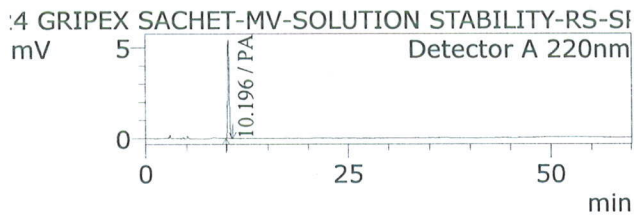
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-RS-STD-01
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-03.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/13/2024 7:49:45 PM
 Date Processed : 1/18/2024 3:13:38 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-03.lcd	PARACETAMOL-RS-STD-01	10.20	68978	14540	1.15
3	RS-SPL-04.lcd	PARACETAMOL-RS-STD-02	10.20	68922	14504	1.14
3	RS-SPL-05.lcd	PARACETAMOL-RS-STD-03	10.20	68934	14549	1.14
3	RS-SPL-06.lcd	PARACETAMOL-RS-STD-04	10.20	68865	14563	1.14
3	RS-SPL-07.lcd	PARACETAMOL-RS-STD-05	10.20	68929	14524	1.14
3	RS-SPL-08.lcd	PARACETAMOL-RS-STD-06	10.20	69092	14461	1.15
	Average		10.20	68953	14523	1.14
	%RSD		0.010	0.112	0.255	0.134

Analysed By

Checked By



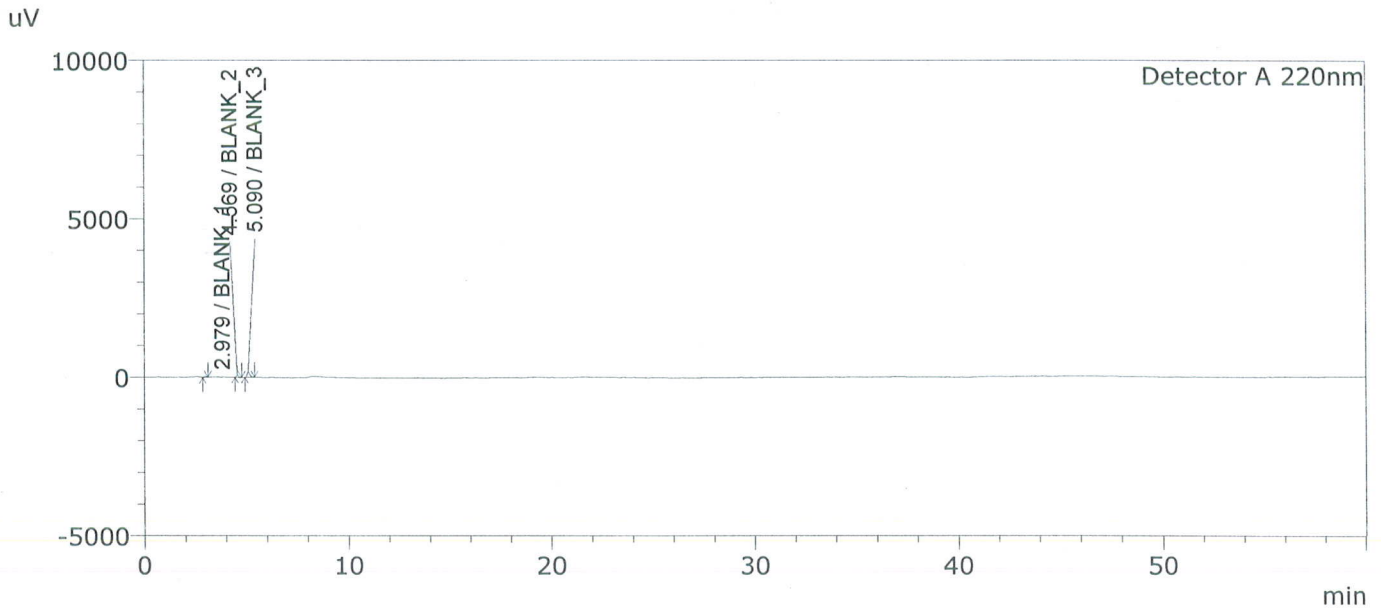
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-09.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 1:53:41 AM
 Date Processed : 1/18/2024 3:23:03 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.98	323	13.72	3438	1.105	--	--
2	BLANK_2	4.57	486	20.63	9864	1.403	8.214	--
3	BLANK_3	5.09	1546	65.65	6528	1.589	2.390	--
Total			2355	100.00				

18/01/24

Analysed By

18/01/2024

Checked By



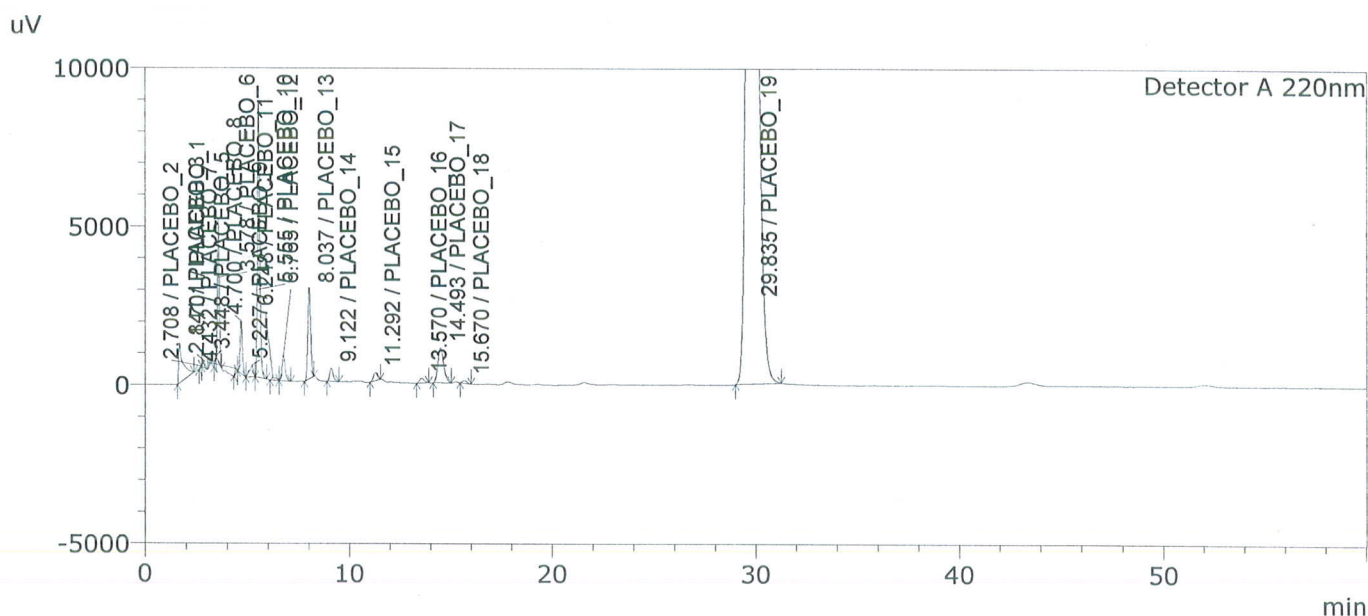
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PLACEBO-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-10.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 2:54:21 AM
 Date Processed : 1/18/2024 3:35:12 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

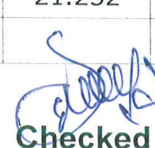
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	18184	1.35	758	4.849	--	--
2	PLACEBO_2	2.71	236	0.02	9914	1.044	5.658	--
3	PLACEBO_3	2.84	1168	0.09	5156	1.320	0.996	--
4	PLACEBO_5	3.45	642	0.05	19137	0.772	4.704	--
5	PLACEBO_6	3.58	25730	1.91	7417	1.220	0.981	--
6	PLACEBO_7	4.43	844	0.06	13244	0.982	5.328	--
7	PLACEBO_8	4.70	12852	0.95	7810	1.120	1.466	--
8	PLACEBO_9	5.23	4530	0.34	5163	0.731	2.091	--
9	PLACEBO_10	5.55	70037	5.19	10221	1.242	1.283	--
10	PLACEBO_11	6.25	1238	0.09	4103	1.625	2.274	--
11	PLACEBO_12	6.76	8563	0.63	9462	1.311	1.545	--
12	PLACEBO_13	8.04	28849	2.14	13887	1.084	4.619	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_14	9.12	5107	0.38	13050	1.431	3.664	--
14	PLACEBO_15	11.29	3387	0.25	15689	1.004	6.383	--
15	PLACEBO_16	13.57	2399	0.18	14300	1.207	5.595	--
16	PLACEBO_17	14.49	21797	1.61	12486	1.187	1.897	--
17	PLACEBO_18	15.67	1285	0.10	22464	1.265	2.512	--
18	PLACEBO_19	29.83	1142881	84.67	17018	1.190	21.252	--
Total			1349728	100.00				

Analysed By


18/01/24

Checked By


19/01/24



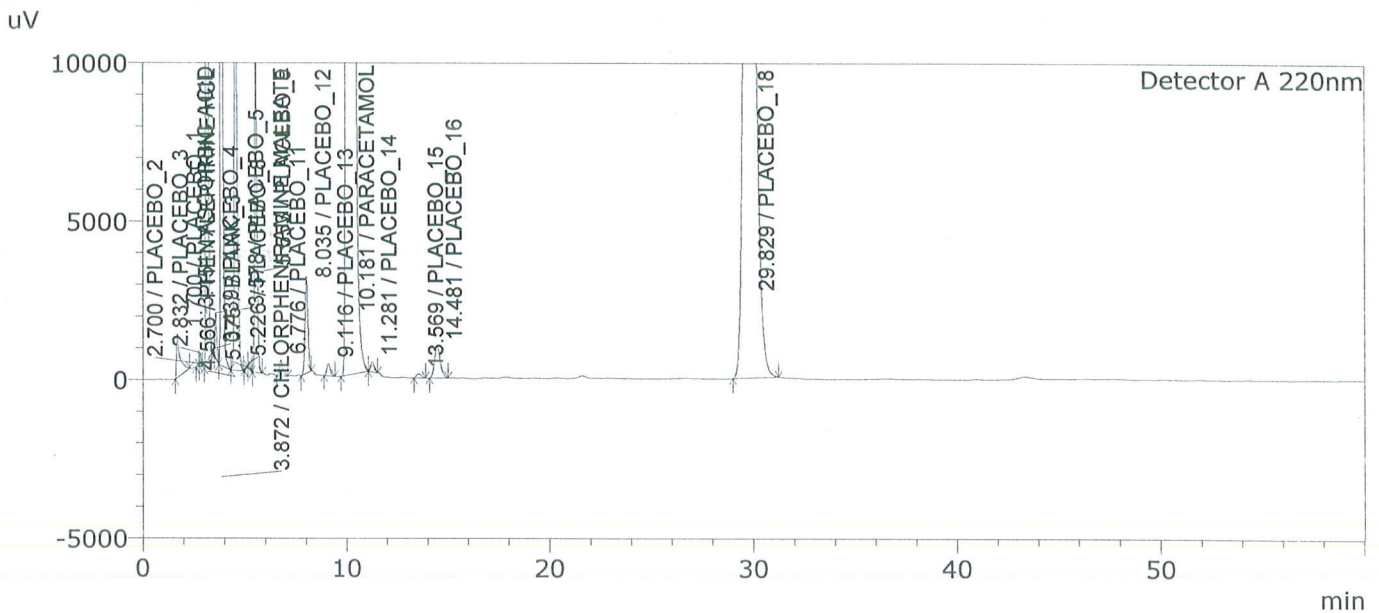
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : GRIPEX-1228-INI-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-11.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 3:55:00 AM
 Date Processed : 1/18/2024 3:43:02 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

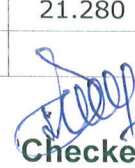
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17115	0.11	868	4.300	--	--
2	PLACEBO_2	2.70	465	0.00	6285	0.844	5.454	--
3	PLACEBO_3	2.83	1880	0.01	6970	1.214	0.970	--
4	ASCORBIC ACID	3.15	423464	2.71	6010	1.287	2.135	--
5	PLACEBO_4	3.44	475	0.00	21647	1.041	2.253	--
6	PLACEBO_5	3.58	8266	0.05	7116	1.268	1.054	--
7	CHLORPHENIRAMINE MALEATE	3.87	309966	1.98	8321	1.276	1.732	--
8	PHENYLEPHRINE HCL	4.57	166242	1.06	8003	1.473	3.713	--
9	BLANK_3	5.08	264	0.00	19636	0.830	2.916	--
10	PLACEBO_8	5.23	1275	0.01	12911	1.219	0.918	--
11	PLACEBO_9	5.55	82072	0.53	10277	1.218	1.624	--
12	PLACEBO_11	6.78	5384	0.03	9281	1.242	4.887	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	30976	0.20	13612	1.030	4.521	--
14	PLACEBO_13	9.12	4572	0.03	12885	1.192	3.625	--
15	PARACETAMOL	10.18	13463570	86.18	14071	1.194	3.204	--
16	PLACEBO_14	11.28	3789	0.02	18118	1.097	3.241	--
17	PLACEBO_15	13.57	2155	0.01	14874	1.220	5.865	--
18	PLACEBO_16	14.48	20324	0.13	12055	1.199	1.875	--
19	PLACEBO_18	29.83	1079973	6.91	17006	1.189	21.280	--
Total			15622227	100.00				

Analysed By


 18/10/24

Checked By


 19/10/24


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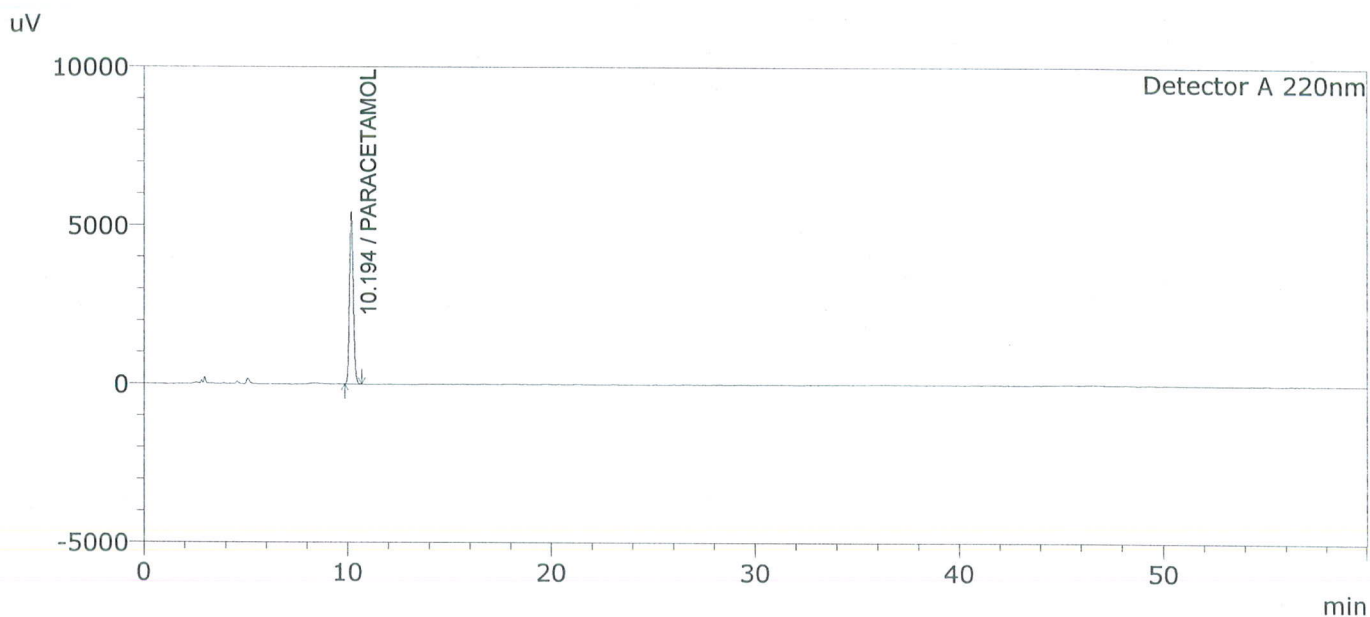
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-RS-STD-BKT
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-12.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 4:55:39 AM
 Date Processed : 1/18/2024 3:13:41 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	68959	100.00	14523	1.139	--	--
Total			68959	100.00				

①
18/01/24

Analysed By

①
19/01/2024

Checked By



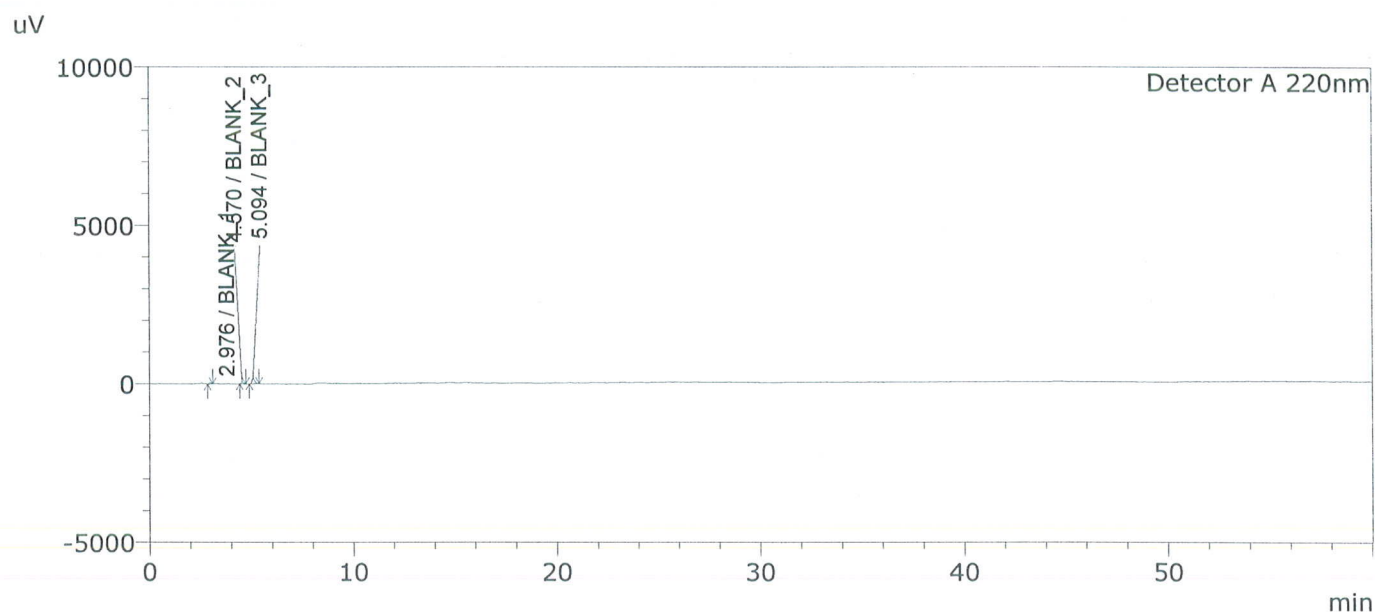
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-13.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 5:56:18 AM
 Date Processed : 1/18/2024 3:44:46 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.98	348	14.38	3431	1.208	--	--
2	BLANK_2	4.57	453	18.76	9897	1.277	8.235	--
3	BLANK_3	5.09	1616	66.86	6412	1.407	2.390	--
Total			2417	100.00				

18/01/24

Analysed By

15/01/2024

Checked By



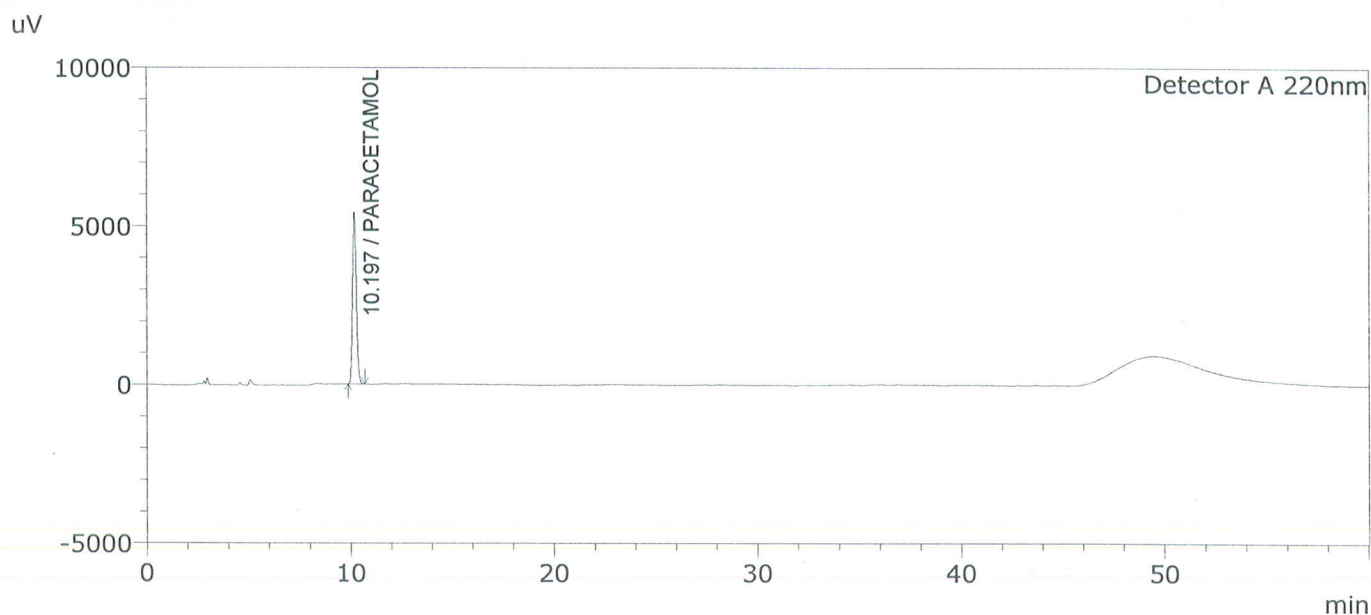
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-14H-RS-STD
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-14.lcd
 Method Filename : GRIPEX-SACH-RS STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 6:56:58 AM
 Date Processed : 1/18/2024 3:13:42 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.20	68987	100.00	14529	1.141	--	--
Total			68987	100.00				

18/01/24

Analysed By

18/01/2024

Checked By



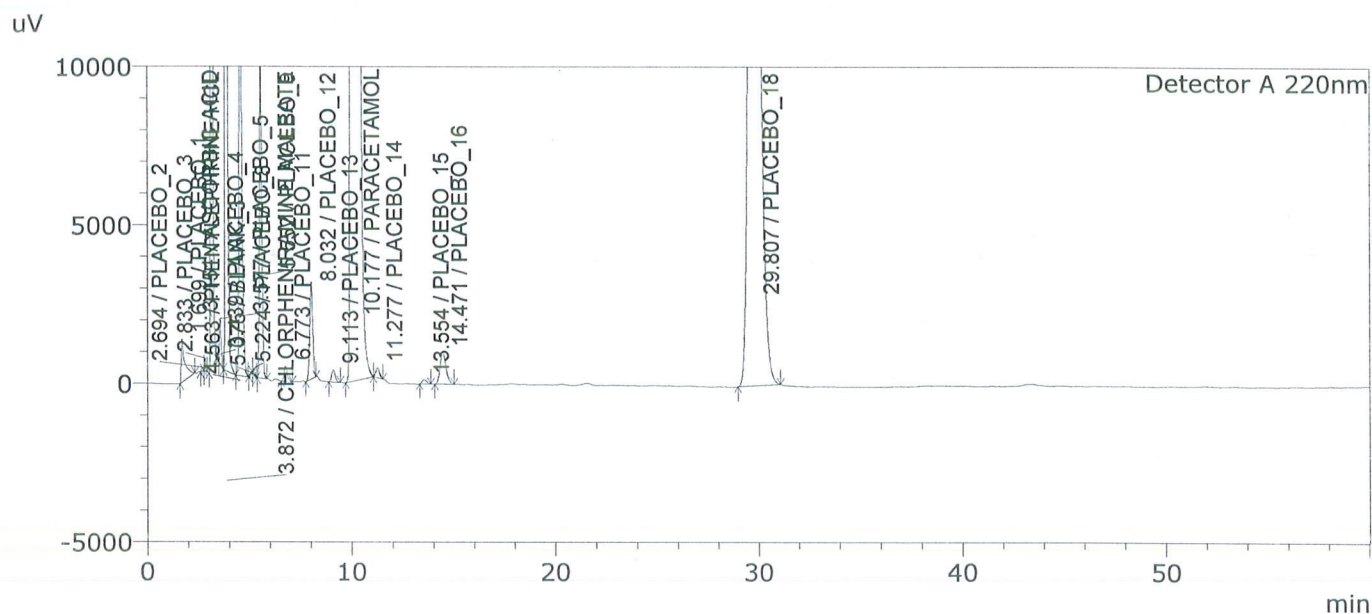
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : GRIPEX-1228-14H-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-15.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 7:57:37 AM
 Date Processed : 1/18/2024 3:48:05 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17222	0.11	867	4.411	--	--
2	PLACEBO_2	2.69	664	0.00	5453	0.906	5.277	--
3	PLACEBO_3	2.83	1842	0.01	6666	1.214	0.975	--
4	ASCORBIC ACID	3.15	406358	2.60	6002	1.295	2.110	--
5	PLACEBO_4	3.44	456	0.00	22167	1.035	2.264	--
6	PLACEBO_5	3.58	8238	0.05	7107	1.270	1.053	--
7	CHLORPHENIRAMINE MALEATE	3.87	309495	1.98	8297	1.280	1.737	--
8	PHENYLEPHRINE HCL	4.56	165885	1.06	7935	1.479	3.686	--
9	BLANK_3	5.08	258	0.00	21115	0.864	2.969	--
10	PLACEBO_8	5.22	1203	0.01	13176	1.220	0.928	--
11	PLACEBO_9	5.55	82152	0.53	10216	1.222	1.629	--
12	PLACEBO_11	6.77	5390	0.03	9270	1.291	4.875	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31101	0.20	13623	1.033	4.524	--
14	PLACEBO_13	9.11	4652	0.03	12661	1.190	3.609	--
15	PARACETAMOL	10.18	13463627	86.29	14022	1.196	3.185	--
16	PLACEBO_14	11.28	3725	0.02	18153	1.090	3.242	--
17	PLACEBO_15	13.55	2039	0.01	15121	1.259	5.872	--
18	PLACEBO_16	14.47	20268	0.13	11876	1.199	1.888	--
19	PLACEBO_18	29.81	1078281	6.91	16980	1.188	21.209	--
Total			15602856	100.00				

Analysed By

Checked By

18/10/24

19/10/2024



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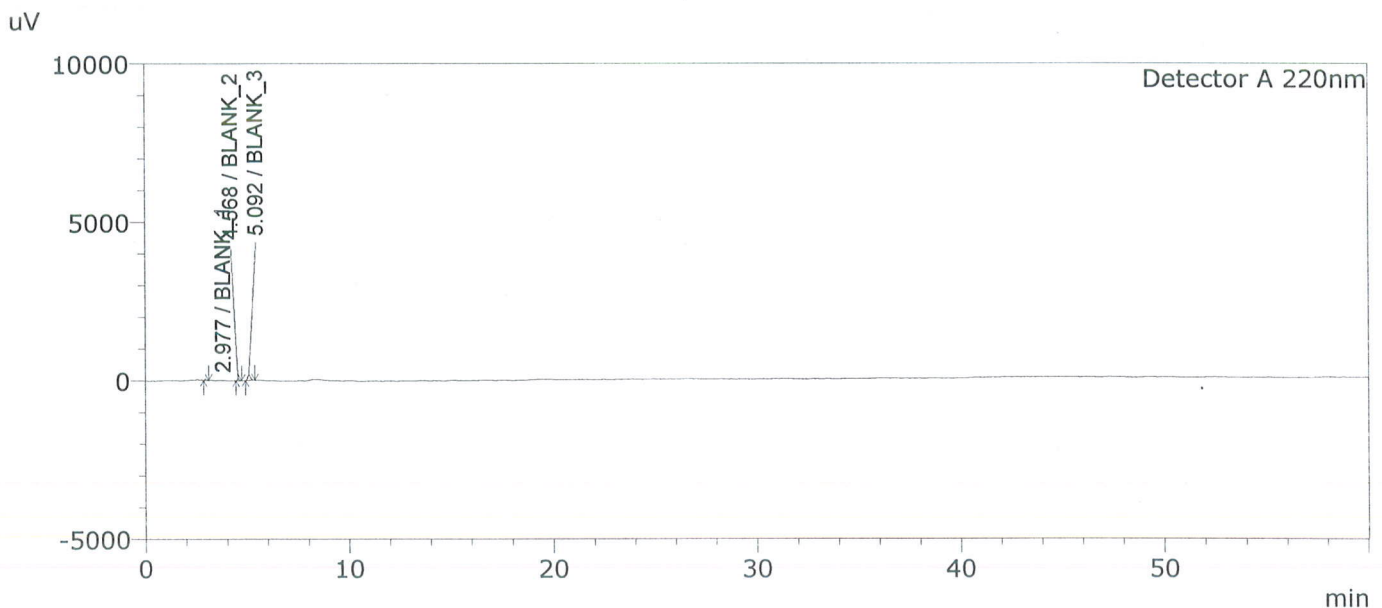
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-16.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 8:58:16 AM
 Date Processed : 1/18/2024 3:48:53 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.98	342	14.14	3894	1.135	--	--
2	BLANK_2	4.57	431	17.84	10719	1.255	8.669	--
3	BLANK_3	5.09	1643	68.02	6524	1.399	2.443	--
Total			2416	100.00				

Analysed By

Checked By


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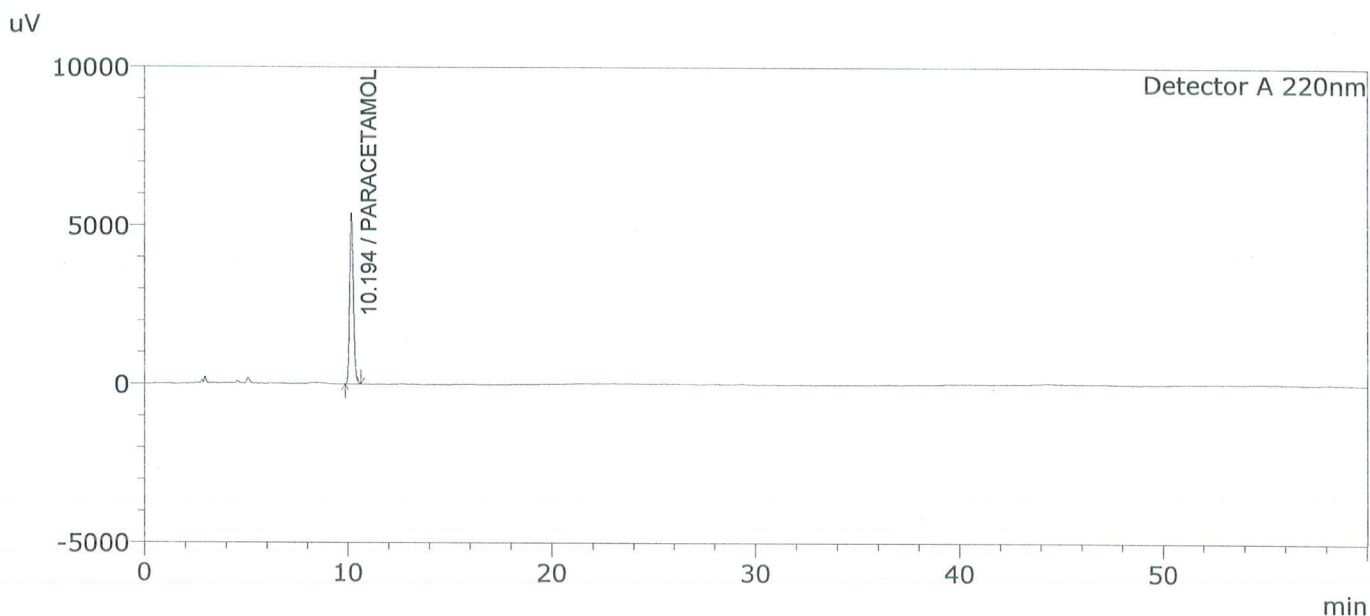
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-17H-RS-STD
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-17.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 9:58:56 AM
 Date Processed : 1/18/2024 3:13:42 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	68816	100.00	14421	1.148	--	--
Total			68816	100.00				

Analysed By

Checked By



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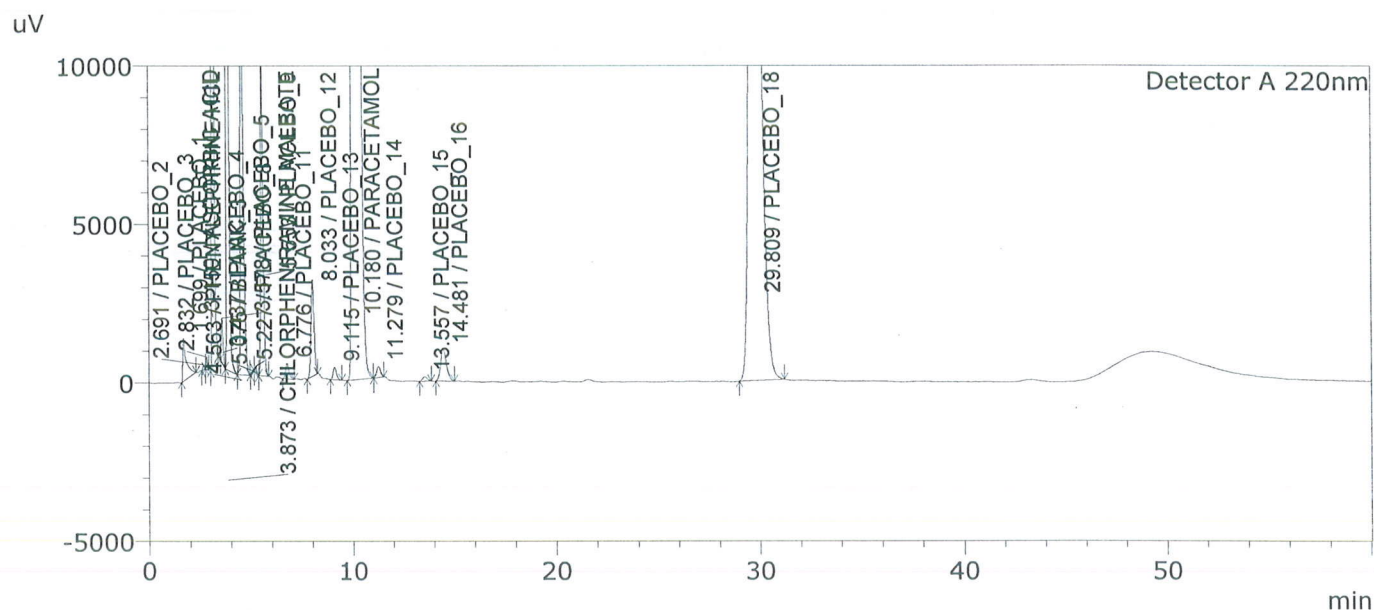
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : GRIPEX-1228-17H-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-18.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 10:59:35 AM
 Date Processed : 1/18/2024 3:53:28 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

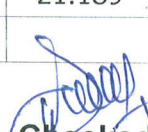
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16897	0.11	871	4.275	--	--
2	PLACEBO_2	2.69	835	0.01	5151	0.926	5.217	--
3	PLACEBO_3	2.83	1784	0.01	6696	1.219	0.983	--
4	ASCORBIC ACID	3.15	393327	2.52	5967	1.318	2.108	--
5	PLACEBO_4	3.44	412	0.00	22566	1.088	2.252	--
6	PLACEBO_5	3.58	8131	0.05	7117	1.274	1.077	--
7	CHLORPHENIRAMINE MALEATE	3.87	309329	1.98	8177	1.298	1.734	--
8	PHENYLEPHRINE HCL	4.56	166109	1.07	7904	1.499	3.661	--
9	BLANK_3	5.08	288	0.00	19989	0.834	2.937	--
10	PLACEBO_8	5.23	1249	0.01	12785	1.197	0.926	--
11	PLACEBO_9	5.55	81955	0.53	10184	1.233	1.609	--
12	PLACEBO_11	6.78	5365	0.03	9296	1.283	4.880	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	30922	0.20	13583	1.039	4.514	--
14	PLACEBO_13	9.11	4652	0.03	12713	1.216	3.613	--
15	PARACETAMOL	10.18	13467257	86.36	13928	1.201	3.186	--
16	PLACEBO_14	11.28	4389	0.03	16513	1.060	3.160	--
17	PLACEBO_15	13.56	2137	0.01	15587	1.130	5.801	--
18	PLACEBO_16	14.48	20216	0.13	11872	1.195	1.912	--
19	PLACEBO_18	29.81	1079107	6.92	16974	1.188	21.189	--
Total			15594361	100.00				

Analysed By


 18/01/24

Checked By


 18/01/2024



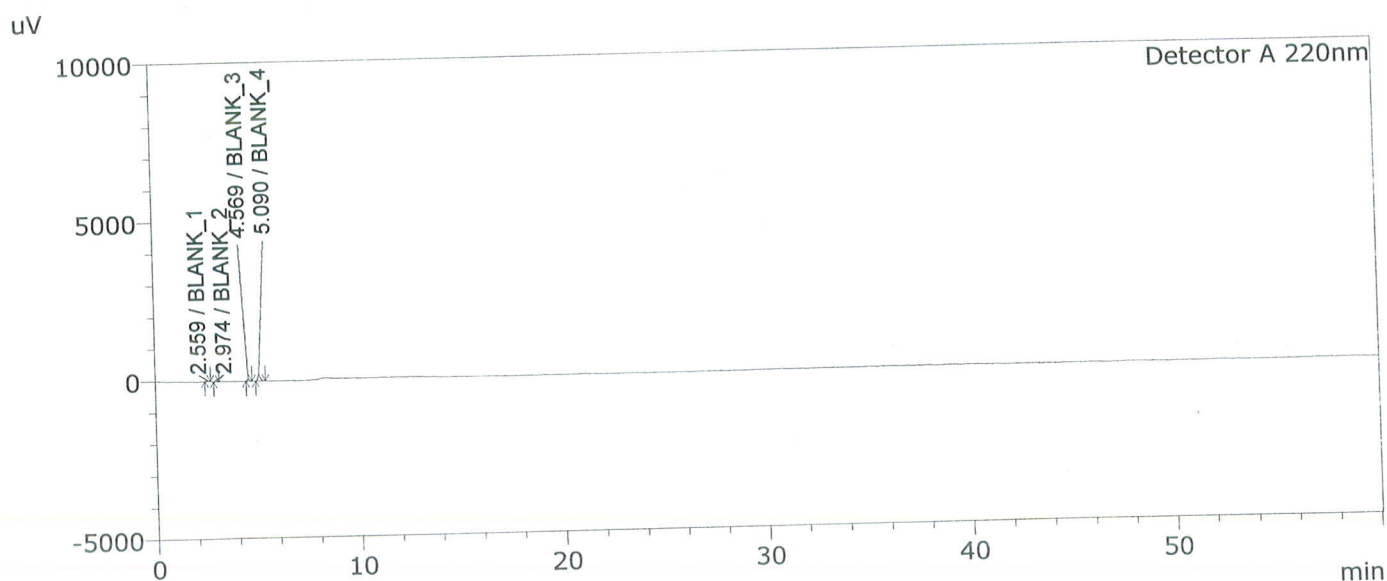
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-19.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 12:00:15 PM
 Date Processed : 1/18/2024 3:58:07 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm								
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.56	201	7.34	2779	1.136	--	--
2	BLANK_2	2.97	358	13.07	3368	1.200	2.079	--
3	BLANK_3	4.57	433	15.83	9322	1.262	8.089	--
4	BLANK_4	5.09	1744	63.76	6288	1.546	2.336	--
Total			2736	100.00				

18/01/24

Analysed By

19/01/2024

Checked By


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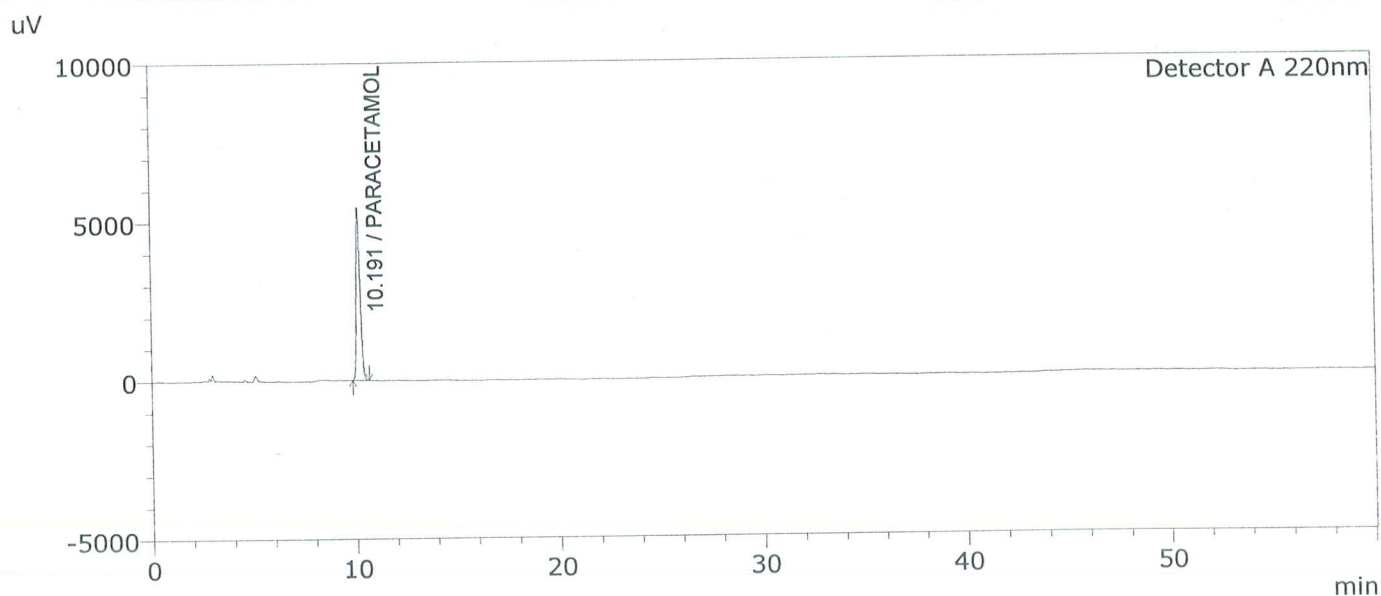
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-20H-RS-STD
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-20.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 1:00:54 PM
 Date Processed : 1/18/2024 3:13:42 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	69267	100.00	14443	1.140	--	--
Total			69267	100.00				


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 18/01/2024
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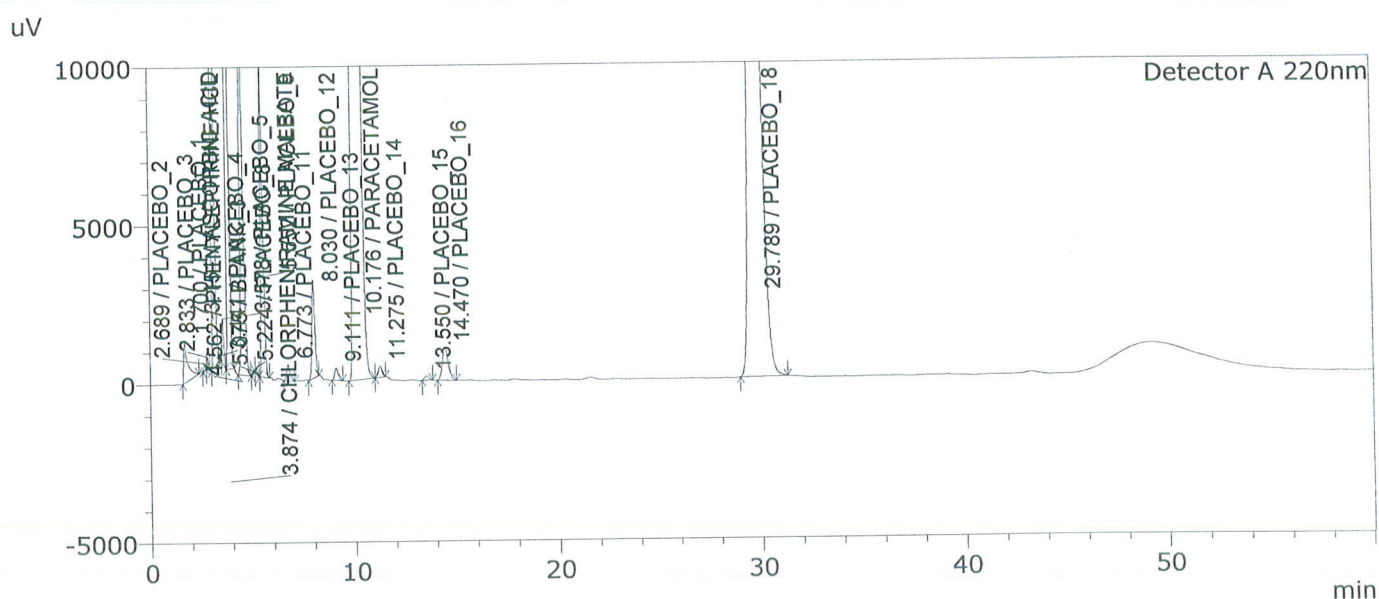
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : GRIPEX-1228-20H-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-21.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 2:01:33 PM
 Date Processed : 1/18/2024 5:04:26 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

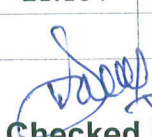
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17982	0.11	768	4.662	--	--
2	PLACEBO_2	2.69	1040	0.01	5039	0.952	4.982	--
3	PLACEBO_3	2.83	1752	0.01	6701	1.219	0.995	--
4	ASCORBIC ACID	3.15	384463	2.45	5762	1.307	2.086	--
5	PLACEBO_4	3.44	459	0.00	22115	0.986	2.247	--
6	PLACEBO_5	3.58	8297	0.05	6879	1.272	1.029	--
7	CHLORPHENIRAMINE MALEATE	3.87	308875	1.97	7999	1.275	1.714	--
8	PHENYLEPHRINE HCL	4.56	168006	1.07	7761	1.484	3.616	--
9	BLANK_3	5.08	295	0.00	18471	0.842	2.878	--
10	PLACEBO_8	5.22	1235	0.01	12877	1.243	0.895	--
11	PLACEBO_9	5.55	83119	0.53	10022	1.223	1.615	--
12	PLACEBO_11	6.77	5560	0.04	9019	1.240	4.814	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31363	0.20	13454	1.037	4.474	--
14	PLACEBO_13	9.11	4628	0.03	12733	1.192	3.602	--
15	PARACETAMOL	10.18	13562237	86.42	13943	1.192	3.189	--
16	PLACEBO_14	11.28	4444	0.03	16135	1.066	3.143	--
17	PLACEBO_15	13.55	1925	0.01	17191	1.138	5.919	--
18	PLACEBO_16	14.47	20868	0.13	11561	1.214	1.935	--
19	PLACEBO_18	29.79	1086877	6.93	17018	1.190	21.104	--
Total			15693424	100.00				

Analysed By


18/10/24

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29/10/2024


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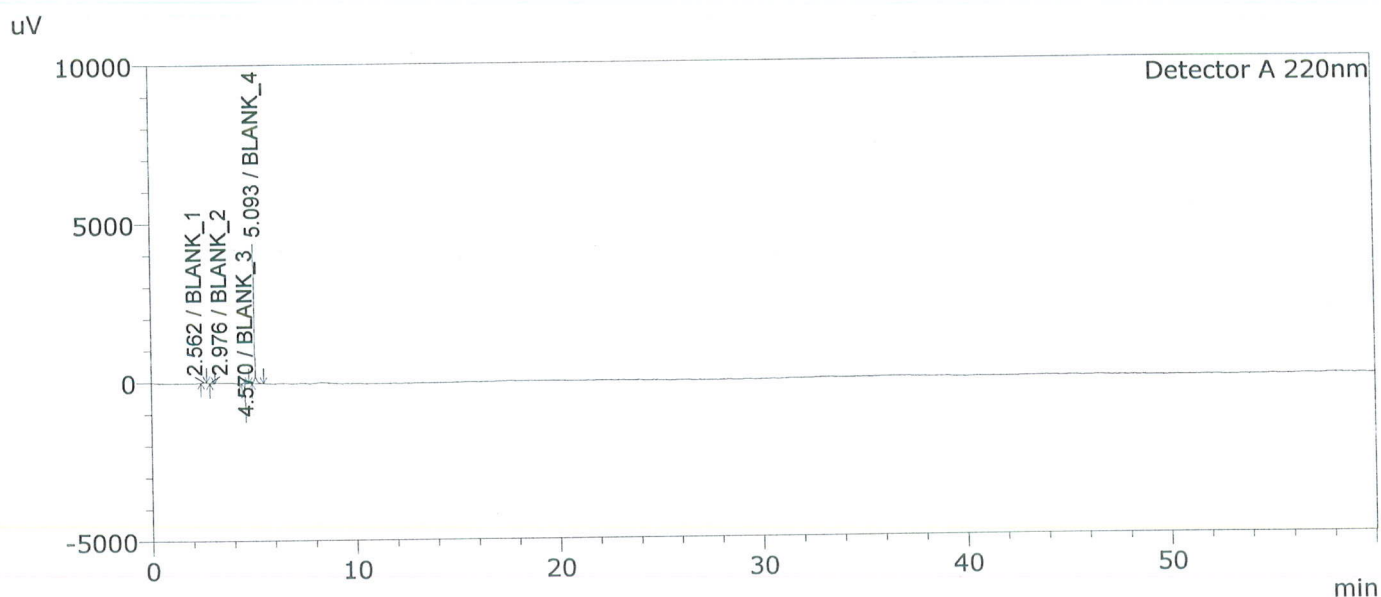
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-22.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 3:02:12 PM
 Date Processed : 1/18/2024 3:57:28 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.56	203	6.70	2531	1.026	--	--
2	BLANK_2	2.98	365	12.03	3523	1.160	2.048	--
3	BLANK_3	4.57	466	15.36	9195	1.317	8.149	--
4	BLANK_4	5.09	1999	65.92	5776	1.653	2.277	--
Total			3033	100.00				

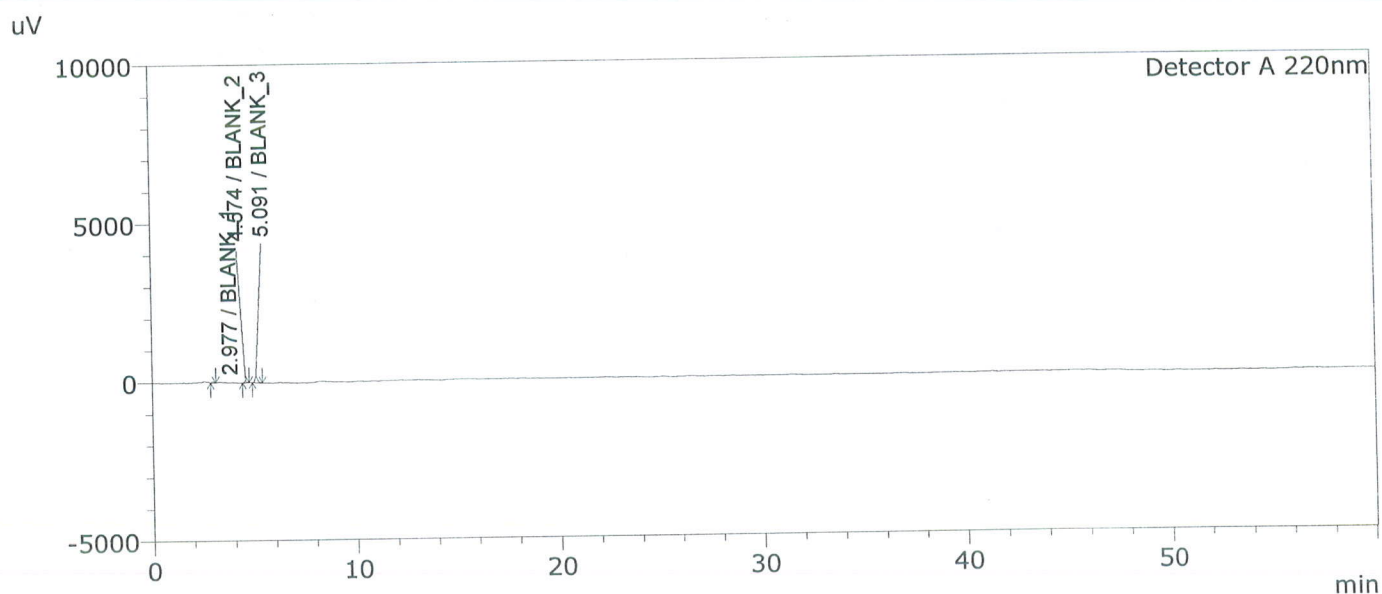
Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-23.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 4:02:51 PM
 Date Processed : 1/18/2024 3:58:58 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.98	365	13.76	3028	1.174	--	--
2	BLANK_2	4.57	423	15.97	9592	1.243	7.919	--
3	BLANK_3	5.09	1861	70.26	6115	1.493	2.313	--
Total			2649	100.00				

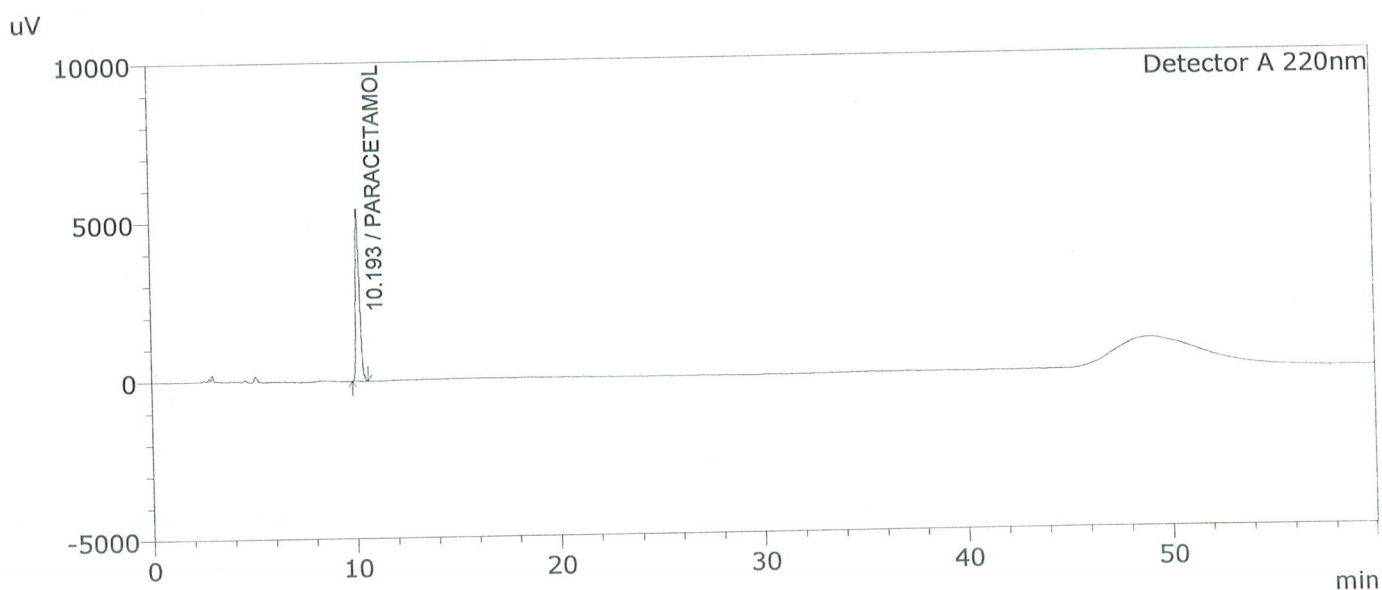
Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-24H-RS-STD
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-24.lcd
 Method Filename : GRIPEX-SACH-RS STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 5:03:31 PM
 Date Processed : 1/18/2024 3:13:43 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	69072	100.00	14437	1.139	--	--
Total			69072	100.00				

Analysed By

Checked By

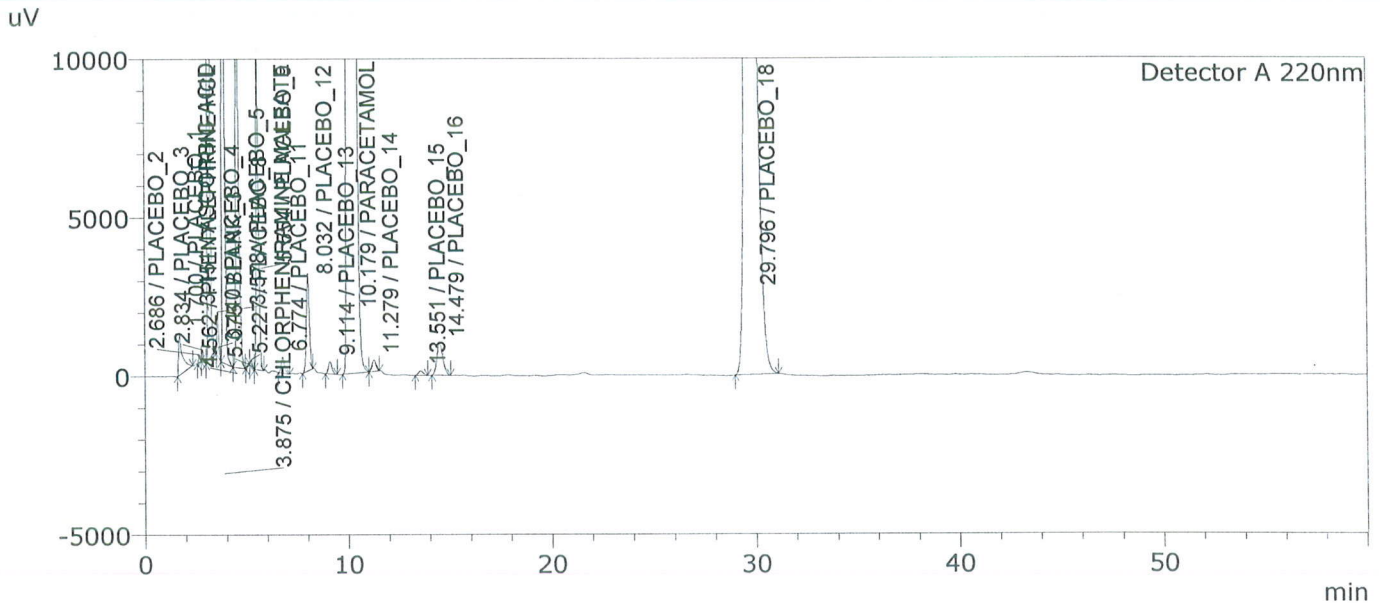

GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : GRIPEX-1228-24H-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-25.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 6:04:10 PM
 Date Processed : 1/18/2024 4:00:36 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

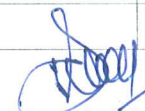
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17128	0.11	795	4.490	--	--
2	PLACEBO_2	2.69	1288	0.01	4969	0.989	5.012	--
3	PLACEBO_3	2.83	1747	0.01	6684	1.231	1.014	--
4	ASCORBIC ACID	3.15	364150	2.34	5809	1.312	2.087	--
5	PLACEBO_4	3.44	444	0.00	22150	1.014	2.247	--
6	PLACEBO_5	3.58	8155	0.05	6961	1.265	1.044	--
7	CHLORPHENIRAMINE MALEATE	3.88	308770	1.98	8035	1.286	1.723	--
8	PHENYLEPHRINE HCL	4.56	166177	1.07	7817	1.496	3.620	--
9	BLANK_3	5.08	315	0.00	19192	0.845	2.910	--
10	PLACEBO_8	5.23	1218	0.01	12760	1.195	0.918	--
11	PLACEBO_9	5.55	82117	0.53	10071	1.227	1.606	--
12	PLACEBO_11	6.77	5561	0.04	9049	1.260	4.820	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31190	0.20	13501	1.040	4.482	--
14	PLACEBO_13	9.11	4716	0.03	12713	1.232	3.609	--
15	PARACETAMOL	10.18	13458987	86.52	13942	1.195	3.188	--
16	PLACEBO_14	11.28	4643	0.03	15724	1.051	3.122	--
17	PLACEBO_15	13.55	2299	0.01	14272	1.204	5.586	--
18	PLACEBO_16	14.48	20097	0.13	11921	1.190	1.886	--
19	PLACEBO_18	29.80	1077122	6.92	17020	1.189	21.215	--
Total			15556124	100.00				

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19/10/2024



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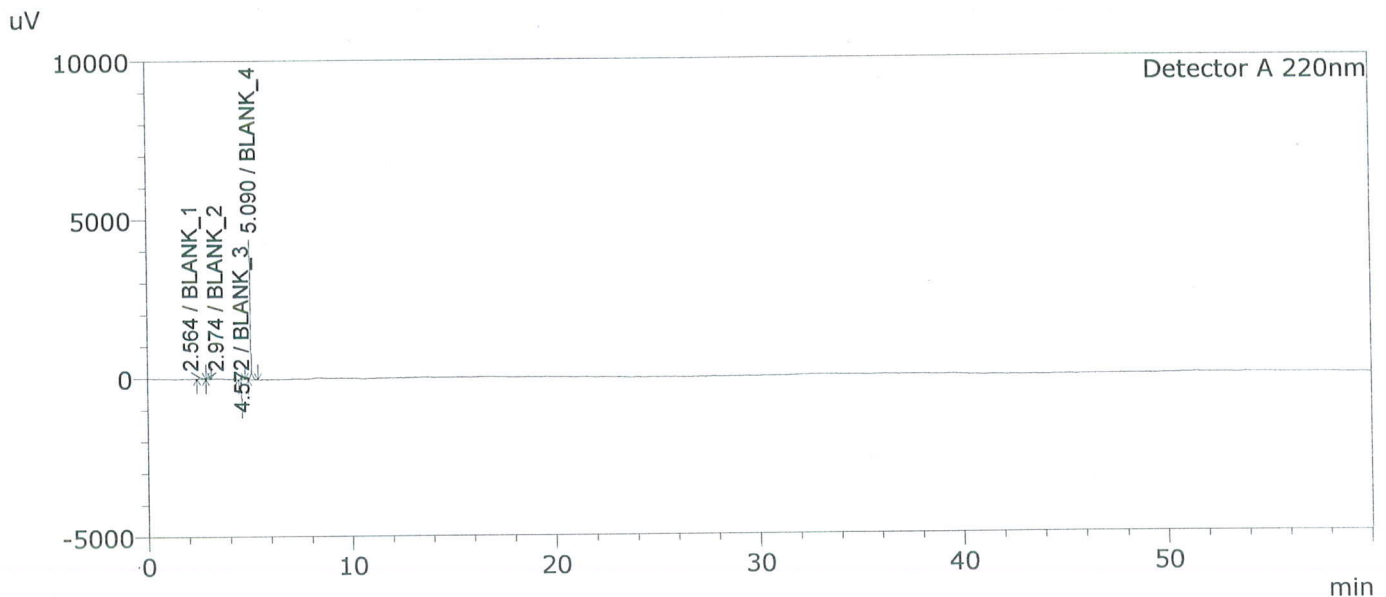
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-26.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 7:04:49 PM
 Date Processed : 1/18/2024 4:01:30 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.56	717	21.92	1186	1.737	--	--
2	BLANK_2	2.97	333	10.17	3637	1.167	1.656	--
3	BLANK_3	4.57	393	12.01	10802	1.458	8.565	--
4	BLANK_4	5.09	1829	55.91	6426	1.498	2.407	--
Total			3271	100.00				

Analysed By

Checked By



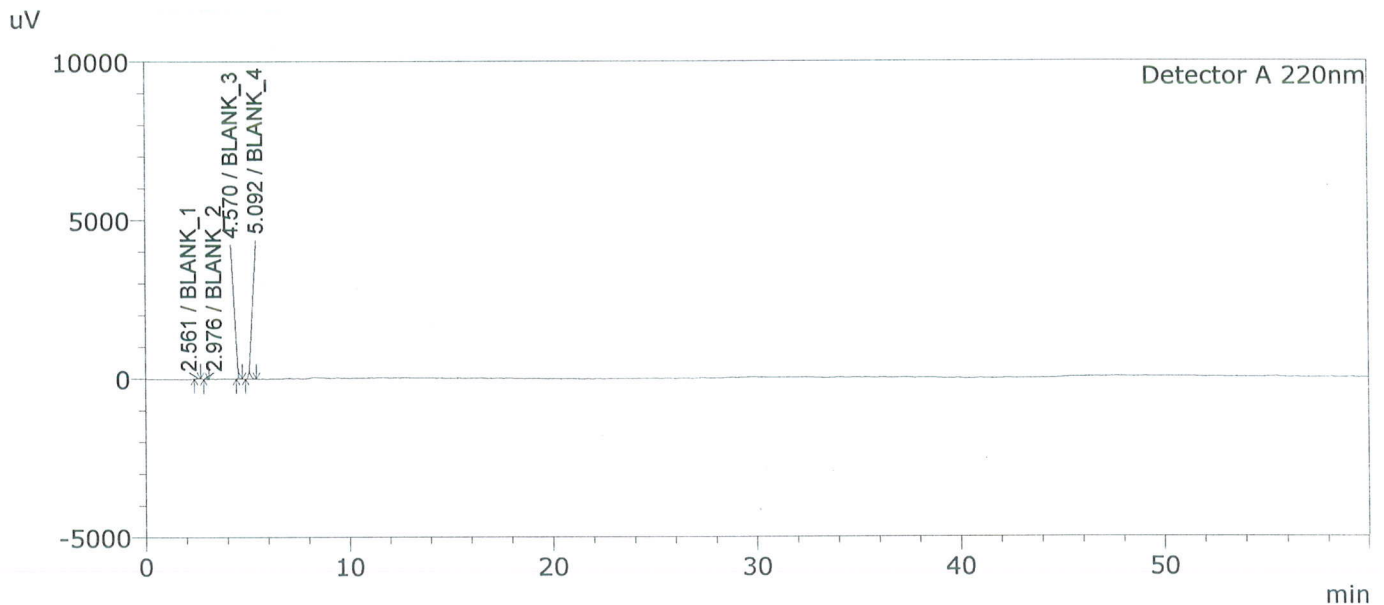
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-27.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 8:05:28 PM
 Date Processed : 1/18/2024 4:02:19 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.56	264	8.69	2422	1.016	--	--
2	BLANK_2	2.98	354	11.66	3276	1.173	1.995	--
3	BLANK_3	4.57	410	13.49	10188	1.380	8.191	--
4	BLANK_4	5.09	2010	66.16	5922	1.590	2.344	--
Total			3038	100.00				

Analysed By

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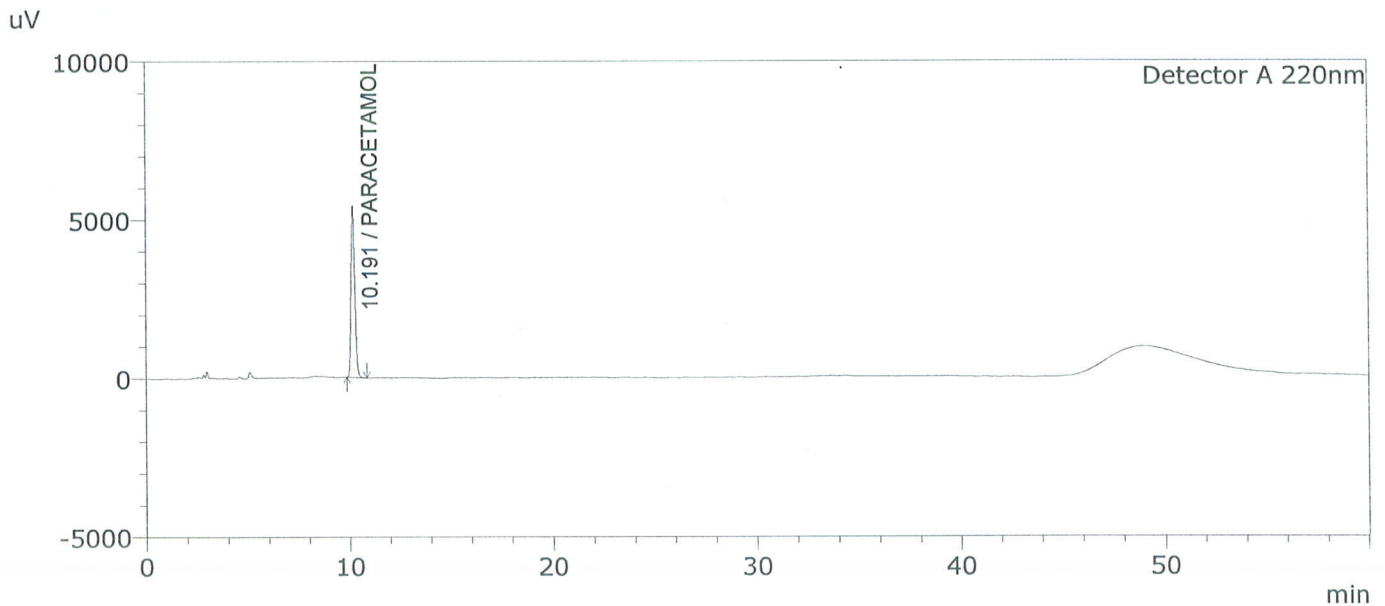
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-28H-RS-STD
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-28.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 9:06:07 PM
 Date Processed : 1/18/2024 3:13:43 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	69064	100.00	14406	1.152	--	--
Total			69064	100.00				

18/01/24

Analysed By

19/01/2024

Checked By



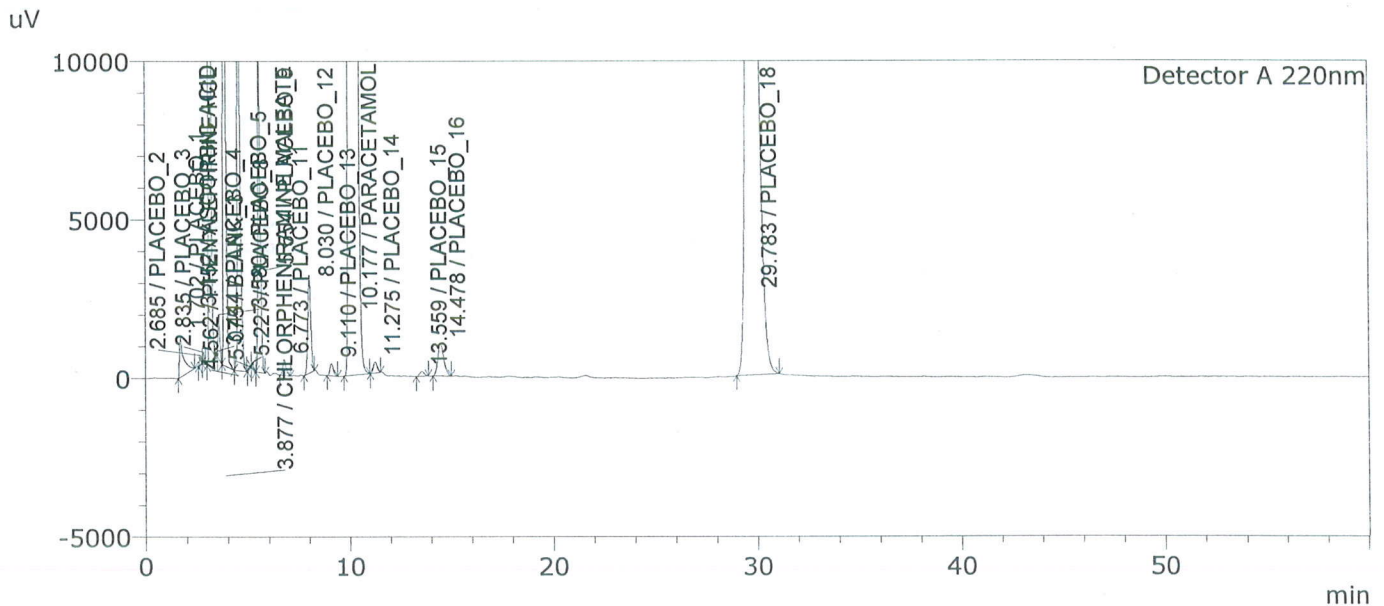
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : GRIPEX-1228-28H-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-29.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 10:06:46 PM
 Date Processed : 1/18/2024 4:21:49 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

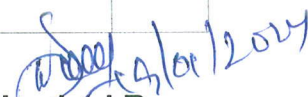
Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	18121	0.12	777	4.685	--	--
2	PLACEBO_2	2.69	1589	0.01	4944	0.999	4.954	--
3	PLACEBO_3	2.84	1648	0.01	7303	1.224	1.053	--
4	ASCORBIC ACID	3.15	347891	2.24	5828	1.278	2.126	--
5	PLACEBO_4	3.44	449	0.00	22071	0.964	2.260	--
6	PLACEBO_5	3.58	8246	0.05	6937	1.258	1.028	--
7	CHLORPHENIRAMINE MALEATE	3.88	308800	1.99	8110	1.257	1.726	--
8	PHENYLEPHRINE HCL	4.56	166281	1.07	7855	1.485	3.623	--
9	BLANK_3	5.08	330	0.00	19214	0.834	2.915	--
10	PLACEBO_8	5.23	1261	0.01	12643	1.215	0.917	--
11	PLACEBO_9	5.55	82410	0.53	10111	1.212	1.605	--
12	PLACEBO_11	6.77	5539	0.04	9130	1.271	4.834	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31263	0.20	13547	1.036	4.492	--
14	PLACEBO_13	9.11	4431	0.03	13089	1.190	3.634	--
15	PARACETAMOL	10.18	13468058	86.60	14035	1.187	3.221	--
16	PLACEBO_14	11.28	4482	0.03	16192	1.037	3.147	--
17	PLACEBO_15	13.56	2377	0.02	15325	1.097	5.763	--
18	PLACEBO_16	14.48	20040	0.13	11903	1.188	1.897	--
19	PLACEBO_18	29.78	1078769	6.94	17044	1.188	21.207	--
Total			15551984	100.00				

Analysed By


18/01/24

Checked By


18/01/2024



GENERIC HEALTHCARE PVT. LTD.

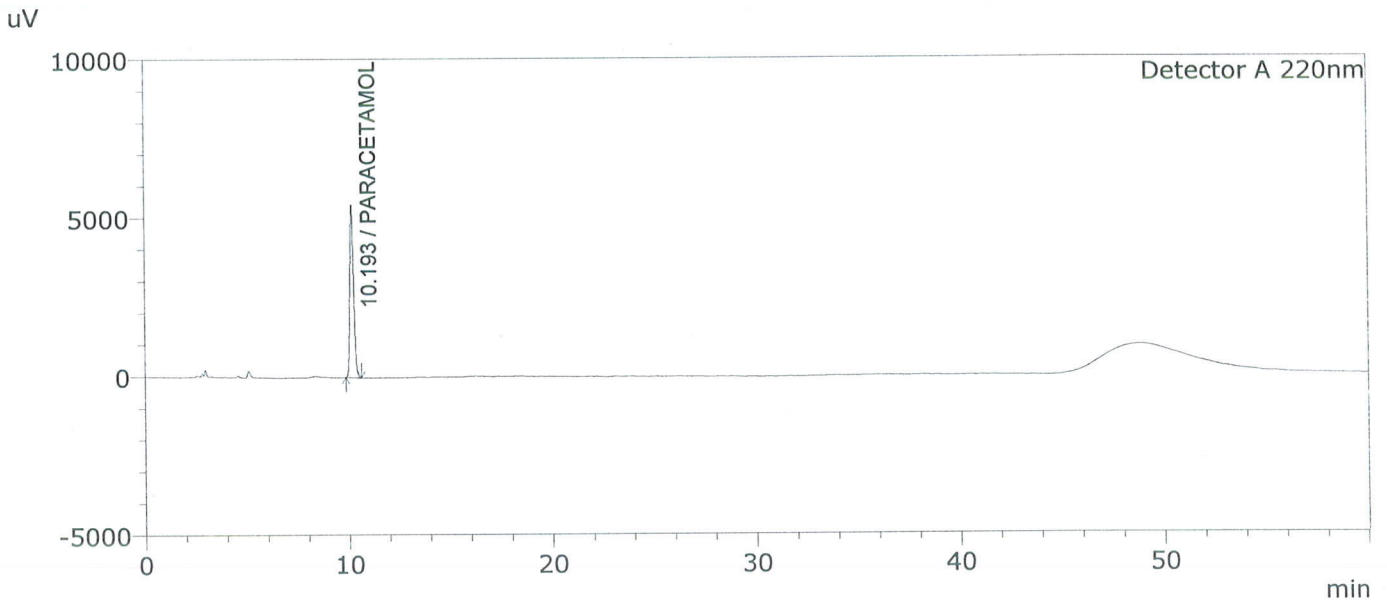
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-38H-RS-STD
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-38.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 7:12:40 AM
 Date Processed : 1/18/2024 3:13:44 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	68871	100.00	14518	1.136	--	--
Total			68871	100.00				

Analysed By

Checked By



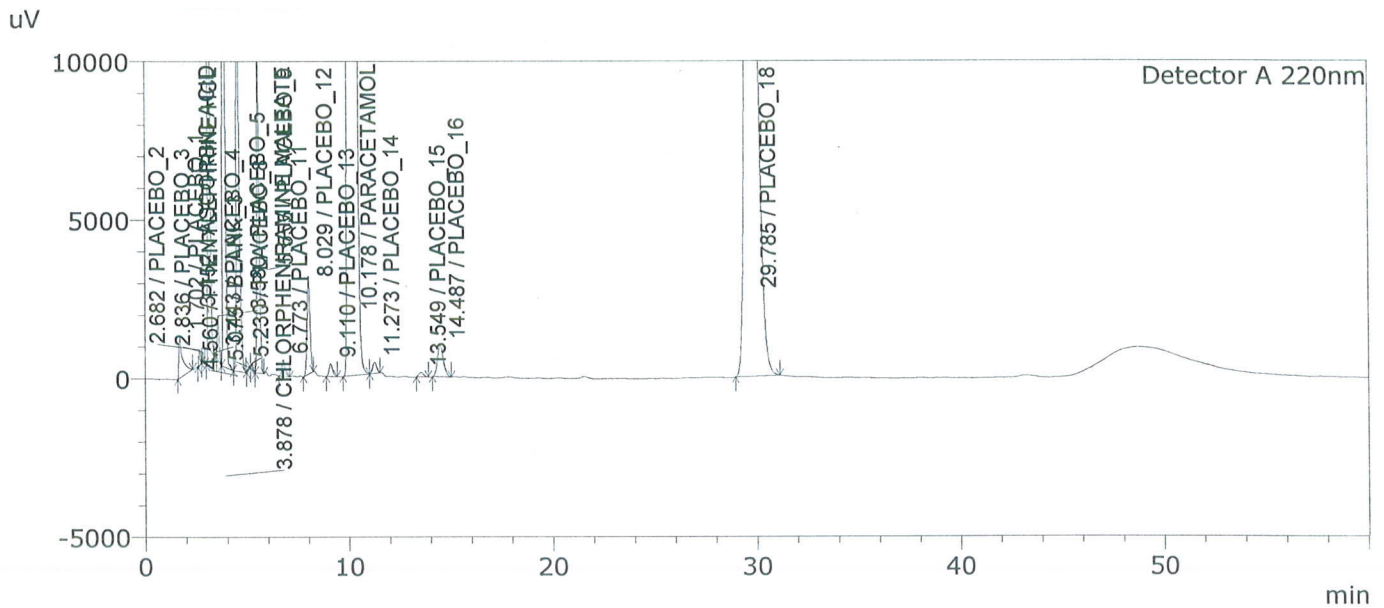
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : GRIPEX-1228-38H-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-39.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 8:13:19 AM
 Date Processed : 1/18/2024 5:01:26 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

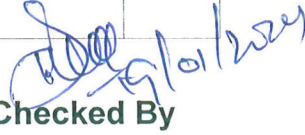
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16929	0.11	793	4.274	--	--
2	PLACEBO_2	2.68	2555	0.02	4715	1.051	4.928	--
3	PLACEBO_3	2.84	1511	0.01	7506	1.239	1.068	--
4	ASCORBIC ACID	3.15	305905	1.98	5810	1.285	2.137	--
5	PLACEBO_4	3.44	453	0.00	21980	0.976	2.254	--
6	PLACEBO_5	3.58	8122	0.05	6965	1.259	1.032	--
7	CHLORPHENIRAMINE MALEATE	3.88	307203	1.98	8102	1.263	1.734	--
8	PHENYLEPHRINE HCL	4.56	165944	1.07	7859	1.492	3.610	--
9	BLANK_3	5.08	387	0.00	17942	0.838	2.880	--
10	PLACEBO_8	5.23	1191	0.01	12961	1.153	0.926	--
11	PLACEBO_9	5.56	82205	0.53	10092	1.212	1.606	--
12	PLACEBO_11	6.77	5660	0.04	9044	1.244	4.812	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31211	0.20	13582	1.032	4.482	--
14	PLACEBO_13	9.11	4686	0.03	12764	1.213	3.615	--
15	PARACETAMOL	10.18	13448568	86.84	14033	1.186	3.206	--
16	PLACEBO_14	11.27	4432	0.03	16288	1.042	3.140	--
17	PLACEBO_15	13.55	2294	0.01	15838	1.203	5.807	--
18	PLACEBO_16	14.49	19842	0.13	12005	1.187	1.955	--
19	PLACEBO_18	29.78	1077036	6.95	17065	1.187	21.234	--
Total			15486134	100.00				

Analysed By


18/10/24

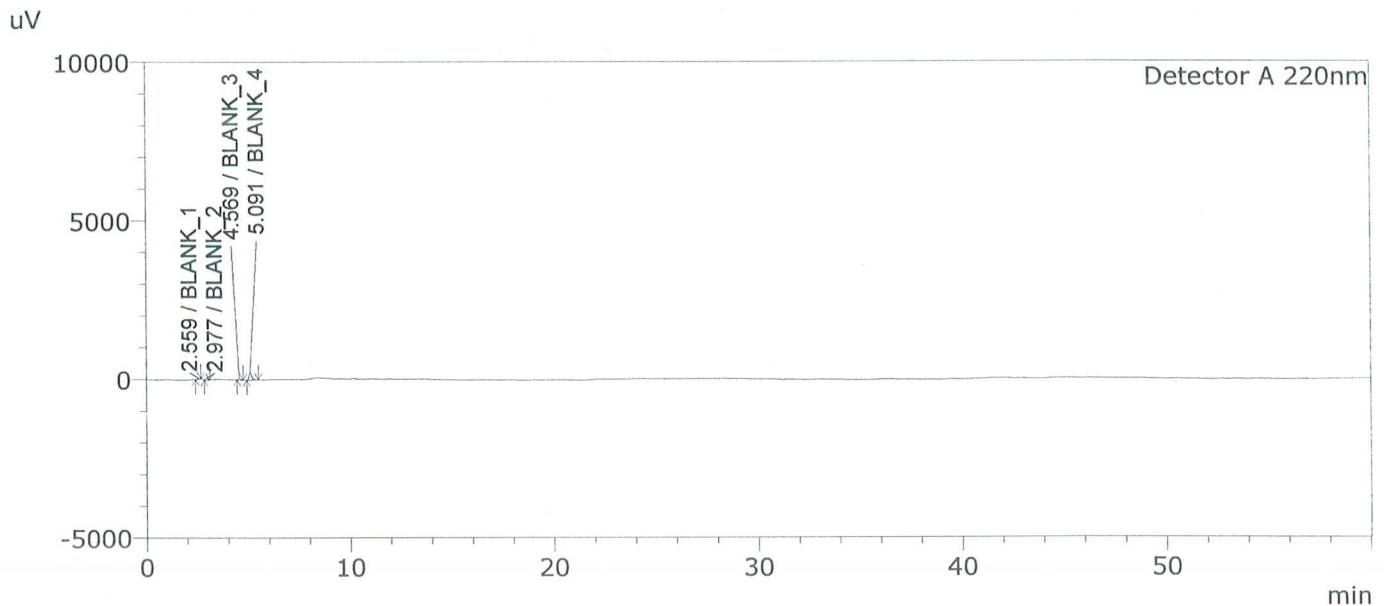
Checked By


18/10/24


GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-40.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 9:13:58 AM
 Date Processed : 1/18/2024 5:07:36 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.56	240	7.46	3131	1.084	--	--
2	BLANK_2	2.98	396	12.30	3430	1.159	2.165	--
3	BLANK_3	4.57	366	11.36	9845	1.263	8.216	--
4	BLANK_4	5.09	2218	68.88	6130	1.676	2.348	--
Total			3220	100.00				

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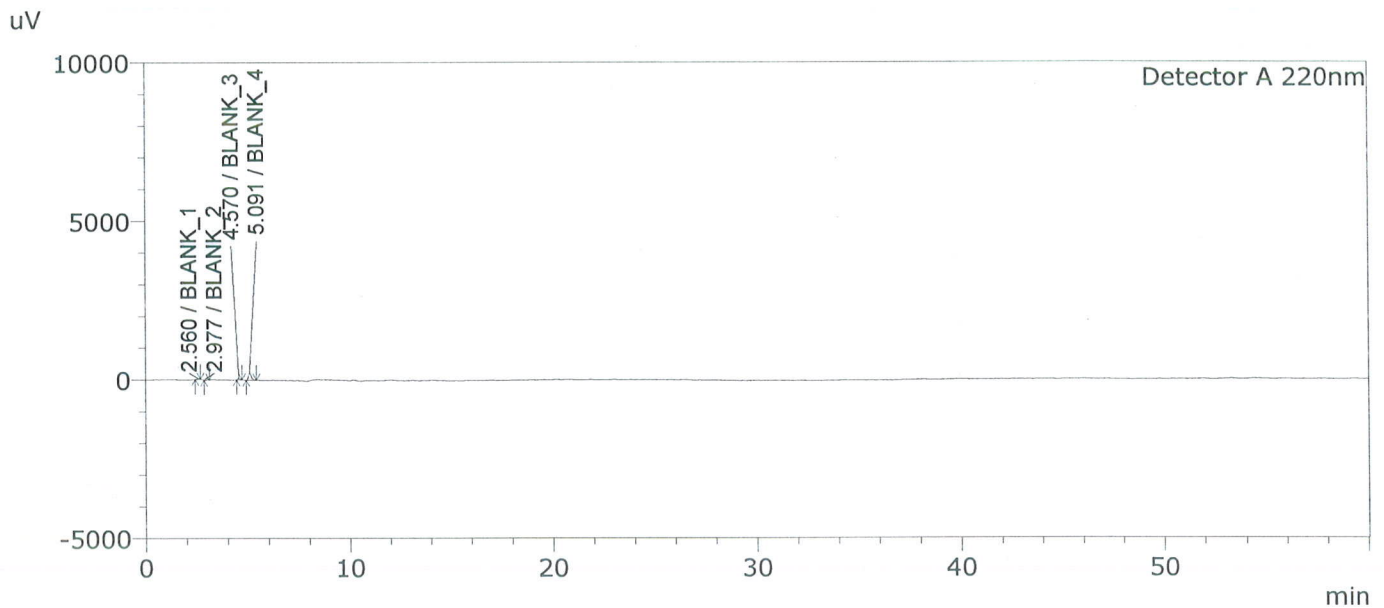
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-41.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 10:14:40 AM
 Date Processed : 1/18/2024 5:08:30 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.56	202	6.43	3090	1.084	--	--
2	BLANK_2	2.98	389	12.35	3367	1.160	2.143	--
3	BLANK_3	4.57	390	12.38	9390	1.167	8.092	--
4	BLANK_4	5.09	2168	68.84	6233	1.452	2.334	--
Total			3150	100.00				

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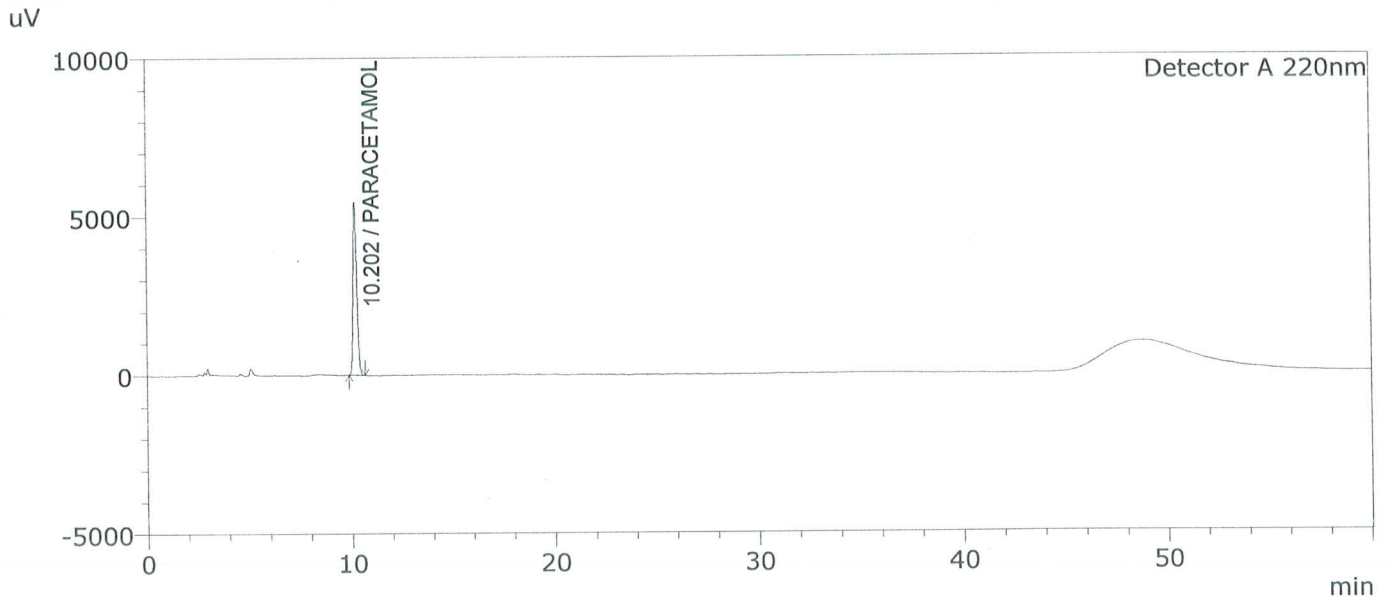
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-42H-RS-STD
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-42.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 11:15:19 AM
 Date Processed : 1/18/2024 3:13:45 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.20	68956	100.00	14552	1.131	--	--
Total			68956	100.00				

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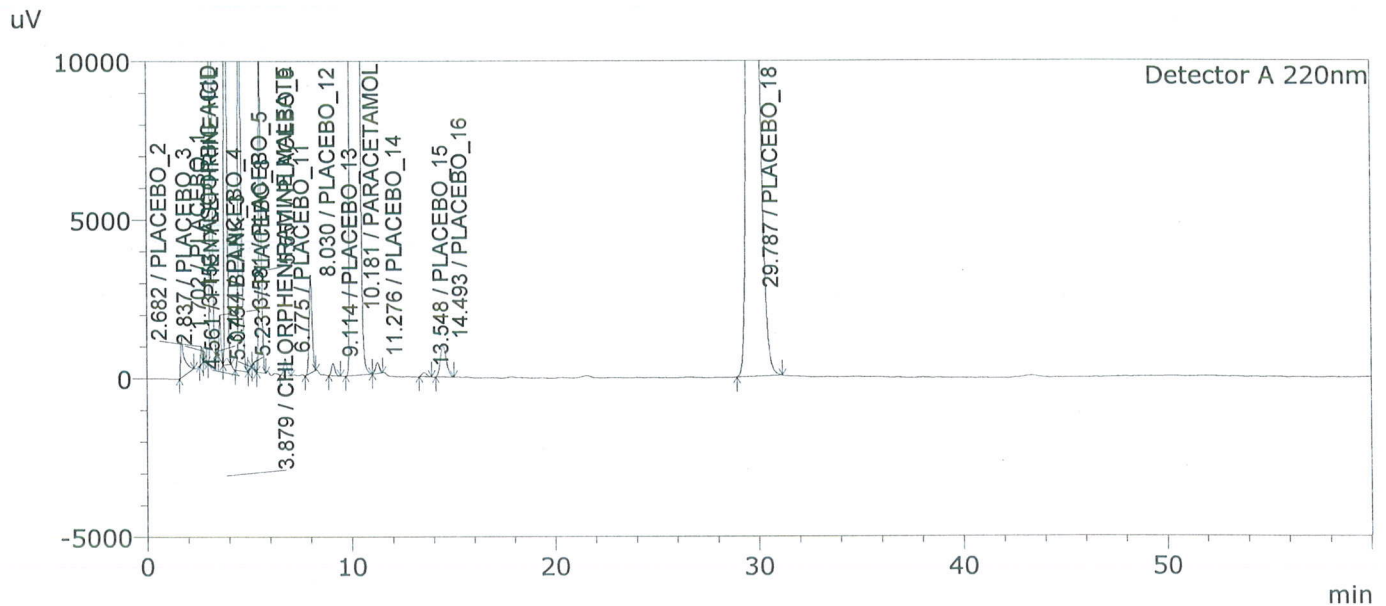
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : GRIPEX-1228-42H-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-43.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 12:15:58 PM
 Date Processed : 1/18/2024 5:16:43 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

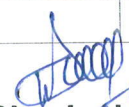
Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16602	0.11	800	4.208	--	--
2	PLACEBO_2	2.68	2948	0.02	4703	1.061	4.934	--
3	PLACEBO_3	2.84	1477	0.01	7574	1.237	1.076	--
4	ASCORBIC ACID	3.15	289994	1.87	5834	1.285	2.141	--
5	PLACEBO_4	3.44	447	0.00	20801	0.973	2.233	--
6	PLACEBO_5	3.58	8068	0.05	7030	1.277	1.028	--
7	CHLORPHENIRAMINE MALEATE	3.88	305086	1.97	8139	1.263	1.741	--
8	PHENYLEPHRINE HCL	4.56	165839	1.07	7877	1.497	3.612	--
9	BLANK_3	5.08	422	0.00	16616	0.848	2.830	--
10	PLACEBO_8	5.23	1215	0.01	12855	1.256	0.912	--
11	PLACEBO_9	5.56	82371	0.53	10093	1.210	1.608	--
12	PLACEBO_11	6.78	5835	0.04	8854	1.173	4.782	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31244	0.20	13588	1.036	4.455	--
14	PLACEBO_13	9.11	4503	0.03	12968	1.233	3.638	--
15	PARACETAMOL	10.18	13457810	86.94	14028	1.186	3.213	--
16	PLACEBO_14	11.28	4372	0.03	16203	1.031	3.137	--
17	PLACEBO_15	13.55	2184	0.01	15194	1.287	5.723	--
18	PLACEBO_16	14.49	19936	0.13	11822	1.187	1.944	--
19	PLACEBO_18	29.79	1079136	6.97	17066	1.186	21.164	--
Total			15479487	100.00				

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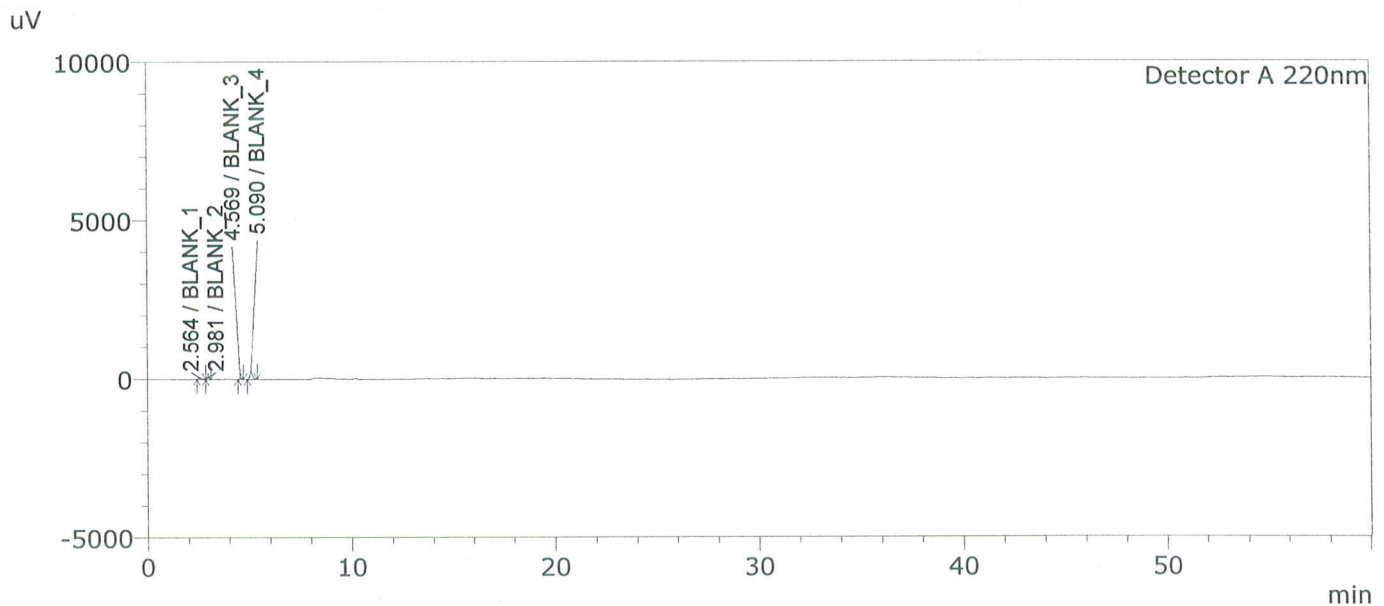
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-44.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 1:16:37 PM
 Date Processed : 1/18/2024 5:27:06 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.56	654	17.52	1231	1.723	--	--
2	BLANK_2	2.98	421	11.27	3031	1.147	1.636	--
3	BLANK_3	4.57	337	9.03	9988	1.164	7.953	--
4	BLANK_4	5.09	2320	62.18	6290	1.564	2.371	--
Total			3731	100.00				

Analysed By

Checked By



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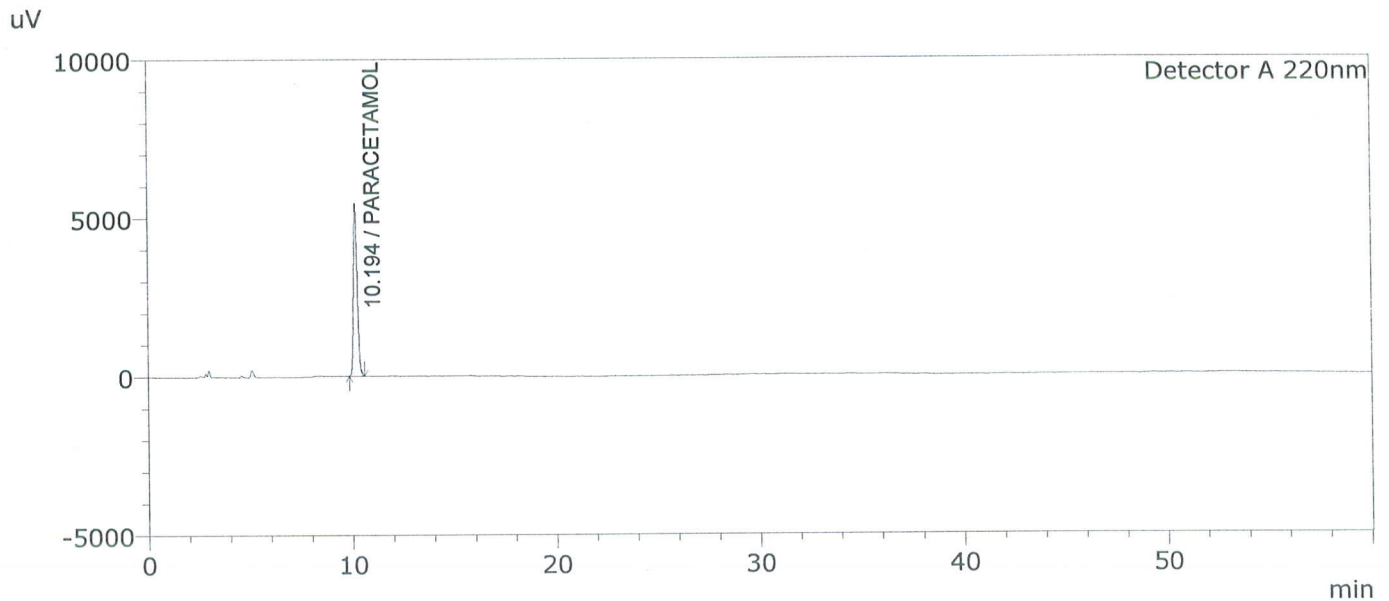
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-45H-RS-STD
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-45.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 2:17:16 PM
 Date Processed : 1/18/2024 3:13:46 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	69041	100.00	14525	1.133	--	--
Total			69041	100.00				

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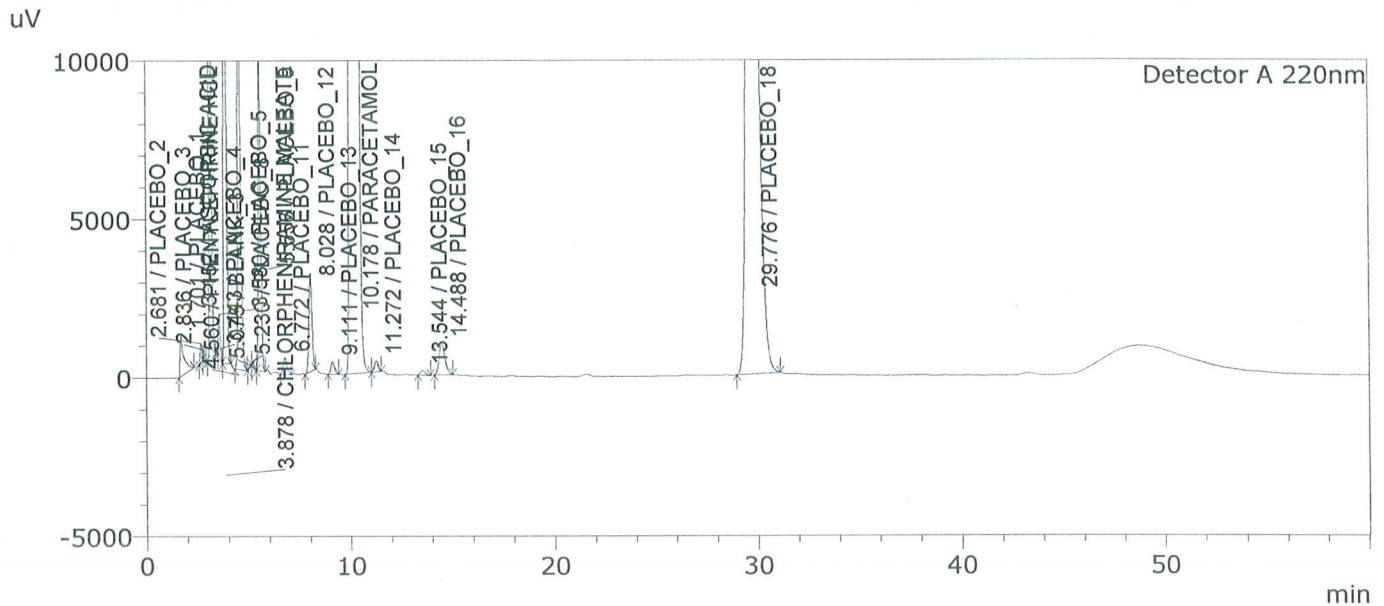
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : GRIPEX-1228-45H-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-46.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 3:17:55 PM
 Date Processed : 1/18/2024 5:33:24 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

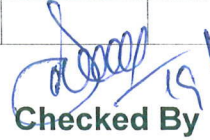
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17060	0.11	784	4.300	--	--
2	PLACEBO_2	2.68	3248	0.02	4674	1.072	4.897	--
3	PLACEBO_3	2.84	1427	0.01	7676	1.248	1.084	--
4	ASCORBIC ACID	3.15	277884	1.80	5826	1.285	2.147	--
5	PLACEBO_4	3.44	439	0.00	22035	0.989	2.254	--
6	PLACEBO_5	3.58	8112	0.05	6959	1.267	1.035	--
7	CHLORPHENIRAMINE MALEATE	3.88	304878	1.97	8138	1.260	1.739	--
8	PHENYLEPHRINE HCL	4.56	165726	1.07	7892	1.494	3.612	--
9	BLANK_3	5.08	411	0.00	18218	0.844	2.898	--
10	PLACEBO_8	5.23	1213	0.01	12997	1.157	0.928	--
11	PLACEBO_9	5.56	82372	0.53	10104	1.211	1.610	--
12	PLACEBO_11	6.77	5841	0.04	8899	1.201	4.788	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31255	0.20	13575	1.033	4.461	--
14	PLACEBO_13	9.11	4589	0.03	13082	1.211	3.646	--
15	PARACETAMOL	10.18	13453311	87.01	14039	1.185	3.221	--
16	PLACEBO_14	11.27	4505	0.03	15959	1.039	3.124	--
17	PLACEBO_15	13.54	2377	0.02	14220	1.333	5.601	--
18	PLACEBO_16	14.49	20020	0.13	11871	1.216	1.915	--
19	PLACEBO_18	29.78	1077603	6.97	17066	1.187	21.180	--
Total			15462271	100.00				

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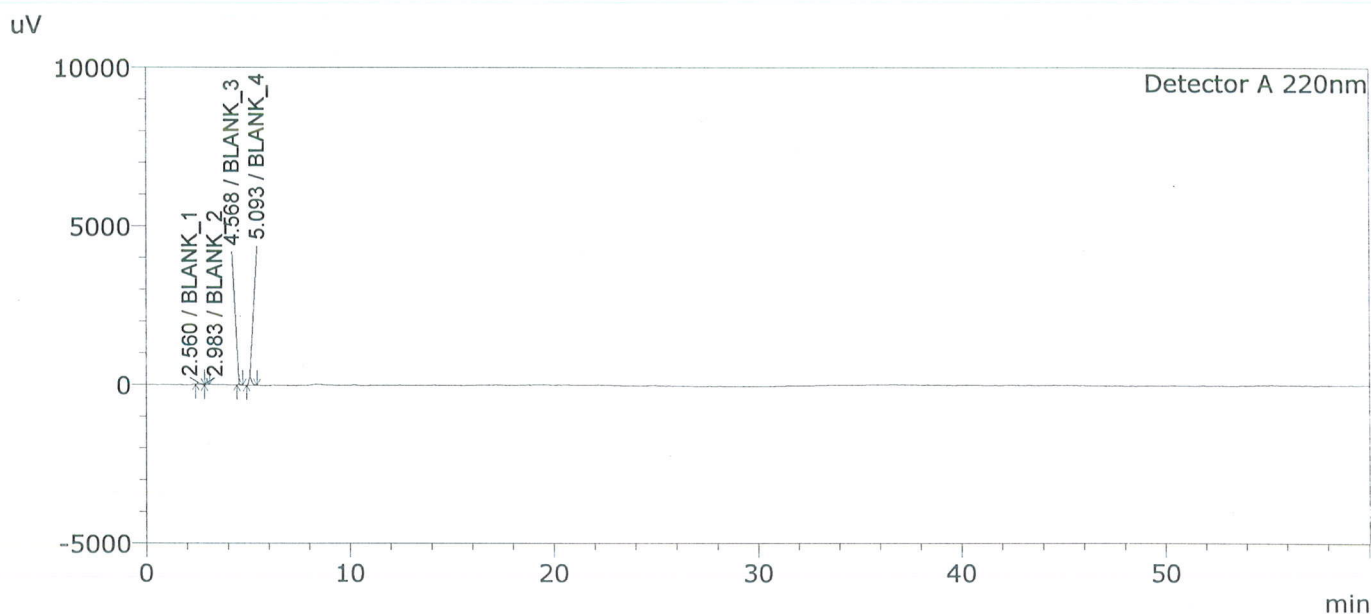
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-47.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 4:18:34 PM
 Date Processed : 1/18/2024 5:34:58 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.56	705	17.98	405	1.935	--	--
2	BLANK_2	2.98	429	10.94	3136	1.101	1.173	--
3	BLANK_3	4.57	349	8.91	9665	1.254	7.946	--
4	BLANK_4	5.09	2438	62.17	6042	1.581	2.343	--
Total			3922	100.00				

Analysed By

Checked By



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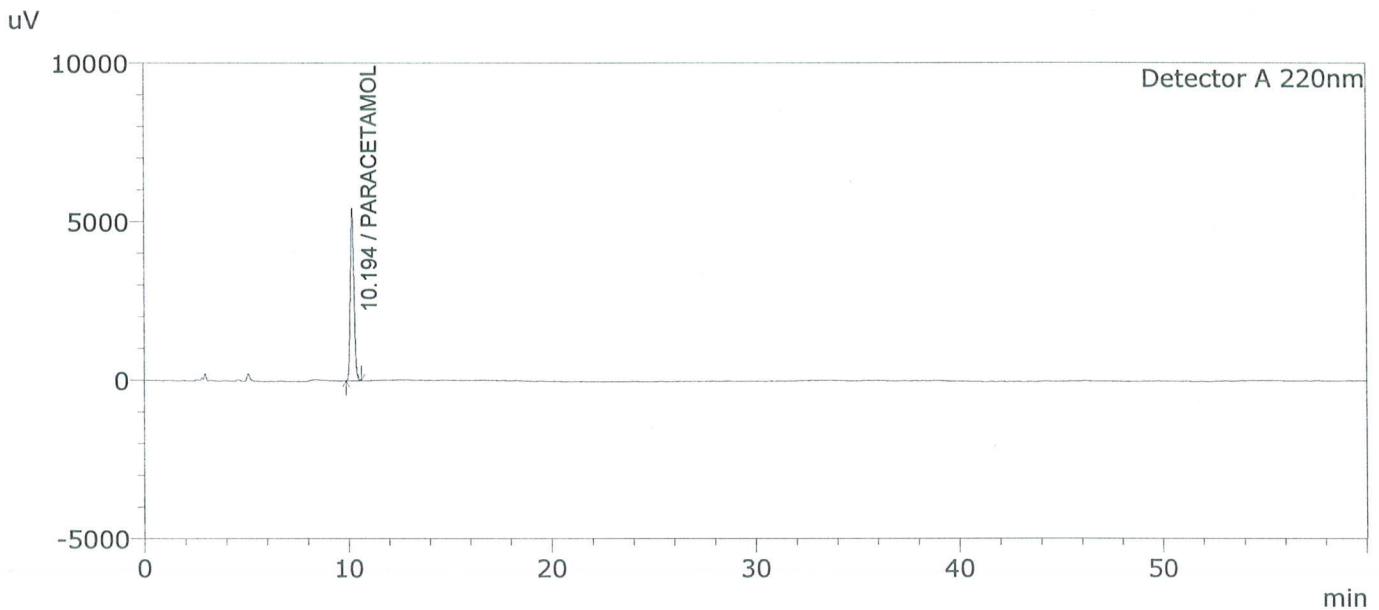
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-48H-RS-STD
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-48.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 5:19:15 PM
 Date Processed : 1/18/2024 3:13:47 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	68961	100.00	14517	1.135	--	--
Total			68961	100.00				

Analysed By

Checked By



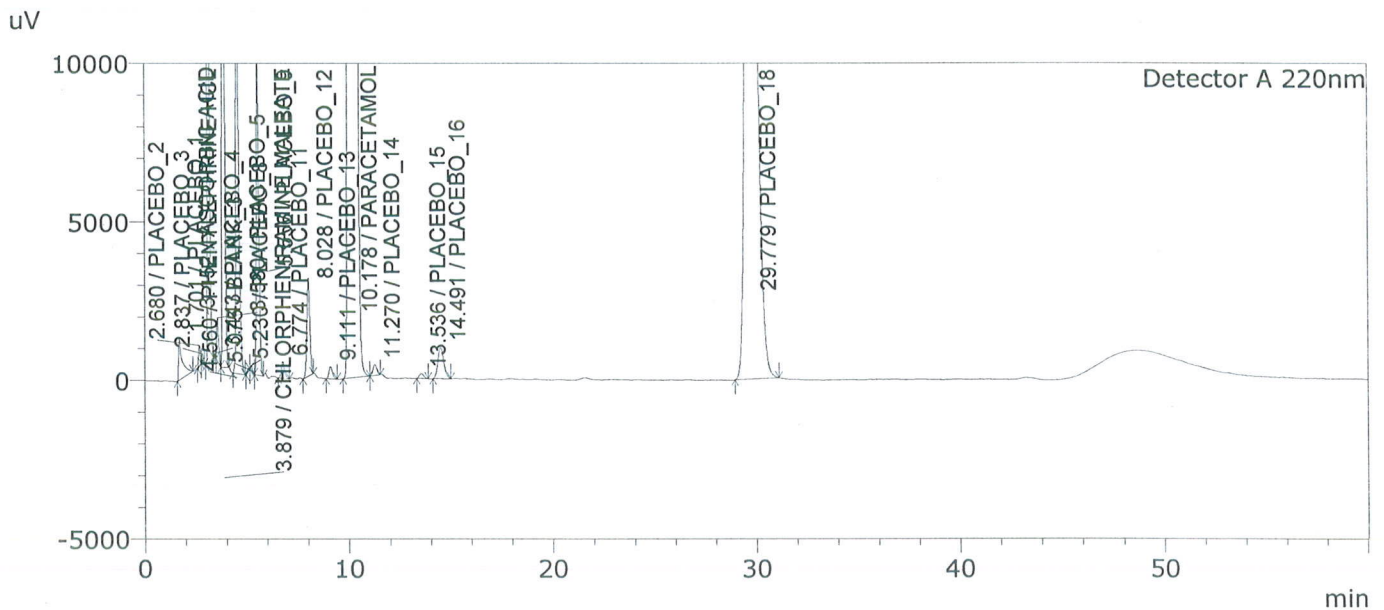
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : GRIPEX-1228-48H-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-49.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 6:19:53 PM
 Date Processed : 1/18/2024 5:39:08 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17291	0.11	793	4.571	--	--
2	PLACEBO_2	2.68	3545	0.02	4662	1.080	4.910	--
3	PLACEBO_3	2.84	1405	0.01	7644	1.251	1.090	--
4	ASCORBIC ACID	3.15	266168	1.72	5848	1.287	2.142	--
5	PLACEBO_4	3.44	424	0.00	21278	0.993	2.243	--
6	PLACEBO_5	3.58	8111	0.05	6971	1.267	1.028	--
7	CHLORPHENIRAMINE MALEATE	3.88	304691	1.97	8146	1.264	1.742	--
8	PHENYLEPHRINE HCL	4.56	165506	1.07	7909	1.497	3.612	--
9	BLANK_3	5.08	436	0.00	16962	0.864	2.856	--
10	PLACEBO_8	5.23	1174	0.01	13215	1.268	0.918	--
11	PLACEBO_9	5.56	82224	0.53	10120	1.212	1.617	--
12	PLACEBO_11	6.77	5794	0.04	8964	1.204	4.803	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31274	0.20	13584	1.032	4.466	--
14	PLACEBO_13	9.11	4592	0.03	12738	1.222	3.619	--
15	PARACETAMOL	10.18	13449031	87.08	14049	1.185	3.202	--
16	PLACEBO_14	11.27	4368	0.03	16232	1.072	3.134	--
17	PLACEBO_15	13.54	2334	0.02	16104	1.187	5.805	--
18	PLACEBO_16	14.49	20084	0.13	11758	1.171	1.988	--
19	PLACEBO_18	29.78	1076834	6.97	17076	1.185	21.144	--
Total			15445287	100.00				

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Batch Table

Batch Table 13012024.GRIPEX.SACHET-MV-RS-SOLUTION.STABILITY.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-01.lcd	10.0	QC/CL/23/032
2	1	SOLUTION STABILITY-RS	RESOLUTION SOLUTION	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-02.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-RS-STD-01	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-03.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-RS-STD-02	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-04.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-RS-STD-03	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-05.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-RS-STD-04	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-06.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-RS-STD-05	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-07.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-RS-STD-06	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-08.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-09.lcd	10.0	QC/CL/23/032
4	1	SOLUTION STABILITY-RS	PLACEBO-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-10.lcd	10.0	QC/CL/23/032
5	1	SOLUTION STABILITY-RS	GRIPEX-1228-14H-RS-SPL	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-11.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-RS-STD-BKT	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-12.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-13.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-14H-RS-STD	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-14.lcd	10.0	QC/CL/23/032
5	1	SOLUTION STABILITY-RS	GRIPEX-1228-14H-RS-SPL	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-15.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-16.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-17H-RS-STD	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-17.lcd	10.0	QC/CL/23/032
5	1	SOLUTION STABILITY-RS	GRIPEX-1228-17H-RS-SPL	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-18.lcd	10.0	QC/CL/23/032

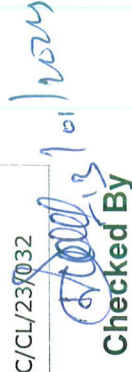
Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-19.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-20H-RS-STD	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-20.lcd	10.0	QC/CL/23/032
5	1	SOLUTION STABILITY-RS	GRIPEX-1228-20H-RS-SPL	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-21.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-22.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-23.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-24H-RS-STD	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-24.lcd	10.0	QC/CL/23/032
5	1	SOLUTION STABILITY-RS	GRIPEX-1228-24H-RS-SPL	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-25.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-26.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-27.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-28H-RS-STD	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-28.lcd	10.0	QC/CL/23/032
5	1	SOLUTION STABILITY-RS	GRIPEX-1228-28H-RS-SPL	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-29.lcd	10.0	QC/CL/23/032
6	1	METHOD PRECISION-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-30.lcd	10.0	QC/CL/23/032
7	1	METHOD PRECISION-RS	GRIPEX-1228-RS-SPL-1	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-31.lcd	10.0	QC/CL/23/032
8	1	METHOD PRECISION-RS	GRIPEX-1228-RS-SPL-2	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-32.lcd	10.0	QC/CL/23/032
9	1	METHOD PRECISION-RS	GRIPEX-1228-RS-SPL-3	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-33.lcd	10.0	QC/CL/23/032
10	1	METHOD PRECISION-RS	GRIPEX-1228-RS-SPL-4	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-34.lcd	10.0	QC/CL/23/032
11	1	METHOD PRECISION-RS	GRIPEX-1228-RS-SPL-5	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-35.lcd	10.0	QC/CL/23/032
12	1	METHOD PRECISION-RS	GRIPEX-1228-RS-SPL-6	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-36.lcd	10.0	QC/CL/23/032
3	1	METHOD PRECISION-RS	PARACETAMOL-RS-STD-BKT-1	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-37.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-38H-RS-STD	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-38.lcd	10.0	QC/CL/23/032
5	1	SOLUTION STABILITY-RS	GRIPEX-1228-38H-RS-SPL	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-39.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-40.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D\GRIPEX-SACH-RS.lcm	3ILITY-RS-SPL-41.lcd	10.0	QC/CL/23/032

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
3	1	SOLUTION STABILITY-RS	PARACETAMOL-42H-RS-STD	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-42.lcd	10.0	QC/CL/23/032
5	1	SOLUTION STABILITY-RS	GRIPEX-1228-42H-RS-SPL	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-43.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-44.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-45H-RS-STD	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-45.lcd	10.0	QC/CL/23/032
5	1	SOLUTION STABILITY-RS	GRIPEX-1228-45H-RS-SPL	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-46.lcd	10.0	QC/CL/23/032
1	1	SOLUTION STABILITY-RS	BLANK-RS	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-47.lcd	10.0	QC/CL/23/032
3	1	SOLUTION STABILITY-RS	PARACETAMOL-48H-RS-STD	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-48.lcd	10.0	QC/CL/23/032
5	1	SOLUTION STABILITY-RS	GRIPEX-1228-48H-RS-SPL	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-49.lcd	10.0	QC/CL/23/032
13	1	FILTER PAPER STUDY-RS	BLANK-RS	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-50.lcd	10.0	QC/CL/23/032
14	1	FILTER PAPER STUDY-RS	GRIPEX-1228-CENTRIFUGE-RS-SPL	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-51.lcd	10.0	QC/CL/23/032
15	1	FILTER PAPER STUDY-RS	GRIPEX-1228-NYLON-1-RS-SPL	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-52.lcd	10.0	QC/CL/23/032
16	1	FILTER PAPER STUDY-RS	GRIPEX-1228-NYLON-2-RS-SPL	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-53.lcd	10.0	QC/CL/23/032
17	1	FILTER PAPER STUDY-RS	GRIPEX-1228-NYLON-3-RS-SPL	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-54.lcd	10.0	QC/CL/23/032
18	1	FILTER PAPER STUDY-RS	GRIPEX-1228-PVDF-1-RS-SPL	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-55.lcd	10.0	QC/CL/23/032
19	1	FILTER PAPER STUDY-RS	GRIPEX-1228-PVDF-2-RS-SPL	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-56.lcd	10.0	QC/CL/23/032
20	1	FILTER PAPER STUDY-RS	GRIPEX-1228-PVDF-3-RS-SPL	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-57.lcd	10.0	QC/CL/23/032
3	1	FILTER PAPER STUDY-RS	PARACETAMOL-RS-STD-BKT-2	D:\GRIPEX-SACH-RS.lcm	BILITY-RS-SPL-58.lcd	10.0	QC/CL/23/032
-1	1	FILTER PAPER STUDY-RS	WASH	WASHING METHOD.lcm	BILITY-RS-SPL-59.lcd	10.0	QC/CL/23/032
-1	1	FILTER PAPER STUDY-RS	SHUTDWON	HUTDOWN METHOD.lcm	BILITY-RS-SPL-61.lcd	10.0	QC/CL/23/032

Analysed By



Checked By





GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	METHOD PRECISION (SAMPLE PREPARATION-1)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution .:	415.05	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.516	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURTY

Limit: NMT 0.50%

Calculation formula :		0
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100	68953
	Standard area x sample dilution X Label claim x 100	ND 0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :		0
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100	68953
	Standard area x sample dilution X Label claim x 100	ND 0.00

Analysed by : E.MEENA
Date : 18-01-2024

Checked by :
Date :

18/01/24

18/01/2024



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	METHOD PRECISION (SAMPLE PREPARATION-2)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.03	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.487	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURITIY

Limit: NMT 0.50%

Calculation formula :

Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :

Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

0.00

Analysed by : E.MEENA

Date : 18-01-2024

Checked by :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	METHOD PRECISION (SAMPLE PREPARATION-3)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution .:	415.26	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.82	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURTY

Limit: NMT 0.50%

Calculation formula :			0
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100		68953
	Standard area x sample dilution X Label claim x 100	ND	0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :			0
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100		68953
	Standard area x sample dilution X Label claim x 100	ND	0.00

Analysed by : E.MEENA

Date : 18-01-2024

Checked by :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	METHOD PRECISION (SAMPLE PREPARATION-4)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

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

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.34	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.933	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled content :	650 mg
Average weight :	4500.0 mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURITIY

Limit: NMT 0.50%

Calculation formula :		0
Any individual impurity in%		68953
Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100		
Standard area x sample dilution X Label claim x 100		
		ND 0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :		0
Total impurities in%		68953
Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100		
Standard area x sample dilution X Label claim x 100		
		ND 0.00

Analysed by : E.MEENA
Date : 18-01-2024

18/01/24

Checked by :
Date : 19/01/2024



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	METHOD PRECISION (SAMPLE PREPARATION-5)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.15	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.66	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled content :	650
Average weight :	4500.0

mg

mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURIT

Limit: NMT 0.50%

Calculation formula :		0
Any individual impurity in%		68953
Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100		
Standard area x sample dilution X Label claim x 100		
		ND
		0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :		0
Total impurities in%		68953
Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100		
Standard area x sample dilution X Label claim x 100		
		ND
		0.00

Analysed by : E.MEENA
Date : 18-01-2024

18/01/24

Checked by :
Date : 19/01/2024



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	METHOD PRECISION (SAMPLE PREPARATION-6)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.20	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.73	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURITIY

Limit: NMT 0.50%

		0
Calculation formula :		68953
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100	
	Standard area x sample dilution X Label claim x 100	ND 0.000

TOTAL IMPURITIES

Limit: NMT 1.00%

		0
Calculation formula :		68953
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100	
	Standard area x sample dilution X Label claim x 100	ND 0.00

Analysed by : E.MEENA
Date : 18-01-2024

18/01/24

Checked by :
Date :

19/01/2024



GENERIC HEALTHCARE PVT. LTD.

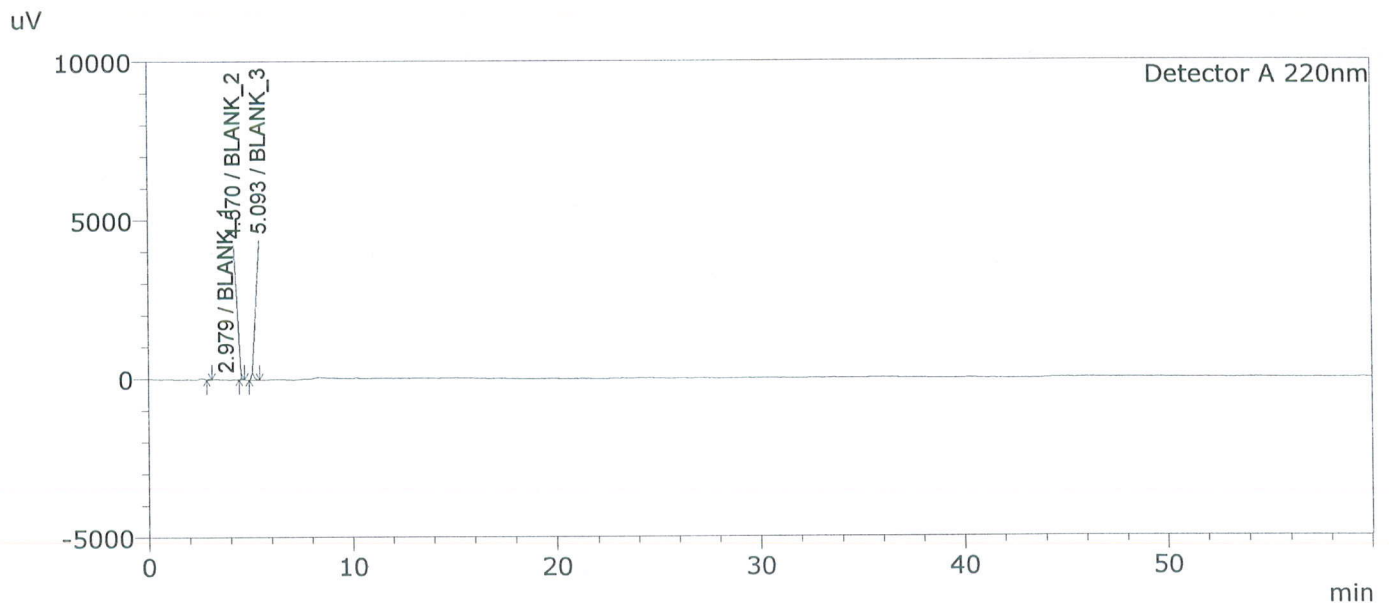
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-30.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-6
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 11:07:25 PM
 Date Processed : 1/18/2024 4:25:17 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.98	260	9.86	1788	1.090	--	--
2	BLANK_2	4.57	369	13.96	10343	1.196	6.894	--
3	BLANK_3	5.09	2011	76.18	6141	1.700	2.380	--
Total			2640	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

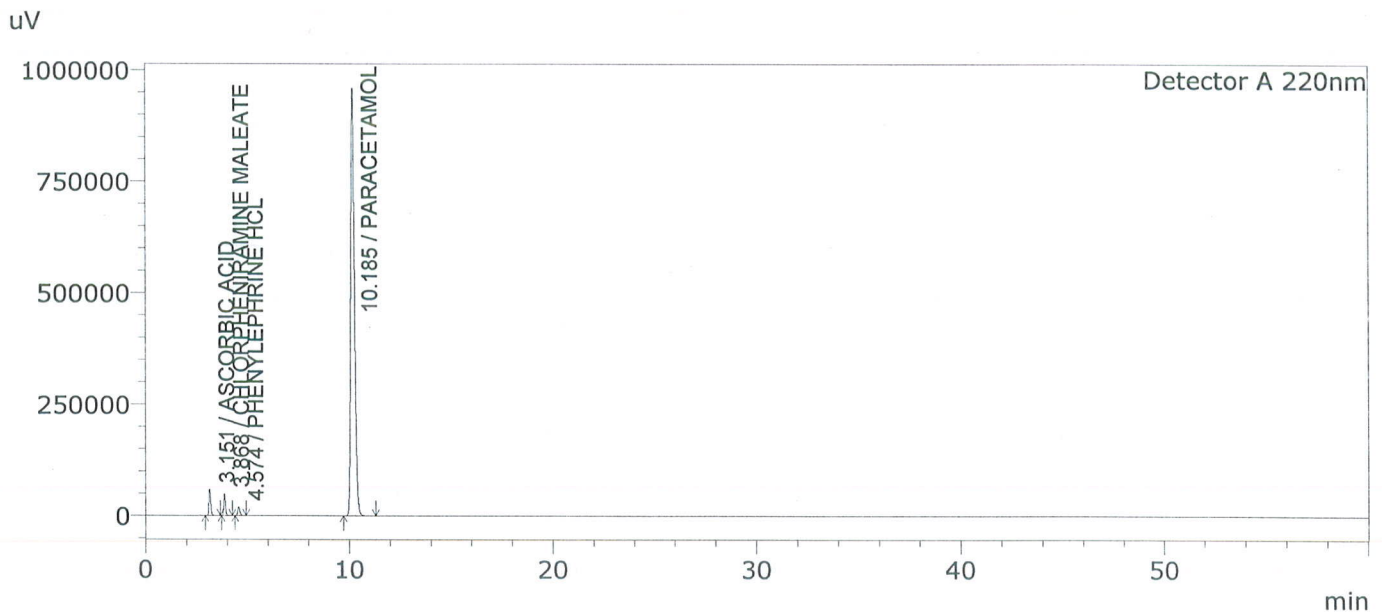
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : RESOLUTION SOLUTION
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-02.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 1/13/2024 6:49:06 PM
 Date Processed : 1/18/2024 3:19:39 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	3.15	343199	2.61	5952	1.300	--	--
2	CHLORPHENIRAMINE MALEATE	3.87	299289	2.27	8269	1.274	4.299	--
3	PHENYLEPHRINE HCL	4.57	140618	1.07	8674	1.235	3.851	--
4	PARACETAMOL	10.19	12379511	94.05	14082	1.193	20.792	--
Total			13162616	100.00				

18/01/24

Analysed By

19/01/2024

Checked By



GENERIC HEALTHCARE PVT. LTD.

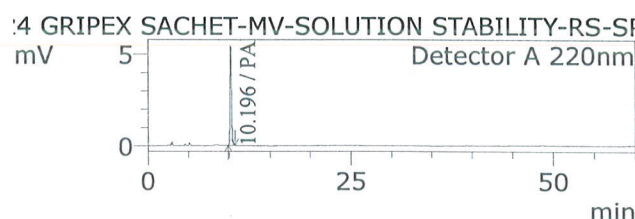
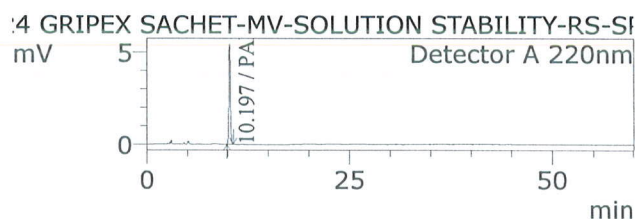
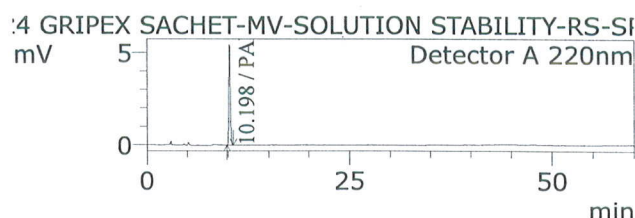
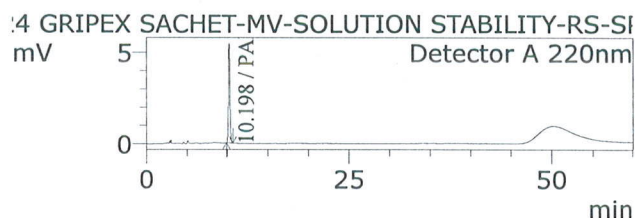
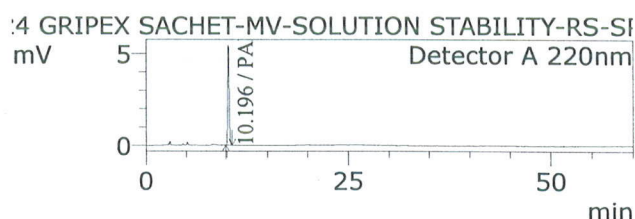
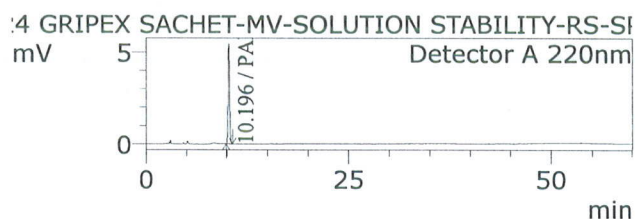
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-RS-STD-01
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-03.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/13/2024 7:49:45 PM
 Date Processed : 1/18/2024 3:13:38 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-03.lcd	PARACETAMOL-RS-STD-01	10.20	68978	14540	1.15
3	RS-SPL-04.lcd	PARACETAMOL-RS-STD-02	10.20	68922	14504	1.14
3	RS-SPL-05.lcd	PARACETAMOL-RS-STD-03	10.20	68934	14549	1.14
3	RS-SPL-06.lcd	PARACETAMOL-RS-STD-04	10.20	68865	14563	1.14
3	RS-SPL-07.lcd	PARACETAMOL-RS-STD-05	10.20	68929	14524	1.14
3	RS-SPL-08.lcd	PARACETAMOL-RS-STD-06	10.20	69092	14461	1.15
	Average		10.20	68953	14523	1.14
	%RSD		0.010	0.112	0.255	0.134

Analysed By

Checked By



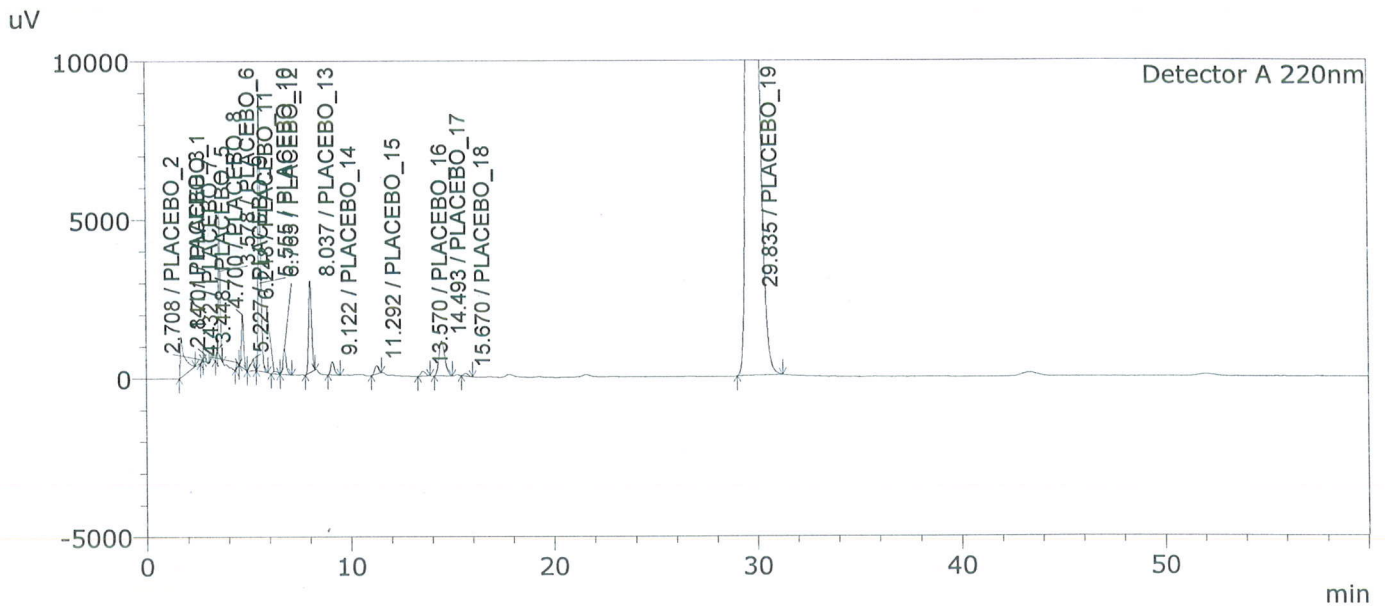
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PLACEBO-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-10.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 2:54:21 AM
 Date Processed : 1/18/2024 3:35:12 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	18184	1.35	758	4.849	--	--
2	PLACEBO_2	2.71	236	0.02	9914	1.044	5.658	--
3	PLACEBO_3	2.84	1168	0.09	5156	1.320	0.996	--
4	PLACEBO_5	3.45	642	0.05	19137	0.772	4.704	--
5	PLACEBO_6	3.58	25730	1.91	7417	1.220	0.981	--
6	PLACEBO_7	4.43	844	0.06	13244	0.982	5.328	--
7	PLACEBO_8	4.70	12852	0.95	7810	1.120	1.466	--
8	PLACEBO_9	5.23	4530	0.34	5163	0.731	2.091	--
9	PLACEBO_10	5.55	70037	5.19	10221	1.242	1.283	--
10	PLACEBO_11	6.25	1238	0.09	4103	1.625	2.274	--
11	PLACEBO_12	6.76	8563	0.63	9462	1.311	1.545	--
12	PLACEBO_13	8.04	28849	2.14	13887	1.084	4.619	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_14	9.12	5107	0.38	13050	1.431	3.664	--
14	PLACEBO_15	11.29	3387	0.25	15689	1.004	6.383	--
15	PLACEBO_16	13.57	2399	0.18	14300	1.207	5.595	--
16	PLACEBO_17	14.49	21797	1.61	12486	1.187	1.897	--
17	PLACEBO_18	15.67	1285	0.10	22464	1.265	2.512	--
18	PLACEBO_19	29.83	1142881	84.67	17018	1.190	21.252	--
Total			1349728	100.00				


Analysed By


Checked By



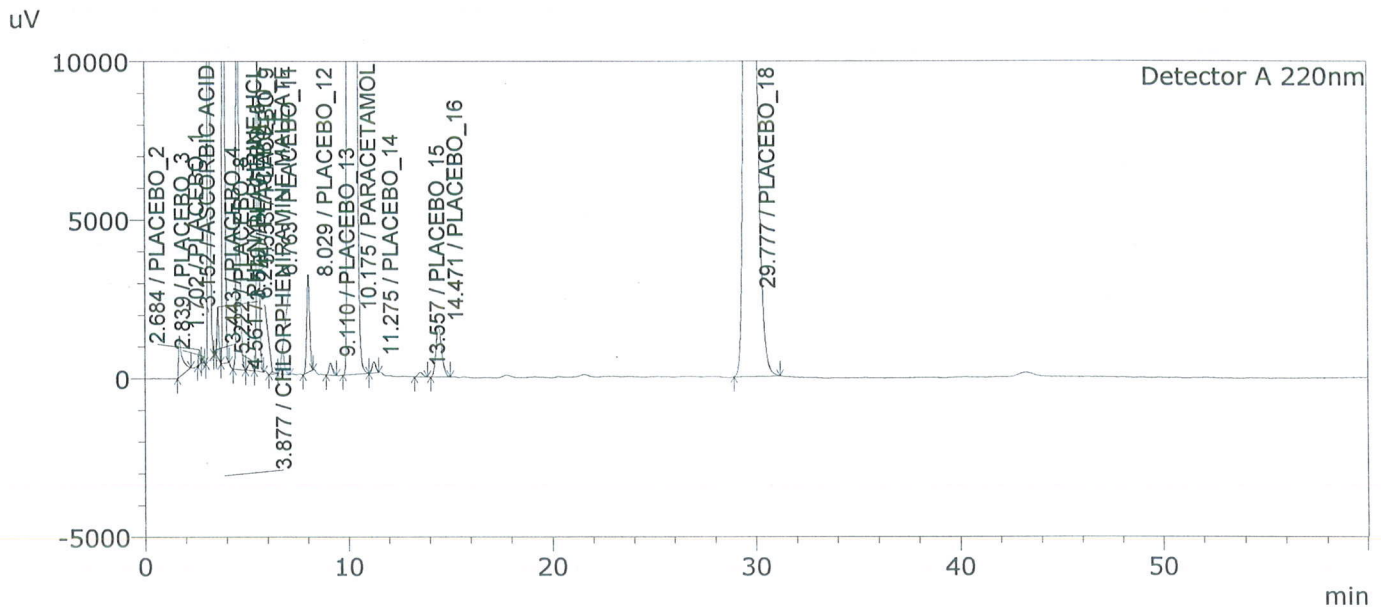
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-1
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-31.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-7
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 12:08:04 AM
 Date Processed : 1/18/2024 4:48:27 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	15904	0.10	810	3.912	--	--
2	PLACEBO_2	2.68	2480	0.02	4567	1.041	4.936	--
3	PLACEBO_3	2.84	940	0.01	7426	1.301	1.067	--
4	ASCORBIC ACID	3.15	273570	1.76	5761	1.276	2.100	--
5	PLACEBO_4	3.44	461	0.00	22160	0.962	2.252	--
6	PLACEBO_5	3.58	9442	0.06	6937	1.256	1.028	--
7	CHLORPHENIRAMINE MALEATE	3.88	286974	1.85	8118	1.249	1.730	--
8	PHENYLEPHRINE HCL	4.56	161328	1.04	7811	1.486	3.615	--
9	PLACEBO_8	5.22	3996	0.03	3245	0.755	2.308	--
10	PLACEBO_9	5.55	85036	0.55	10078	1.211	1.126	--
11	PLACEBO_10	6.24	1003	0.01	4397	1.501	2.310	--
12	PLACEBO_11	6.76	8813	0.06	8782	1.227	1.560	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31072	0.20	13582	1.034	4.489	--
14	PLACEBO_13	9.11	4512	0.03	13045	1.189	3.637	--
15	PARACETAMOL	10.18	13526550	87.09	14009	1.187	3.213	--
16	PLACEBO_14	11.28	4436	0.03	16350	1.041	3.158	--
17	PLACEBO_15	13.56	2296	0.01	14569	1.165	5.690	--
18	PLACEBO_16	14.47	30904	0.20	12338	1.178	1.884	--
19	PLACEBO_18	29.78	1082482	6.97	17054	1.188	21.360	--
Total			15532198	100.00				

Analysed By

①
18/01/24

Checked By

①
18/01/24



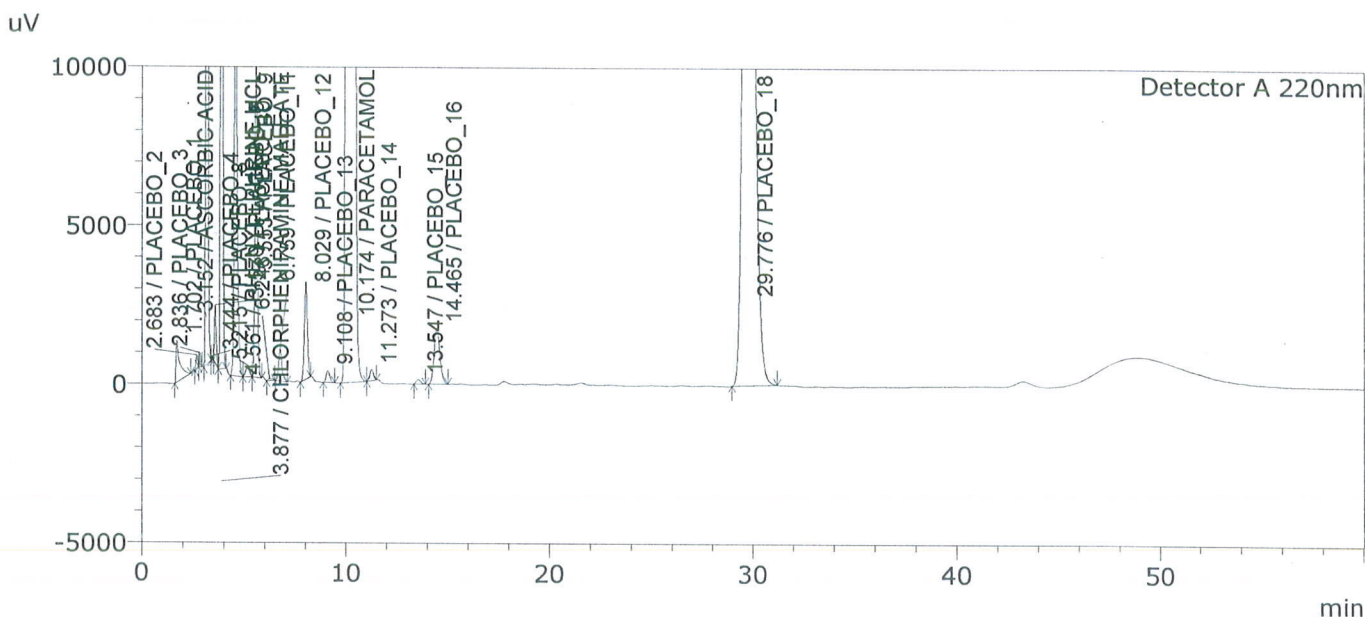
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-2
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-32.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-8
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 1:08:44 AM
 Date Processed : 1/18/2024 4:49:22 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17720	0.11	781	4.587	--	--
2	PLACEBO_2	2.68	2216	0.01	4934	1.025	4.950	--
3	PLACEBO_3	2.84	1929	0.01	7782	1.181	1.085	--
4	ASCORBIC ACID	3.15	364906	2.33	5794	1.277	2.151	--
5	PLACEBO_4	3.44	420	0.00	22966	0.944	2.273	--
6	PLACEBO_5	3.58	10798	0.07	6940	1.251	1.031	--
7	CHLORPHENIRAMINE MALEATE	3.88	286719	1.83	8120	1.248	1.731	--
8	PHENYLEPHRINE HCL	4.56	156750	1.00	7783	1.492	3.610	--
9	PLACEBO_8	5.21	4704	0.03	3263	0.776	2.285	--
10	PLACEBO_9	5.55	83837	0.54	10051	1.214	1.155	--
11	PLACEBO_10	6.25	858	0.01	4570	1.459	2.351	--
12	PLACEBO_11	6.76	10828	0.07	8892	1.254	1.557	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31149	0.20	13536	1.033	4.511	--
14	PLACEBO_13	9.11	4434	0.03	12796	1.245	3.610	--
15	PARACETAMOL	10.17	13573140	86.66	14030	1.188	3.201	--
16	PLACEBO_14	11.27	4395	0.03	16549	1.038	3.169	--
17	PLACEBO_15	13.55	2192	0.01	16050	1.309	5.842	--
18	PLACEBO_16	14.47	34486	0.22	12452	1.179	1.941	--
19	PLACEBO_18	29.78	1070504	6.84	17035	1.188	21.398	--
Total			15661985	100.00				

Analysed By

18/01/24

Checked By

18/01/24



GENERIC HEALTHCARE PVT. LTD.

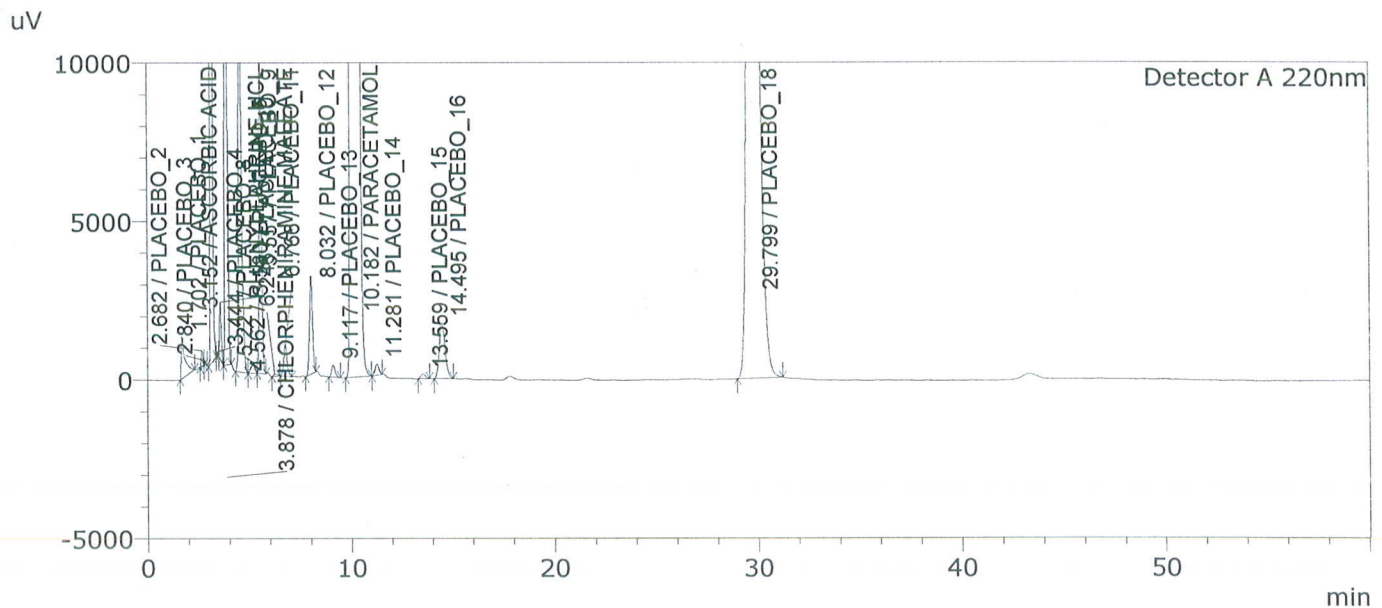
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-3
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-33.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-9
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 2:09:24 AM
 Date Processed : 1/18/2024 4:50:21 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16818	0.11	804	4.236	--	--
2	PLACEBO_2	2.68	2682	0.02	4439	1.076	4.890	--
3	PLACEBO_3	2.84	593	0.00	7628	1.237	1.084	--
4	ASCORBIC ACID	3.15	339873	2.18	5774	1.279	2.107	--
5	PLACEBO_4	3.44	451	0.00	22452	0.954	2.265	--
6	PLACEBO_5	3.58	10638	0.07	6945	1.249	1.035	--
7	CHLORPHENIRAMINE MALEATE	3.88	311983	2.00	8138	1.249	1.730	--
8	PHENYLEPHRINE HCL	4.56	169344	1.09	7856	1.490	3.621	--
9	PLACEBO_8	5.22	4354	0.03	3187	0.766	2.290	--
10	PLACEBO_9	5.56	84963	0.55	10073	1.210	1.135	--
11	PLACEBO_10	6.25	898	0.01	4718	1.534	2.353	--
12	PLACEBO_11	6.77	10907	0.07	8994	1.219	1.603	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31253	0.20	13598	1.035	4.515	--
14	PLACEBO_13	9.12	4520	0.03	13169	1.257	3.657	--
15	PARACETAMOL	10.18	13450368	86.39	14066	1.186	3.223	--
16	PLACEBO_14	11.28	4432	0.03	16240	1.018	3.150	--
17	PLACEBO_15	13.56	2284	0.01	16104	1.159	5.831	--
18	PLACEBO_16	14.50	34783	0.22	12412	1.175	1.975	--
19	PLACEBO_18	29.80	1088010	6.99	17066	1.187	21.362	--
Total			15569153	100.00				

Analysed By

18/10/24

Checked By

18/10/24



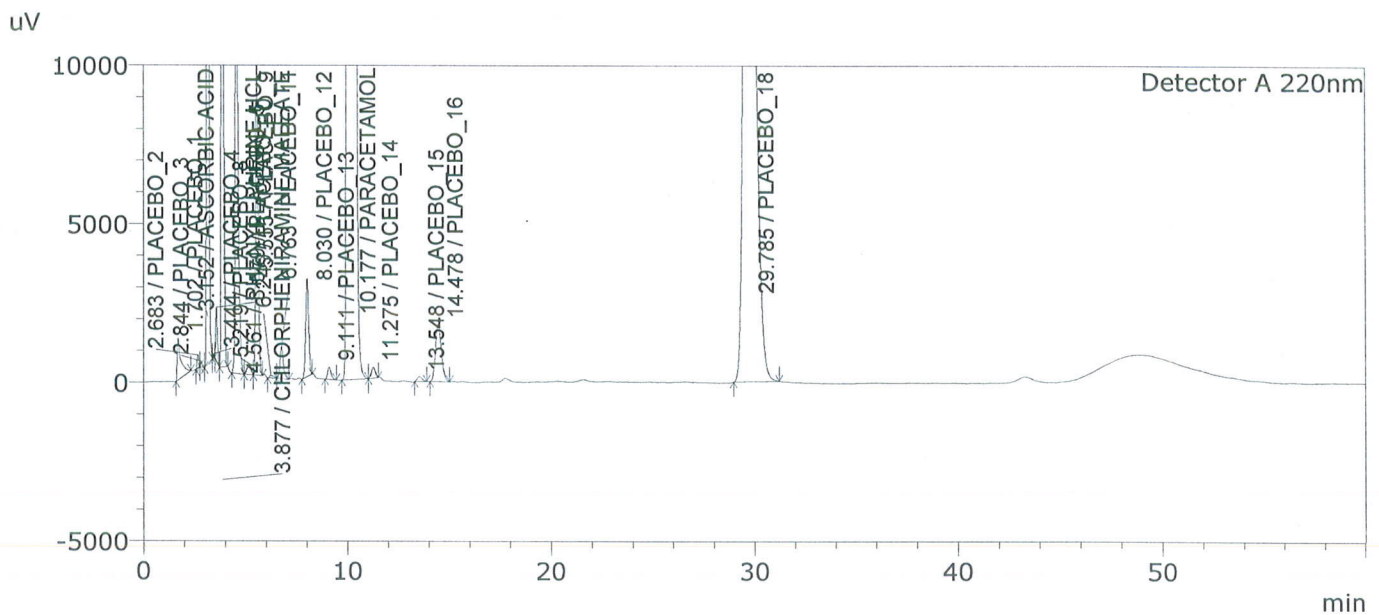
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-4
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-34.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-10
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 3:10:03 AM
 Date Processed : 1/18/2024 4:51:13 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16986	0.11	796	4.288	--	--
2	PLACEBO_2	2.68	2316	0.01	4576	1.062	4.906	--
3	PLACEBO_3	2.84	863	0.01	6974	1.279	1.093	--
4	ASCORBIC ACID	3.15	337451	2.16	5771	1.278	2.039	--
5	PLACEBO_4	3.44	439	0.00	22414	0.946	2.265	--
6	PLACEBO_5	3.58	9976	0.06	6952	1.252	1.026	--
7	CHLORPHENIRAMINE MALEATE	3.88	291999	1.87	8121	1.250	1.734	--
8	PHENYLEPHRINE HCL	4.56	178969	1.15	7872	1.477	3.619	--
9	PLACEBO_8	5.22	4436	0.03	3287	0.768	2.310	--
10	PLACEBO_9	5.55	83801	0.54	10056	1.215	1.147	--
11	PLACEBO_10	6.25	1203	0.01	4154	1.442	2.279	--
12	PLACEBO_11	6.76	10975	0.07	8948	1.238	1.525	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31277	0.20	13553	1.034	4.509	--
14	PLACEBO_13	9.11	4619	0.03	12606	1.254	3.600	--
15	PARACETAMOL	10.18	13499023	86.56	14022	1.186	3.191	--
16	PLACEBO_14	11.28	4377	0.03	16162	1.029	3.145	--
17	PLACEBO_15	13.55	2407	0.02	14057	1.251	5.598	--
18	PLACEBO_16	14.48	35365	0.23	12486	1.171	1.907	--
19	PLACEBO_18	29.78	1078832	6.92	17042	1.188	21.396	--
Total			15595312	100.00				

Analysed By

① 18/01/24

Checked By

① 19/01/2024



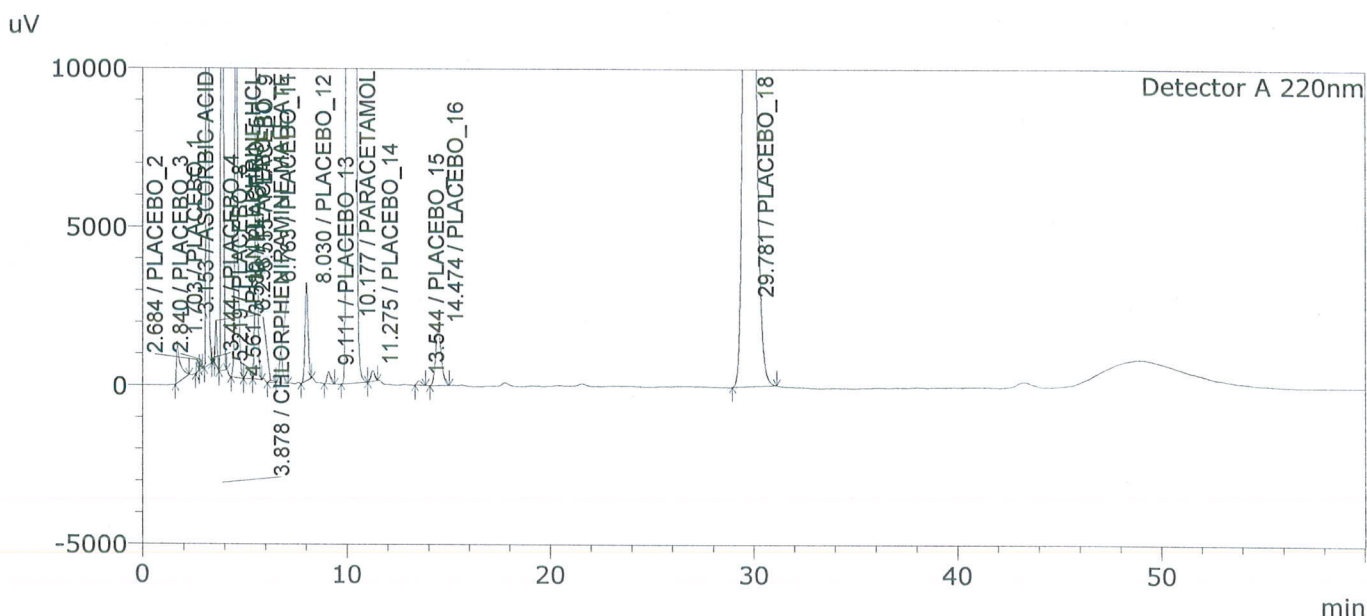
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-5
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-35.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-11
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 4:10:43 AM
 Date Processed : 1/18/2024 4:52:40 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T: Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16227	0.10	808	4.015	--	--
2	PLACEBO_2	2.68	2118	0.01	4739	1.033	4.965	--
3	PLACEBO_3	2.84	1381	0.01	7856	1.110	1.097	--
4	ASCORBIC ACID	3.15	320396	2.06	5789	1.279	2.126	--
5	PLACEBO_4	3.44	463	0.00	21908	0.955	2.253	--
6	PLACEBO_5	3.58	8279	0.05	6922	1.259	1.024	--
7	CHLORPHENIRAMINE MALEATE	3.88	307571	1.98	8118	1.251	1.731	--
8	PHENYLEPHRINE HCL	4.56	165104	1.06	7809	1.490	3.609	--
9	PLACEBO_8	5.22	4297	0.03	3240	0.772	2.295	--
10	PLACEBO_9	5.55	84387	0.54	10049	1.215	1.141	--
11	PLACEBO_10	6.26	983	0.01	4640	1.391	2.389	--
12	PLACEBO_11	6.76	10535	0.07	9010	1.228	1.546	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31384	0.20	13566	1.040	4.519	--
14	PLACEBO_13	9.11	4454	0.03	12845	1.205	3.620	--
15	PARACETAMOL	10.18	13487745	86.66	14009	1.187	3.203	--
16	PLACEBO_14	11.27	4256	0.03	16736	1.047	3.171	--
17	PLACEBO_15	13.54	2033	0.01	16508	1.212	5.892	--
18	PLACEBO_16	14.47	35082	0.23	12399	1.178	1.976	--
19	PLACEBO_18	29.78	1077100	6.92	17058	1.187	21.378	--
Total			15563795	100.00				

Analysed By

18/10/24

Checked By

10/1/2024



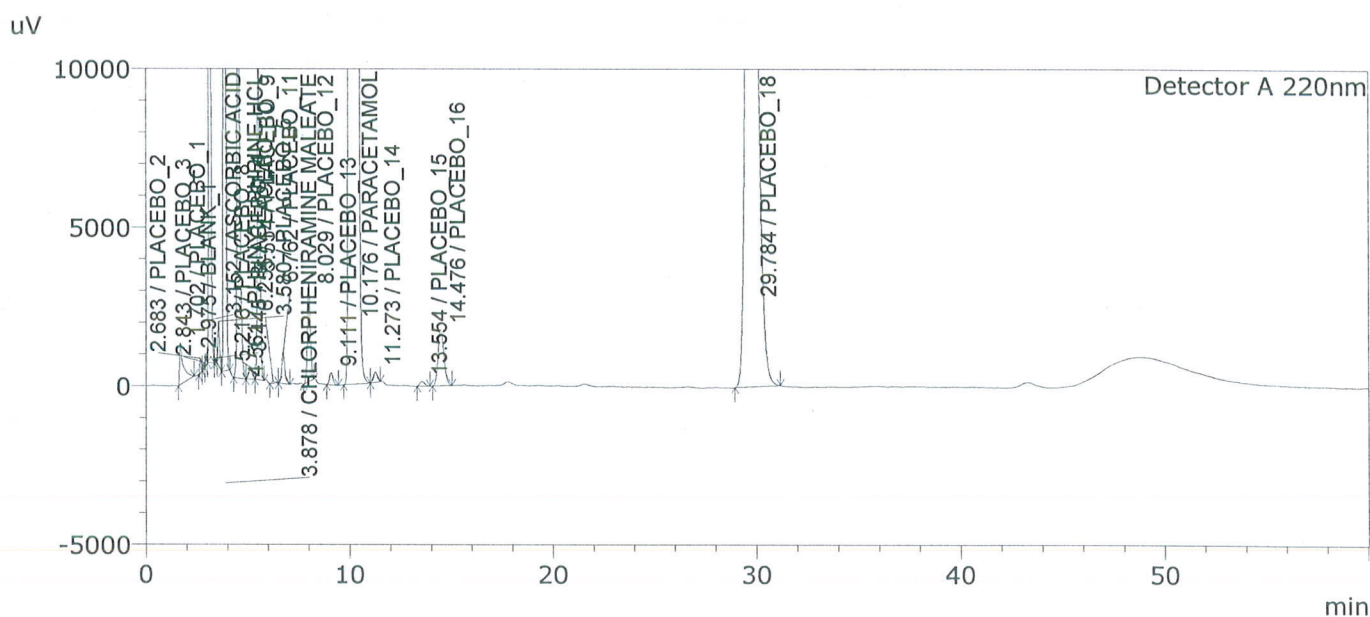
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-6
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-36.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-12
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 5:11:22 AM
 Date Processed : 1/18/2024 4:58:14 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

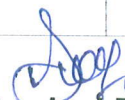
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17421	0.11	791	4.533	--	--
2	PLACEBO_2	2.68	2510	0.02	4598	1.044	4.903	--
3	PLACEBO_3	2.84	944	0.01	9549	0.993	1.162	--
4	BLANK_1	2.97	1345	0.01	11173	0.983	1.151	--
5	ASCORBIC ACID	3.15	301070	1.94	5792	1.282	1.277	--
6	PLACEBO_4	3.44	474	0.00	21730	0.949	2.255	--
7	PLACEBO_5	3.58	8188	0.05	6921	1.264	1.018	--
8	CHLORPHENIRAMINE MALEATE	3.88	302995	1.96	8103	1.252	1.731	--
9	PHENYLEPHRINE HCL	4.56	165874	1.07	7824	1.488	3.608	--
10	PLACEBO_8	5.22	4946	0.03	3306	0.772	2.302	--
11	PLACEBO_9	5.55	85678	0.55	10027	1.215	1.158	--
12	PLACEBO_10	6.26	874	0.01	4332	1.467	2.327	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	6.76	10409	0.07	9135	1.233	1.530	--
14	PLACEBO_12	8.03	31220	0.20	13544	1.035	4.533	--
15	PLACEBO_13	9.11	4546	0.03	12947	1.201	3.628	--
16	PARACETAMOL	10.18	13425654	86.72	14013	1.186	3.208	--
17	PLACEBO_14	11.27	4147	0.03	16753	1.051	3.168	--
18	PLACEBO_15	13.55	2417	0.02	14873	1.288	5.756	--
19	PLACEBO_16	14.48	35041	0.23	12433	1.166	1.912	--
20	PLACEBO_18	29.78	1076194	6.95	17046	1.187	21.383	--
Total			15481947	100.00				

Analysed By


18/01/24

Checked By


18/01/2024



GENERIC HEALTHCARE PVT. LTD.

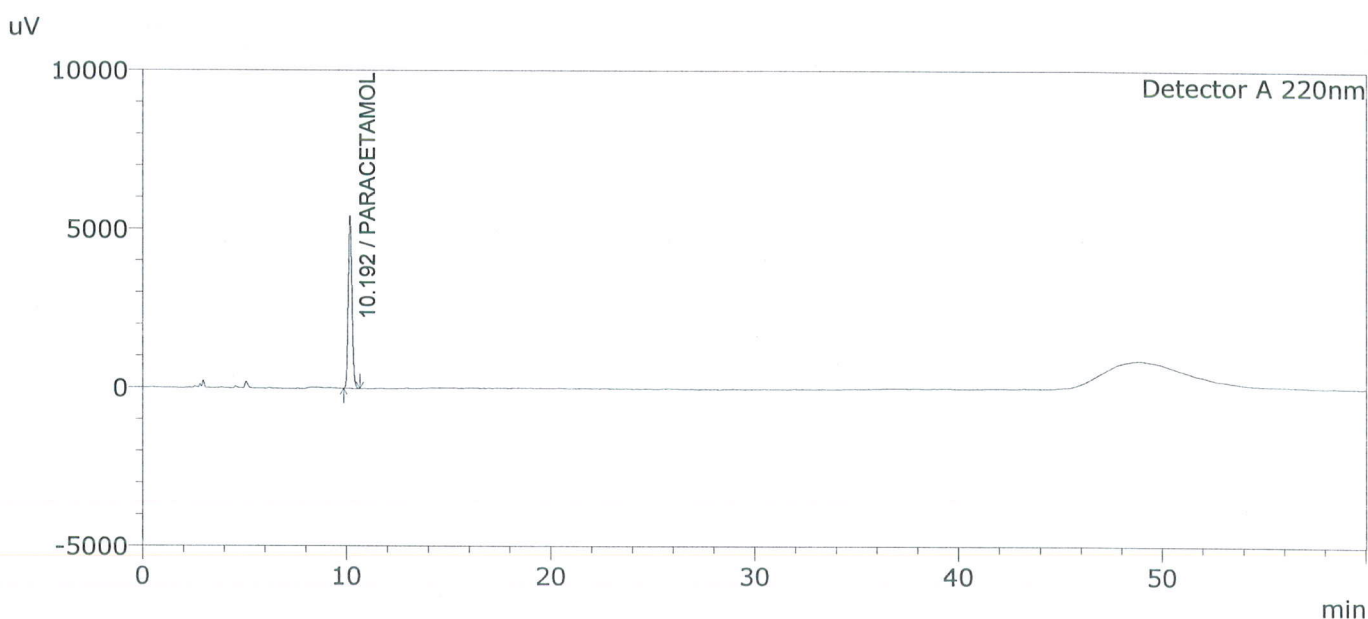
Analysis Report

<Sample Information>

Sample Name : METHOD PRECISION-RS
 Sample ID : PARACETAMOL-RS-STD-BKT-1
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-37.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 6:12:01 AM
 Date Processed : 1/18/2024 3:13:47 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	69093	100.00	14496	1.135	--	--
Total			69093	100.00				

18/01/24

Analysed By

Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Tittle

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Parameter :	FILTER PAPER STUDY	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
----------------	-------------	-------------	--------------	---------	--------------	----------------	------

Standard dilution :	60.16	mg to ---->	100	ml to ---->	5	ml to ---->	100
Std.conc (in ppm)-3.008	5	ml to ---->	50	ml to ---->	1	ml to ---->	1

Test dilution .:	415.05	mg to ---->	100	ml to ---->	1	ml to ---->	1
Test.conc (in ppm)-600	1	ml to ---->	1	ml to ---->	1	ml to ---->	1

S.No	Sample Name	Single maximum unknown Impurity (%)	% Difference from unfiltered sample	Total unknown impurity (%)	% Difference from unfiltered sample
1	Unfiltered sample (Centrifuged)	Not Detected	Not applicable	Not Detected	Not applicable
2	Filter set-1 (0.45µ Nylon membrane)	Not Detected	0.0	Not Detected	0.0
3	Filter set-2 (0.45µ Nylon membrane)	Not Detected	0.0	Not Detected	0.0
4	Filter set-3 (0.45µ Nylon membrane)	Not Detected	0.0	Not Detected	0.0
5	Filter set-1 (0.45µ PVDF membrane)	Not Detected	0.0	Not Detected	0.0
6	Filter set-2 (0.45µ PVDF membrane)	Not Detected	0.0	Not Detected	0.0
7	Filter set-3 (0.45µ PVDF membrane)	Not Detected	0.0	Not Detected	0.0

Results :

- 1) There is No any interference due to Filter paper in test solution.
- 2) Results are complies as per the acceptance criteria.

Acceptance criteria:

- 1) % RSD for single maximum unknown impurities above 0.1% Percentage difference shows ± 20 against than unfiltered (centrifuge)
- 2) %RSD for total unknown impurities above 0.1% in six preparations should not be more than 15.

Analysed by :
Date :E.MEENA
18-01-2024

18/01/24

Checked by
Date :

S. I. K. K. K.



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	UNFILTERED CENTRIFUGED SAMPLE	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
----------------	-------------	-------------	--------------	---------	--------------	----------------	------

Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.05	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.516	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURTY

Limit: NMT 0.50%

Calculation formula :

Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

0
68953
0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :

Total impurities in%	Total impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

0
68953
0.00

Analysed by :

E.MEENA

Date :

18-01-2024

Checked by :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	FILTERED SET- 1 (0.45µ Nylon membrane filter)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
----------------	-------------	-------------	--------------	---------	--------------	----------------	------

Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.05	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.516	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled content :	650 mg
Average weight :	4500.0 mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURITY

Limit: NMT 0.50%

Calculation formula :

Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

0
68953
ND
0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :

Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

0
68953
ND
0.00

Analysed by :

E.MEENA

Date :

18-01-2024

Checked by :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	FILTERED SET- 2 (0.45µ Nylon membrane filter)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
----------------	-------------	-------------	--------------	---------	--------------	----------------	------

Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.05	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.516	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURITIY

Limit: NMT 0.50%

Calculation formula :		0
Any individual impurity in%		68953
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100	
	Standard area x sample dilution X Label claim x 100	ND 0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :		0
Total impurities in%		68953
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100	
	Standard area x sample dilution X Label claim x 100	ND 0.00

Analysed by : E.MEENA

Date : 18-01-2024

Checked by :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	FILTERED SET- 3 (0.45µ Nylon membrane filter)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
----------------	-------------	-------------	--------------	---------	--------------	----------------	------

Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.05	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.516	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURITIY

Limit: NMT 0.50%

Calculation formula :		0
		68953
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100 Standard area x sample dilution X Label claim x 100	ND 0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :		0
		68953
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100 Standard area x sample dilution X Label claim x 100	ND 0.00

Analysed by : E.MEENA
Date : 18-01-2024

Checked by :
Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	FILTERED SET- 1 (0.45µ PVDF membrane filter)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
----------------	-------------	-------------	--------------	---------	--------------	----------------	------

Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.05	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.516	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labeled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112
With Bracketing std.	69093						68973	87.9	0.127

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.299
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.851
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.792

SINGLE MAXIMUM UNKNOWN IMPURITIY

Limit: NMT 0.50%

Calculation formula :		0
Any individual impurity in%		68953
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100	
	Standard area x sample dilution X Label claim x 100	ND 0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :		0
Total impurities in%		68953
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100	
	Standard area x sample dilution X Label claim x 100	ND 0.00

Analysed by : E.MEENA

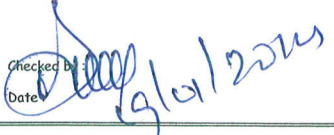
Date : 18-01-2024

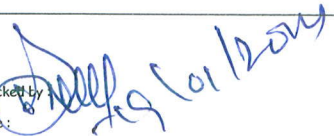
Checked by :

Date :

18/01/24

19/01/2024

		GENERIC HEALTHCARE PVT.LTD								
QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET										
Title		RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET								
Product Name :	GRIPEX					Batch size :	Not applicable			
Batch Number :	G17231228					Mfg.Date :	Dec-23			
Stage :	FILTERED SET- 2 (0.45µ PVDF membrane filter)					Exp.Date :	Nov-26			
Each 4.5 gm sachet contains: Paracetamol BP ----- 650 mg Chlorphenamine Maleate BP ----- 20 mg Phenylephrine Hydrochloride BP ----- 10 mg Ascorbic Acid BP----- 50 mg										
RELATED SUBSTANCE OF PARACETAMOL										
Instrument ID:	ST/QCLC/007		Balance ID:	ST/QC/EQ/041		WS No.:	ST/WS/23/012		% Purity (aib)	99.9
Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100			
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1			
Test dilution.:	415.05	mg to --->	100	ml to --->	1	ml to --->	1			
Test.conc (in ppm)-599.516	1	ml to --->	1	ml to --->	1	ml to --->	1			
Conversion factor :	1.0000									
Labelled content :	650		mg							
Average weight :	4500.0		mg							
System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %	
Paracetamol	68978	68922	68934	68865	68929	69092	68953	76.9	0.112	
With Bracketing std.	69093						68973	87.9	0.127	
Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area						
UNKNOWN Imp.				0						
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
UNKNOWN Imp.										
Total Impurity Area			0							
SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0					4.299				
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0					3.851				
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0					20.792				
SINGLE MAXIMUM UNKNOWN IMPURITIY								Limit: NMT 0.50%		
								0		
								68953		
Calculation formula :										
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100									
	Standard area x sample dilution X Label claim x 100								ND	0.000
TOTAL IMPURITIES								Limit: NMT 1.00%		
								0		
								68953		
Calculation formula :										
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100									
	Standard area x sample dilution X Label claim x 100								ND	0.00
Analysed by : E.MEENA Date : 18-01-2024  Checked by : Date : 										

		GENERIC HEALTHCARE PVT.LTD																																																																																																	
QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET																																																																																																			
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Product Name :	GRIPEX					Batch size :	Not applicable																																																																																												
Batch Number :	G17231228					Mfg.Date :	Dec-23																																																																																												
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Standard dilution.:	60.16	mg to --->	100	ml to --->	5	ml to --->	100																																																																																												
Std.conc (in ppm)-3.008	5	ml to --->	50	ml to --->	1	ml to --->	1																																																																																												
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Analysed by : E.MEENA Date : 18-01-2024  Checked by :  Date :																																																																																																			



GENERIC HEALTHCARE PVT. LTD.

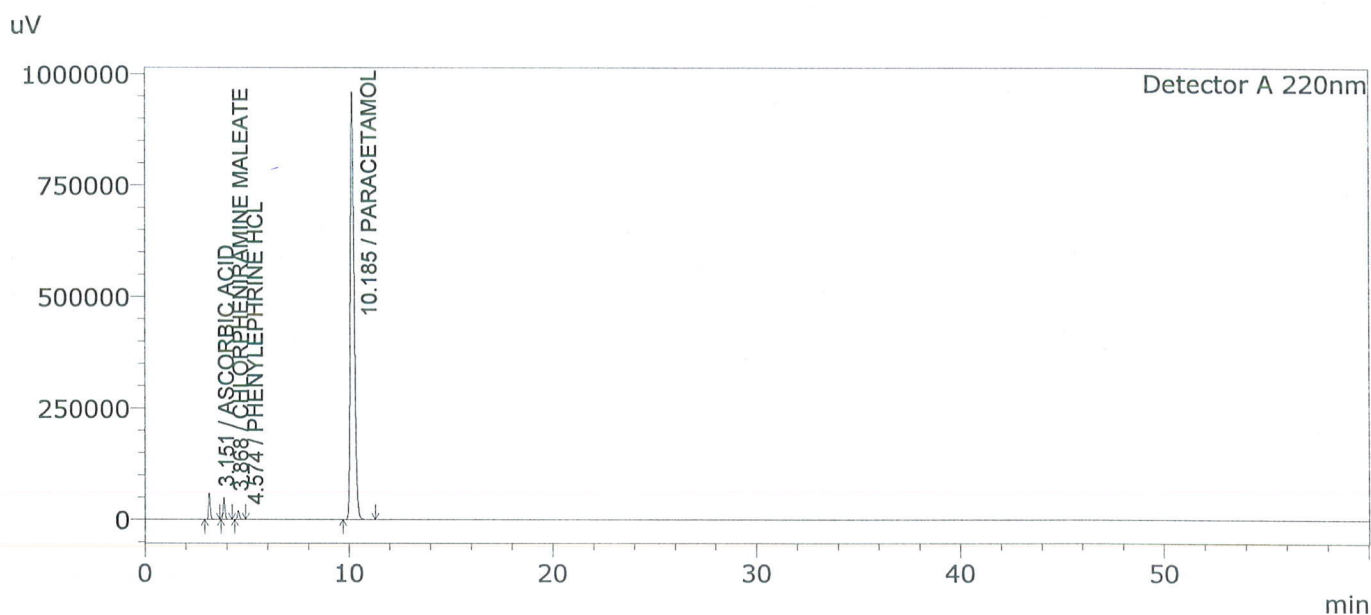
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : RESOLUTION SOLUTION
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-02.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 1/13/2024 6:49:06 PM
 Date Processed : 1/18/2024 3:19:39 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	3.15	343199	2.61	5952	1.300	--	--
2	CHLORPHENIRAMINE MALEATE	3.87	299289	2.27	8269	1.274	4.299	--
3	PHENYLEPHRINE HCL	4.57	140618	1.07	8674	1.235	3.851	--
4	PARACETAMOL	10.19	12379511	94.05	14082	1.193	20.792	--
Total			13162616	100.00				

18/01/24

Analysed By

15/01/2024

Checked By



GENERIC HEALTHCARE PVT. LTD.

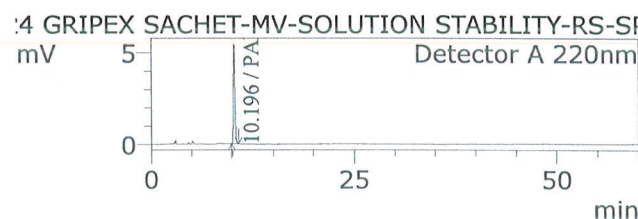
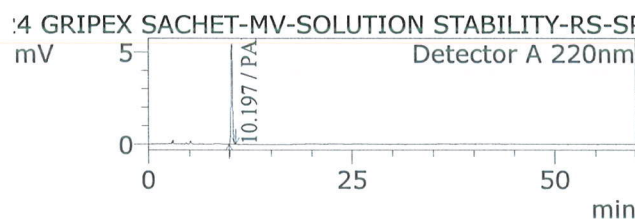
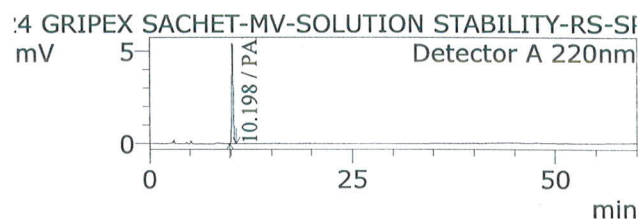
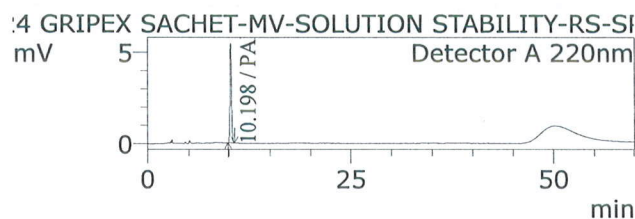
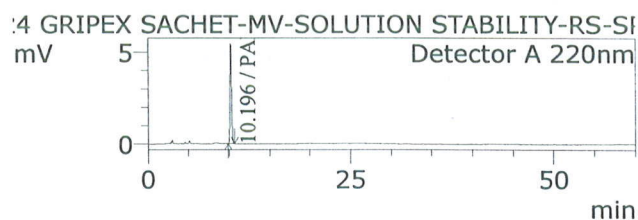
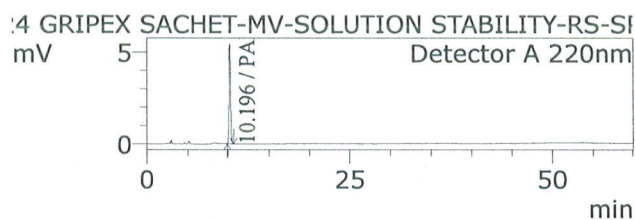
Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PARACETAMOL-RS-STD-01
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-03.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/13/2024 7:49:45 PM
 Date Processed : 1/18/2024 3:13:38 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-03.lcd	PARACETAMOL-RS-STD-01	10.20	68978	14540	1.15
3	RS-SPL-04.lcd	PARACETAMOL-RS-STD-02	10.20	68922	14504	1.14
3	RS-SPL-05.lcd	PARACETAMOL-RS-STD-03	10.20	68934	14549	1.14
3	RS-SPL-06.lcd	PARACETAMOL-RS-STD-04	10.20	68865	14563	1.14
3	RS-SPL-07.lcd	PARACETAMOL-RS-STD-05	10.20	68929	14524	1.14
3	RS-SPL-08.lcd	PARACETAMOL-RS-STD-06	10.20	69092	14461	1.15
	Average		10.20	68953	14523	1.14
	%RSD		0.010	0.112	0.255	0.134

Analysed By

Checked By



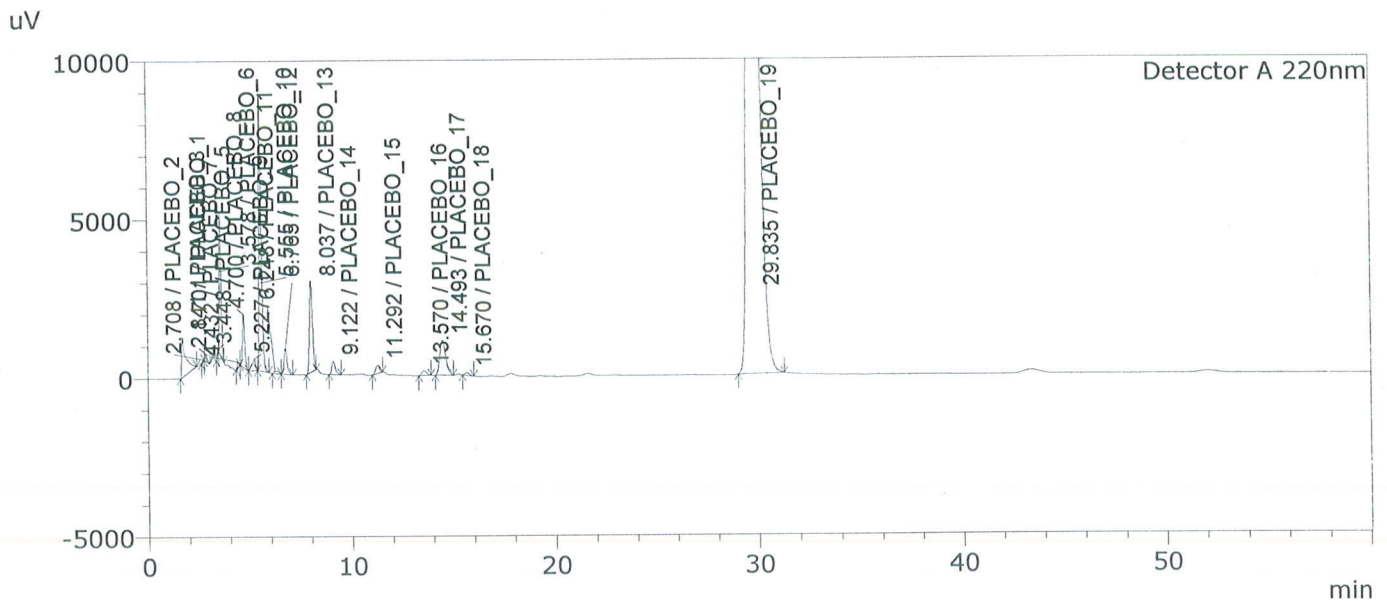
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SOLUTION STABILITY-RS
 Sample ID : PLACEBO-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-10.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 1/14/2024 2:54:21 AM
 Date Processed : 1/18/2024 3:35:12 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	18184	1.35	758	4.849	--	--
2	PLACEBO_2	2.71	236	0.02	9914	1.044	5.658	--
3	PLACEBO_3	2.84	1168	0.09	5156	1.320	0.996	--
4	PLACEBO_5	3.45	642	0.05	19137	0.772	4.704	--
5	PLACEBO_6	3.58	25730	1.91	7417	1.220	0.981	--
6	PLACEBO_7	4.43	844	0.06	13244	0.982	5.328	--
7	PLACEBO_8	4.70	12852	0.95	7810	1.120	1.466	--
8	PLACEBO_9	5.23	4530	0.34	5163	0.731	2.091	--
9	PLACEBO_10	5.55	70037	5.19	10221	1.242	1.283	--
10	PLACEBO_11	6.25	1238	0.09	4103	1.625	2.274	--
11	PLACEBO_12	6.76	8563	0.63	9462	1.311	1.545	--
12	PLACEBO_13	8.04	28849	2.14	13887	1.084	4.619	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_14	9.12	5107	0.38	13050	1.431	3.664	--
14	PLACEBO_15	11.29	3387	0.25	15689	1.004	6.383	--
15	PLACEBO_16	13.57	2399	0.18	14300	1.207	5.595	--
16	PLACEBO_17	14.49	21797	1.61	12486	1.187	1.897	--
17	PLACEBO_18	15.67	1285	0.10	22464	1.265	2.512	--
18	PLACEBO_19	29.83	1142881	84.67	17018	1.190	21.252	--
Total			1349728	100.00				


Analysed By


Checked By



GENERIC HEALTHCARE PVT. LTD.

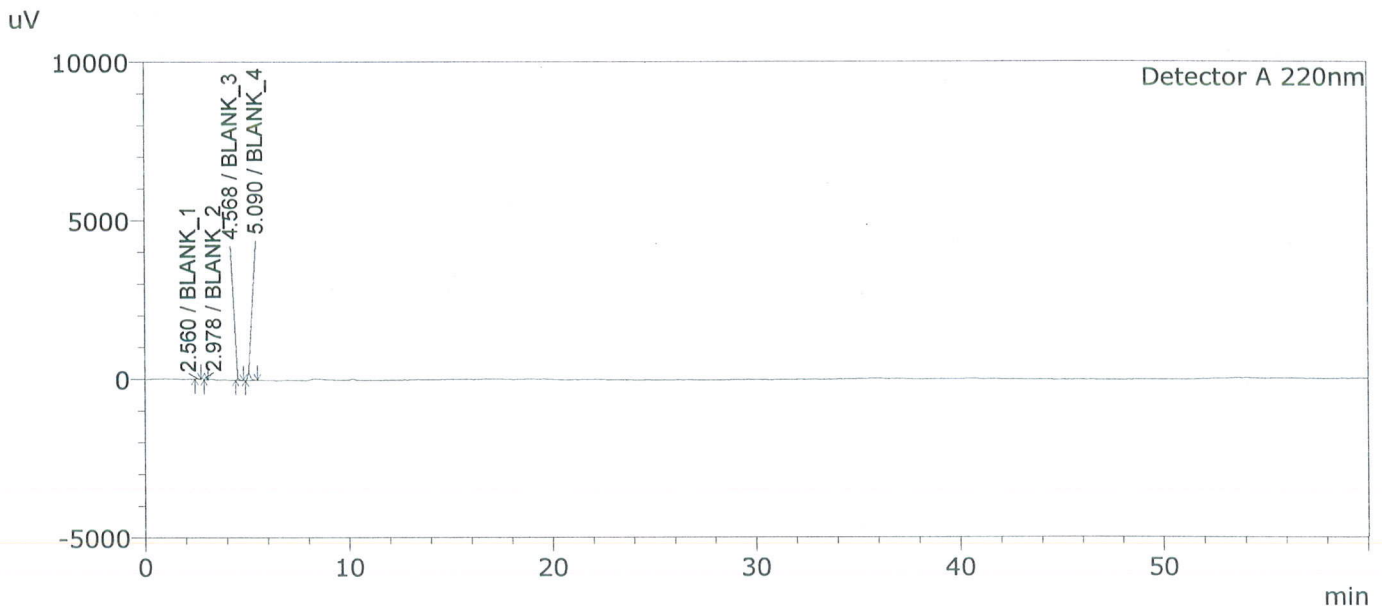
Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-50.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-13
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 7:20:33 PM
 Date Processed : 1/18/2024 5:40:34 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.56	216	6.38	2468	1.620	--	--
2	BLANK_2	2.98	368	10.86	4540	1.337	2.182	--
3	BLANK_3	4.57	500	14.75	5037	1.714	7.325	--
4	BLANK_4	5.09	2304	68.01	6110	1.801	2.016	--
Total			3388	100.00				

Analysed By

Checked By



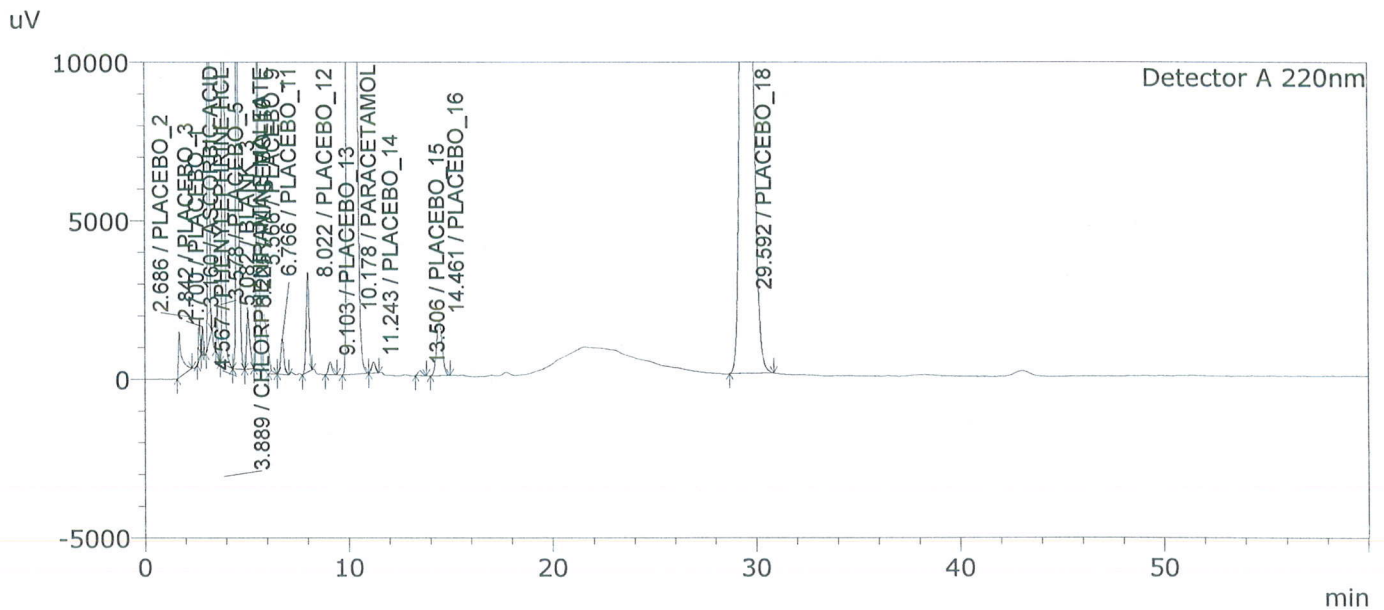
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY-RS
 Sample ID : GRIPEX-1228-CENTRIFUGE-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-51.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-14
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 8:21:02 PM
 Date Processed : 1/18/2024 5:45:25 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17436	0.11	995	4.496	--	--
2	PLACEBO_2	2.69	6890	0.04	4899	1.068	5.340	--
3	PLACEBO_3	2.84	3634	0.02	8521	1.214	1.130	--
4	ASCORBIC ACID	3.16	136297	0.88	6611	1.173	2.279	--
5	PLACEBO_5	3.58	8456	0.05	7895	1.253	2.641	--
6	CHLORPHENIRAMINE MALEATE	3.89	275729	1.79	8736	1.207	1.899	--
7	PHENYLEPHRINE HCL	4.57	162006	1.05	8492	1.426	3.722	--
8	BLANK_3	5.08	18777	0.12	5535	1.521	2.183	--
9	PLACEBO_9	5.57	84667	0.55	10631	1.120	1.981	--
10	PLACEBO_10	6.23	1300	0.01	7609	1.520	2.629	--
11	PLACEBO_11	6.77	12174	0.08	8875	1.112	1.886	--
12	PLACEBO_12	8.02	31497	0.20	13822	0.977	4.486	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_13	9.10	4728	0.03	13216	1.196	3.664	--
14	PARACETAMOL	10.18	13520105	87.68	14309	1.093	3.274	--
15	PLACEBO_14	11.24	4498	0.03	16239	1.030	3.070	--
16	PLACEBO_15	13.51	2318	0.02	15998	1.142	5.804	--
17	PLACEBO_16	14.46	34288	0.22	12512	1.070	2.021	--
18	PLACEBO_18	29.59	1095512	7.10	17494	1.098	21.431	--
Total			15420311	100.00				

Analysed By

18/10/24

Checked By

15/10/2024



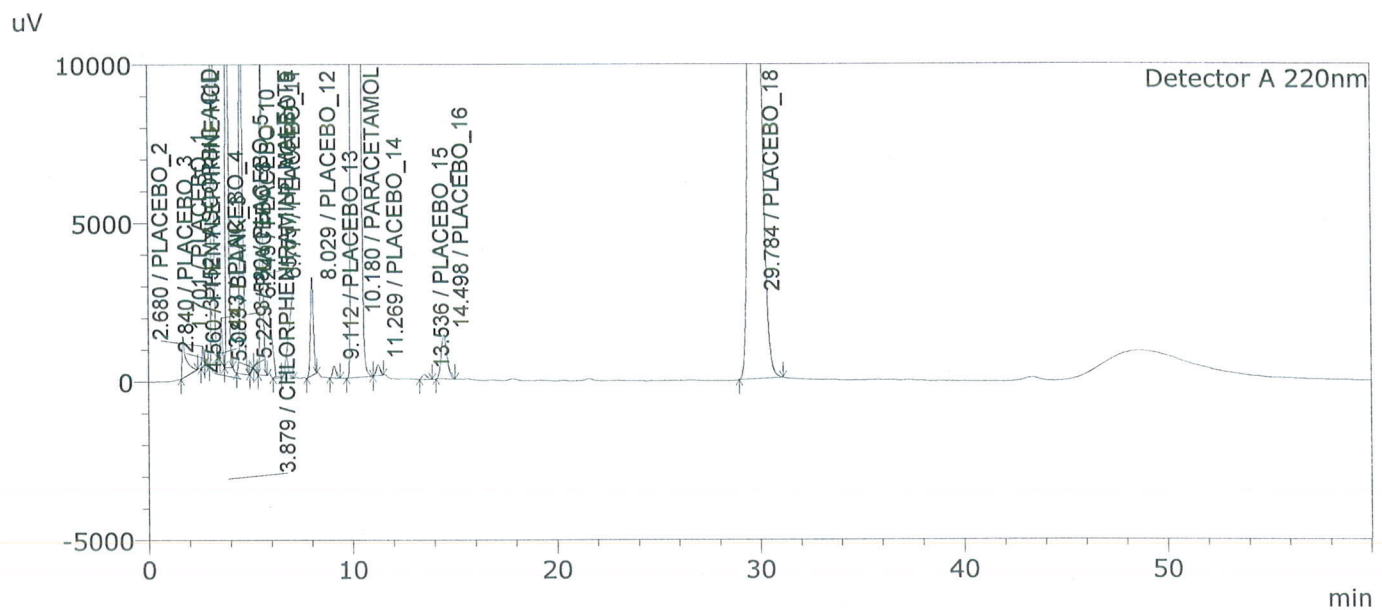
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY-RS
 Sample ID : GRIPEX-1228-NYLON-1-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-52.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-15
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 9:21:52 PM
 Date Processed : 1/18/2024 7:08:07 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

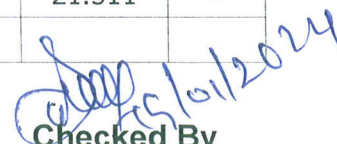
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	18391	0.12	773	4.861	--	--
2	PLACEBO_2	2.68	3516	0.02	4493	1.109	4.837	--
3	PLACEBO_3	2.84	802	0.01	7485	1.239	1.098	--
4	ASCORBIC ACID	3.15	291368	1.88	5787	1.290	2.098	--
5	PLACEBO_4	3.44	436	0.00	21020	0.987	2.236	--
6	PLACEBO_5	3.58	8148	0.05	6953	1.268	1.025	--
7	CHLORPHENIRAMINE MALEATE	3.88	304310	1.96	8141	1.266	1.741	--
8	PHENYLEPHRINE HCL	4.56	165661	1.07	7901	1.502	3.609	--
9	BLANK_3	5.08	534	0.00	16752	0.810	2.889	--
10	PLACEBO_8	5.23	1116	0.01	13495	1.240	0.864	--
11	PLACEBO_9	5.56	84934	0.55	10087	1.211	1.637	--
12	PLACEBO_10	6.25	890	0.01	4400	1.477	2.311	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	6.77	7556	0.05	9115	1.211	1.583	--
14	PLACEBO_12	8.03	31233	0.20	13596	1.035	4.498	--
15	PLACEBO_13	9.11	4313	0.03	13425	1.176	3.671	--
16	PARACETAMOL	10.18	13451866	86.85	14031	1.185	3.247	--
17	PLACEBO_14	11.27	4452	0.03	16001	1.053	3.110	--
18	PLACEBO_15	13.54	2484	0.02	14450	1.311	5.620	--
19	PLACEBO_16	14.50	27658	0.18	12315	1.174	1.978	--
20	PLACEBO_18	29.78	1078465	6.96	17068	1.186	21.311	--
Total			15488133	100.00				

Analysed By


 18/01/24

Checked By


 15/01/2024



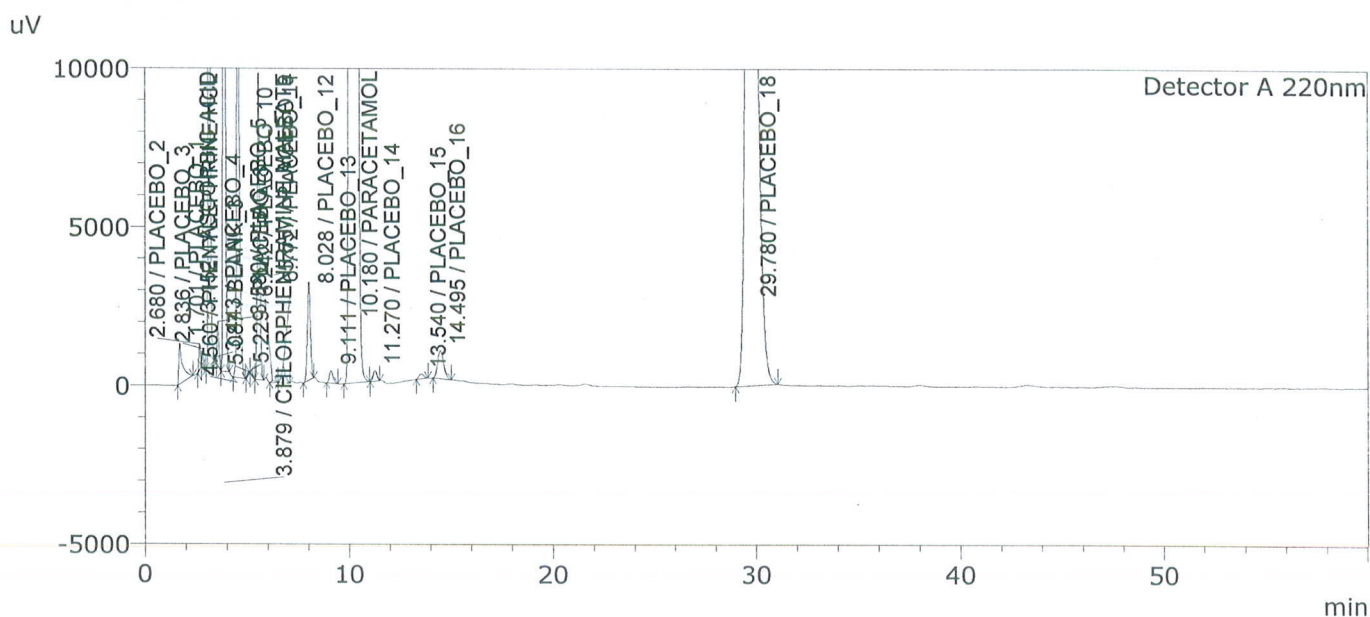
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY-RS
 Sample ID : GRIPEX-1228-NYLON-2-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-53.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-16
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 10:22:30 PM
 Date Processed : 1/18/2024 7:09:15 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

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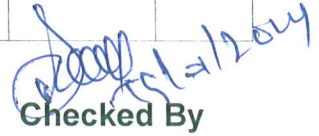


<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16773	0.11	804	4.419	--	--
2	PLACEBO_2	2.68	4423	0.03	4730	1.069	4.945	--
3	PLACEBO_3	2.84	2653	0.02	6941	1.330	1.072	--
4	ASCORBIC ACID	3.15	229584	1.50	5825	1.288	2.097	--
5	PLACEBO_4	3.44	420	0.00	21314	1.008	2.239	--
6	PLACEBO_5	3.58	8157	0.05	6979	1.277	1.031	--
7	CHLORPHENIRAMINE MALEATE	3.88	298042	1.95	8146	1.267	1.744	--
8	PHENYLEPHRINE HCL	4.56	165146	1.08	7922	1.496	3.611	--
9	BLANK_3	5.09	627	0.00	16119	0.782	2.887	--
10	PLACEBO_8	5.23	1070	0.01	13433	1.274	0.835	--
11	PLACEBO_9	5.56	77700	0.51	10107	1.210	1.634	--
12	PLACEBO_10	6.24	828	0.01	4393	1.559	2.291	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	6.77	5848	0.04	8539	1.170	1.584	--
14	PLACEBO_12	8.03	31323	0.20	13588	1.032	4.417	--
15	PLACEBO_13	9.11	4542	0.03	13071	1.200	3.645	--
16	PARACETAMOL	10.18	13354860	87.26	14045	1.185	3.226	--
17	PLACEBO_14	11.27	4275	0.03	16246	1.051	3.129	--
18	PLACEBO_15	13.54	2551	0.02	14860	1.198	5.689	--
19	PLACEBO_16	14.50	18110	0.12	11631	1.171	1.946	--
20	PLACEBO_18	29.78	1076966	7.04	17087	1.185	21.098	--
Total			15303900	100.00				

Analysed By
18/10/24**Checked By**
18/10/24



GENERIC HEALTHCARE PVT. LTD.

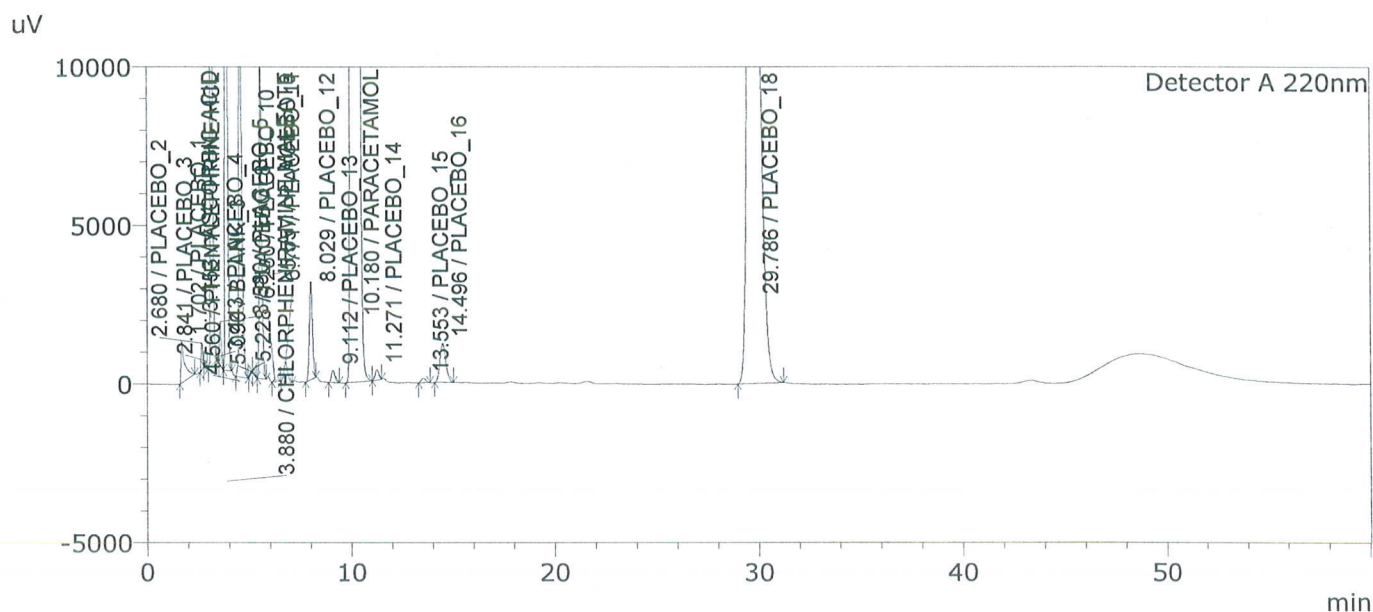
Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY-RS
 Sample ID : GRIPEX-1228-NYLON-3-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-54.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-17
 Injection Volume : 10 uL
 Date Acquired : 1/15/2024 11:23:10 PM
 Date Processed : 1/18/2024 7:13:01 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

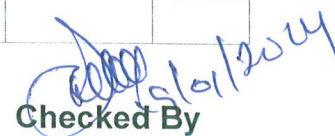
Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16718	0.11	802	4.324	--	--
2	PLACEBO_2	2.68	4638	0.03	4471	1.111	4.885	--
3	PLACEBO_3	2.84	912	0.01	7223	1.302	1.094	--
4	ASCORBIC ACID	3.15	231925	1.51	5802	1.287	2.080	--
5	PLACEBO_4	3.44	382	0.00	24305	1.065	2.286	--
6	PLACEBO_5	3.58	8036	0.05	6972	1.272	1.059	--
7	CHLORPHENIRAMINE MALEATE	3.88	302880	1.97	8134	1.266	1.744	--
8	PHENYLEPHRINE HCL	4.56	164709	1.07	7897	1.503	3.605	--
9	BLANK_3	5.09	501	0.00	18898	0.739	2.998	--
10	PLACEBO_8	5.23	1167	0.01	12959	1.216	0.832	--
11	PLACEBO_9	5.56	84312	0.55	10092	1.211	1.627	--
12	PLACEBO_10	6.25	910	0.01	4258	1.505	2.292	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	6.77	6904	0.04	8922	1.194	1.554	--
14	PLACEBO_12	8.03	31261	0.20	13557	1.037	4.472	--
15	PLACEBO_13	9.11	4479	0.03	13117	1.193	3.649	--
16	PARACETAMOL	10.18	13397696	87.21	14036	1.185	3.225	--
17	PLACEBO_14	11.27	4127	0.03	16551	1.019	3.143	--
18	PLACEBO_15	13.55	2230	0.01	15487	1.142	5.808	--
19	PLACEBO_16	14.50	24328	0.16	12158	1.162	1.960	--
20	PLACEBO_18	29.79	1074806	7.00	17066	1.186	21.268	--
Total			15362923	100.00				

Analysed By


 18/10/24

Checked By


 18/10/2024



GENERIC HEALTHCARE PVT. LTD.

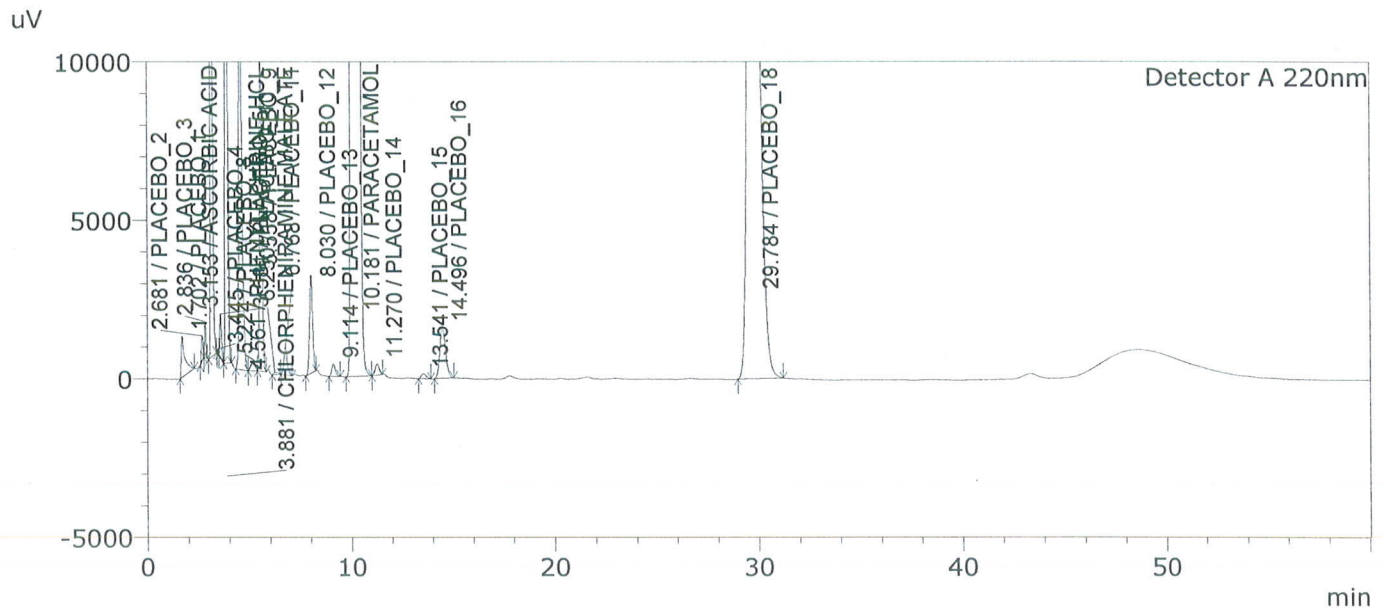
Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY-RS
 Sample ID : GRIPEX-1228-PVDF-1-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-55.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-18
 Injection Volume : 10 uL
 Date Acquired : 1/16/2024 12:23:49 AM
 Date Processed : 1/18/2024 7:17:58 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

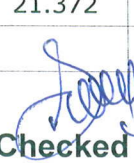
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16197	0.11	806	4.094	--	--
2	PLACEBO_2	2.68	4286	0.03	4962	1.035	4.993	--
3	PLACEBO_3	2.84	5140	0.03	6903	1.249	1.070	--
4	ASCORBIC ACID	3.15	221909	1.44	5791	1.286	2.101	--
5	PLACEBO_4	3.44	400	0.00	24150	1.025	2.293	--
6	PLACEBO_5	3.58	7876	0.05	7007	1.276	1.049	--
7	CHLORPHENIRAMINE MALEATE	3.88	294000	1.91	8134	1.265	1.746	--
8	PHENYLEPHRINE HCL	4.56	165034	1.07	7893	1.507	3.603	--
9	PLACEBO_8	5.22	4510	0.03	3122	0.766	2.289	--
10	PLACEBO_9	5.56	85352	0.55	10067	1.215	1.124	--
11	PLACEBO_10	6.25	1009	0.01	4507	1.514	2.328	--
12	PLACEBO_11	6.77	9437	0.06	9128	1.206	1.581	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31231	0.20	13577	1.036	4.513	--
14	PLACEBO_13	9.11	4665	0.03	12473	1.214	3.602	--
15	PARACETAMOL	10.18	13443132	87.23	14049	1.186	3.186	--
16	PLACEBO_14	11.27	4481	0.03	15993	1.037	3.111	--
17	PLACEBO_15	13.54	2599	0.02	14091	1.285	5.589	--
18	PLACEBO_16	14.50	31582	0.20	12514	1.158	1.960	--
19	PLACEBO_18	29.78	1078324	7.00	17054	1.186	21.372	--
Total			15411163	100.00				

Analysed By


 18/10/24

Checked By


 18/10/2024



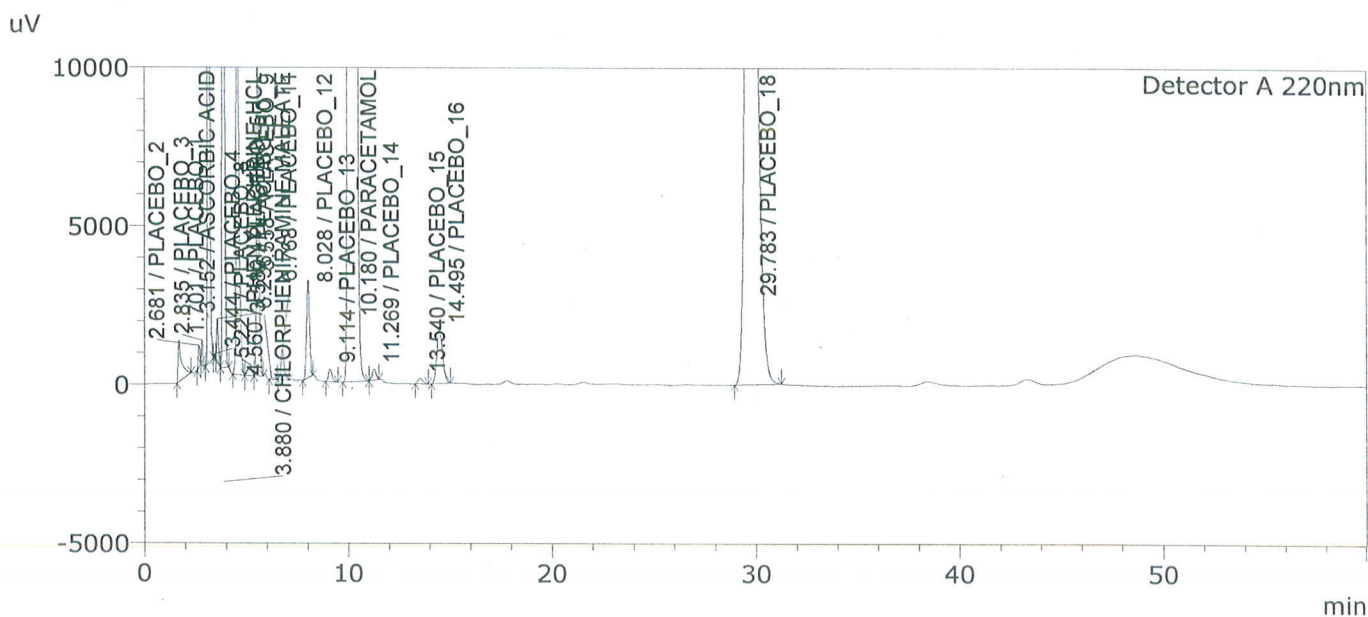
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY-RS
 Sample ID : GRIPEX-1228-PVDF-2-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-56.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-19
 Injection Volume : 10 uL
 Date Acquired : 1/16/2024 1:24:28 AM
 Date Processed : 1/18/2024 7:19:50 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16450	0.11	804	4.216	--	--
2	PLACEBO_2	2.68	3676	0.02	4892	1.038	4.979	--
3	PLACEBO_3	2.84	3581	0.02	6612	1.321	1.057	--
4	ASCORBIC ACID	3.15	276683	1.79	5820	1.289	2.081	--
5	PLACEBO_4	3.44	452	0.00	21041	0.974	2.244	--
6	PLACEBO_5	3.58	7843	0.05	7075	1.284	1.022	--
7	CHLORPHENIRAMINE MALEATE	3.88	297842	1.92	8142	1.265	1.753	--
8	PHENYLEPHRINE HCL	4.56	165703	1.07	7895	1.507	3.605	--
9	PLACEBO_8	5.22	4516	0.03	3150	0.769	2.290	--
10	PLACEBO_9	5.56	85753	0.55	10072	1.216	1.134	--
11	PLACEBO_10	6.24	893	0.01	4584	1.718	2.298	--
12	PLACEBO_11	6.77	9973	0.06	9314	1.211	1.642	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.03	31061	0.20	13654	1.040	4.537	--
14	PLACEBO_13	9.11	4876	0.03	12404	1.283	3.605	--
15	PARACETAMOL	10.18	13453765	86.90	14033	1.186	3.177	--
16	PLACEBO_14	11.27	4455	0.03	16070	1.047	3.116	--
17	PLACEBO_15	13.54	2784	0.02	14218	1.280	5.608	--
18	PLACEBO_16	14.50	33228	0.21	12554	1.145	1.967	--
19	PLACEBO_18	29.78	1079012	6.97	17065	1.186	21.390	--
Total			15482547	100.00				

Analysed By

18/01/24

Checked By

19/01/2024



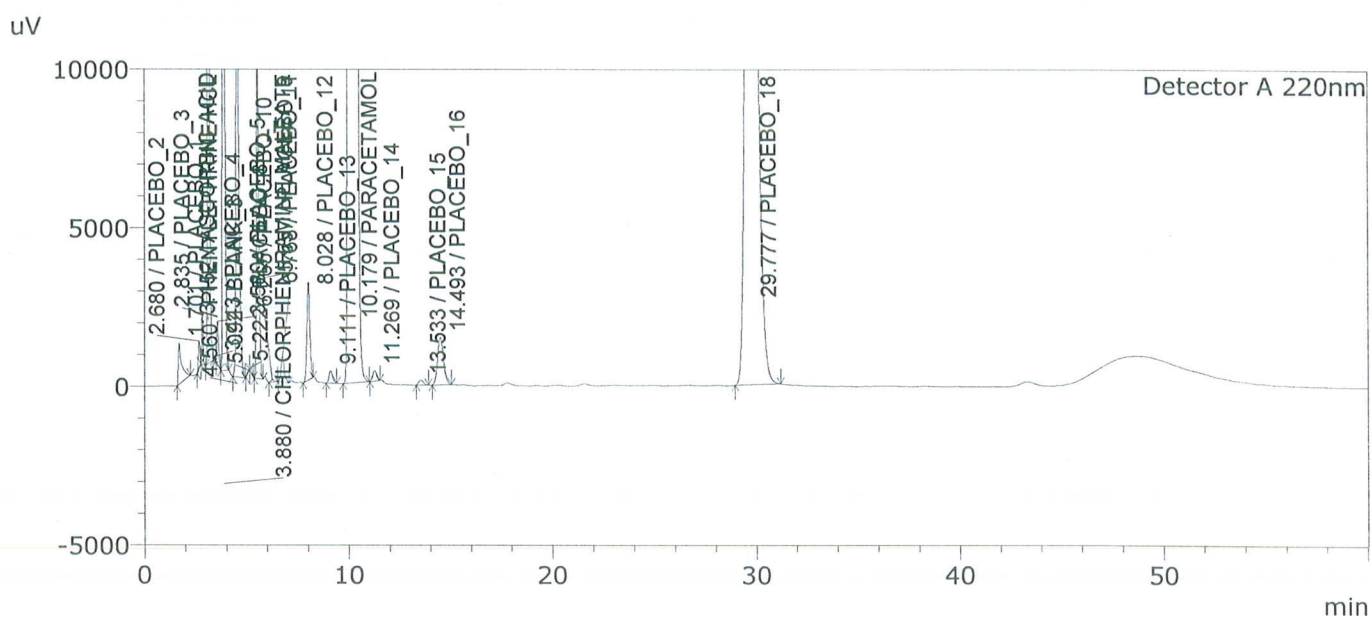
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY-RS
 Sample ID : GRIPEX-1228-PVDF-3-RS-SPL
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-57.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-20
 Injection Volume : 10 uL
 Date Acquired : 1/16/2024 2:25:07 AM
 Date Processed : 1/18/2024 7:24:43 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	15702	0.10	817	3.912	--	--
2	PLACEBO_2	2.68	4599	0.03	5013	1.033	5.026	--
3	PLACEBO_3	2.83	7415	0.05	6707	1.264	1.067	--
4	ASCORBIC ACID	3.15	212590	1.39	5788	1.287	2.089	--
5	PLACEBO_4	3.44	411	0.00	21712	1.018	2.244	--
6	PLACEBO_5	3.58	7876	0.05	7066	1.284	1.038	--
7	CHLORPHENIRAMINE MALEATE	3.88	286096	1.86	8143	1.265	1.752	--
8	PHENYLEPHRINE HCL	4.56	164597	1.07	7899	1.506	3.604	--
9	BLANK_3	5.09	467	0.00	17184	0.774	2.951	--
10	PLACEBO_8	5.22	1026	0.01	13542	1.354	0.776	--
11	PLACEBO_9	5.56	83512	0.54	10072	1.215	1.675	--
12	PLACEBO_10	6.27	992	0.01	4576	1.309	2.391	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	6.77	8680	0.06	8992	1.196	1.532	--
14	PLACEBO_12	8.03	31204	0.20	13594	1.034	4.494	--
15	PLACEBO_13	9.11	4569	0.03	12986	1.210	3.640	--
16	PARACETAMOL	10.18	13406474	87.35	14036	1.186	3.219	--
17	PLACEBO_14	11.27	4303	0.03	16325	1.044	3.130	--
18	PLACEBO_15	13.53	2450	0.02	15725	1.276	5.771	--
19	PLACEBO_16	14.49	29698	0.19	12265	1.148	2.011	--
20	PLACEBO_18	29.78	1075262	7.01	17057	1.186	21.295	--
Total			15347924	100.00				

Analysed By

18/01/24

Checked By

18/01/2024



GENERIC HEALTHCARE PVT. LTD.

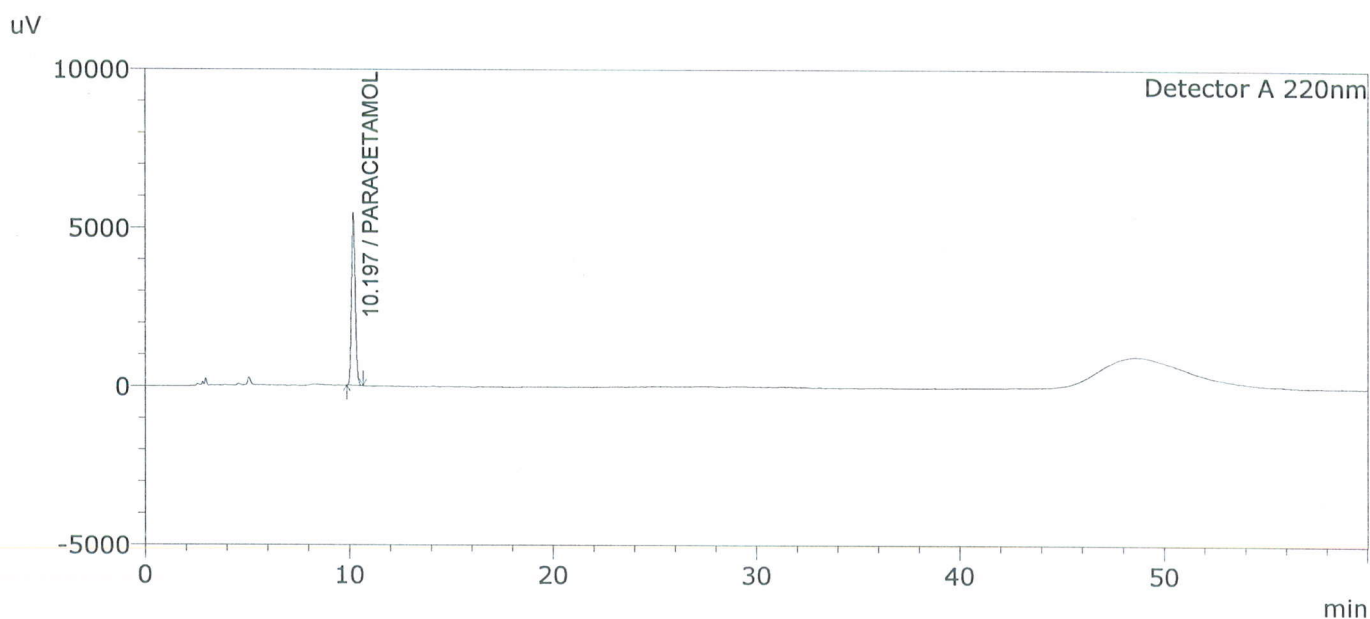
Analysis Report

<Sample Information>

Sample Name : FILTER PAPER STUDY-RS
 Sample ID : PARACETAMOL-RS-STD-BKT-2
 Data Filename : 13012024 GRIPEX SACHET-MV-SOLUTION STABILITY-RS-SPL-58.lcd
 Method Filename : GRIPEX-SACH-RS_STD_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-SOLUTION STABILITY.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/16/2024 3:25:47 AM
 Date Processed : 1/18/2024 3:13:48 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.20	69162	100.00	14487	1.136	--	--
Total			69162	100.00				

18/01/24

Analysed By

18/01/2024

Checked By

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Parameter :	PRECISION (METHOD PRECISION and INTERMEDIATE PRECISION)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007 & ST/QCLC/006	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution :	about 60 mg	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution .:	Sample weight	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-600	1	ml to --->	1	ml to --->	1	ml to --->	1

METHOD PRECISION			INTERMEDIATE PRECISION			CUMMULATIVE PRECISION	
No. of preparation	Single Maximum Unknown Impurity (%)	Total unknown impurity (%)	No. of preparation	Single Maximum Unknown Impurity (%)	Total unknown impurity (%)	Single Maximum Unknown Impurity (%)	Total unknown impurity (%)
1	Not Detected	Not Detected	1	Not Detected	Not Detected	Average	
2	Not Detected	Not Detected	2	Not Detected	Not Detected	0.00	0.00
3	Not Detected	Not Detected	3	Not Detected	Not Detected		
4	Not Detected	Not Detected	4	Not Detected	Not Detected	% RSD	
5	Not Detected	Not Detected	5	Not Detected	Not Detected	0.00	0.00
6	Not Detected	Not Detected	6	Not Detected	Not Detected		
Average	0.00	0.00	Average	0.00	0.00	0.00	0.00
% RSD			% RSD				

Results:

- 1) % RSD for Individual impurity in Method precision
- 2) % RSD for Total impurities in Method precision
- 3) % RSD for Individual impurity in Intermediate precision
- 4) % RSD for Total impurities in Intermediate precision
- 5) Cumulative % RSD of total impurities of method precision and intermediate precision

0.00
0.00
0.00
0.00
0.00

Acceptance criteria:

- 1) % RSD for single maximum unknown impurities above 0.1% in six preparations should not be more than 15.
- 2) % RSD for total unknown impurities in six preparations should not be more than 10.
- 3) Cumulative % RSD of total impurities of method precision and intermediate precision should not be more than 10.

Analysed by :
Date :S.ELAVARASAN
18-01-2024Checked by :
Date :
19/01/2024



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	INTERMEDIATE PRECISION (SAMPLE PREPARATION-1)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.07	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.0035	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.03	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.482	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	66530	66642	66576	66542	66550	66565	66568	40.0	0.060
With Bracketing std.	66536						66563	38.4	0.058

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Single Maximum unknown Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	3.595
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.033
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	18.035

SINGLE MAXIMUM UNKNOWN IMPURITIY

Limit: NMT 0.50%

Calculation formula :		0
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100	66568
	Standard area x sample dilution X Label claim x 100	ND 0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :		0
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100	66568
	Standard area x sample dilution X Label claim x 100	ND 0.00

Analysed by : S.ELAVARASAN
Date : 18-01-2024

Checked by :
Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Title

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	INTERMEDIATE PRECISION (SAMPLE PREPARATION-2)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

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

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCL/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.07	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.0035	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.31	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.892	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	66530	66642	66576	66542	66550	66565	66568	40.0	0.060
With Bracketing std.	66536						66563	38.4	0.058

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	3.595
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.033
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	18.035

SINGLE MAXIMUM UNKNOWN IMPURIT

Limit: NMT 0.50%

Calculation formula :

Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

0
66568

0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :

Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

0
66568

0.00

Analysed by :

S.ELAVARASAN

Date :

18-01-2024

Checked by :

Date :

15/01/2024



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Title

Product Name : GRIPEX

Batch size :

Not applicable

Batch Number : G17231228

Mfg.Date :

Dec-23

Stage : INTERMEDIATE PRECISION (SAMPLE PREPARATION-3)

Exp.Date :

Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP ----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/Q/LC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.07	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.0035	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.04	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.502	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	66530	66642	66576	66542	66550	66565	66568	40.0	0.060
With Bracketing std.	66536						66563	38.4	0.058

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	3.595
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.033
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	18.035

SINGLE MAXIMUM UNKNOWN IMPURITIV

Limit: NMT 0.50%

Calculation formula :

Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

0
66568

0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :

Total impurities in%	Total impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

0
66568

0.00

Analysed by :

S.ELAVARASAN

Date :

18-01-2024

Checked by :

Date :

19/01/2024

	GENERIC HEALTHCARE PVT.LTD																																																																																																	
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Batch Number :	G17231228					Mfg.Date :	Dec-23																																																																																											
Stage :	INTERMEDIATE PRECISION (SAMPLE PREPARATION-4)					Exp.Date :	Nov-26																																																																																											
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Std.conc (in ppm)-3.0035	5	ml to --->	50	ml to --->	1	ml to --->	1																																																																																											
Test dilution.:	415.10	mg to --->	100	ml to --->	1	ml to --->	1																																																																																											
Test.conc (in ppm)-599.58	1	ml to --->	1	ml to --->	1	ml to --->	1																																																																																											
Conversion factor :	1.0000																																																																																																	
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Analysed by : S.ELAVARASAN Date : 18-01-2024 Checked by : Date : 19/01/2024																																																																																																		



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	INTERMEDIATE PRECISION (SAMPLE PREPARATION-5)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.07	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.0035	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.15	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-248859	415	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	66530	66642	66576	66542	66550	66565	66568	40.0	0.060
With Bracketing std.	66536						66563	38.4	0.058

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	3.595
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.033
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	18.035

SINGLE MAXIMUM UNKNOWN IMPURITY

Limit: NMT 0.50%

Calculation formula :		0
		66568
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100 Standard area x sample dilution X Label claim x 100	ND 0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :		0
		66568
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100 Standard area x sample dilution X Label claim x 100	ND 0.00

Analysed by :

S.ELAVARASAN

Date :

18-01-2024

Checked by :

Date :

GENERIC HEALTHCARE PVT.LTD QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET																																																																																																									
Title																																																																																																									
Product Name :	GRIPEX					Batch size :	Not applicable																																																																																																		
Batch Number :	G17231228					Mfg.Date :	Dec-23																																																																																																		
Stage :	INTERMEDIATE PRECISION (SAMPLE PREPARATION-6)					Exp.Date :	Nov-26																																																																																																		
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Std.conc (in ppm)-3.0035	5	ml to --->	50	ml to --->	1	ml to --->	1																																																																																																		
Test dilution.:	414.95	mg to --->	100	ml to --->	1	ml to --->	1																																																																																																		
Test.conc (in ppm)-599.372	1	ml to --->	1	ml to --->	1	ml to --->	1																																																																																																		
Conversion factor :	1.0000																																																																																																								
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Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100																																																																																																								
	Standard area x sample dilution X Label claim x 100					ND		0.00																																																																																																	
Analysed by : S.ELAVARASAN Date : 18-01-2024 Checked by : Date : 19/01/2024																																																																																																									



GENERIC HEALTHCARE PVT. LTD.

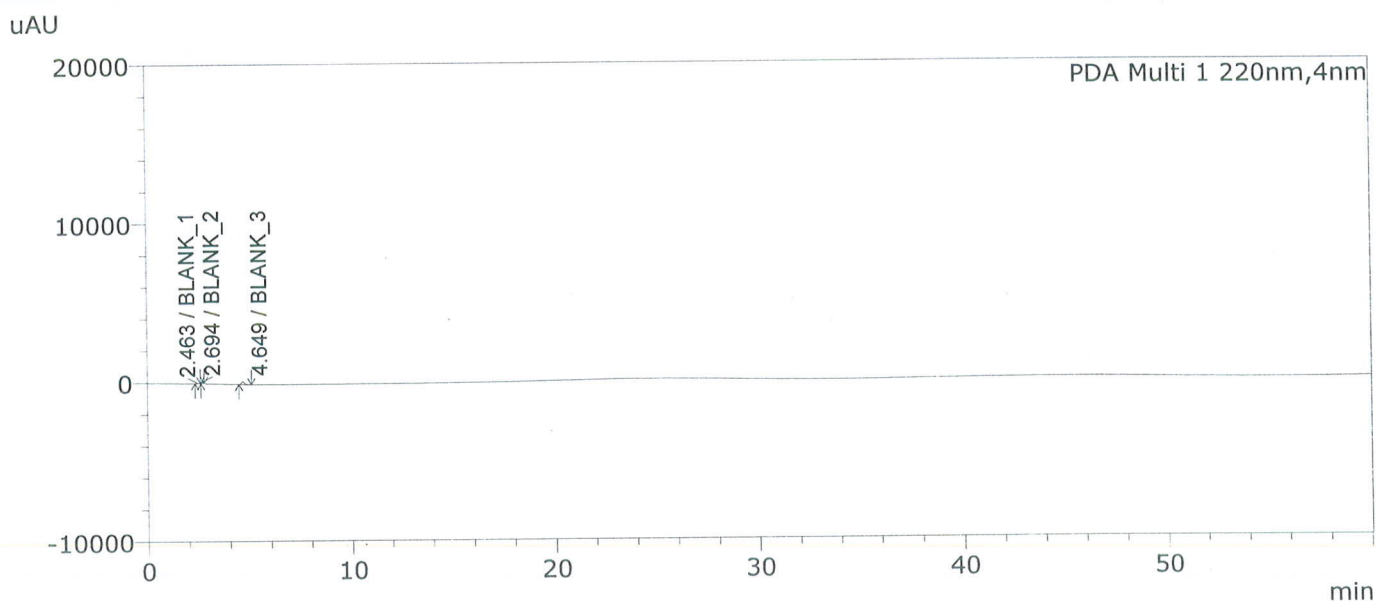
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-01.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 13-01-2024 18:35:18
 Date Processed : 18-01-2024 20:44:06

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.46	215	8.96	1521	0.963	--	--
2	BLANK_2	2.69	420	17.52	7865	1.074	1.236	--
3	BLANK_3	4.65	1764	73.53	5072	1.630	10.220	--
Total			2398	100.00				

Analysed By

Signature
18/01/2024

Checked By

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18/01/2024


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

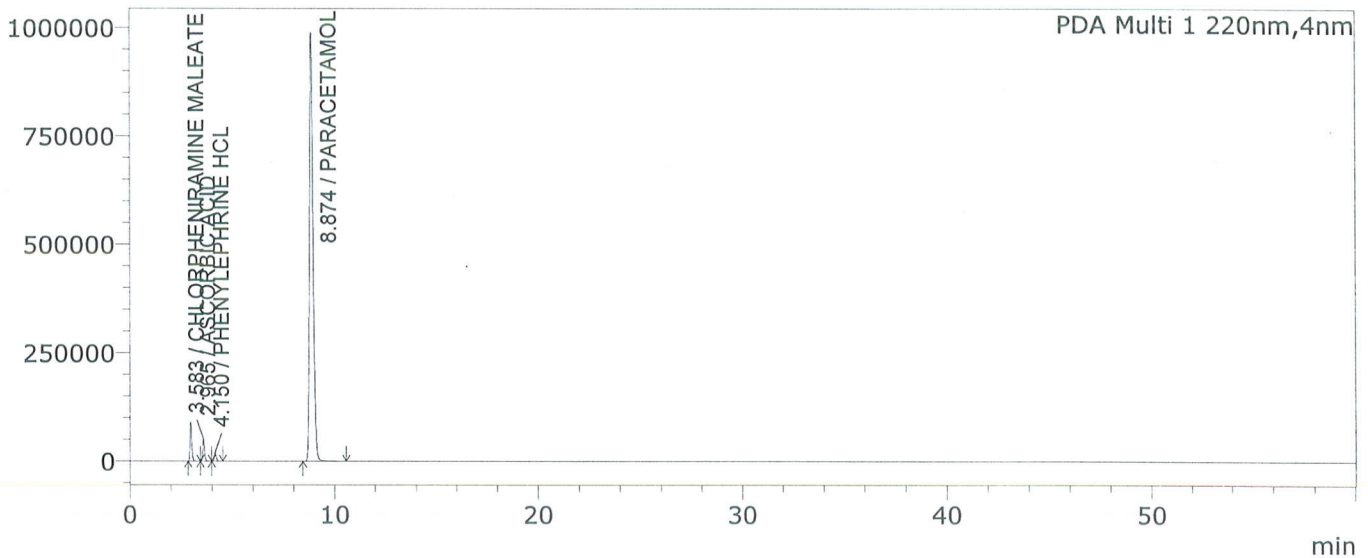
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Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : RESOLUTION SOLUTION
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-02.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 13-01-2024 19:35:53
 Date Processed : 18-01-2024 21:15:49

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>

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<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	2.96	509797	3.96	5001	1.324	--	--
2	CHLORPHENIRAMINE MALEATE	3.58	302771	2.35	6621	1.295	3.595	--
3	PHENYLEPHRINE HCL	4.15	134044	1.04	7034	1.243	3.033	--
4	PARACETAMOL	8.87	11911697	92.64	11861	1.170	18.035	--
Total			12858309	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

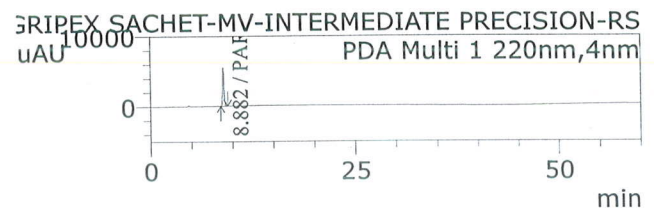
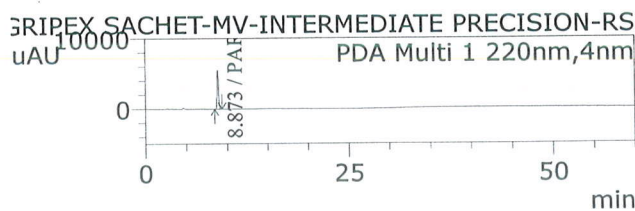
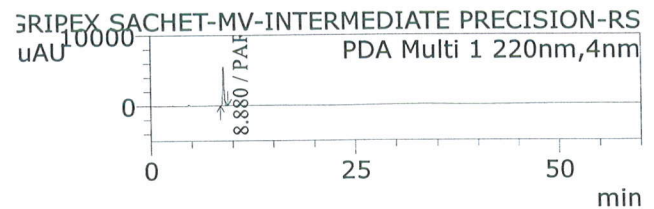
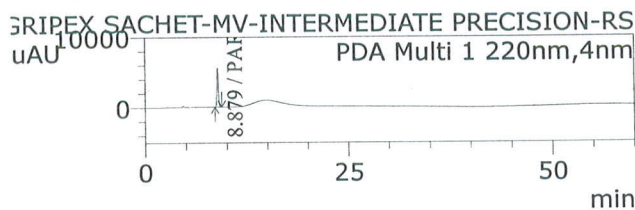
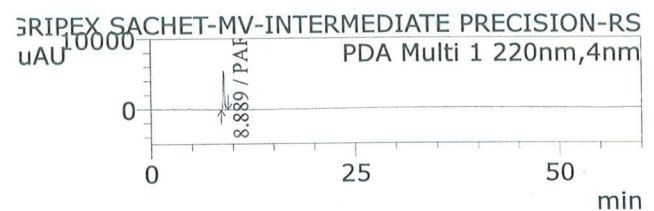
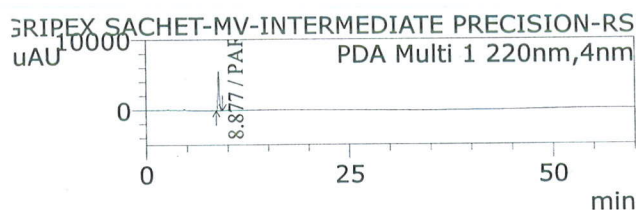
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : PARACETAMOL-RS-STD-01
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-03.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 13-01-2024 20:36:25
 Date Processed : 18-01-2024 19:54:47

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-03.lcd	PARACETAMOL-RS-STD-01	8.88	66530	12040	1.13
3	RS-SPL-04.lcd	PARACETAMOL-RS-STD-02	8.89	66642	12012	1.13
3	RS-SPL-05.lcd	PARACETAMOL-RS-STD-03	8.88	66576	11933	1.13
3	RS-SPL-06.lcd	PARACETAMOL-RS-STD-04	8.88	66542	11944	1.13
3	RS-SPL-07.lcd	PARACETAMOL-RS-STD-05	8.87	66550	11875	1.13
3	RS-SPL-08.lcd	PARACETAMOL-RS-STD-06	8.88	66565	11892	1.13
Average			8.88	66567	11949	1.13
%RSD			0.061	0.060	0.548	0.080

Analysed By

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18/01/2024

Checked By

[Signature]
19/01/2024



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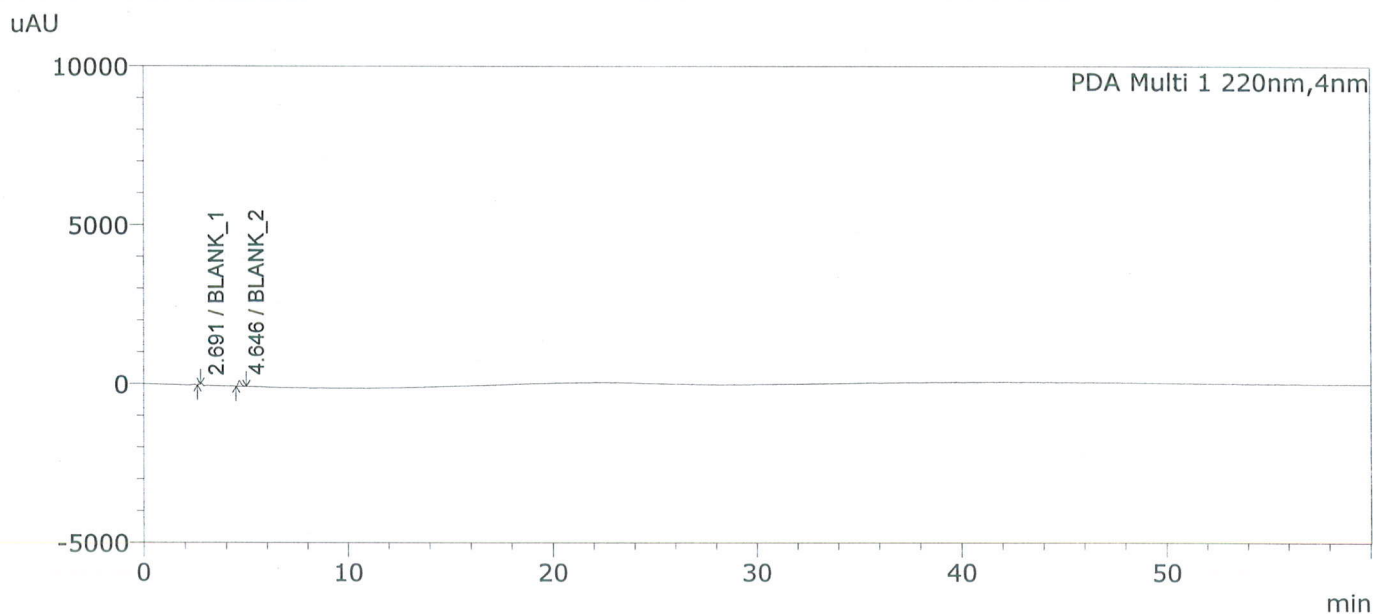
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-09.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 02:39:45
 Date Processed : 18-01-2024 20:48:07

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.69	421	19.16	7905	1.071	--	--
2	BLANK_2	4.65	1775	80.84	5012	1.592	10.191	--
Total			2196	100.00				

Analysed By

[Signature]
12/01/2024

Checked By

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15/01/2024



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

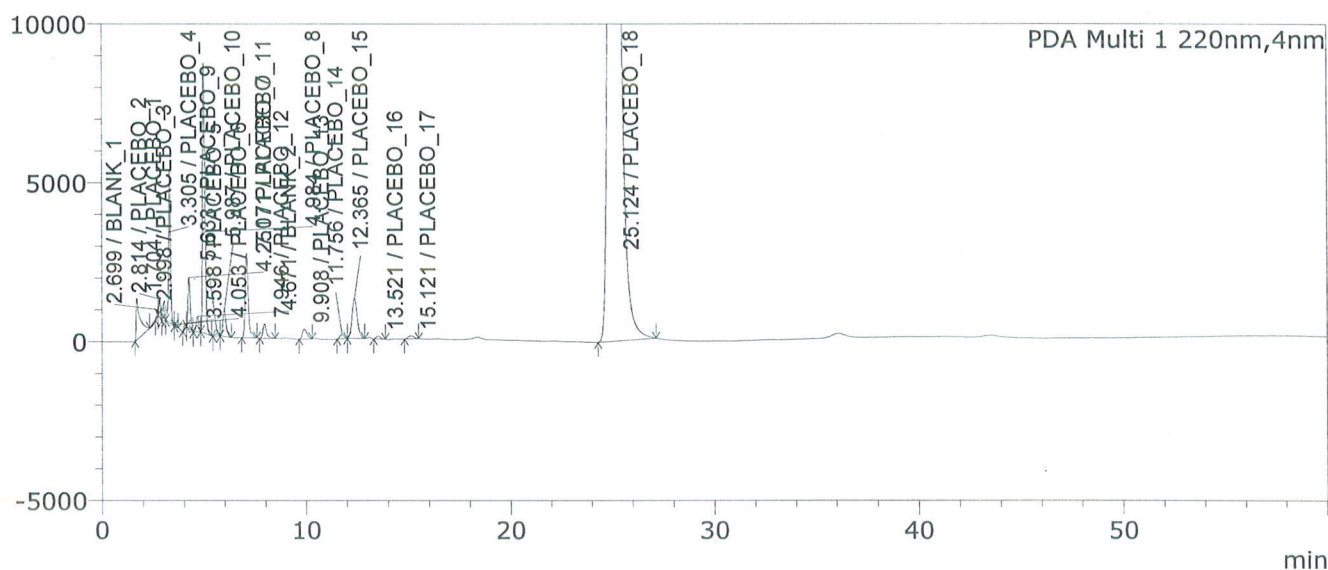
<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : PLACEBO-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-10.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 03:40:19
 Date Processed : 18-01-2024 20:53:06

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>

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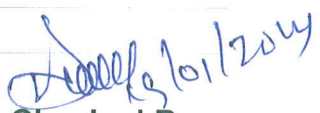
<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	18213	1.26	618	4.695	--	--
2	BLANK_1	2.70	911	0.06	10327	0.913	5.230	--
3	PLACEBO_2	2.81	2553	0.18	6524	1.257	0.932	--
4	PLACEBO_3	3.00	2231	0.15	6395	1.177	1.275	--
5	PLACEBO_4	3.31	30544	2.12	5181	0.972	1.842	--
6	PLACEBO_5	3.60	296	0.02	7401	1.577	1.665	--
7	PLACEBO_6	4.05	803	0.06	11196	0.918	2.845	--
8	PLACEBO_7	4.25	11611	0.81	6602	1.197	1.088	--
9	BLANK_2	4.67	4102	0.28	6202	0.917	1.883	--
10	PLACEBO_8	4.98	67026	4.65	8044	1.235	1.362	--
11	PLACEBO_9	5.63	1015	0.07	4489	0.860	2.324	--
12	PLACEBO_10	5.99	8904	0.62	6670	1.292	1.125	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	7.07	28203	1.96	10439	1.493	3.803	--
14	PLACEBO_12	7.95	5550	0.38	11111	1.746	3.026	--
15	PLACEBO_13	9.91	5129	0.36	7748	1.305	5.220	--
16	PLACEBO_14	11.76	1983	0.14	14564	1.021	4.400	--
17	PLACEBO_15	12.36	22917	1.59	10514	1.191	1.395	--
18	PLACEBO_16	13.52	1329	0.09	16818	1.313	2.572	--
19	PLACEBO_17	15.12	1928	0.13	12405	1.138	3.332	--
20	PLACEBO_18	25.12	1226665	85.07	13177	1.263	14.103	--
Total			1441910	100.00				

Analysed By 
10/01/2024


Checked By



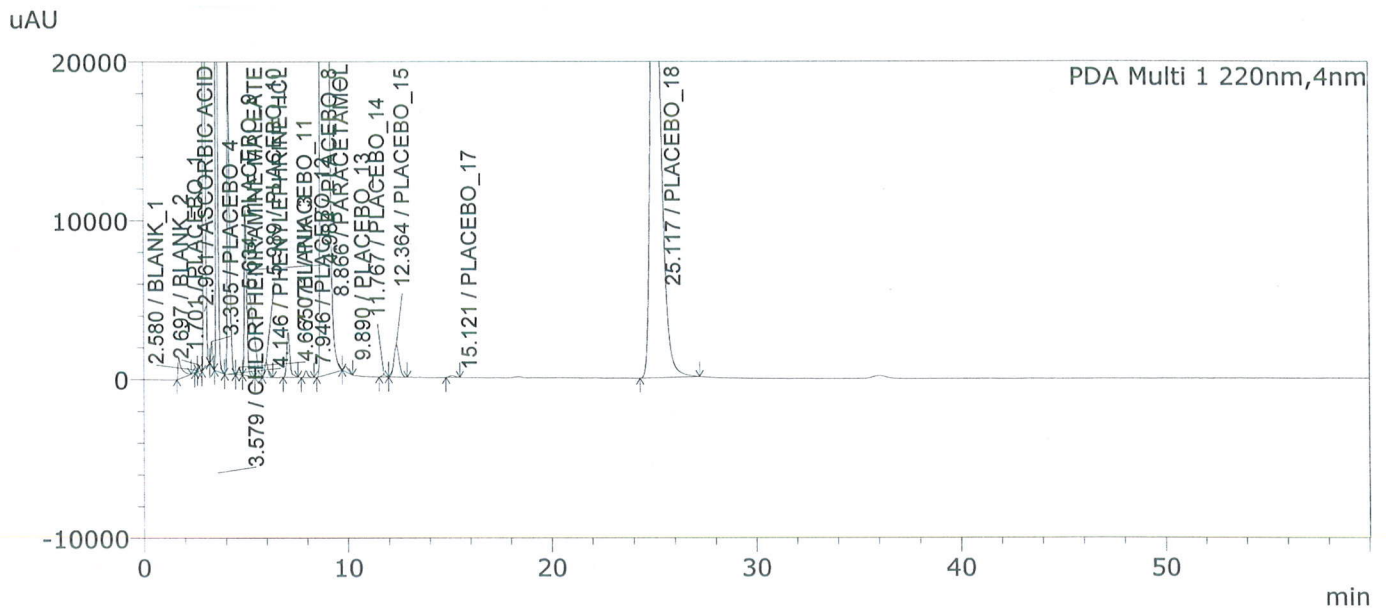
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-1
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-11.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 04:40:53
 Date Processed : 18-01-2024 20:59:27
 Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17657	0.12	740	4.545	--	--
2	BLANK_1	2.58	374	0.00	7554	0.774	4.766	--
3	BLANK_2	2.70	1753	0.01	6233	1.256	0.912	--
4	ASCORBIC ACID	2.96	355879	2.33	4926	1.296	1.731	--
5	PLACEBO_4	3.30	8411	0.05	5980	1.253	2.023	--
6	CHLORPHENIRAMINE MALEATE	3.58	288513	1.89	6722	1.300	1.587	--
7	PHENYLEPHRINE HCL	4.15	155348	1.02	5998	1.374	2.918	--
8	BLANK_3	4.67	3915	0.03	6316	1.012	2.314	--
9	PLACEBO_8	4.98	81826	0.54	8120	1.219	1.399	--
10	PLACEBO_9	5.63	822	0.01	4989	0.845	2.406	--
11	PLACEBO_10	5.99	10448	0.07	6486	1.273	1.150	--
12	PLACEBO_11	7.07	30024	0.20	10249	1.406	3.754	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	7.95	4869	0.03	11106	1.389	3.012	--
14	PARACETAMOL	8.87	13120446	85.79	11574	1.178	2.912	--
15	PLACEBO_13	9.89	4605	0.03	9544	1.508	2.789	--
16	PLACEBO_14	11.77	1723	0.01	15553	0.972	4.798	--
17	PLACEBO_15	12.36	36413	0.24	10421	1.164	1.386	--
18	PLACEBO_17	15.12	2192	0.01	13400	1.088	5.477	--
19	PLACEBO_18	25.12	1168253	7.64	13171	1.262	14.300	--
Total			15293472	100.00				

Analysed By

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12/01/2024

Checked By

12/01/2024



GENERIC HEALTHCARE PVT. LTD.

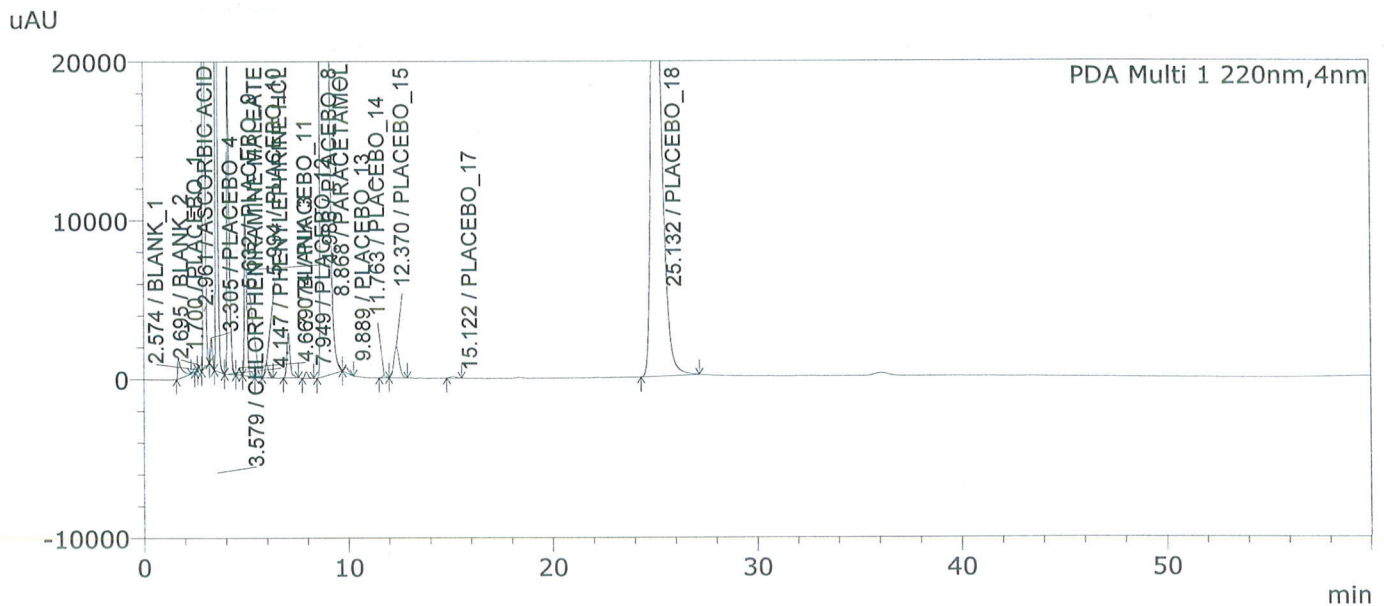
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-2
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-12.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-6
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 05:41:26
 Date Processed : 18-01-2024 21:02:41

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

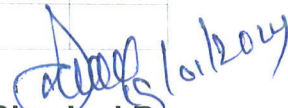
Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17632	0.11	726	4.446	--	--
2	BLANK_1	2.57	472	0.00	6999	0.832	4.655	--
3	BLANK_2	2.70	1602	0.01	6847	1.233	0.956	--
4	ASCORBIC ACID	2.96	412489	2.69	4880	1.298	1.770	--
5	PLACEBO_4	3.31	9685	0.06	5941	1.251	2.018	--
6	CHLORPHENIRAMINE MALEATE	3.58	288393	1.88	6684	1.298	1.583	--
7	PHENYLEPHRINE HCL	4.15	150579	0.98	5956	1.378	2.909	--
8	BLANK_3	4.67	3680	0.02	6317	1.020	2.321	--
9	PLACEBO_8	4.99	80139	0.52	8104	1.220	1.391	--
10	PLACEBO_9	5.63	680	0.00	5023	0.851	2.394	--
11	PLACEBO_10	5.99	9954	0.06	6425	1.259	1.174	--
12	PLACEBO_11	7.07	29850	0.19	10266	1.374	3.734	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	7.95	4539	0.03	11402	1.314	3.032	--
14	PARACETAMOL	8.87	13141481	85.64	11577	1.178	2.930	--
15	PLACEBO_13	9.89	4599	0.03	9767	1.517	2.797	--
16	PLACEBO_14	11.76	1783	0.01	15216	1.017	4.796	--
17	PLACEBO_15	12.37	35304	0.23	10365	1.172	1.400	--
18	PLACEBO_17	15.12	1990	0.01	12356	1.287	5.342	--
19	PLACEBO_18	25.13	1150974	7.50	13144	1.261	14.089	--
Total			15345826	100.00				

Analysed By


18/01/2024

Checked By


18/01/2024



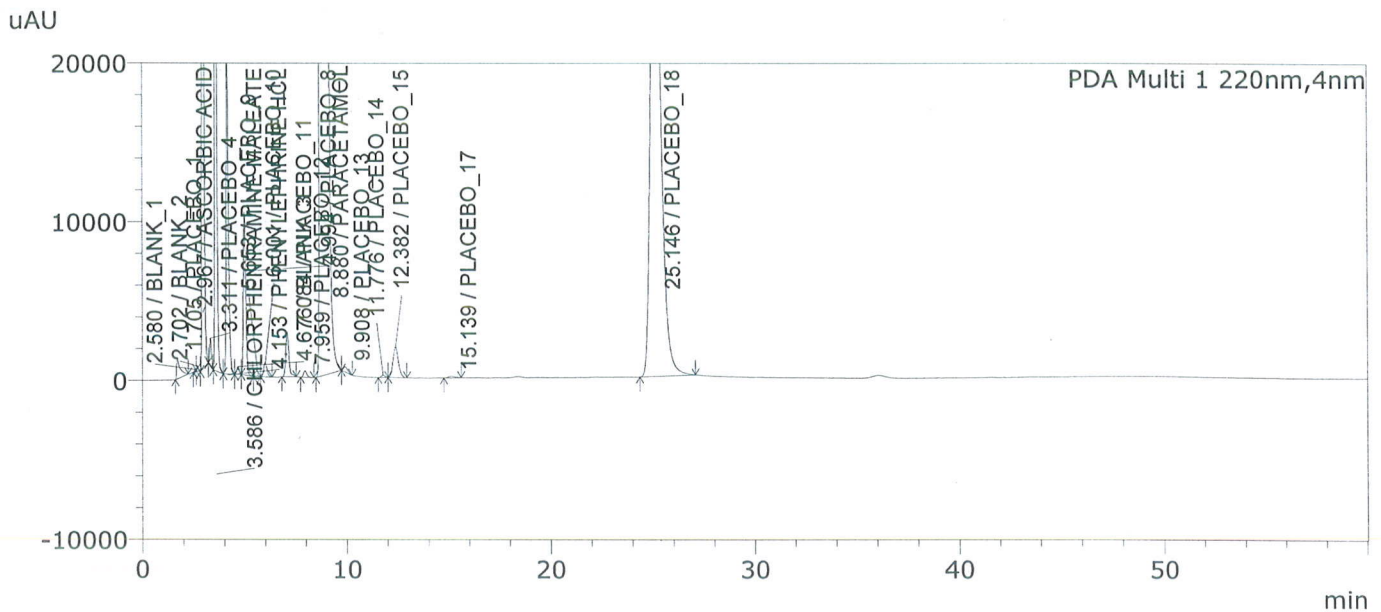
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-3
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-13.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-7
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 06:41:59
 Date Processed : 18-01-2024 21:05:35
 Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

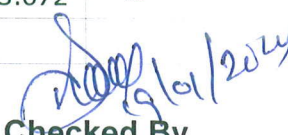
Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16416	0.11	729	4.026	--	--
2	BLANK_1	2.58	540	0.00	6644	0.858	4.616	--
3	BLANK_2	2.70	1292	0.01	6129	1.252	0.921	--
4	ASCORBIC ACID	2.97	399500	2.62	4942	1.299	1.728	--
5	PLACEBO_4	3.31	9561	0.06	5990	1.242	2.025	--
6	CHLORPHENIRAMINE MALEATE	3.59	313825	2.06	6636	1.289	1.583	--
7	PHENYLEPHRINE HCL	4.15	162848	1.07	5959	1.370	2.901	--
8	BLANK_3	4.68	3926	0.03	6358	1.002	2.322	--
9	PLACEBO_8	4.99	81051	0.53	8080	1.213	1.393	--
10	PLACEBO_9	5.65	780	0.01	4871	0.831	2.413	--
11	PLACEBO_10	6.00	9635	0.06	6339	1.254	1.114	--
12	PLACEBO_11	7.08	29864	0.20	10269	1.394	3.726	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	7.96	4718	0.03	11358	1.352	3.028	--
14	PARACETAMOL	8.88	13007226	85.26	11561	1.178	2.927	--
15	PLACEBO_13	9.91	4678	0.03	9450	1.471	2.786	--
16	PLACEBO_14	11.78	1760	0.01	15986	1.037	4.789	--
17	PLACEBO_15	12.38	34814	0.23	10418	1.170	1.413	--
18	PLACEBO_17	15.14	2209	0.01	10678	1.151	5.147	--
19	PLACEBO_18	25.15	1170444	7.67	13131	1.261	13.672	--
Total			15255088	100.00				

Analysed By


18/01/2024

Checked By


19/01/2024



GENERIC HEALTHCARE PVT. LTD.

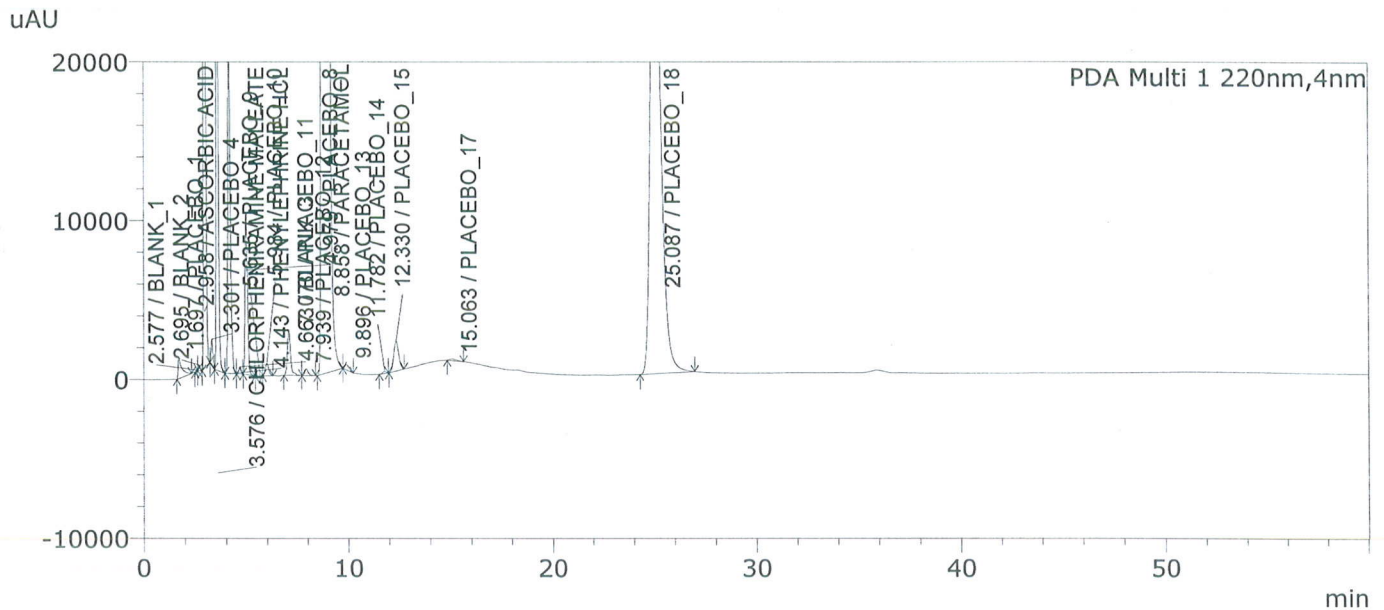
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-4
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-14.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-8
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 07:42:33
 Date Processed : 18-01-2024 21:07:16

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17849	0.12	703	4.590	--	--
2	BLANK_1	2.58	345	0.00	7167	0.799	4.656	--
3	BLANK_2	2.69	1605	0.01	6504	1.241	0.922	--
4	ASCORBIC ACID	2.96	414204	2.70	5027	1.297	1.756	--
5	PLACEBO_4	3.30	9163	0.06	5903	1.244	2.021	--
6	CHLORPHENIRAMINE MALEATE	3.58	294877	1.92	6639	1.293	1.585	--
7	PHENYLEPHRINE HCL	4.14	172464	1.13	5966	1.359	2.905	--
8	BLANK_3	4.66	3523	0.02	6651	1.027	2.345	--
9	PLACEBO_8	4.98	79899	0.52	8087	1.213	1.406	--
10	PLACEBO_9	5.64	819	0.01	5007	0.847	2.431	--
11	PLACEBO_10	5.98	8569	0.06	6140	1.259	1.117	--
12	PLACEBO_11	7.07	30470	0.20	10213	1.453	3.710	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	7.94	4736	0.03	11230	1.410	3.002	--
14	PARACETAMOL	8.86	13081084	85.37	11548	1.180	2.919	--
15	PLACEBO_13	9.90	4705	0.03	10024	1.408	2.865	--
16	PLACEBO_14	11.78	1488	0.01	18610	0.832	5.091	--
17	PLACEBO_15	12.33	32543	0.21	10861	1.115	1.338	--
18	PLACEBO_17	15.06	2322	0.02	8864	1.672	4.910	--
19	PLACEBO_18	25.09	1161831	7.58	13107	1.261	13.220	--
Total			15322495	100.00				

Analysed By


12/01/2024

Checked By


12/01/2024


GENERIC HEALTHCARE PVT. LTD.

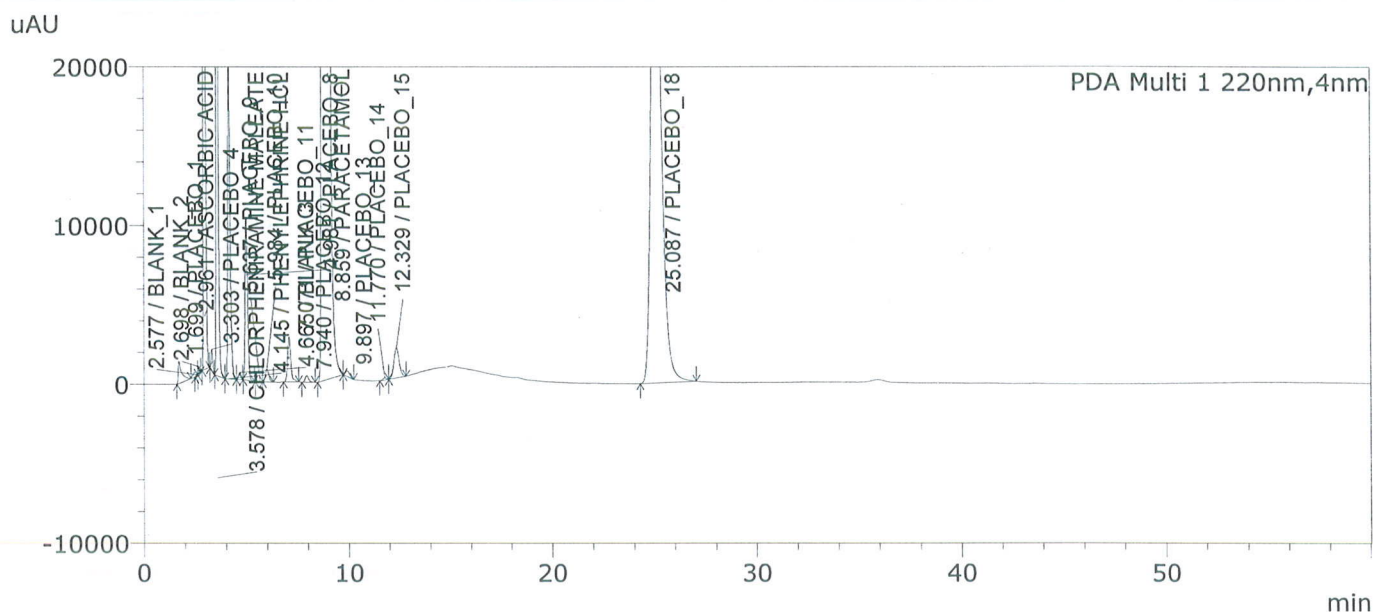
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-5
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-15.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-9
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 08:43:07
 Date Processed : 18-01-2024 21:10:16

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

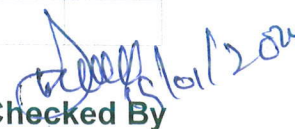
Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17303	0.11	718	4.314	--	--
2	BLANK_1	2.58	409	0.00	7296	0.806	4.687	--
3	BLANK_2	2.70	1800	0.01	8667	1.005	1.024	--
4	ASCORBIC ACID	2.96	367288	2.40	4918	1.290	1.847	--
5	PLACEBO_4	3.30	7307	0.05	5888	1.269	2.007	--
6	CHLORPHENIRAMINE MALEATE	3.58	309933	2.03	6685	1.298	1.585	--
7	PHENYLEPHRINE HCL	4.15	159235	1.04	5949	1.365	2.907	--
8	BLANK_3	4.67	3513	0.02	6702	1.016	2.348	--
9	PLACEBO_8	4.98	80900	0.53	8030	1.214	1.403	--
10	PLACEBO_9	5.64	643	0.00	4786	0.831	2.394	--
11	PLACEBO_10	5.98	9091	0.06	5976	1.279	1.091	--
12	PLACEBO_11	7.07	30122	0.20	10208	1.393	3.688	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	7.94	4734	0.03	11153	1.367	2.993	--
14	PARACETAMOL	8.86	13086337	85.64	11544	1.179	2.914	--
15	PLACEBO_13	9.90	4923	0.03	9764	1.391	2.842	--
16	PLACEBO_14	11.77	1531	0.01	18256	0.911	5.000	--
17	PLACEBO_15	12.33	33754	0.22	10598	1.164	1.353	--
18	PLACEBO_18	25.09	1162076	7.60	13091	1.262	18.815	--
Total			15280899	100.00				

Analysed By


15/01/2024

Checked By


15/01/2024


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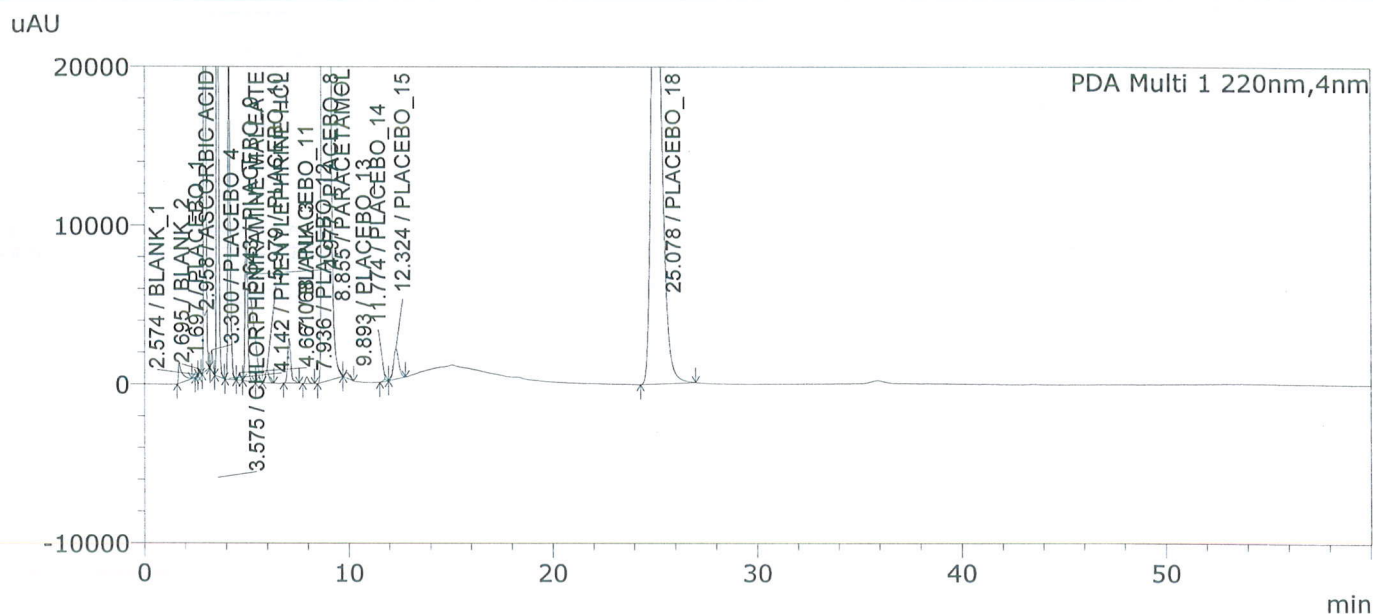
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : GRIPEX-1228-RS-SPL-6
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-16.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-10
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 09:43:40
 Date Processed : 18-01-2024 21:12:17

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

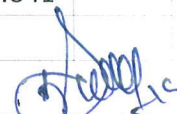
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	17816	0.12	713	4.572	--	--
2	BLANK_1	2.57	473	0.00	6767	0.812	4.627	--
3	BLANK_2	2.70	1559	0.01	7592	1.065	0.971	--
4	ASCORBIC ACID	2.96	372635	2.45	5053	1.289	1.812	--
5	PLACEBO_4	3.30	7160	0.05	6256	1.289	2.050	--
6	CHLORPHENIRAMINE MALEATE	3.58	305799	2.01	6628	1.286	1.610	--
7	PHENYLEPHRINE HCL	4.14	160313	1.05	5993	1.361	2.909	--
8	BLANK_3	4.66	3708	0.02	6625	1.018	2.343	--
9	PLACEBO_8	4.98	81848	0.54	8100	1.214	1.405	--
10	PLACEBO_9	5.64	643	0.00	5147	0.789	2.483	--
11	PLACEBO_10	5.98	9403	0.06	5944	1.292	1.077	--
12	PLACEBO_11	7.07	29931	0.20	10255	1.379	3.694	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	7.94	4696	0.03	11255	1.374	3.001	--
14	PARACETAMOL	8.86	13025627	85.58	11504	1.178	2.922	--
15	PLACEBO_13	9.89	4766	0.03	9904	1.394	2.852	--
16	PLACEBO_14	11.77	1496	0.01	17330	0.875	4.979	--
17	PLACEBO_15	12.32	34015	0.22	10723	1.153	1.319	--
18	PLACEBO_18	25.08	1158919	7.61	13059	1.261	18.841	--
Total			15220806	100.00				

Analysed By



Checked By

 19/01/2024



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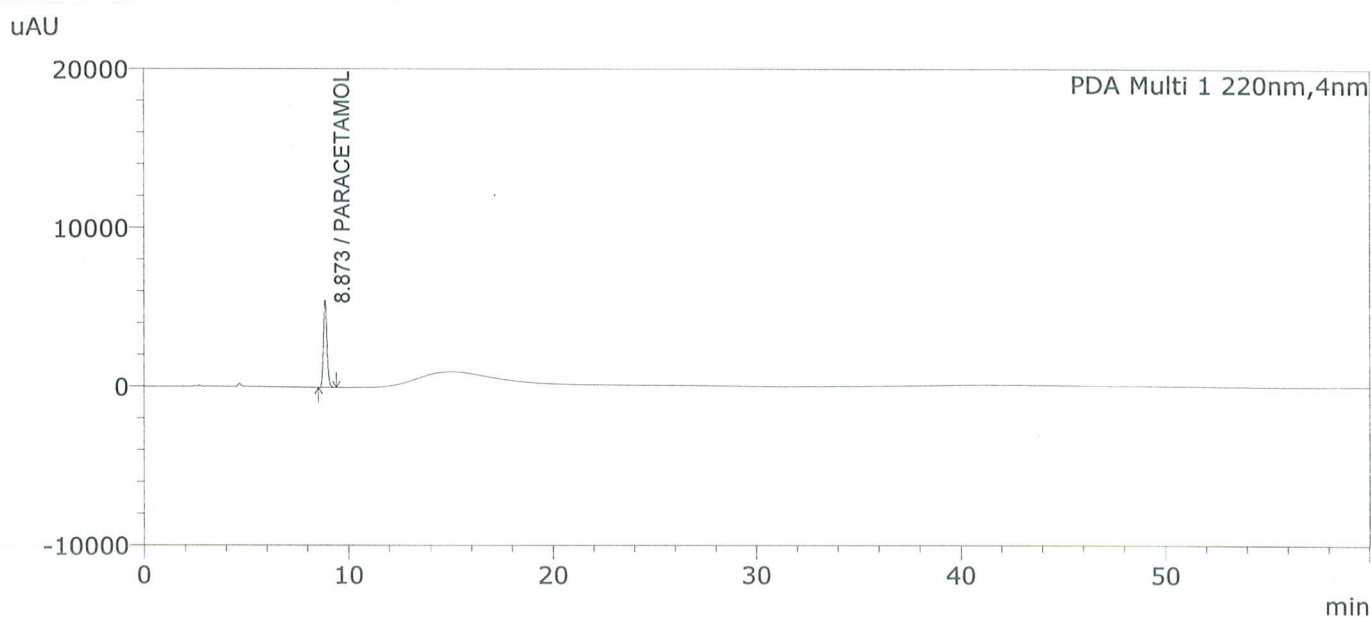
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : PARACETAMOL-RS-STD-BKT
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-17.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 10:44:14
 Date Processed : 18-01-2024 19:54:48

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	8.87	66536	100.00	11705	1.130	--	--
Total			66536	100.00				

Analysed By

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18/01/2024

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[Signature]
19/01/2024



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Tittle

RELATED SUBSTANCES OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Parameter :	SPECIFICITY	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
Standard dilution :	60.07	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.0035	5	ml to --->	50	ml to --->	1	ml to --->	1
Placebo dilution :	348.29	mg to --->	100	ml to --->	1	ml to --->	1
	1	ml to --->	1	ml to --->	1	ml to --->	1
Test dilution :	415.03	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-600	1	ml to --->	1	ml to --->	1	ml to --->	1

S.No.	Sample ID.	Peak Name	Retention time	Peak purity
1	Blank	Blank peaks	No peak	Not applicable
2	Resolution Solution	Ascorbic Acid	2.965	1.000
		Chlorpheniramine Maleate	3.583	1.000
		Phenylephrine Hcl	4.150	1.000
		Paracetamol	8.874	1.000
3	Standard preparation	Paracetamol	8.875	1.000
4	Blank	Blank peaks	No peak	Not applicable
5	Paracetamol WS	Paracetamol	8.875	1.000
6	Phenylephrine Hcl WS	Phenylephrine Hcl	4.152	1.000
7	Chlorpheniramine Maleate WS	Chlorpheniramine Maleate	3.583	1.000
8	Ascorbic Acid WS	Ascorbic Acid	2.958	1.000
9	Paracetamol WS + Chlorpheniramine Maleate WS + Phenylephrine Hcl WS + Ascorbic Acid WS	Ascorbic Acid	2.957	1.000
		Chlorpheniramine Maleate	3.575	1.000
		Phenylephrine Hcl	4.141	1.000
		Paracetamol	8.853	1.000
10	Blank	Blank peaks	No peak	Not applicable
11	Plain placebo	Placebo peaks	No peak	Not applicable
12	Placebo + Paracetamol WS	Paracetamol	8.859	1.000
13	Placebo + Phenylephrine Hcl WS	Phenylephrine Hcl	4.150	1.000
14	Placebo + Chlorpheniramine Maleate WS	Chlorpheniramine Maleate	3.580	1.000
15	Placebo + Ascorbic Acid WS	Ascorbic Acid	2.964	1.000
16	Placebo + Paracetamol WS + Chlorpheniramine Maleate WS + Phenylephrine Hcl WS + Ascorbic Acid WS	Ascorbic Acid	2.962	1.000
		Chlorpheniramine Maleate	3.579	1.000
		Phenylephrine Hcl	4.145	1.000
		Paracetamol	8.854	1.000
17	Blank	Blank peaks	No peak	Not applicable
18	Test preparation B.No.G17231228	Paracetamol	8.860	1.000

Results :

- 1) Blank peaks, Placebo peaks are not interfere with Principle 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 0.995 according to Lab Solution Software.

Analysed by :

S.ELAVARASAN

Date :

18-01-2024

Checked by :

Date :

75/01/2024


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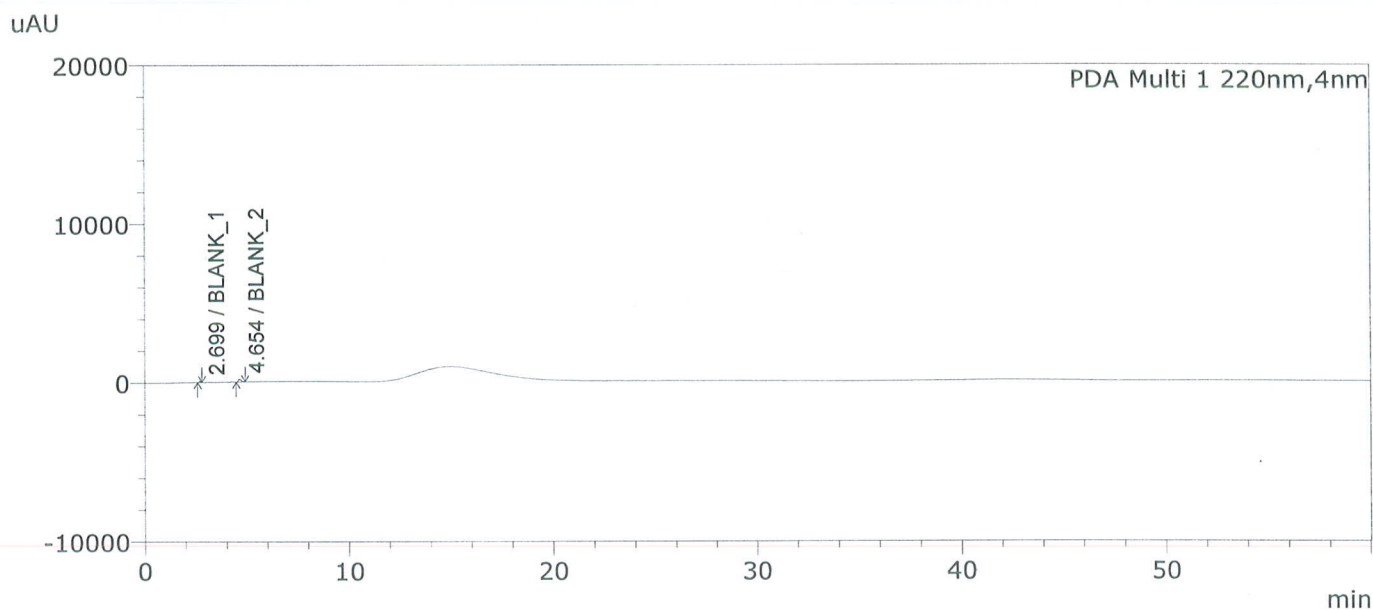
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-18.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-11
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 11:44:47
 Date Processed : 18-01-2024 21:15:19

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.70	439	20.43	6085	1.081	--	--
2	BLANK_2	4.65	1709	79.57	5329	1.396	9.941	--
Total			2147	100.00				

Analysed By

Checked By



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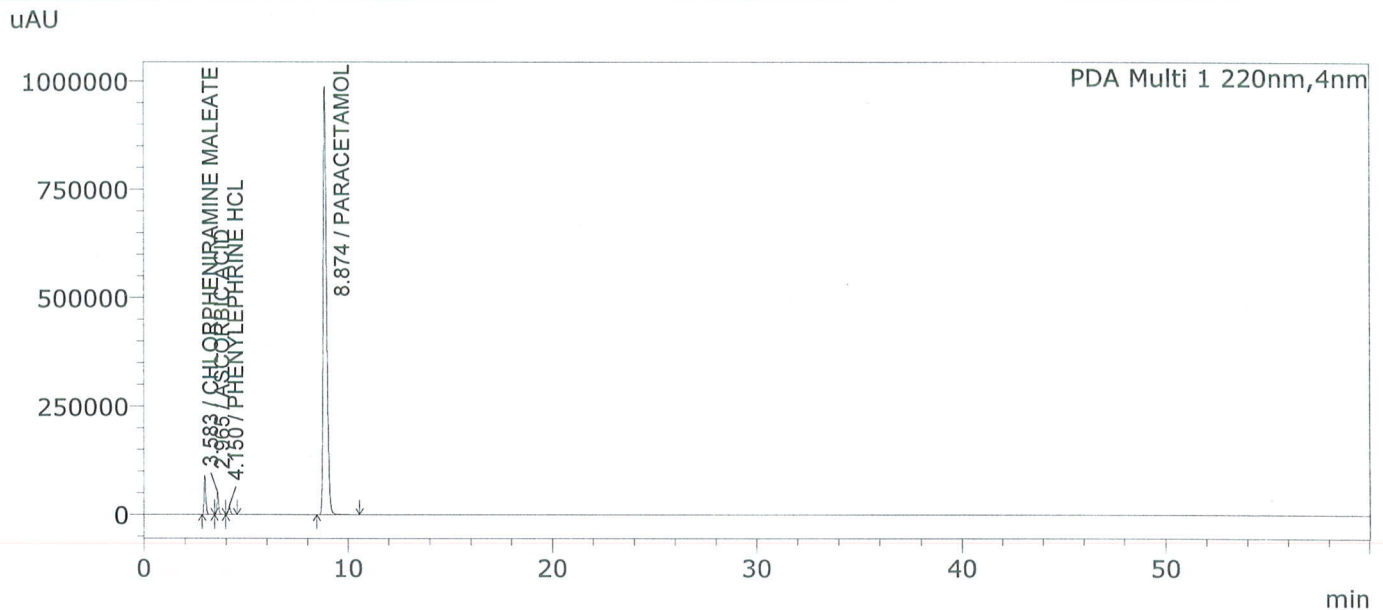
Analysis Report

<Sample Information>

Sample Name : INTERMEDIATE PRECISION-RS
 Sample ID : RESOLUTION SOLUTION
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-02.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 13-01-2024 19:35:53
 Date Processed : 18-01-2024 21:15:49

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	2.96	509797	3.96	5001	1.324	--	--
2	CHLORPHENIRAMINE MALEATE	3.58	302771	2.35	6621	1.295	3.595	--
3	PHENYLEPHRINE HCL	4.15	134044	1.04	7034	1.243	3.033	--
4	PARACETAMOL	8.87	11911697	92.64	11861	1.170	18.035	--
Total			12858309	100.00				

Analysed By

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Checked By

[Signature]
19/01/2024


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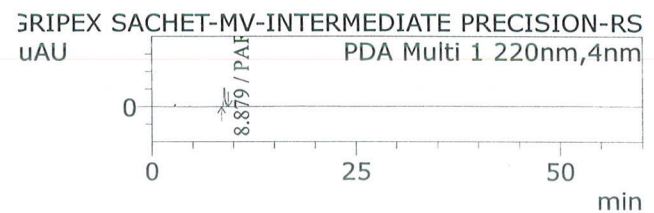
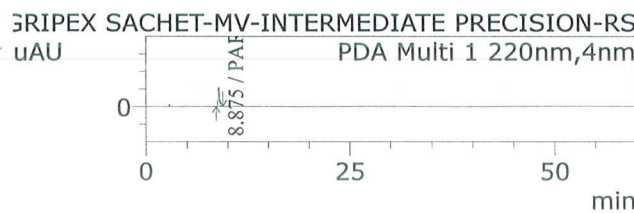
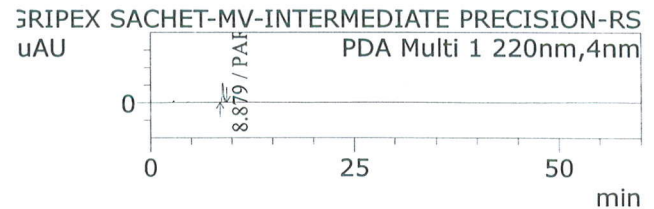
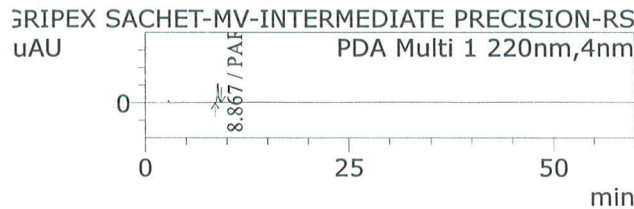
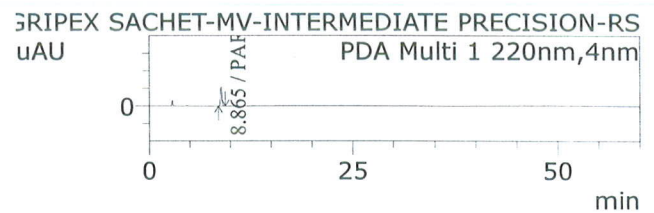
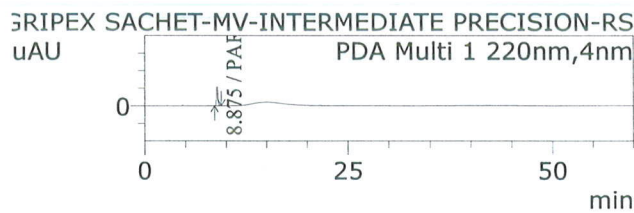
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PARACETAMOL-RS-STD-01
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-19.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-12
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 12:45:20
 Date Processed : 18-01-2024 19:54:48

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
12	RS-SPL-19.lcd	PARACETAMOL-RS-STD-01	8.88	66603	11714	1.13
12	RS-SPL-20.lcd	PARACETAMOL-RS-STD-02	8.87	66761	11664	1.13
12	RS-SPL-21.lcd	PARACETAMOL-RS-STD-03	8.87	66450	11660	1.12
12	RS-SPL-22.lcd	PARACETAMOL-RS-STD-04	8.88	66554	11645	1.13
12	RS-SPL-23.lcd	PARACETAMOL-RS-STD-05	8.88	66566	11643	1.13
12	RS-SPL-24.lcd	PARACETAMOL-RS-STD-06	8.88	66619	11626	1.13
Average			8.87	66592	11659	1.13
%RSD			0.066	0.152	0.262	0.199

Analysed By

Checked By


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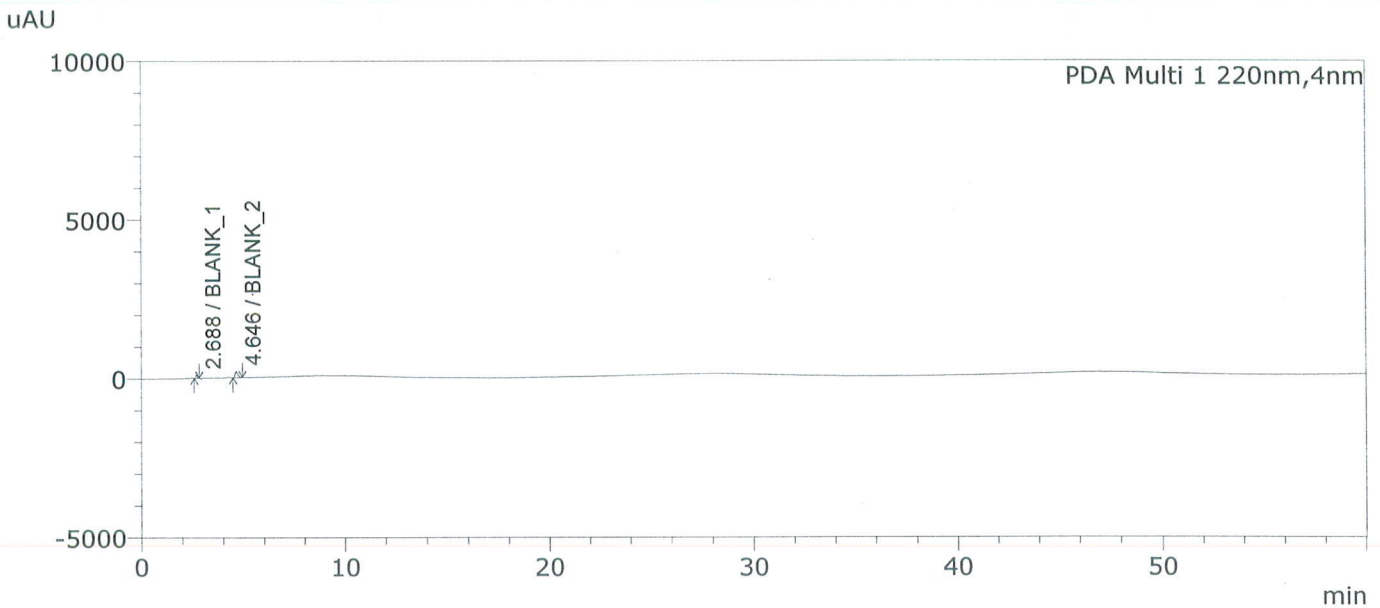
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-25.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-11
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 18:48:40
 Date Processed : 18-01-2024 21:16:46

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.69	470	20.15	5700	1.262	--	--
2	BLANK_2	4.65	1861	79.85	5191	1.505	9.779	--
Total			2330	100.00				

Analysed By

Checked By



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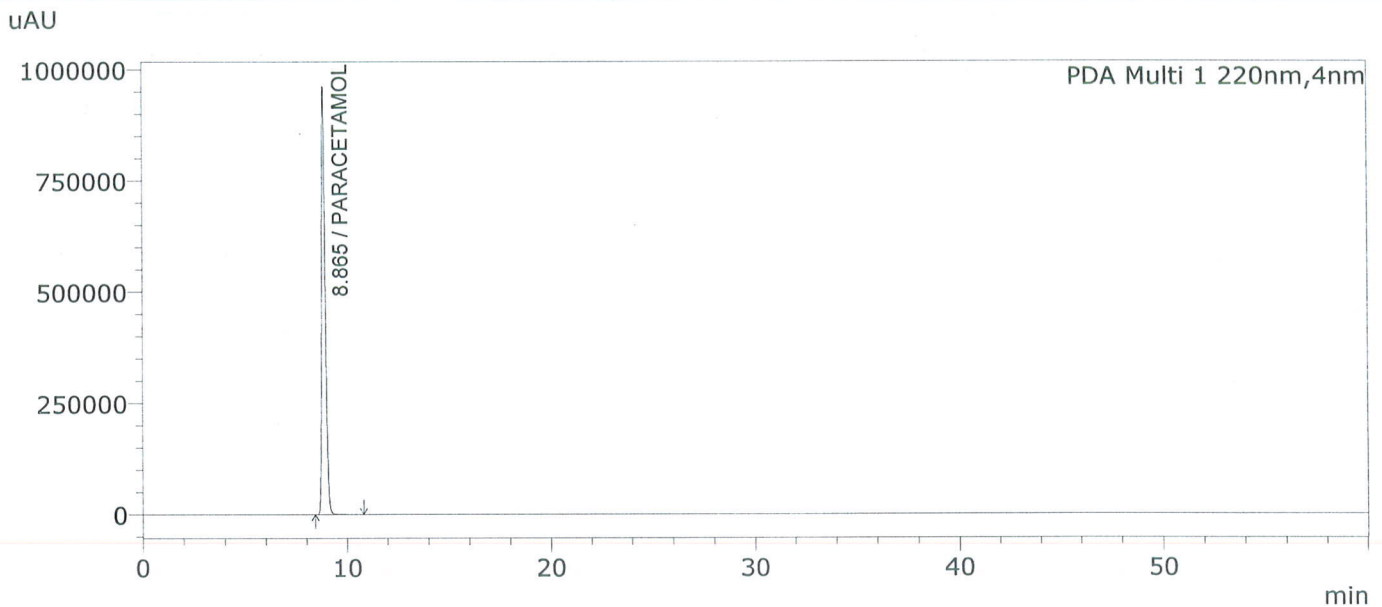
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PARACETAMOL WS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-26.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-13
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 19:49:14
 Date Processed : 18-01-2024 19:54:50

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	8.87	11861444	100.00	11380	1.170	--	--
Total			11861444	100.00				

Analysed By

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18/01/2024

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19/01/2024



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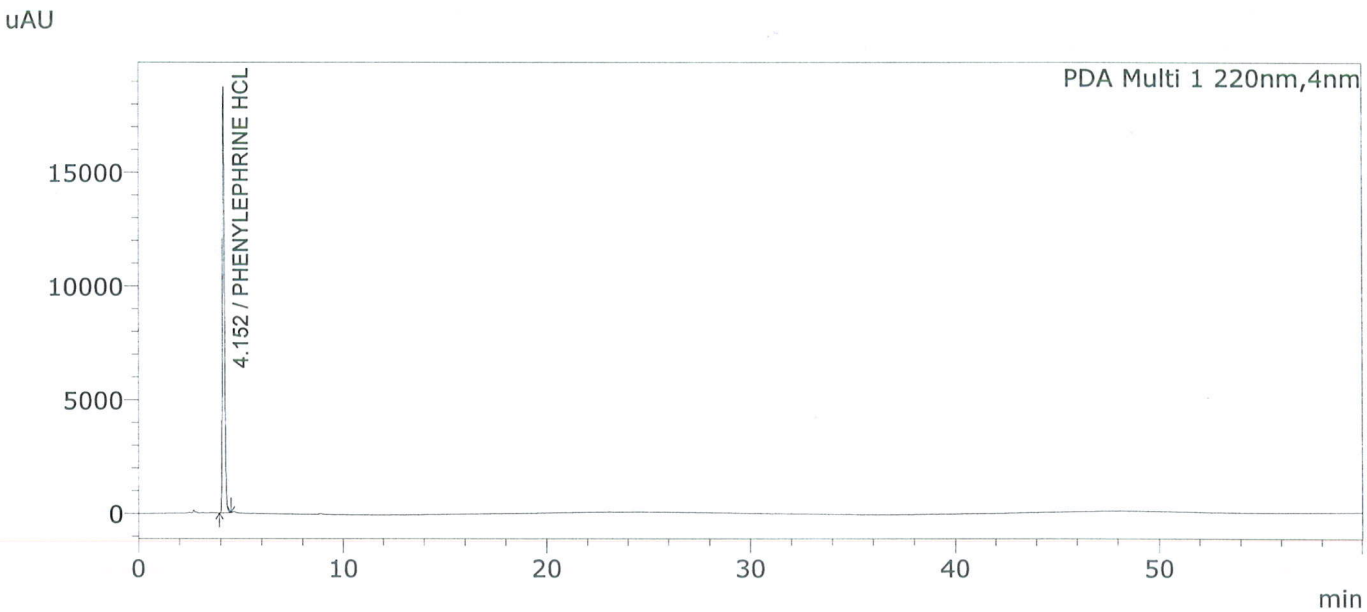
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PHENYLEPHRINE HCL WS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-27.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-14
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 20:49:47
 Date Processed : 18-01-2024 21:17:48

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PHENYLEPHRINE HCL	4.15	131947	100.00	6805	1.225	--	--
Total			131947	100.00				

Analysed By

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19/01/2024



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Analysis Report

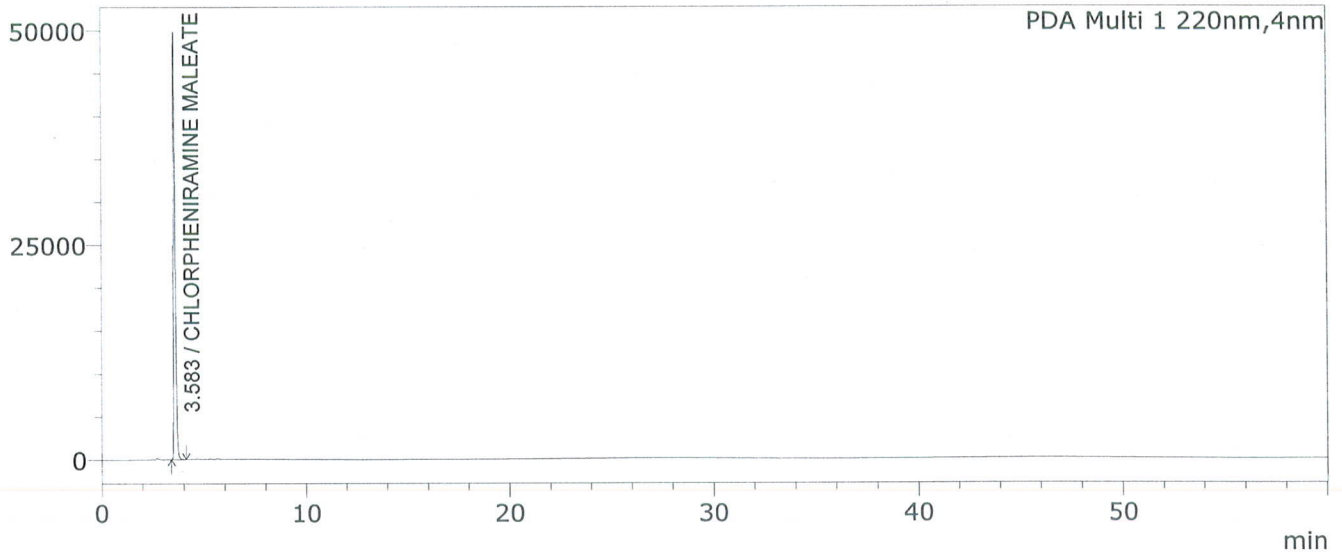
<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : CHLORPHENIRAMINE MALEATE WS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-28.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-15
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 21:50:20
 Date Processed : 18-01-2024 21:19:07

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>

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<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	CHLORPHENIRAMINE MALEATE	3.58	300714	100.00	6431	1.278	--	--
Total			300714	100.00				

Analysed By

Checked By



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Analysis Report

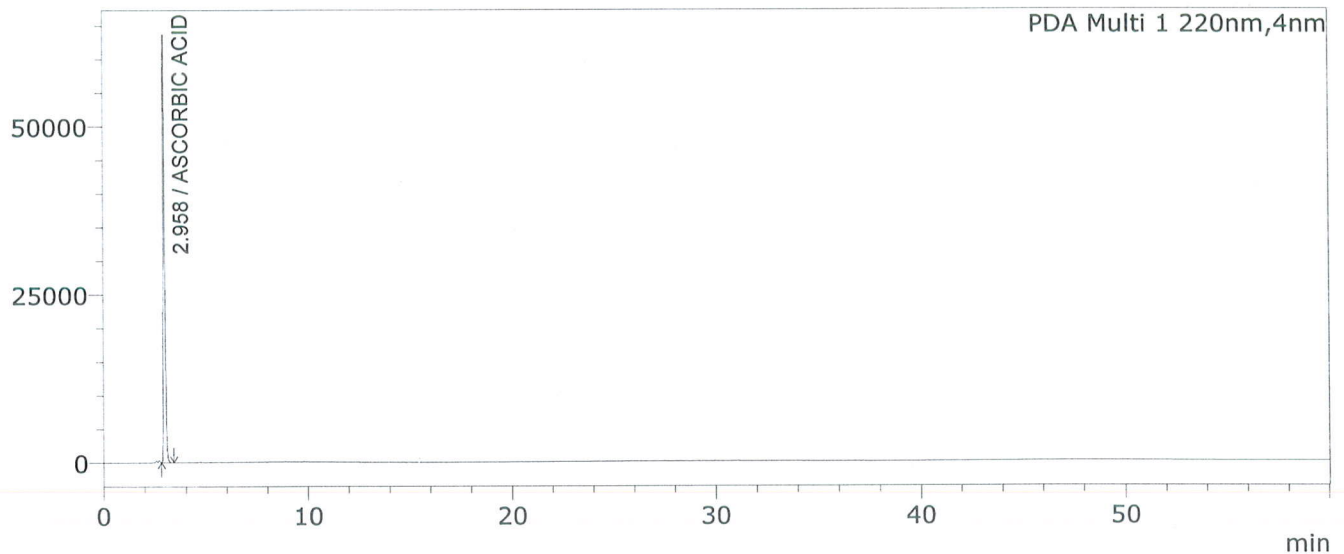
<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : ASCORBIC ACID WS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-29.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-16
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 22:50:53
 Date Processed : 18-01-2024 21:22:24

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>

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<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	2.96	360998	100.00	5029	1.295	--	--
Total			360998	100.00				

Analysed By

18/01/2024

Checked By

19/01/2024



GENERIC HEALTHCARE PVT. LTD.

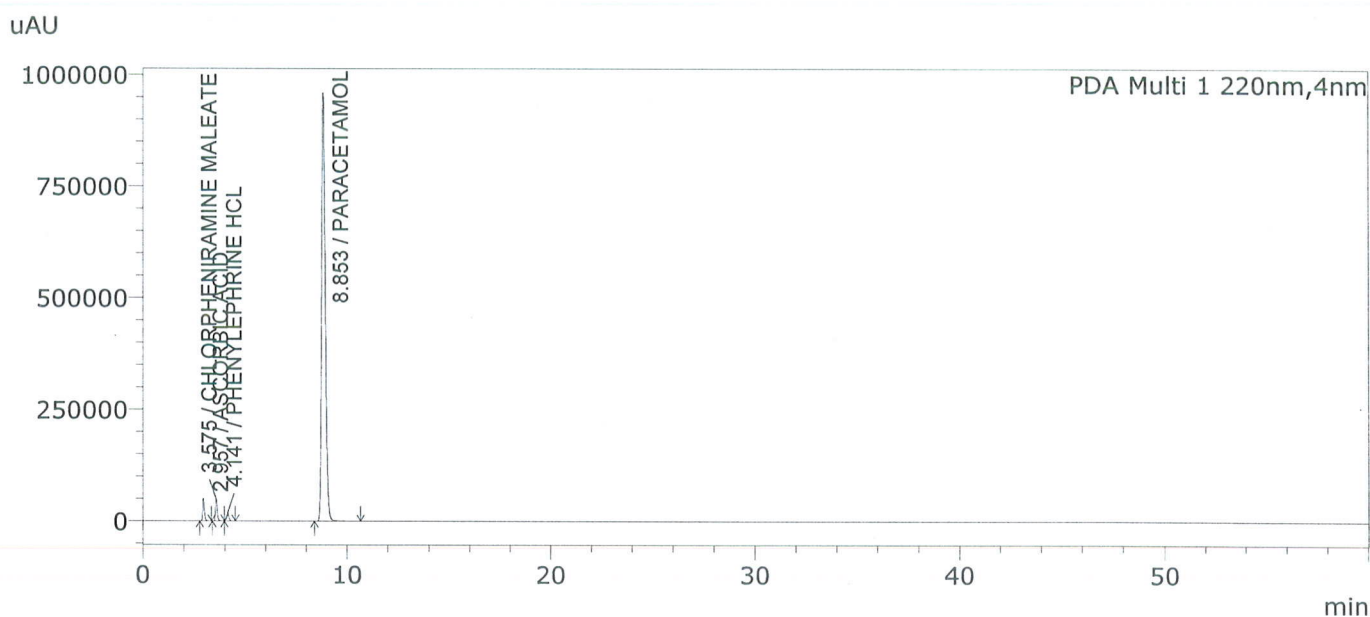
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PARA+PHP+CPM+ASCORBIC ACID WS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-30.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-17
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 23:51:27
 Date Processed : 18-01-2024 21:26:47

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	2.96	294351	2.34	4939	1.304	--	--
2	CHLORPHENIRAMINE MALEATE	3.58	298289	2.37	6539	1.278	3.580	--
3	PHENYLEPHRINE HCL	4.14	133084	1.06	6750	1.232	2.990	--
4	PARACETAMOL	8.85	11845891	94.23	11307	1.168	17.627	--
Total			12571615	100.00				

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19/01/2024



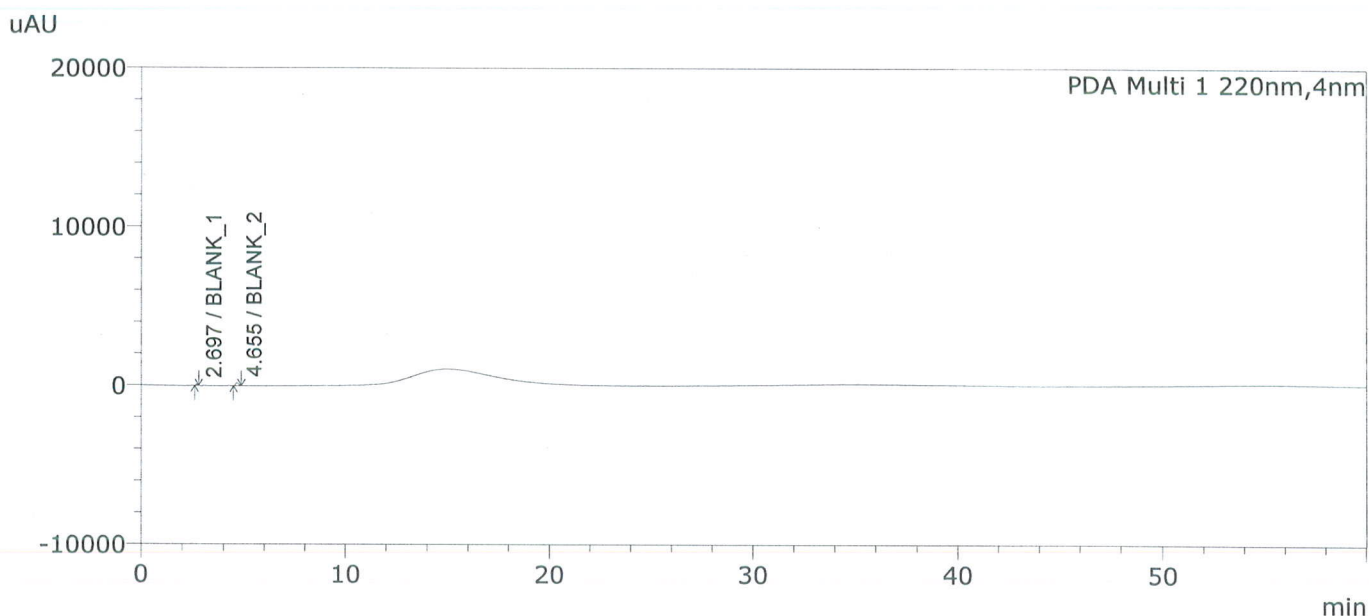
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-31.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-11
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 00:52:01
 Date Processed : 18-01-2024 21:27:45
 Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.70	420	19.33	6515	1.123	--	--
2	BLANK_2	4.65	1754	80.67	5360	1.287	10.093	--
Total			2175	100.00				

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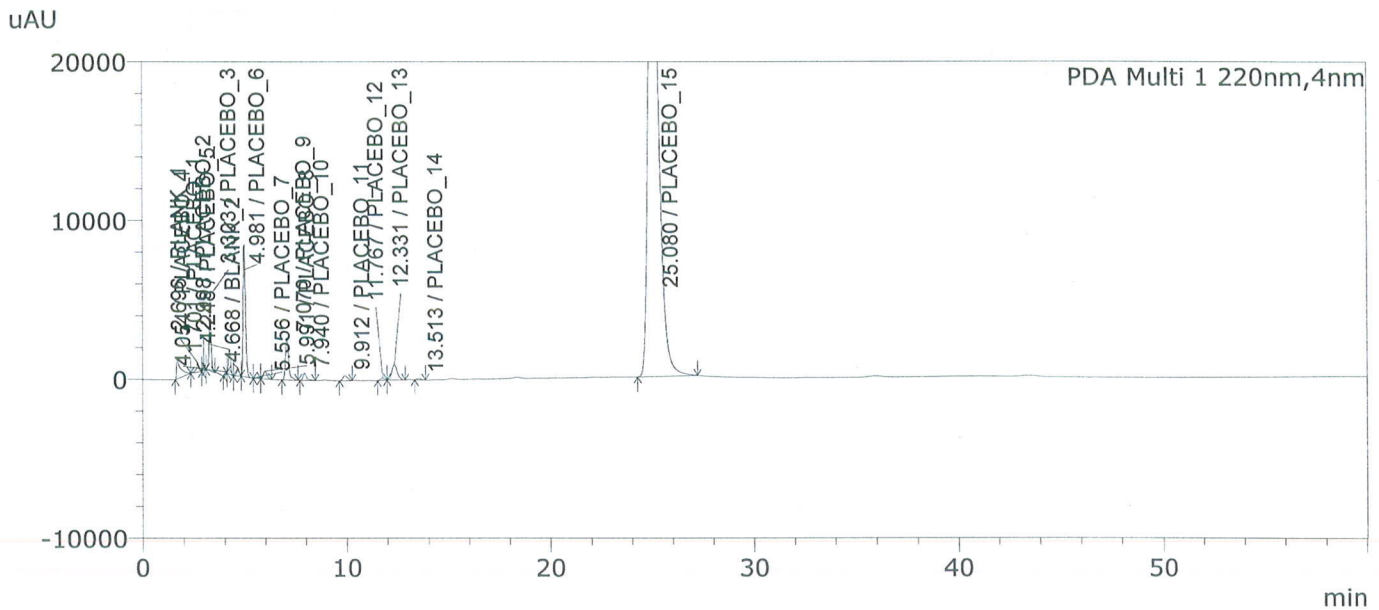
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-32.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-18
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 01:52:35
 Date Processed : 18-01-2024 21:32:18

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

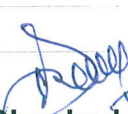
Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	18120	1.27	620	4.743	--	--
2	BLANK_1	2.70	4984	0.35	2959	0.804	4.223	--
3	PLACEBO_2	3.00	2584	0.18	5646	1.117	1.691	--
4	PLACEBO_3	3.30	30655	2.14	5198	0.973	1.778	--
5	PLACEBO_4	4.05	744	0.05	12220	0.868	4.549	--
6	PLACEBO_5	4.25	11207	0.78	6608	1.191	1.092	--
7	BLANK_2	4.67	4072	0.28	6379	0.924	1.897	--
8	PLACEBO_6	4.98	65984	4.61	7842	1.220	1.366	--
9	PLACEBO_7	5.56	912	0.06	4517	1.363	2.070	--
10	PLACEBO_8	5.99	5764	0.40	5872	1.258	1.351	--
11	PLACEBO_9	7.07	28286	1.97	10254	1.516	3.645	--
12	PLACEBO_10	7.94	5583	0.39	10725	1.746	2.969	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	9.91	4815	0.34	7949	1.217	5.248	--
14	PLACEBO_12	11.77	1943	0.14	14817	0.933	4.464	--
15	PLACEBO_13	12.33	17698	1.24	10170	1.229	1.288	--
16	PLACEBO_14	13.51	1225	0.09	18429	1.377	2.663	--
17	PLACEBO_15	25.08	1227844	85.72	12759	1.260	17.986	--
Total			1432422	100.00				

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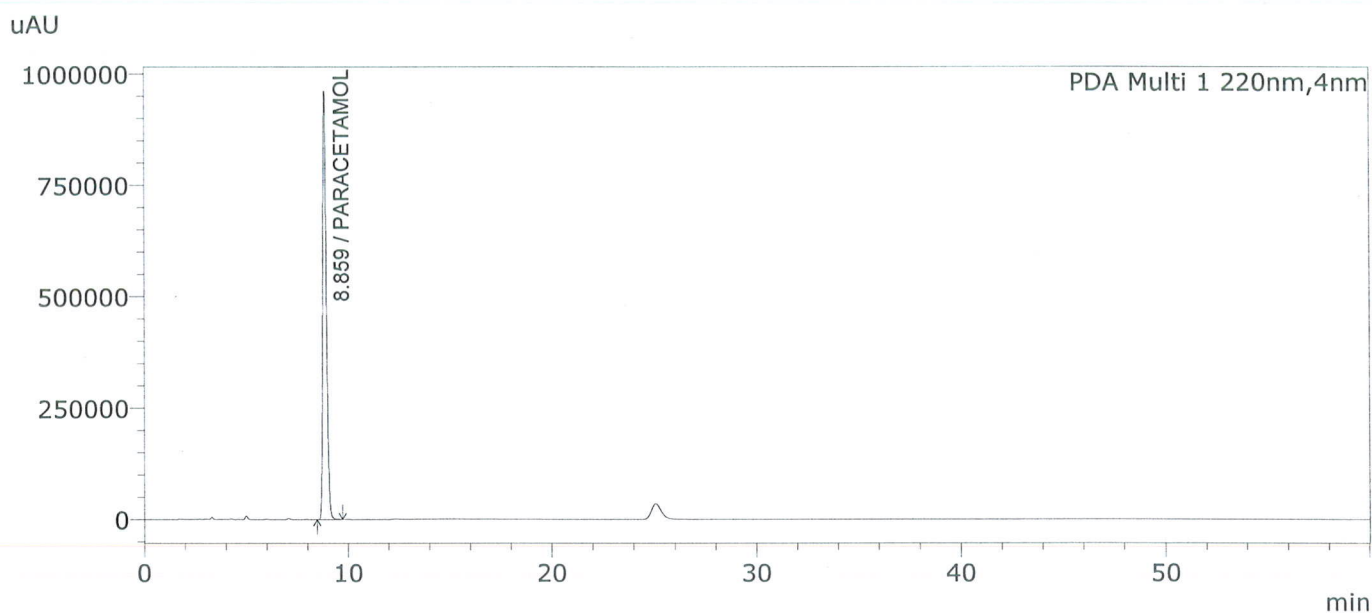
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO+PARACETAMOL
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-33.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-19
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 02:53:09
 Date Processed : 18-01-2024 19:54:50

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	8.86	11891813	100.00	11249	1.166	--	--
Total			11891813	100.00				

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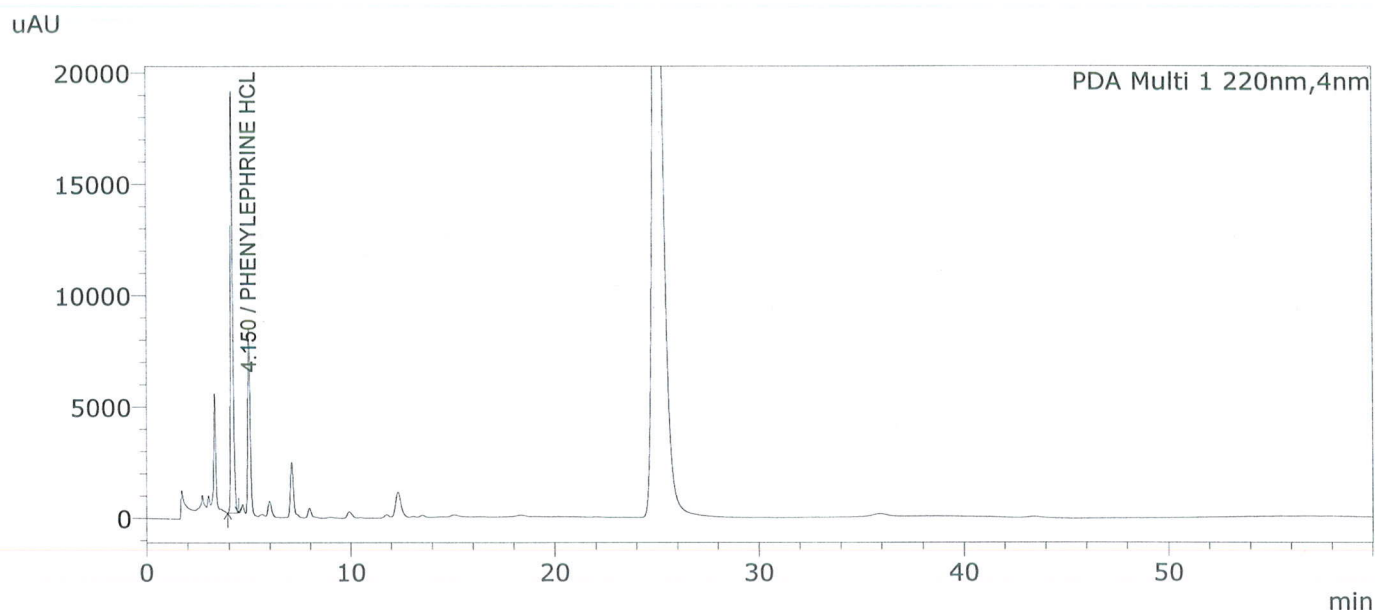
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO+PHENYLEPHRINE HCL
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-34.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-20
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 03:53:42
 Date Processed : 18-01-2024 21:35:18

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PHENYLEPHRINE HCL	4.15	146492	100.00	5989	1.360	--	--
Total			146492	100.00				

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Analysis Report

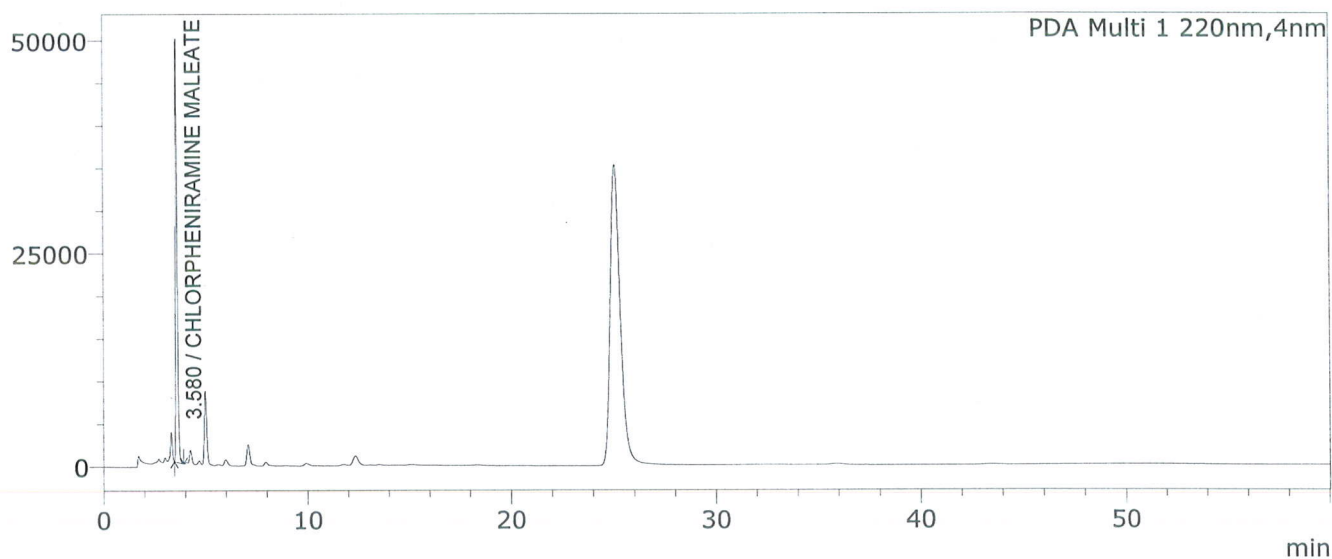
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Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO+CHLORPHENIRAMINE
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-35.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-21
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 04:54:14
 Date Processed : 18-01-2024 21:37:07

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>

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<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	CHLORPHENIRAMINE MALEATE	3.58	300127	100.00	6622	1.279	--	--
Total			300127	100.00				

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Analysis Report

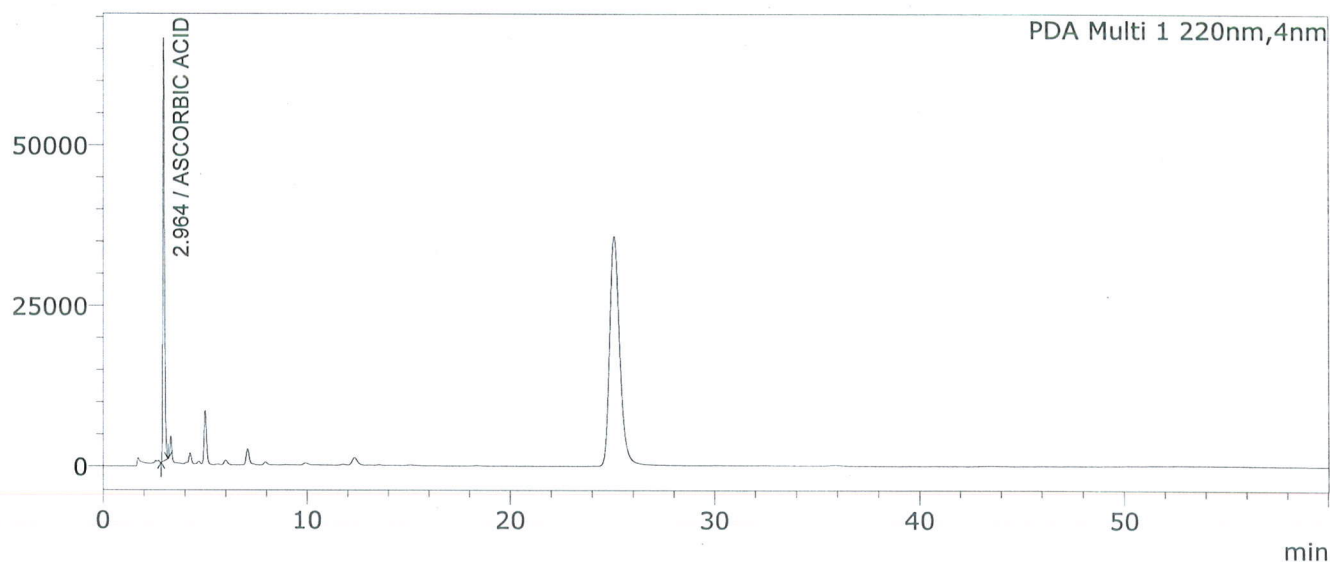
<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO+ASCORBIC ACID
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-36.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-22
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 05:54:48
 Date Processed : 18-01-2024 21:39:51

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>

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<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	2.96	376196	100.00	4797	1.275	--	--
Total			376196	100.00				

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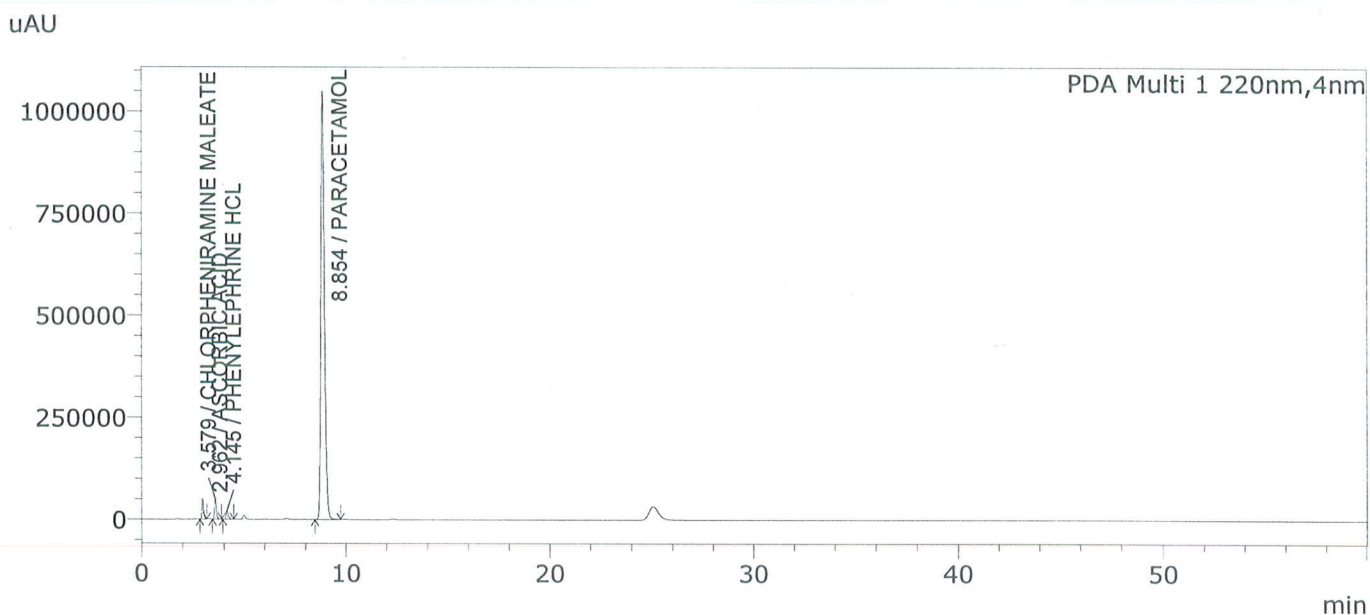
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO+PARA+PHP+CPM+ASCORBIC
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-37.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-23
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 06:55:21
 Date Processed : 18-01-2024 21:52:06

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	2.96	285110	2.08	4859	1.269	--	--
2	CHLORPHENIRAMINE MALEATE	3.58	302704	2.20	6582	1.283	3.562	--
3	PHENYLEPHRINE HCL	4.15	159265	1.16	5834	1.344	2.880	--
4	PARACETAMOL	8.85	12990688	94.56	11195	1.169	17.066	--
Total			13737767	100.00				

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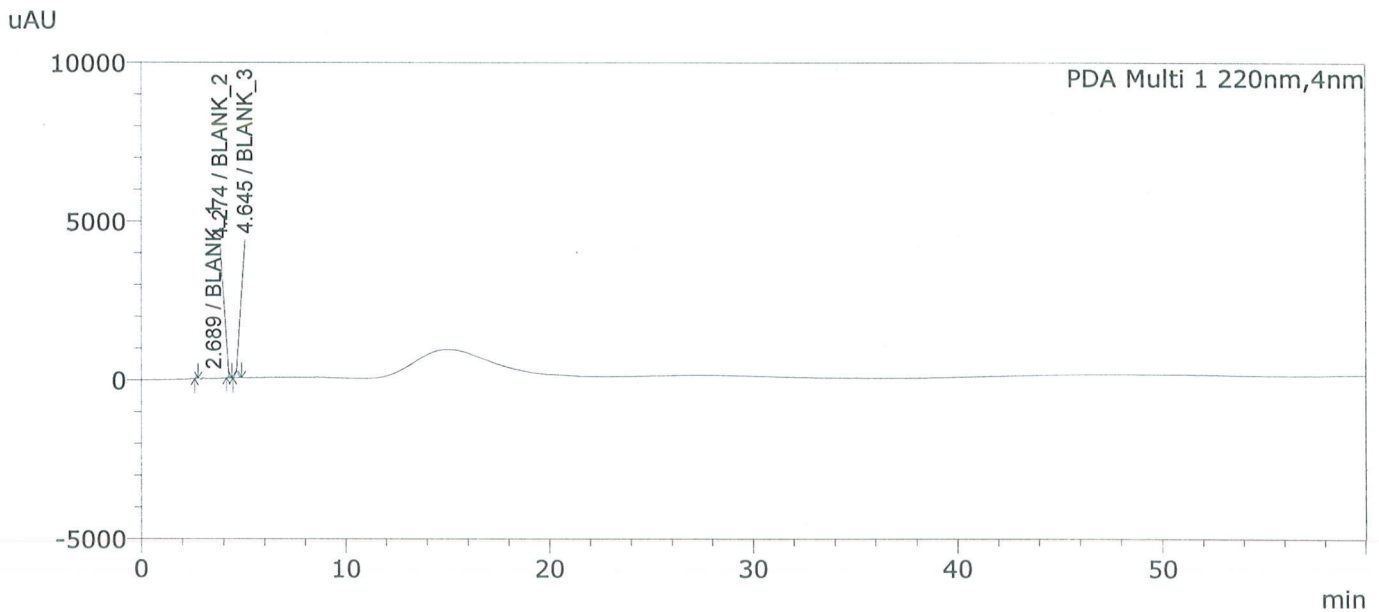
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : BLANK-RS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-38.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-11
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 07:55:53
 Date Processed : 18-01-2024 21:44:47

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.69	447	15.89	6796	1.082	--	--
2	BLANK_2	4.27	380	13.53	7433	1.174	9.647	--
3	BLANK_3	4.65	1983	70.57	5163	1.351	1.623	--
Total			2810	100.00				

Analysed By

18/01/2024

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19/01/2024



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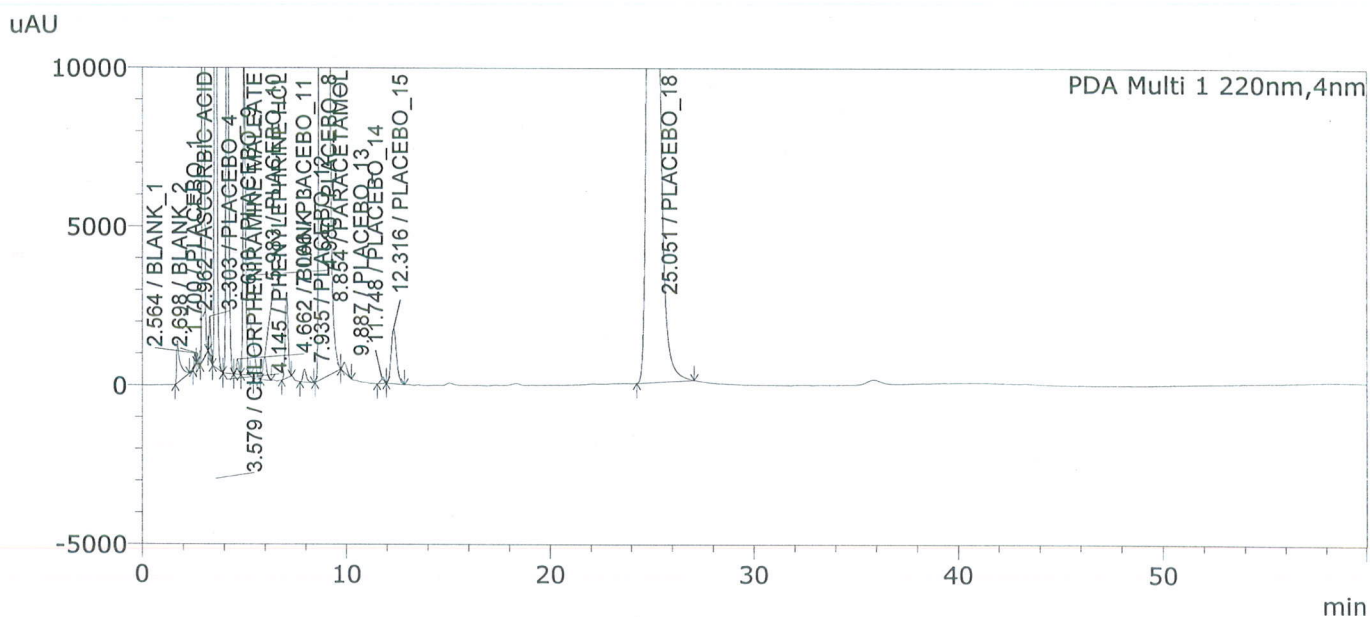
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : GRIPEX-1228-RS-SPL-1
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-39.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-24
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 08:56:28
 Date Processed : 18-01-2024 21:47:58

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



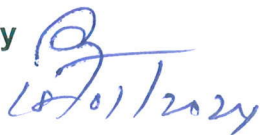
<Peak Table>

PDA Ch1 220nm

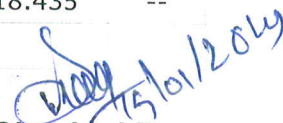
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16957	0.11	719	4.378	--	--
2	BLANK_1	2.56	2049	0.01	5136	0.979	4.353	--
3	BLANK_2	2.70	1367	0.01	6557	1.277	0.971	--
4	ASCORBIC ACID	2.96	286369	1.90	4850	1.273	1.740	--
5	PLACEBO_4	3.30	6956	0.05	5858	1.270	1.989	--
6	CHLORPHENIRAMINE MALEATE	3.58	303152	2.01	6580	1.285	1.582	--
7	PHENYLEPHRINE HCL	4.15	159228	1.06	5835	1.345	2.880	--
8	BLANK_3	4.66	3837	0.03	6588	1.023	2.313	--
9	PLACEBO_8	4.98	79979	0.53	7966	1.187	1.402	--
10	PLACEBO_9	5.63	586	0.00	4969	0.850	2.398	--
11	PLACEBO_10	5.98	8438	0.06	5828	1.274	1.116	--
12	PLACEBO_11	7.07	26745	0.18	10571	1.054	3.680	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	7.93	4739	0.03	10872	1.361	2.999	--
14	PARACETAMOL	8.85	12990518	86.09	11195	1.169	2.877	--
15	PLACEBO_13	9.89	4464	0.03	9800	1.428	2.813	--
16	PLACEBO_14	11.75	1636	0.01	15889	0.964	4.821	--
17	PLACEBO_15	12.32	31695	0.21	10113	1.186	1.316	--
18	PLACEBO_18	25.05	1160014	7.69	12625	1.257	18.435	--
Total			15088728	100.00				

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Analysis Report

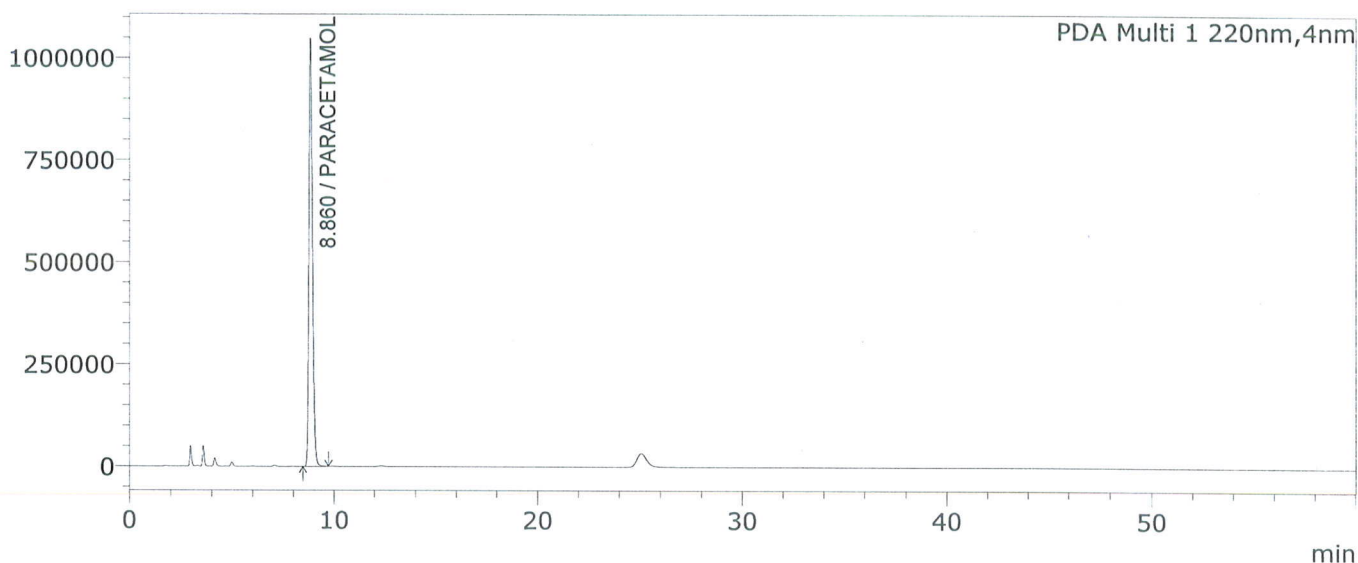
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Sample Name : SPECIFICITY-RS
 Sample ID : GRIPEX-1228-RS-SPL-2
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-40.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-24
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 09:57:01
 Date Processed : 18-01-2024 19:54:50

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>

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<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	8.86	13006719	100.00	11174	1.168	--	--
Total			13006719	100.00				

Analysed By

Checked By



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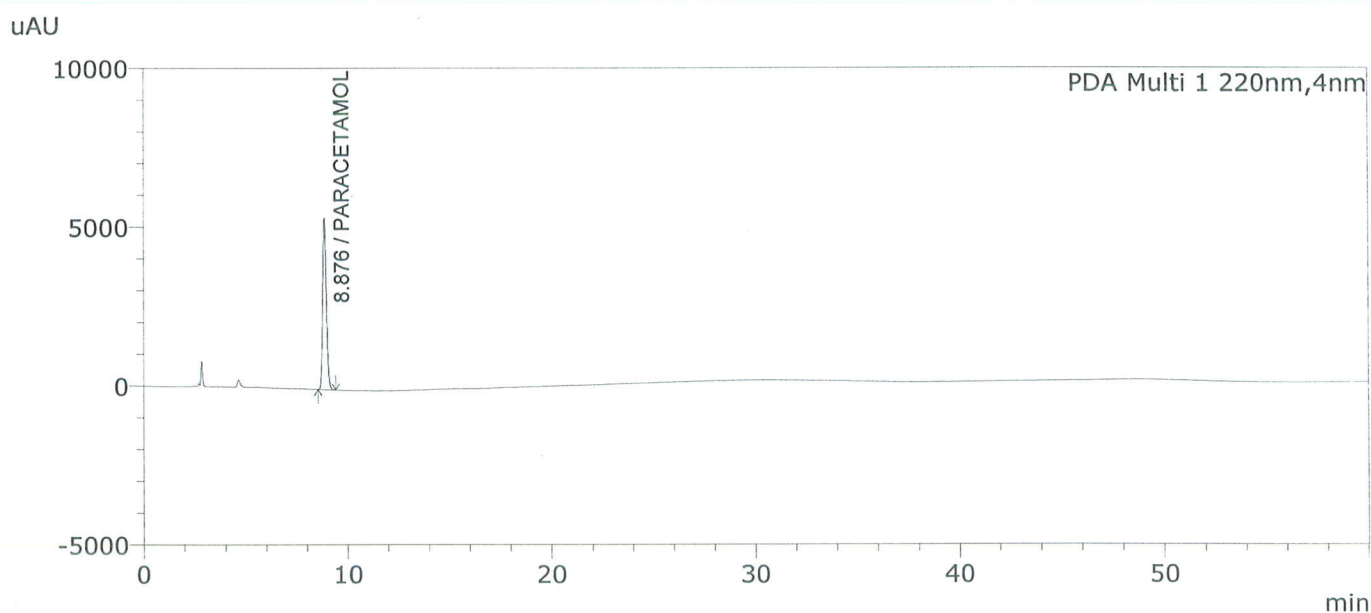
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PARACETAMOL-RS-STD-BKT
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-41.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-12
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 10:57:33
 Date Processed : 18-01-2024 19:54:51

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	8.88	66421	100.00	11378	1.125	--	--
Total			66421	100.00				

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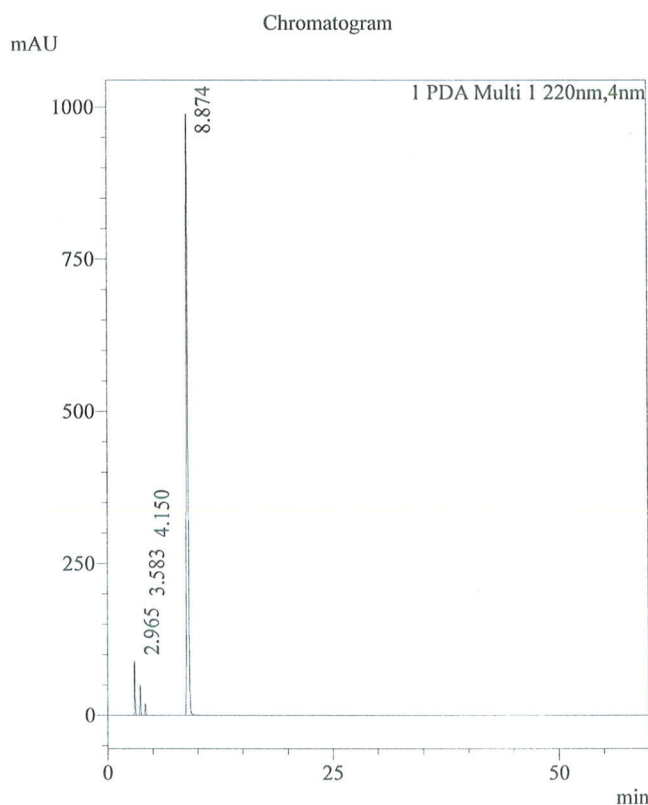
Checked By

[Signature]
15/01/2024

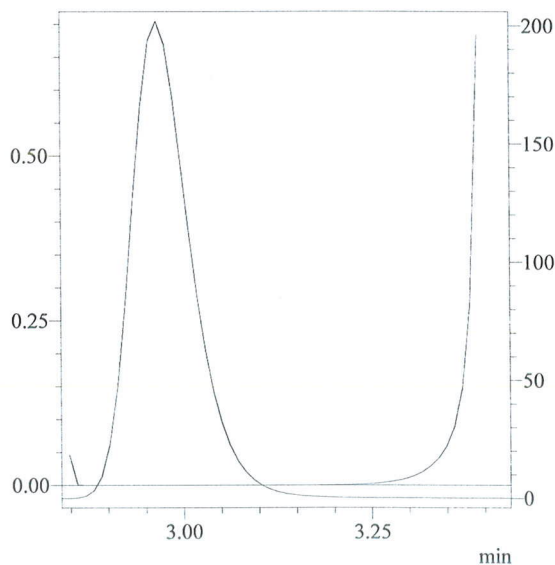
**GENERIC HEALTHCARE PVT. LTD.****Analysis Report****<Sample Information>**

Sample Name : INTERMEDIATE PRECISION-RS
Sample ID : RESOLUTION SOLUTION
Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-02.lcd
Method Filename : GRIPEX-RS.lcm
Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
Vial # : 1-2
Injection Volume : 10 uL
Date Acquired : 13-01-2024 19:35:53
Date Processed : 18-01-2024 21:15:49

Acquired by : S.ELAVARASAN
Processed by : C.K.SARAVANAN

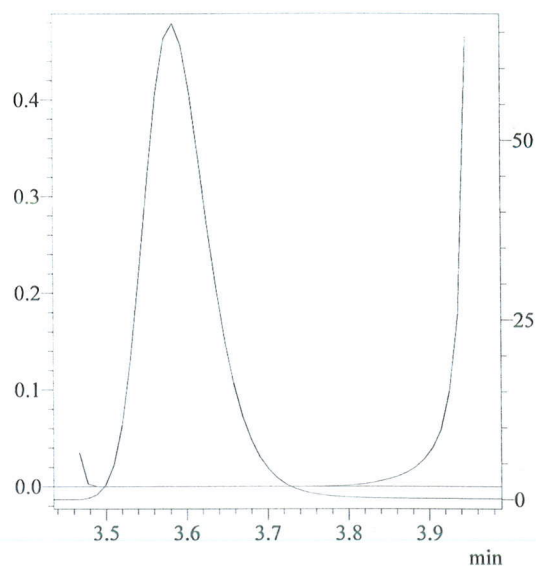
<Peak Purity>

ID# : 1
Retention Time : 2.965 min
Compound Name : ASCORBIC ACID



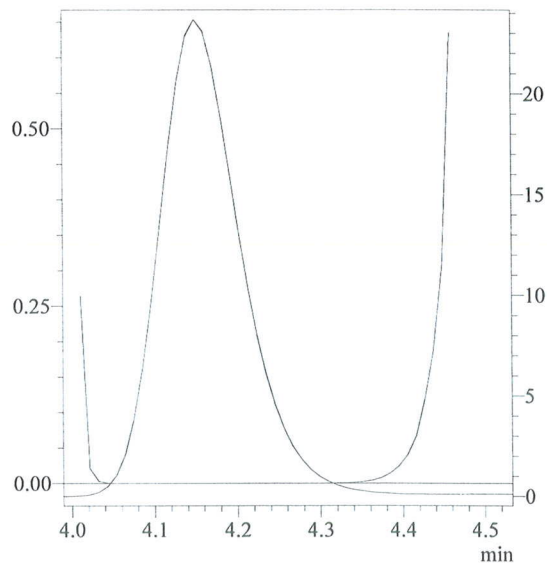
Impurity : Not Detected
Peak purity index : 1.000000
Single point threshold : 1.000000
Minimum peak purity index : 0

ID# : 2
Retention Time : 3.583 min
Compound Name : CHLORPHENIRAMINE MALEATE



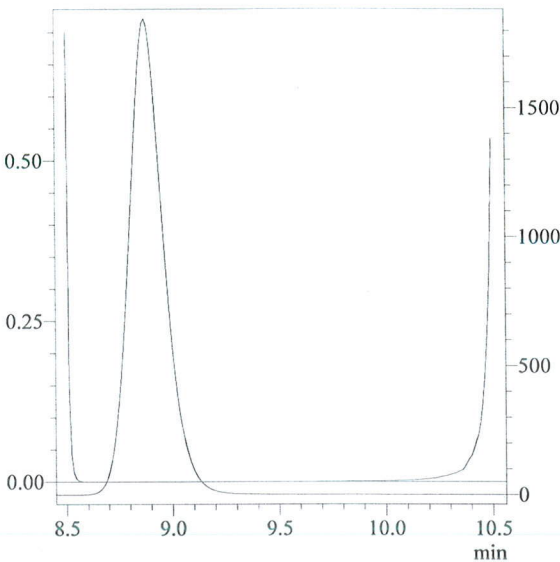
Impurity : Not Detected
Peak purity index : 1.000000
Single point threshold : 1.000000
Minimum peak purity index : 0

ID# : 3
Retention Time : 4.150 min
Compound Name : PHENYLEPHRINE HCL



Impurity : Not Detected
Peak purity index : 1.000000
Single point threshold : 0.999999
Minimum peak purity index : 0

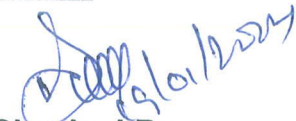
ID# : 4
Retention Time : 8.874 min
Compound Name : PARACETAMOL



Impurity : Not Detected
Peak purity index : 0.999999
Single point threshold : 1.000000
Minimum peak purity index : 0

Peak Table				
PDA Ch1 220nm				
Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	2.965	1.000000	1.000000	ASCORBIC ACID
2	3.583	1.000000	1.000000	CHLORPHENIRAMINE MALEATE
3	4.150	1.000000	0.999999	PHENYLEPHRINE HCL
4	8.874	0.999999	1.000000	PARACETAMOL
Total				

Analysed By 
12/01/2024


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Analysis Report

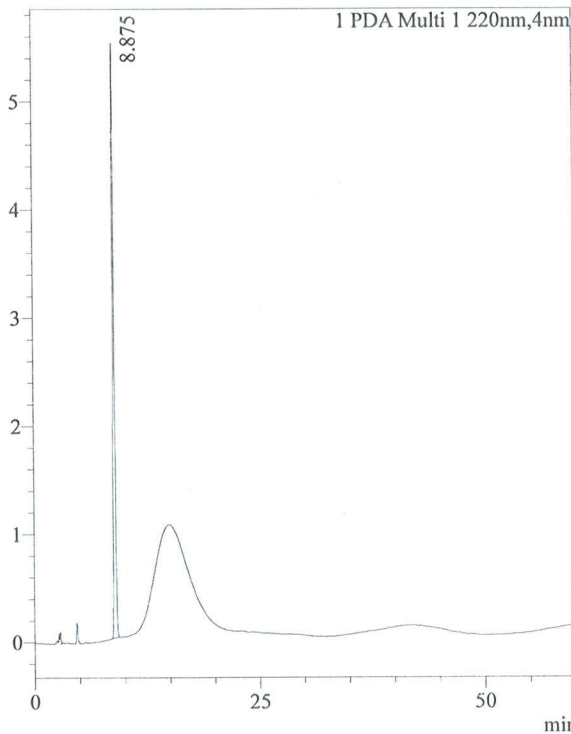
<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PARACETAMOL-RS-STD-01
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-19.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-12
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 12:45:20
 Date Processed : 18-01-2024 19:54:48

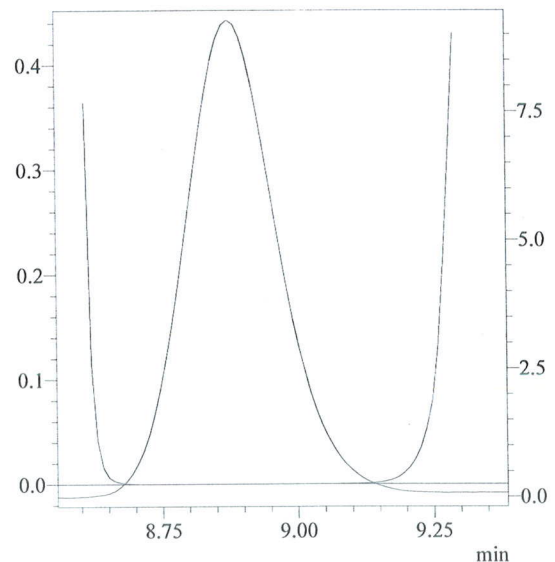
Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>

mAU Chromatogram



ID# : 1
 Retention Time : 8.875 min
 Compound Name : PARACETAMOL



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999997
 Minimum peak purity index : 3

PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	8.875	1.000000	0.999997	PARACETAMOL
Total				

Analysed By

[Signature]
18/01/2024

Checked By

[Signature]
19/01/2024



GENERIC HEALTHCARE PVT. LTD.

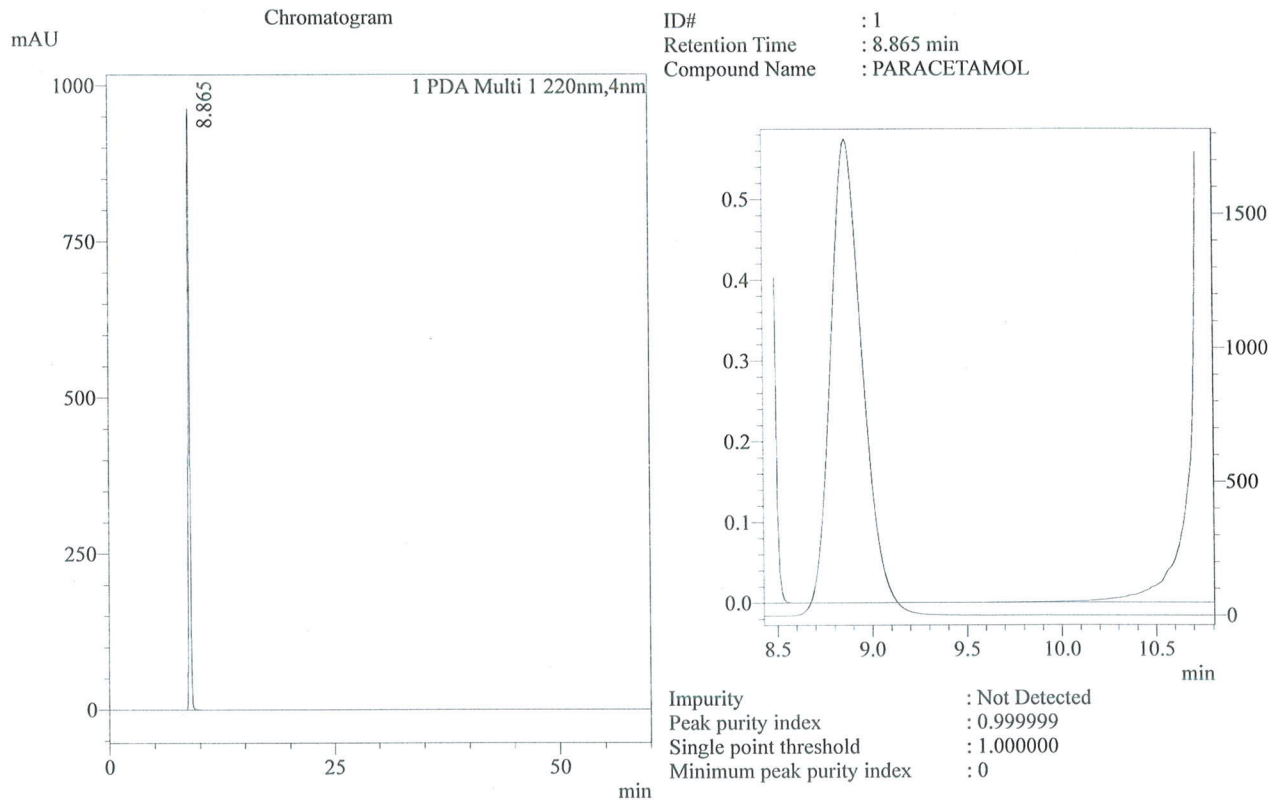
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PARACETAMOL WS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-26.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-13
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 19:49:14
 Date Processed : 18-01-2024 19:54:50

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>



PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	8.865	0.999999	1.000000	PARACETAMOL
Total				

Analysed By

[Signature]
12/01/2024

Checked By

[Signature]
18/01/2024



GENERIC HEALTHCARE PVT. LTD.

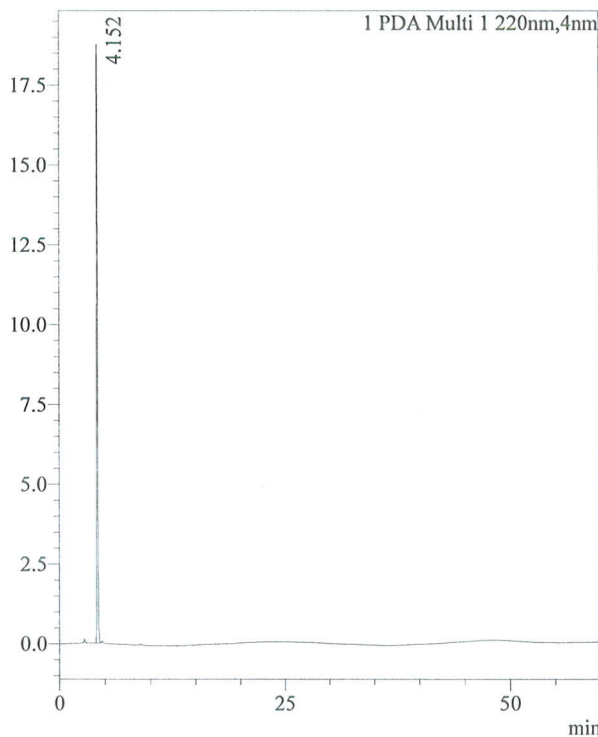
Analysis Report

<Sample Information>

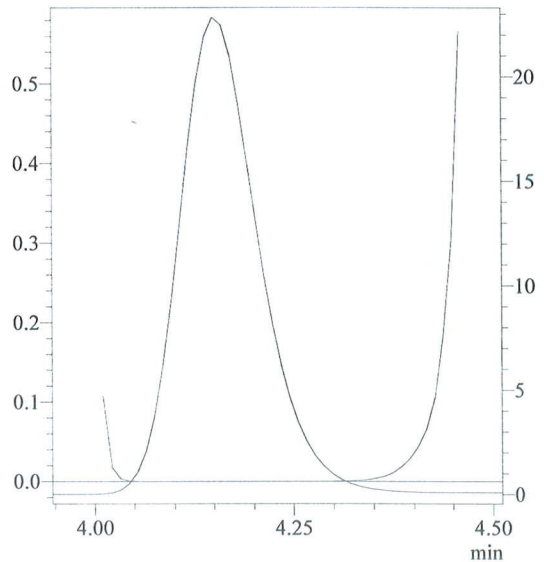
Sample Name : SPECIFICITY-RS
 Sample ID : PHENYLEPHRINE HCL WS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-27.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-14
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 20:49:47
 Date Processed : 18-01-2024 21:17:48
 Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>

mAU Chromatogram



ID# : 1
 Retention Time : 4.152 min
 Compound Name : PHENYLEPHRINE HCL



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999999
 Minimum peak purity index : 1

PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	4.152	1.000000	0.999999	PHENYLEPHRINE HCL
Total				

Analysed By

[Signature]
18/01/2024

Checked By

[Signature]
19/01/2024



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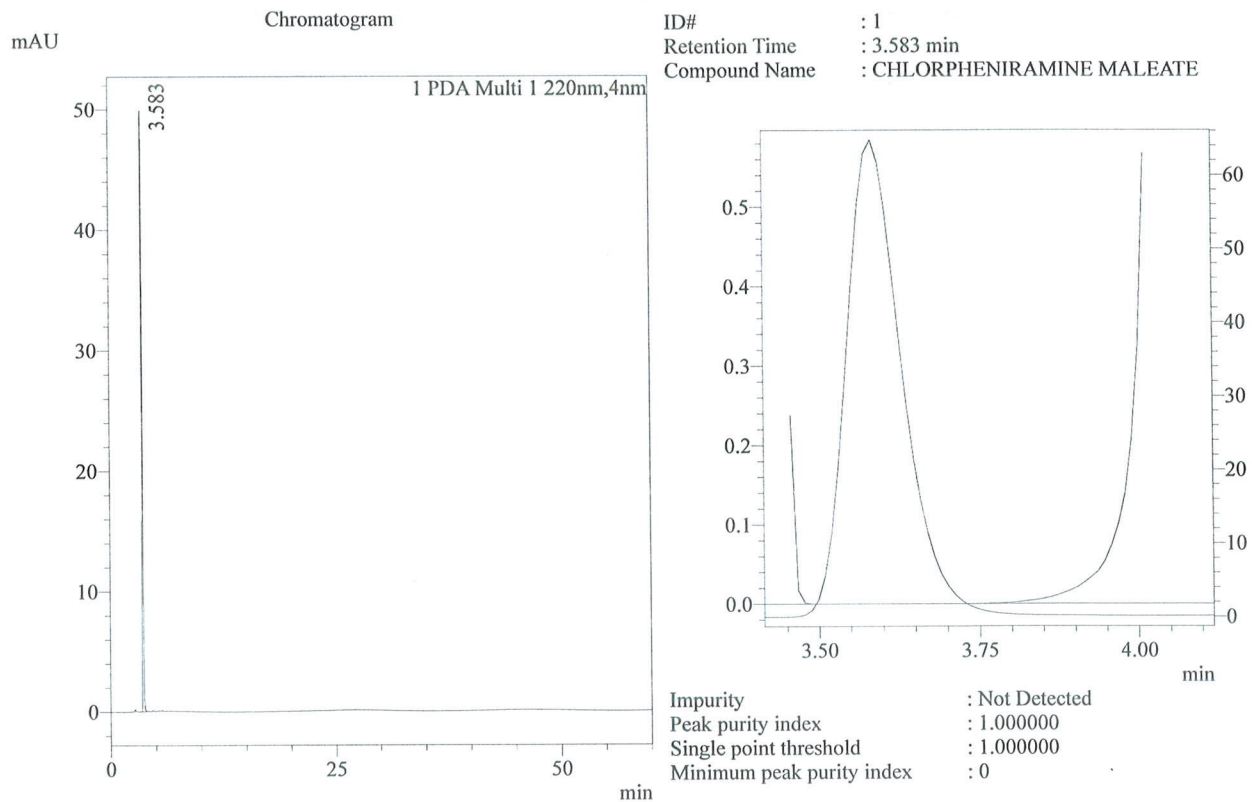
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : CHLORPHENIRAMINE MALEATE WS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-28.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-15
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 21:50:20
 Date Processed : 18-01-2024 21:19:07

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>



PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	3.583	1.000000	1.000000	CHLORPHENIRAMINE MALEATE
Total				

Analysed By

[Signature]
15/01/2024

[Signature]
15/01/2024
Checked By



GENERIC HEALTHCARE PVT. LTD.

Analysis Report

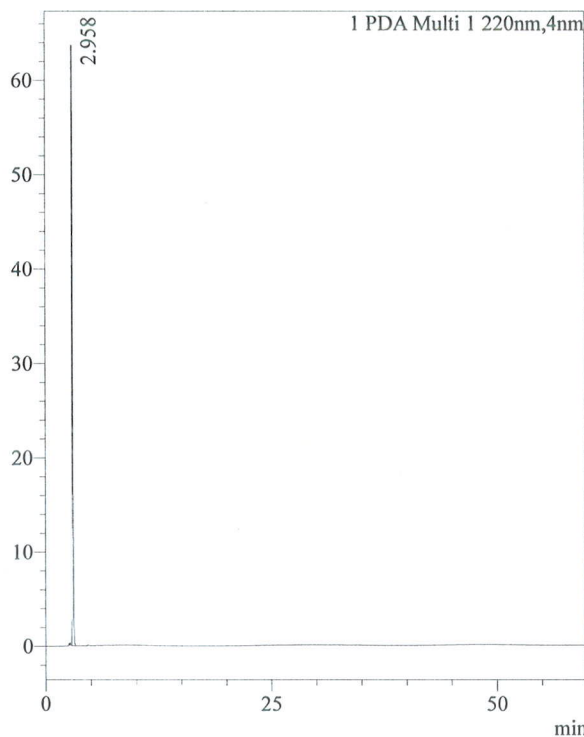
<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : ASCORBIC ACID WS
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-29.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-16
 Injection Volume : 10 uL
 Date Acquired : 14-01-2024 22:50:53
 Date Processed : 18-01-2024 21:22:24

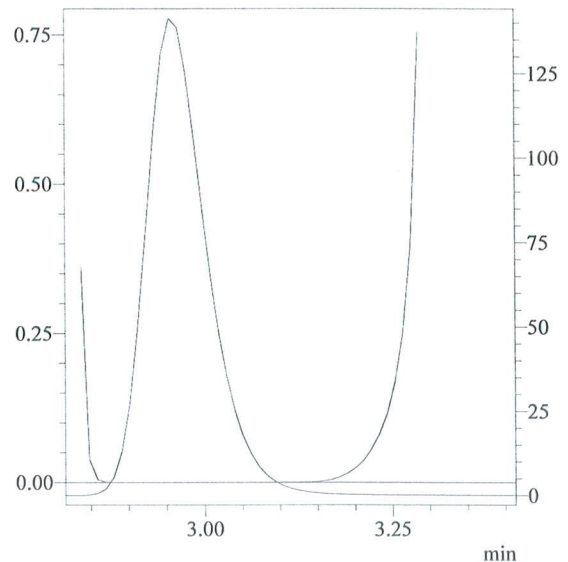
Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>

mAU Chromatogram



ID# : 1
 Retention Time : 2.958 min
 Compound Name : ASCORBIC ACID



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999999
 Minimum peak purity index : 0

PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	2.958	1.000000	0.999999	ASCORBIC ACID
Total				

Analysed By

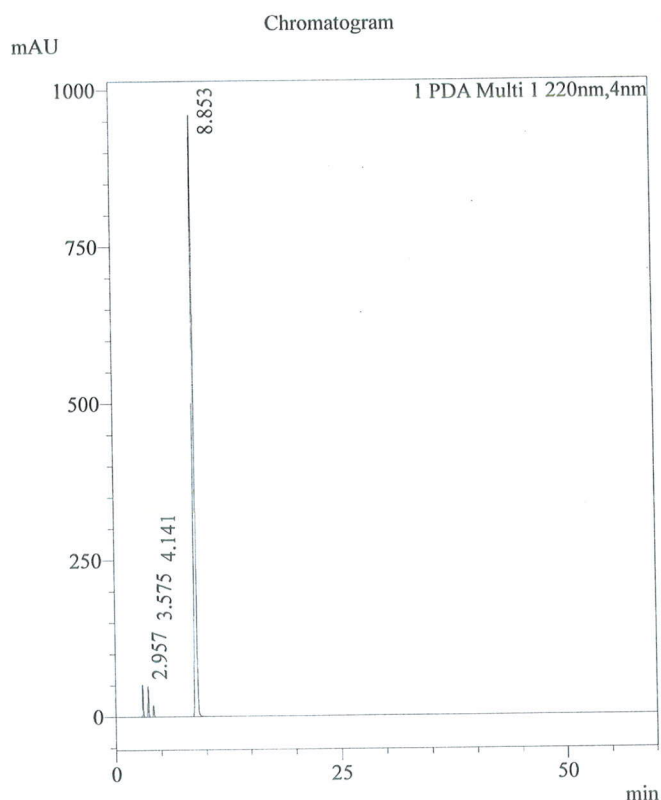
[Signature]
12/01/2024

Checked By

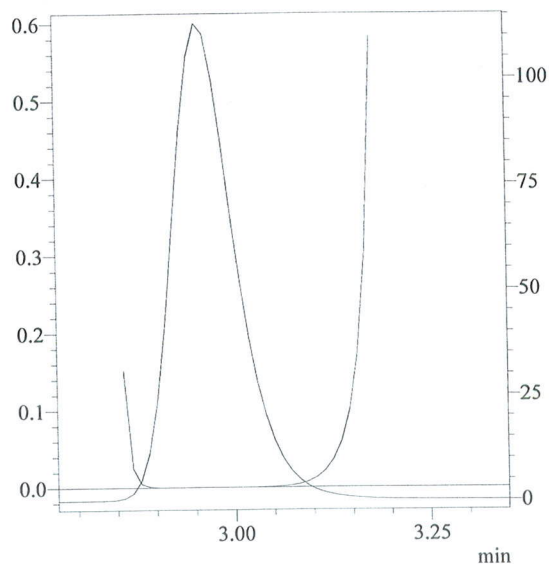
[Signature]
12/01/2024

**GENERIC HEALTHCARE PVT. LTD.****Analysis Report****<Sample Information>**

Sample Name : SPECIFICITY-RS
Sample ID : PARA+PHP+CPM+ASCORBIC ACID WS
Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-30.lcd
Method Filename : GRIPEX-RS.lcm
Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
Vial # : 1-17
Injection Volume : 10 uL
Date Acquired : 14-01-2024 23:51:27
Date Processed : 18-01-2024 21:26:47
Acquired by : S.ELAVARASAN
Processed by : C.K.SARAVANAN

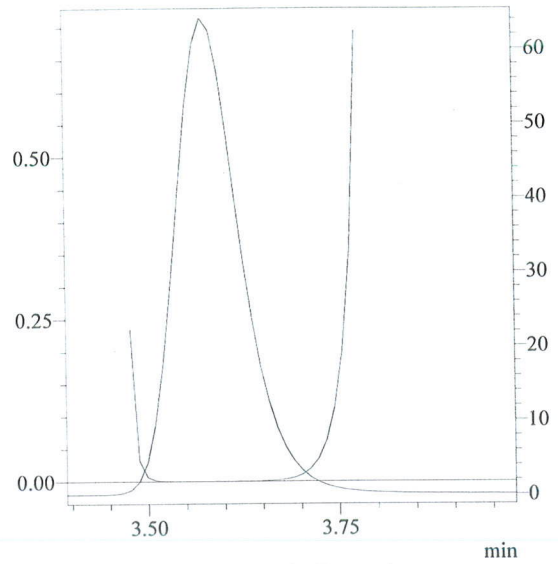
<Peak Purity>

ID# : 1
Retention Time : 2.957 min
Compound Name : ASCORBIC ACID



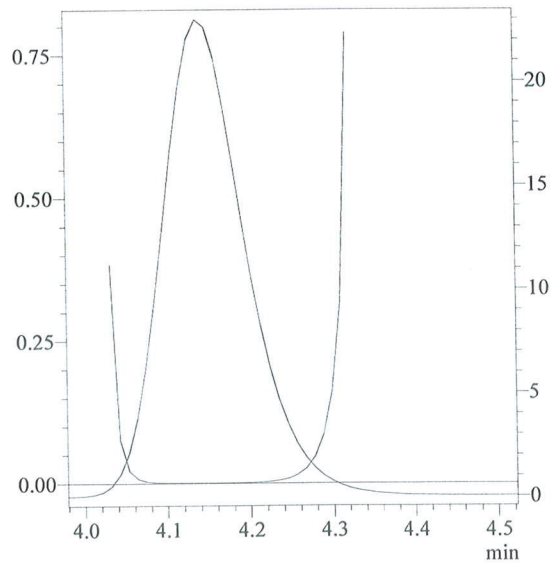
Impurity : Not Detected
Peak purity index : 1.000000
Single point threshold : 0.999972
Minimum peak purity index : 28

ID# : 2
Retention Time : 3.575 min
Compound Name : CHLORPHENIRAMINE MALEATE



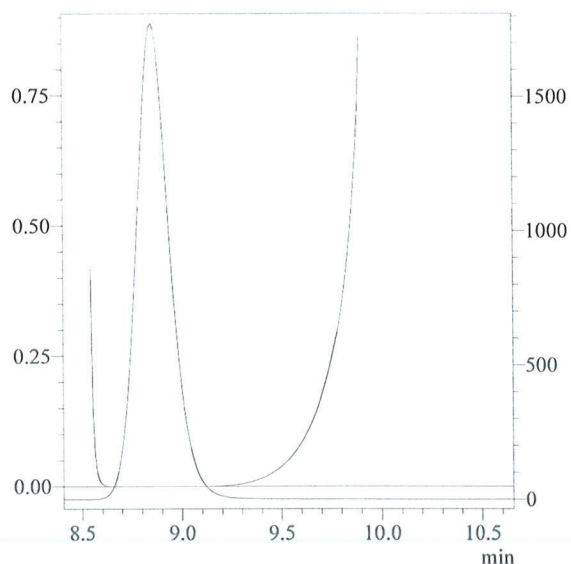
Impurity : Not Detected
Peak purity index : 1.000000
Single point threshold : 0.999900
Minimum peak purity index : 99

ID# : 3
Retention Time : 4.141 min
Compound Name : PHENYLEPHRINE HCL



Impurity : Not Detected
Peak purity index : 1.000000
Single point threshold : 0.999372
Minimum peak purity index : 628

ID# : 4
 Retention Time : 8.853 min
 Compound Name : PARACETAMOL



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999997
 Minimum peak purity index : 3

Peak Table

PDA Ch1 220nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	2.957	1.000000	0.999972	ASCORBIC ACID
2	3.575	1.000000	0.999900	CHLORPHENIRAMINE MALEATE
3	4.141	1.000000	0.999372	PHENYLEPHRINE HCL
4	8.853	1.000000	0.999997	PARACETAMOL
Total				

Analysed By

[Signature]
 16/01/2024

Checked By

[Signature]
 16/01/2024



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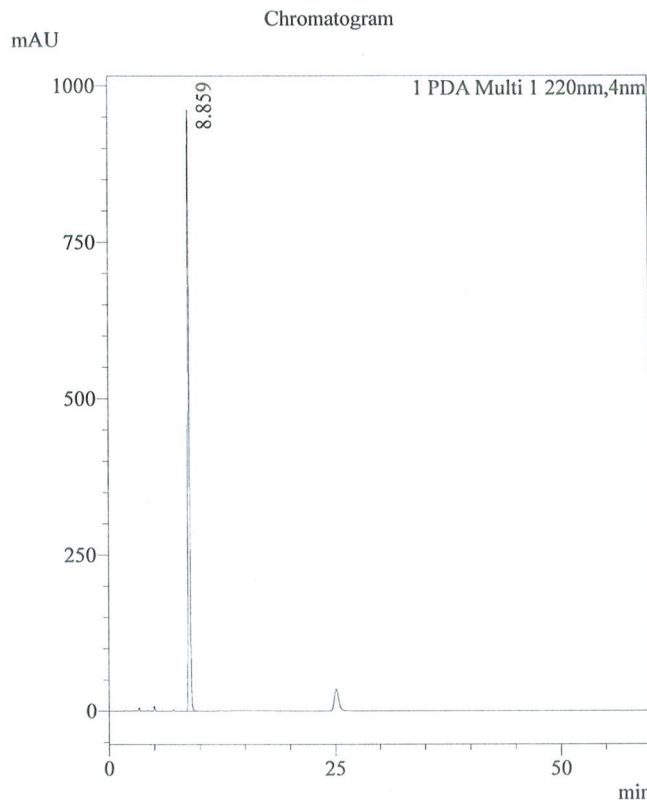
Analysis Report

<Sample Information>

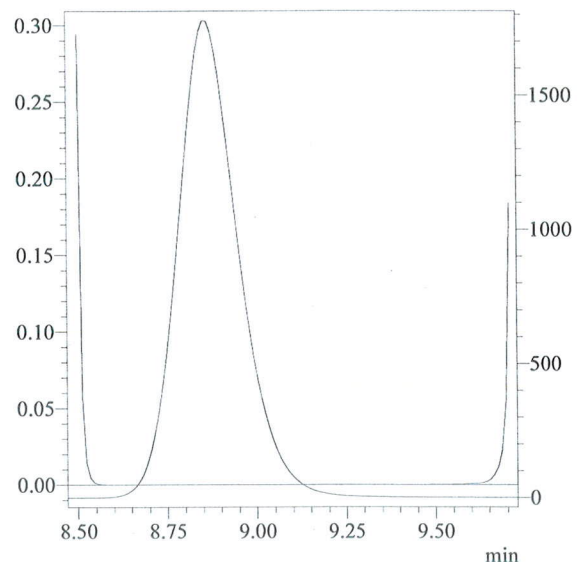
Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO+PARACETAMOL
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-33.lcd
 Method Filename : GRIPEX-RS P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-19
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 02:53:09
 Date Processed : 18-01-2024 19:54:50

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>



ID# : 1
 Retention Time : 8.859 min
 Compound Name : PARACETAMOL



Impurity : Not Detected
 Peak purity index : 0.999999
 Single point threshold : 1.000000
 Minimum peak purity index : 0

PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	8.859	0.999999	1.000000	PARACETAMOL
Total				

Analysed By

[Signature]
18/01/2024

[Signature]
Checked By



GENERIC HEALTHCARE PVT. LTD.

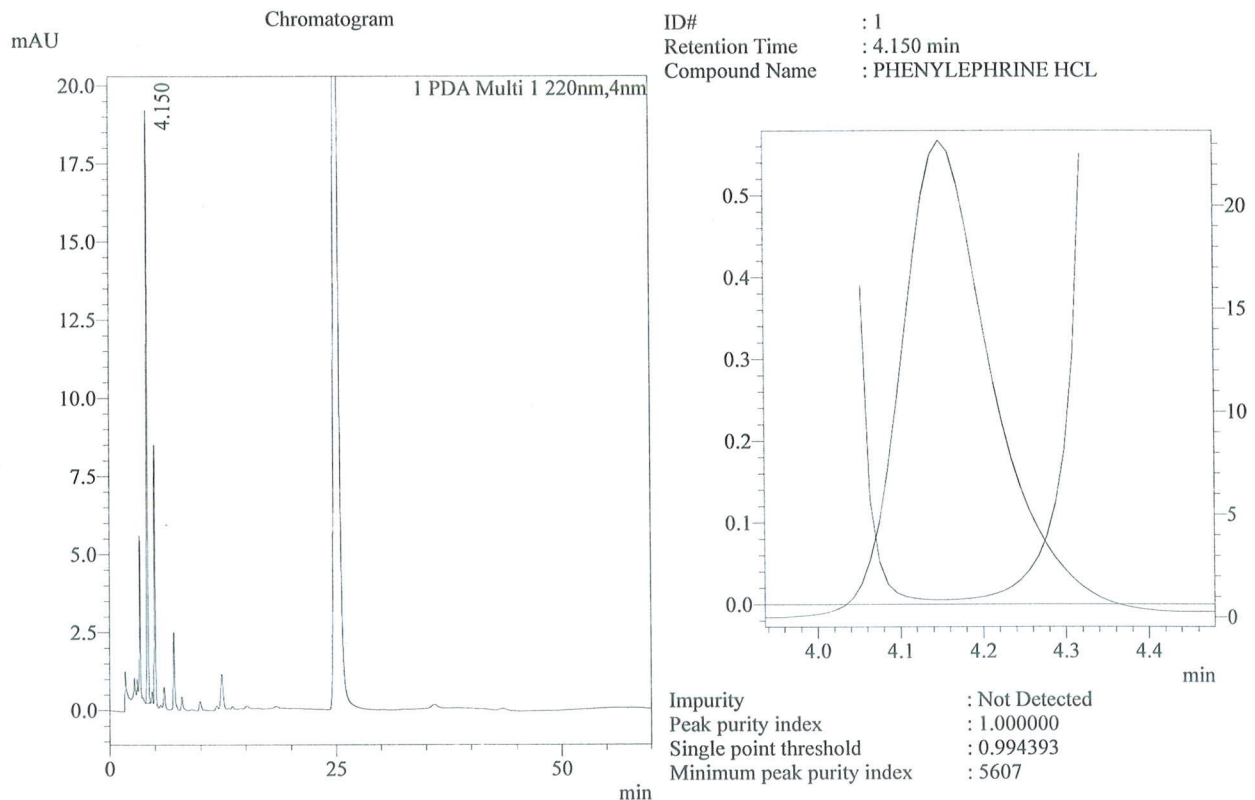
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO+PHENYLEPHRINE HCL
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-34.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-20
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 03:53:42
 Date Processed : 18-01-2024 21:35:18

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>



PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	4.150	1.000000	0.994393	PHENYLEPHRINE HCL
Total				

Analysed By

[Signature]
15/01/2024

Checked By

[Signature]
15/01/2024



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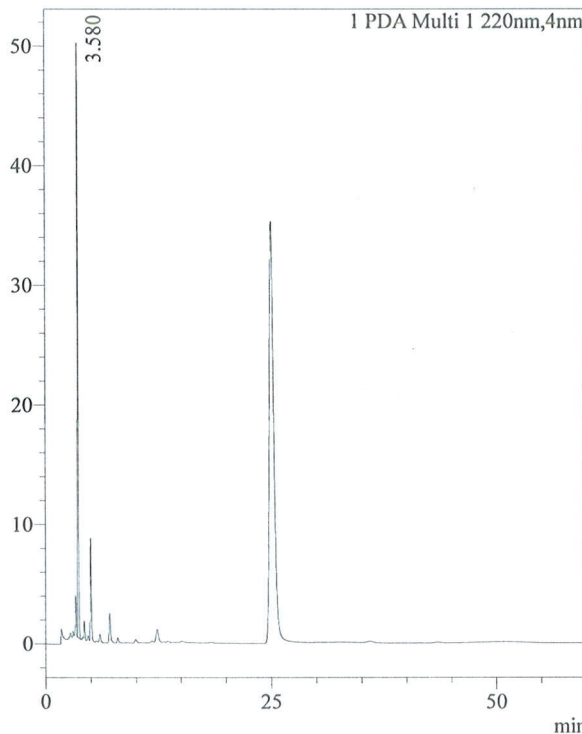
Analysis Report

<Sample Information>

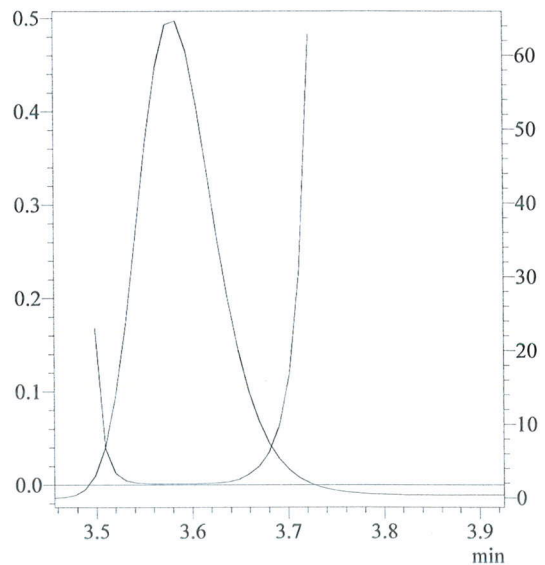
Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO+CHLORPHENIRAMINE
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-35.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-21
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 04:54:14
 Date Processed : 18-01-2024 21:37:07
 Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>

mAU Chromatogram



ID# : 1
 Retention Time : 3.580 min
 Compound Name : CHLORPHENIRAMINE MALEATE



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.998818
 Minimum peak purity index : 1181

PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	3.580	1.000000	0.998818	CHLORPHENIRAMINE MALEATE
Total				

Analysed By

[Signature]
18/01/2024

Checked By

[Signature]


GENERIC HEALTHCARE PVT. LTD.

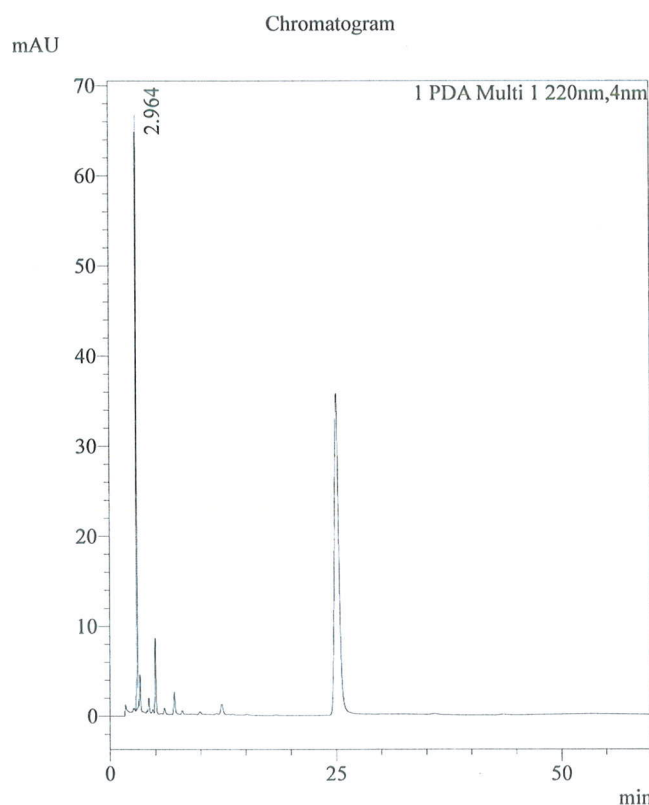
Analysis Report

<Sample Information>

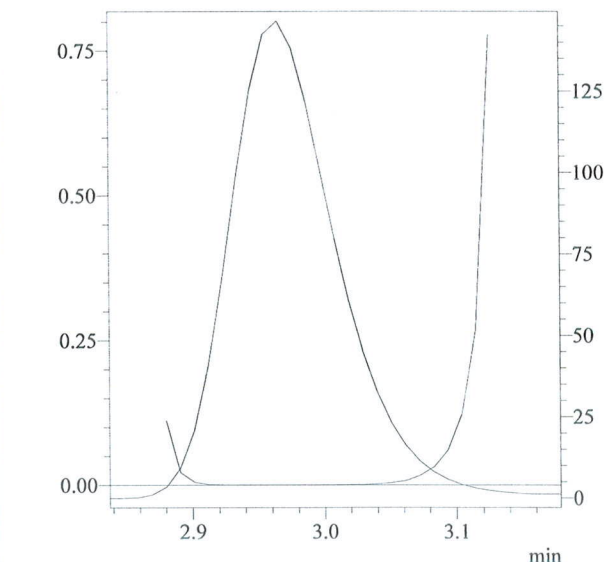
Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO+ASCORBIC ACID
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-36.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-22
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 05:54:48
 Date Processed : 18-01-2024 21:39:51

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>



ID# : 1
 Retention Time : 2.964 min
 Compound Name : ASCORBIC ACID



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999732
 Minimum peak purity index : 267

PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	2.964	1.000000	0.999732	ASCORBIC ACID
Total				

Analysed By

18/01/2024

Checked By


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Analysis Report

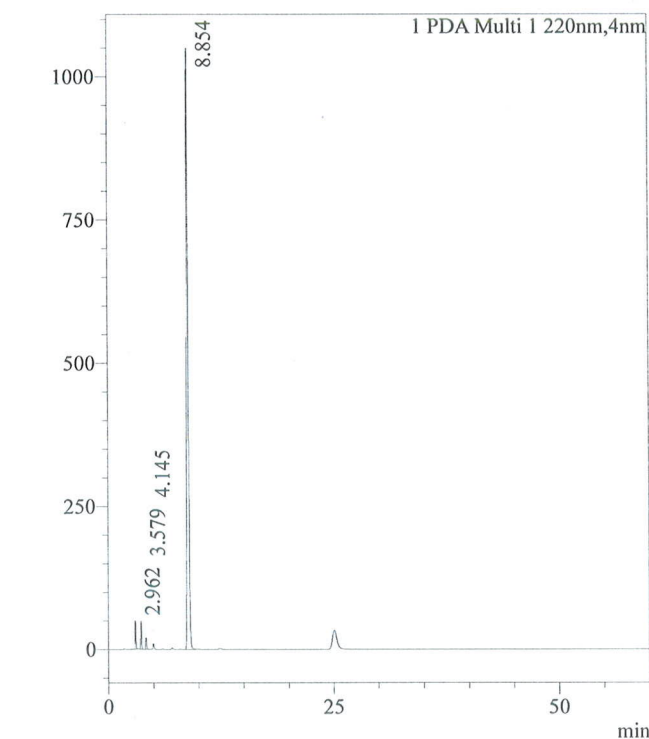
<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : PLACEBO+PARA+PHP+CPM+ASCORBIC
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-37.lcd
 Method Filename : GRIPEX-RS.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-23
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 06:55:21
 Date Processed : 18-01-2024 21:52:06

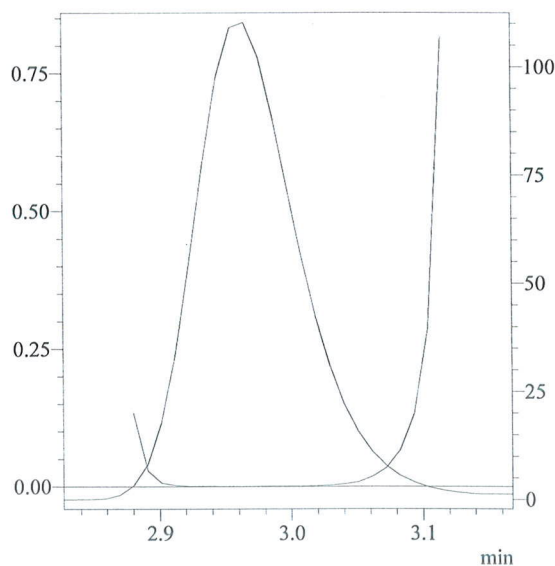
Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>

mAU Chromatogram

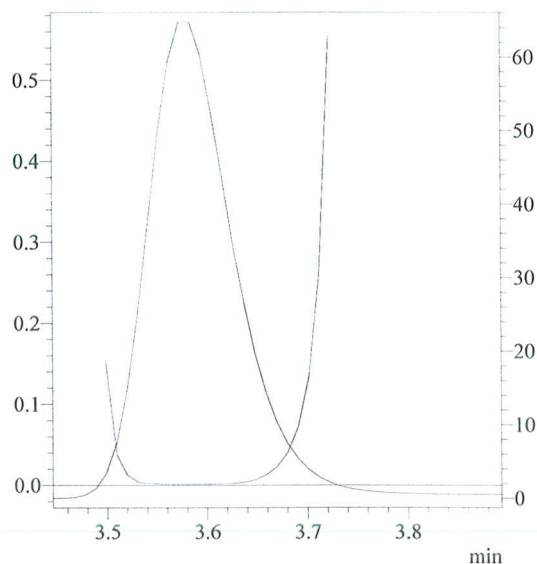


ID# : 1
 Retention Time : 2.962 min
 Compound Name : ASCORBIC ACID



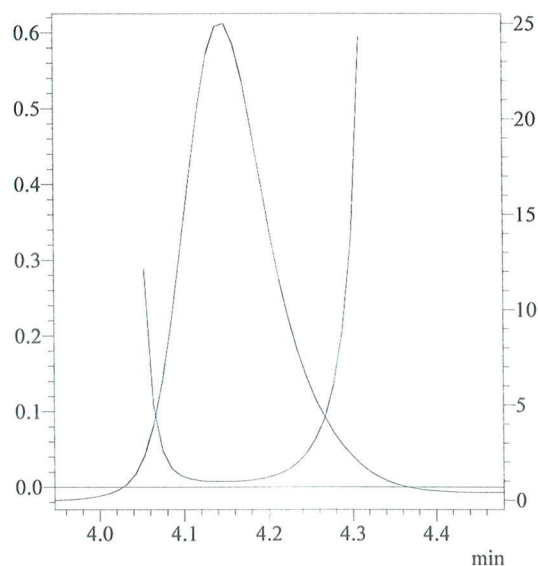
Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999546
 Minimum peak purity index : 453

ID# : 2
Retention Time : 3.579 min
Compound Name : CHLORPHENIRAMINE MALEATE



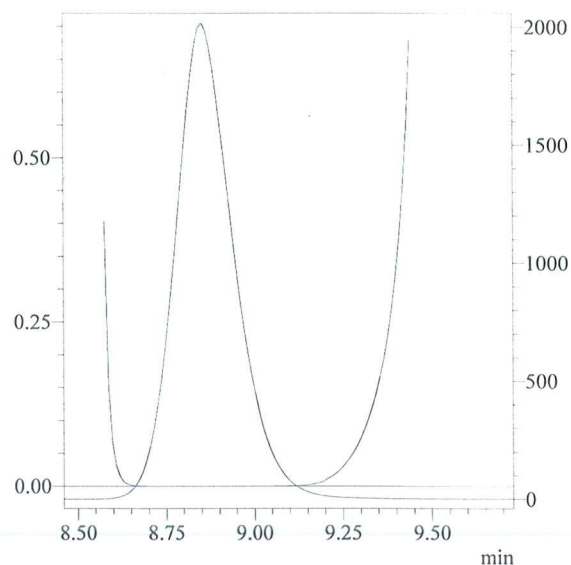
Impurity : Not Detected
Peak purity index : 1.000000
Single point threshold : 0.998698
Minimum peak purity index : 1302

ID# : 3
Retention Time : 4.145 min
Compound Name : PHENYLEPHRINE HCL



Impurity : Not Detected
Peak purity index : 1.000000
Single point threshold : 0.992570
Minimum peak purity index : 7429

ID# : 4
 Retention Time : 8.854 min
 Compound Name : PARACETAMOL



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999933
 Minimum peak purity index : 67

Peak Table

PDA Ch1 220nm

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	2.962	1.000000	0.999546	ASCORBIC ACID
2	3.579	1.000000	0.998698	CHLORPHENIRAMINE MALEATE
3	4.145	1.000000	0.992570	PHENYLEPHRINE HCL
4	8.854	1.000000	0.999933	PARACETAMOL
Total				

Analysed By

[Signature]
 15/01/2024

Checked By

[Signature]
 19/1/2024



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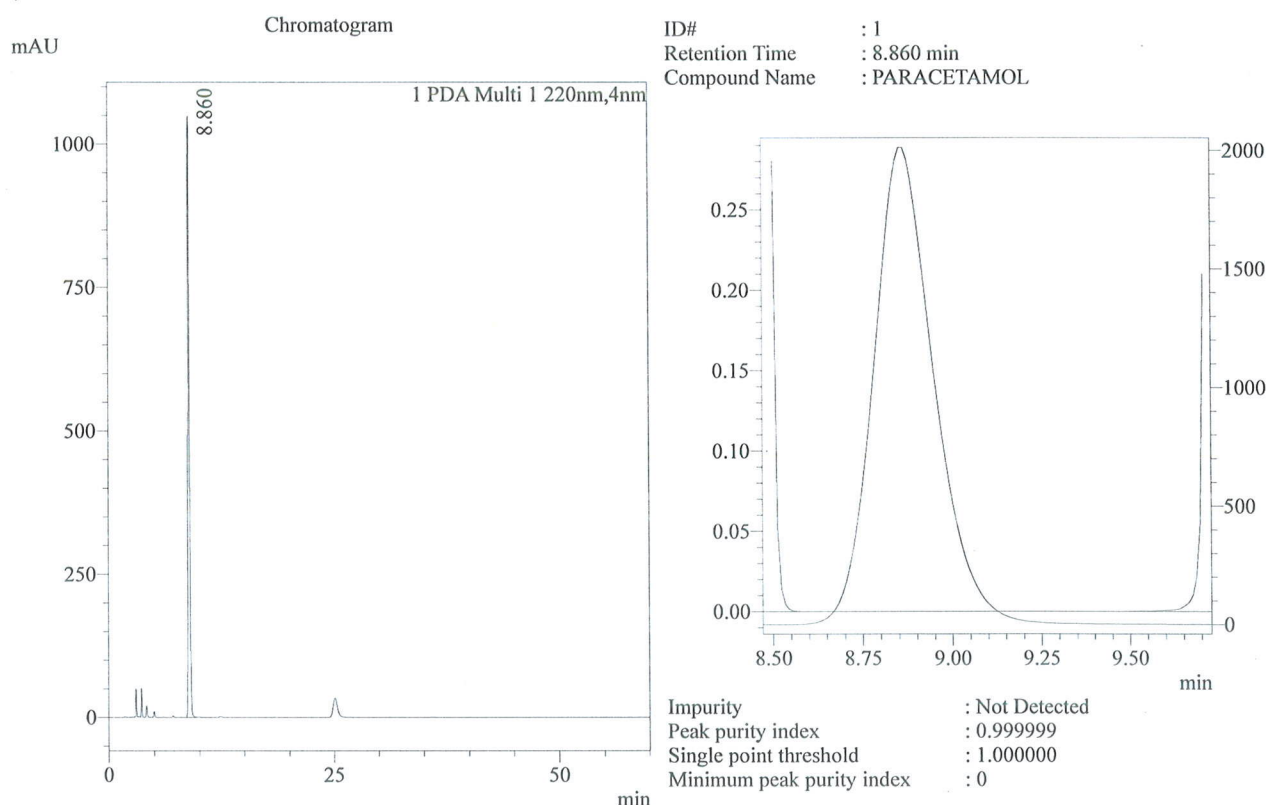
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
 Sample ID : GRIPEX-1228-RS-SPL-2
 Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-40.lcd
 Method Filename : GRIPEX-RS_P.lcm
 Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
 Vial # : 1-24
 Injection Volume : 10 uL
 Date Acquired : 15-01-2024 09:57:01
 Date Processed : 18-01-2024 19:54:50

Acquired by : S.ELAVARASAN
 Processed by : C.K.SARAVANAN

<Peak Purity>



PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	8.860	0.999999	1.000000	PARACETAMOL
Total				

Analysed By

18/01/2024

Checked By

18/01/2024



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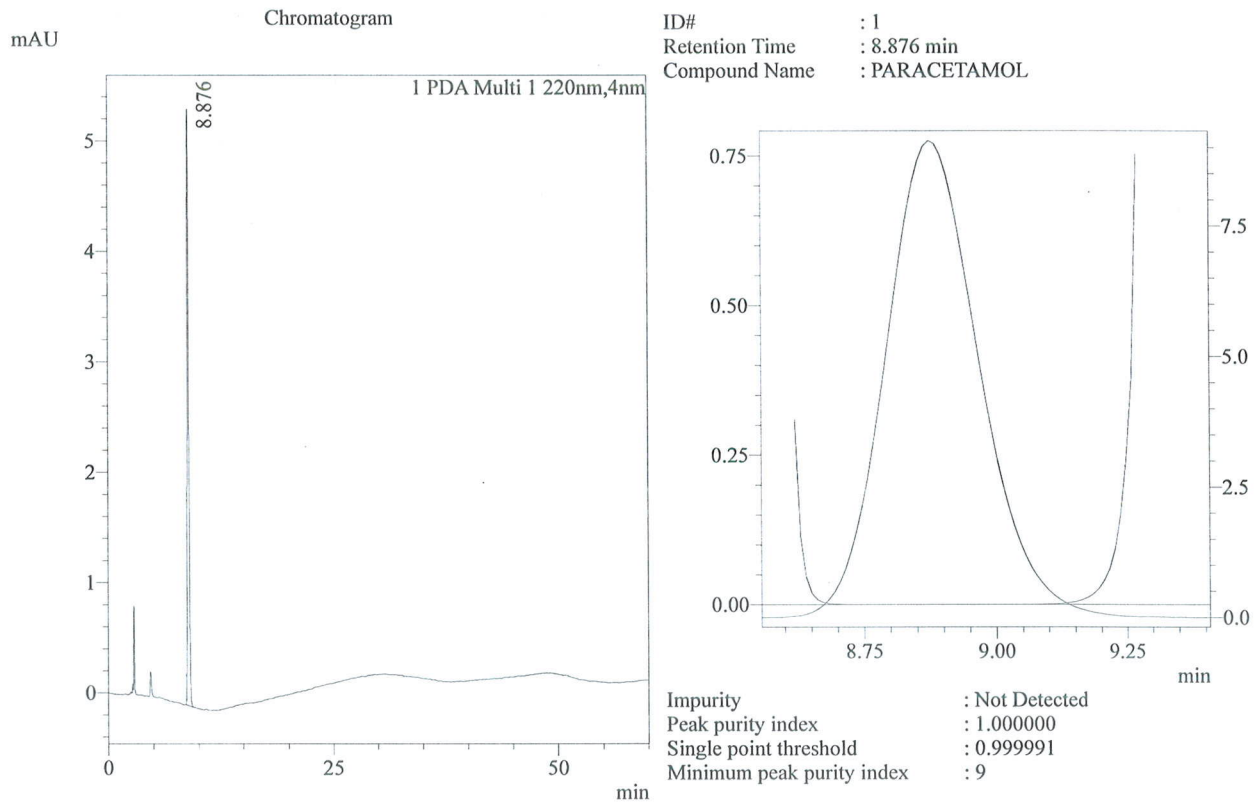
Analysis Report

<Sample Information>

Sample Name : SPECIFICITY-RS
Sample ID : PARACETAMOL-RS-STD-BKT
Data Filename : 13012024 GRIPEX SACHET-MV-INTERMEDIATE PRECISION-RS-SPL-41.lcd
Method Filename : GRIPEX-RS_P.lcm
Batch Filename : 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb
Vial # : 1-12
Injection Volume : 10 uL
Date Acquired : 15-01-2024 10:57:33
Date Processed : 18-01-2024 19:54:51

Acquired by : S.ELAVARASAN
Processed by : C.K.SARAVANAN

<Peak Purity>



PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	8.876	1.000000	0.999991	PARACETAMOL
Total				

Analysed By

[Signature]
18/01/2024

Checked By

[Signature]
18/01/2024



GENERIC HEALTHCARE PVT. LTD.

Batch Table

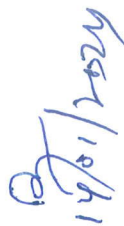
Batch Table 13012024 GRIPEX SACHET-MV-RS-INTERMEDIATE PRECISION.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	1	INTERMEDIATE PRECISION-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-01.lcd	10.0	QC/CL/23/033
2	1	INTERMEDIATE PRECISION-RS	RESOLUTION SOLUTION	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-02.lcd	10.0	QC/CL/23/033
3	1	INTERMEDIATE PRECISION-RS	PARACETAMOL-RS-STD-01	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-03.lcd	10.0	QC/CL/23/033
3	1	INTERMEDIATE PRECISION-RS	PARACETAMOL-RS-STD-02	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-04.lcd	10.0	QC/CL/23/033
3	1	INTERMEDIATE PRECISION-RS	PARACETAMOL-RS-STD-03	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-05.lcd	10.0	QC/CL/23/033
3	1	INTERMEDIATE PRECISION-RS	PARACETAMOL-RS-STD-04	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-06.lcd	10.0	QC/CL/23/033
3	1	INTERMEDIATE PRECISION-RS	PARACETAMOL-RS-STD-05	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-07.lcd	10.0	QC/CL/23/033
3	1	INTERMEDIATE PRECISION-RS	PARACETAMOL-RS-STD-06	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-08.lcd	10.0	QC/CL/23/033
1	1	INTERMEDIATE PRECISION-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-09.lcd	10.0	QC/CL/23/033
4	1	INTERMEDIATE PRECISION-RS	PLACEBO-RS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-10.lcd	10.0	QC/CL/23/033
5	1	INTERMEDIATE PRECISION-RS	GRIPEX-1228-RS-SPL-1	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-11.lcd	10.0	QC/CL/23/033
6	1	INTERMEDIATE PRECISION-RS	GRIPEX-1228-RS-SPL-2	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-12.lcd	10.0	QC/CL/23/033
7	1	INTERMEDIATE PRECISION-RS	GRIPEX-1228-RS-SPL-3	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-13.lcd	10.0	QC/CL/23/033
8	1	INTERMEDIATE PRECISION-RS	GRIPEX-1228-RS-SPL-4	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-14.lcd	10.0	QC/CL/23/033
9	1	INTERMEDIATE PRECISION-RS	GRIPEX-1228-RS-SPL-5	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-15.lcd	10.0	QC/CL/23/033
10	1	INTERMEDIATE PRECISION-RS	GRIPEX-1228-RS-SPL-6	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-16.lcd	10.0	QC/CL/23/033
3	1	INTERMEDIATE PRECISION-RS	PARACETAMOL-RS-STD-BKT	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-17.lcd	10.0	QC/CL/23/033
11	1	SPECIFICITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-18.lcd	10.0	QC/CL/23/033

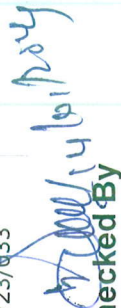
Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
12	1	SPECIFICITY-RS	PARACETAMOL-RS-STD-01	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-19.lcd	10.0	QC/CL/23/033
12	1	SPECIFICITY-RS	PARACETAMOL-RS-STD-02	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-20.lcd	10.0	QC/CL/23/033
12	1	SPECIFICITY-RS	PARACETAMOL-RS-STD-03	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-21.lcd	10.0	QC/CL/23/033
12	1	SPECIFICITY-RS	PARACETAMOL-RS-STD-04	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-22.lcd	10.0	QC/CL/23/033
12	1	SPECIFICITY-RS	PARACETAMOL-RS-STD-05	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-23.lcd	10.0	QC/CL/23/033
12	1	SPECIFICITY-RS	PARACETAMOL-RS-STD-06	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-24.lcd	10.0	QC/CL/23/033
11	1	SPECIFICITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-25.lcd	10.0	QC/CL/23/033
13	1	SPECIFICITY-RS	PARACETAMOL WS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-26.lcd	10.0	QC/CL/23/033
14	1	SPECIFICITY-RS	PHENYLEPHRINE HCL WS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-27.lcd	10.0	QC/CL/23/033
15	1	SPECIFICITY-RS	CHLORPHENIRAMINE MALEATE WS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-28.lcd	10.0	QC/CL/23/033
16	1	SPECIFICITY-RS	ASCORBIC ACID WS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-29.lcd	10.0	QC/CL/23/033
17	1	SPECIFICITY-RS	PARA+PHP+CPM+ASCORBIC ACID WS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-30.lcd	10.0	QC/CL/23/033
11	1	SPECIFICITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-31.lcd	10.0	QC/CL/23/033
18	1	SPECIFICITY-RS	PLACEBO-RS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-32.lcd	10.0	QC/CL/23/033
19	1	SPECIFICITY-RS	PLACEBO+PARACETAMOL	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-33.lcd	10.0	QC/CL/23/033
20	1	SPECIFICITY-RS	PLACEBO+PHENYLEPHRINE HCL	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-34.lcd	10.0	QC/CL/23/033
21	1	SPECIFICITY-RS	PLACEBO+CHLORPHENIRAMINE	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-35.lcd	10.0	QC/CL/23/033
22	1	SPECIFICITY-RS	PLACEBO+ASCORBIC ACID	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-36.lcd	10.0	QC/CL/23/033
23	1	SPECIFICITY-RS	PLACEBO+PARA+PHP+CPM+ASCORBIC ACID WS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-37.lcd	10.0	QC/CL/23/033
11	1	SPECIFICITY-RS	BLANK-RS	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-38.lcd	10.0	QC/CL/23/033
24	1	SPECIFICITY-RS	GRIPEX-1228-RS-SPL-1	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-39.lcd	10.0	QC/CL/23/033
24	1	SPECIFICITY-RS	GRIPEX-1228-RS-SPL-2	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-40.lcd	10.0	QC/CL/23/033
12	1	SPECIFICITY-RS	PARACETAMOL-RS-STD-BKT	METHOD\GRIPEX-RS.lcm	ISION-RS-SPL-41.lcd	10.0	QC/CL/23/033

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
-1	1	SPECIFICITY-RS	WASH	IOD\WASH METHOD.lcm	ISION-RS-SPL-42.lcd	10.0	QC/CL/23/033
-1	1	SPECIFICITY-RS	SHUT	HUTDOWN METHOD.lcm	ISION-RS-SPL-43.lcd	10.0	QC/CL/23/033

Analysed By


14/01/2024

Checked By


14/01/2024

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET**

Title

RELATED SUBSTANCES OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Parameter :	ROBUSTNESS	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

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

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID :	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard Dilution :	60.14	mg to --->	100	ml to --->	5	ml to ---->	100
Std.conc (in ppm)-3.007	5	ml to --->	50	ml to --->	1	ml to ---->	1

Test dilution .:	415.15	mg to --->	100	ml to --->	1	ml to ---->	1
Test.conc (in ppm)-599.6611	1	ml to --->	1	ml to --->	1	ml to ---->	1

Chromatographic variation's	Tailing factor	Theoretical plate	RSD %	Single Maximum Unknown Imp (%)	% RSD	Total Impurities(%)	% RSD
Low wavelength (217nm)	1.07	15303	0.442	Not detected	Nil	Not detected	Nil
High wavelength (223nm)	1.06	14981	0.255	Not detected		Not detected	
Low flow rate (0.9ml/minute)	1.06	15612	0.719	Not detected		Not detected	
High flow rate (1.1ml/minute)	1.05	13595	0.303	Not detected		Not detected	
Low oven temperature	1.06	13937	2.045	Not detected		Not detected	
High Oven temperature	1.05	13375	0.334	Not detected		Not detected	

Results:

- 1) % RSD of impurities within limits.
- 2) Each chromatographic variation System suitability parameters are within limits

Acceptance criteria:

- 1) % RSD for Single maximum unknown Impurities above to 0.1% should not be more than 20%.
- 2) % RSD for Total unknown Impurities above 0.1% should not be more than 15%.

Analysed by :
Date :

E.MEENA
22-01-2024

Checked by
Date :

[Signature]
23/01/2024



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	WAVELENGTH CHANGE (LOW WAVELENGTH AT 217NM)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
----------------	-------------	-------------	--------------	---------	--------------	----------------	------

Standard dilution.:	60.14	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.007	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.15	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.66	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labeled content :	650 mg
Average weight :	4500.0 mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	63296	63449	63923	63303	63167	63195	63389	279.9	0.442
With Bracketing std.	62996						63333	295.5	0.467

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.429
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.989
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	21.414

SINGLE MAXIMUM UNKNOWN IMPURITIY

Limit: NMT 0.50%

Calculation formula :

Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

0
63389
ND
0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :

Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

0
63389
ND
0.00

Analysed by :

E.MEENA

Date :

22-01-2024

Checked by :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	WAVELENGTH CHANGE (HIGH WAVELENGTH AT 223NM)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

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

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
----------------	-------------	-------------	--------------	---------	--------------	----------------	------

Standard dilution.:	60.14	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.007	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.15	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.66	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	76700	77019	77227	77160	76997	76839	76990	196.4	0.255
With Bracketing std.	76849						76970	187.1	0.243

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.434
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.834
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	21.164

SINGLE MAXIMUM UNKNOWN IMPURIT

Limit: NMT 0.50%

Calculation formula :

Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

0
76990
ND
0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :

Total impurities in%	Total impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

0
76990
ND
0.00

Analysed by : E.MEENA
Date : 22-01-2024

22/01/24

Checked by :
Date :

23/01/2024



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	FLOW RATE CHANGE (LOW FLOW RATE 0.9ML/MINUTE)	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QCLC/007	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.14	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.007	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.15	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.661	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	74944	76297	75036	74954	75527	74975	75289	541.6	0.719
With Bracketing std.	75350						75298	494.9	0.657

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.				0
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			0	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.659
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.969
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	21.818

SINGLE MAXIMUM UNKNOWN IMPURTY

Limit: NMT 0.50%

Calculation formula :		0
		75289
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100 Standard area x sample dilution X Label claim x 100	ND 0.00

TOTAL IMPURITIES

Limit: NMT 1.00%

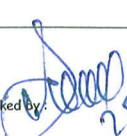
Calculation formula :		0
		75289
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100 Standard area x sample dilution X Label claim x 100	ND 0.00

Analysed by : E.MEENA
Date : 22-01-2024

22/01/24

Checked by :
Date : 22/01/2024



		GENERIC HEALTHCARE PVT.LTD								
QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET										
Title		RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET								
Product Name :	GRIPEX					Batch size :	Not applicable			
Batch Number :	G17231228					Mfg.Date :	Dec-23			
Stage :	COLUMN TEMPERATURE CHANGE (AT OVEN TEMPERATURE 35°C)					Exp.Date :	Nov-26			
Each 4.5 gm sachet contains: Paracetamol BP ----- 650 mg Chlorphenamine Maleate BP ----- 20 mg Phenylephrine Hydrochloride BP ----- 10 mg Ascorbic Acid BP----- 50 mg										
RELATED SUBSTANCE OF PARACETAMOL										
Instrument ID:	ST/QCLC/007		Balance ID:	ST/QC/EQ/041		WS No.:	ST/WS/23/012		% Purity (aib)	99.9
Standard dilution.:	60.14	mg to --->	100	ml to --->	5	ml to --->	100			
Std.conc (in ppm)-3.007	5	ml to --->	50	ml to --->	1	ml to --->	1			
Test dilution.:	415.15	mg to --->	100	ml to --->	1	ml to --->	1			
Test.conc (in ppm)-599.661	1	ml to --->	1	ml to --->	1	ml to --->	1			
Conversion factor :	1.0000									
Labelled content :	650 mg									
Average weight :	4500.0 mg									
System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %	
Paracetamol	68279	67834	67855	67687	67714	67684	67842	226.5	0.334	
With Bracketing std.	68099						67879	228.4	0.337	
	Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area					
	UNKNOWN Imp.				0					
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	UNKNOWN Imp.									
	Total Impurity Area			0						
SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0					3.989				
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0					3.506				
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0					19.226				
SINGLE MAXIMUM UNKNOWN IMPURITIY								Limit: NMT 0.50%		
								0		
Calculation formula :								67842		
Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100									
	Standard area x sample dilution X Label claim x 100					ND 0.000				
TOTAL IMPURITIES								Limit: NMT 1.00%		
								0		
Calculation formula :								67842		
Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100									
	Standard area x sample dilution X Label claim x 100					ND 0.00				
Analysed by :	E.MEENA		22/01/24		Checked By: 					
Date :	22-01-2024				Date: 23/01/2024					



GENERIC HEALTHCARE PVT. LTD.

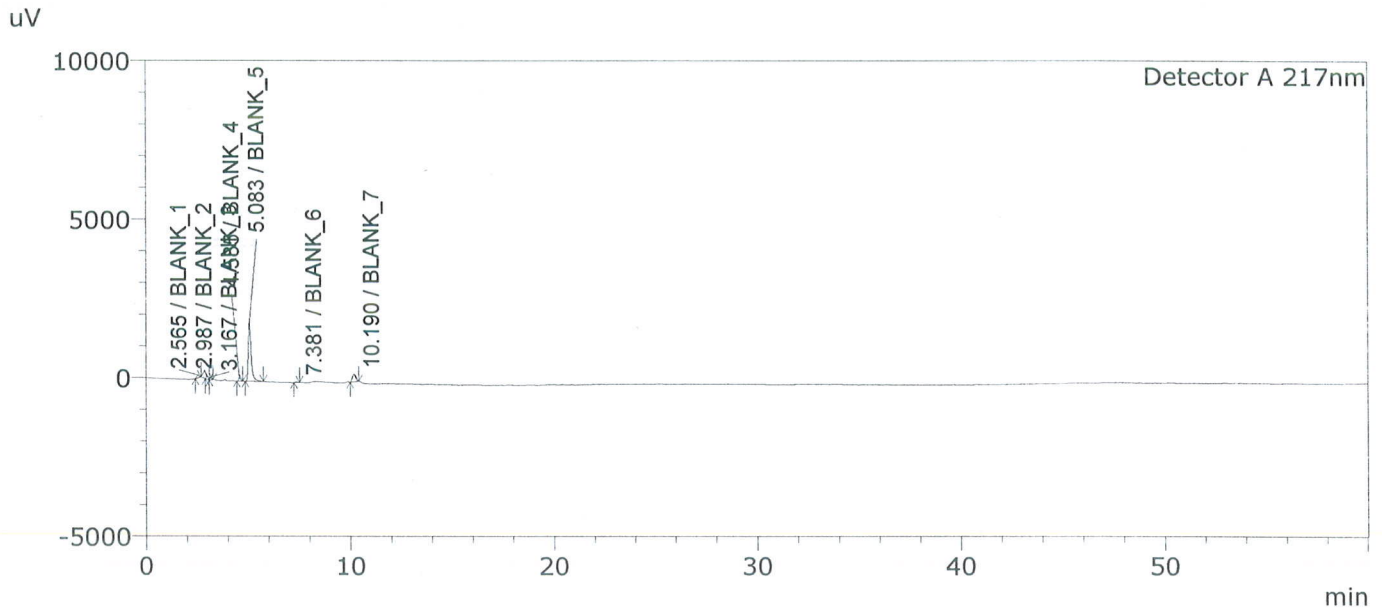
Analysis Report

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Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-LWL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-01.lcd
 Method Filename : GRIPEX-SACH-LWL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/18/2024 6:23:39 PM
 Date Processed : 1/22/2024 12:28:29 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 217nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.57	679	2.89	2403	1.000	--	--
2	BLANK_2	2.99	694	2.95	5202	1.236	2.249	--
3	BLANK_3	3.17	507	2.16	7601	1.357	1.156	--
4	BLANK_4	4.59	685	2.91	10286	1.118	8.700	--
5	BLANK_5	5.08	18137	77.17	6668	1.606	2.317	--
6	BLANK_6	7.38	255	1.09	18115	1.071	9.814	--
7	BLANK_7	10.19	2546	10.83	19356	1.035	10.965	--
Total			23501	100.00				

Analysed By

Checked By


GENERIC HEALTHCARE PVT. LTD.

Analysis Report

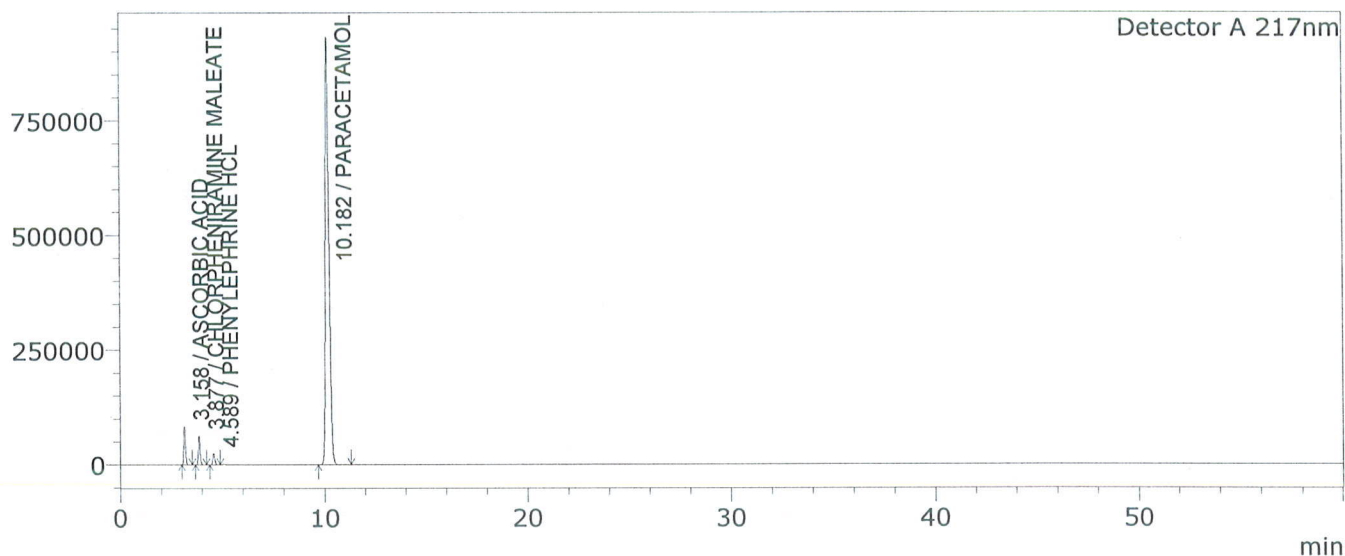
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Sample Name : ROBUSTNESS-RS
 Sample ID : RESOLUTION SOLUTION-LWL
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-02.lcd
 Method Filename : GRIPEX-SACH-LWL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 1/18/2024 7:24:20 PM
 Date Processed : 1/22/2024 12:29:34 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

uV



<Peak Table>

Detector A 217nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	3.16	468021	3.73	6264	1.264	--	--
2	CHLORPHENIRAMINE MALEATE	3.88	369514	2.95	8799	1.229	4.429	--
3	PHENYLEPHRINE HCL	4.59	170304	1.36	9184	1.173	3.989	--
4	PARACETAMOL	10.18	11527572	91.96	15155	1.108	21.414	--
Total			12535411	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

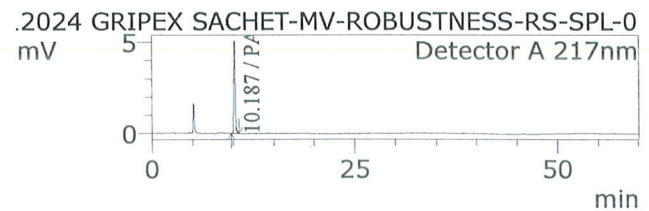
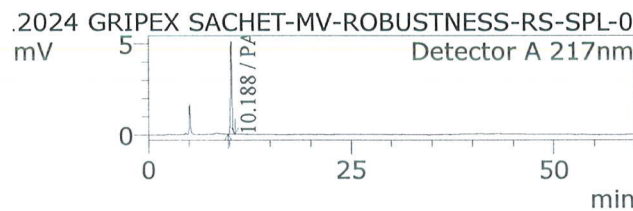
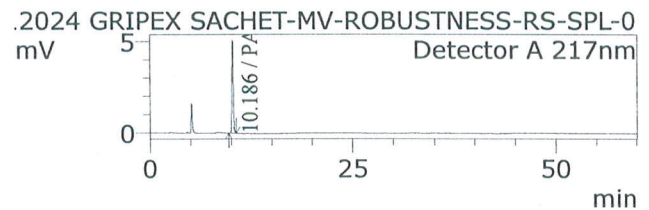
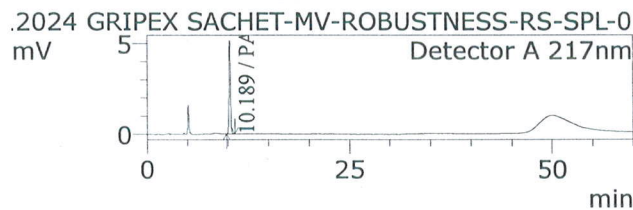
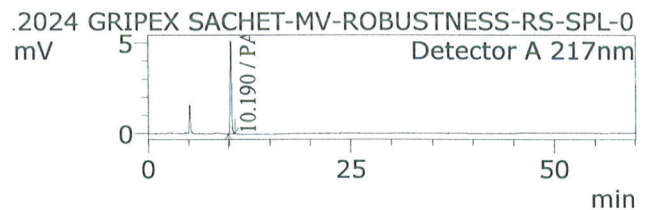
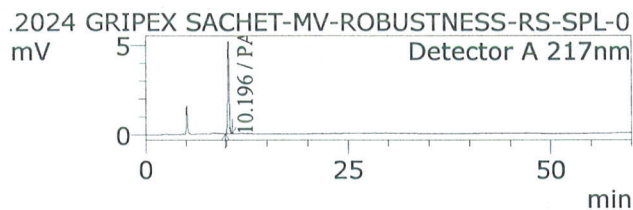
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-LWL-STD-01
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-03.lcd
 Method Filename : GRIPEX-SACH-LWL-RS_P.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/18/2024 8:25:01 PM
 Date Processed : 1/22/2024 12:37:47 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-03.lcd	PARACETAMOL-RS-LWL-STD-01	10.20	63296	15533	1.06
3	RS-SPL-04.lcd	PARACETAMOL-RS-LWL-STD-02	10.19	63449	15334	1.07
3	RS-SPL-05.lcd	PARACETAMOL-RS-LWL-STD-03	10.19	63923	15173	1.07
3	RS-SPL-06.lcd	PARACETAMOL-RS-LWL-STD-04	10.19	63303	15298	1.07
3	RS-SPL-07.lcd	PARACETAMOL-RS-LWL-STD-05	10.19	63167	15244	1.07
3	RS-SPL-08.lcd	PARACETAMOL-RS-LWL-STD-06	10.19	63195	15233	1.07
	Average		10.19	63389	15303	1.07
	%RSD		0.034	0.442	0.823	0.308

Analysed By

Checked By



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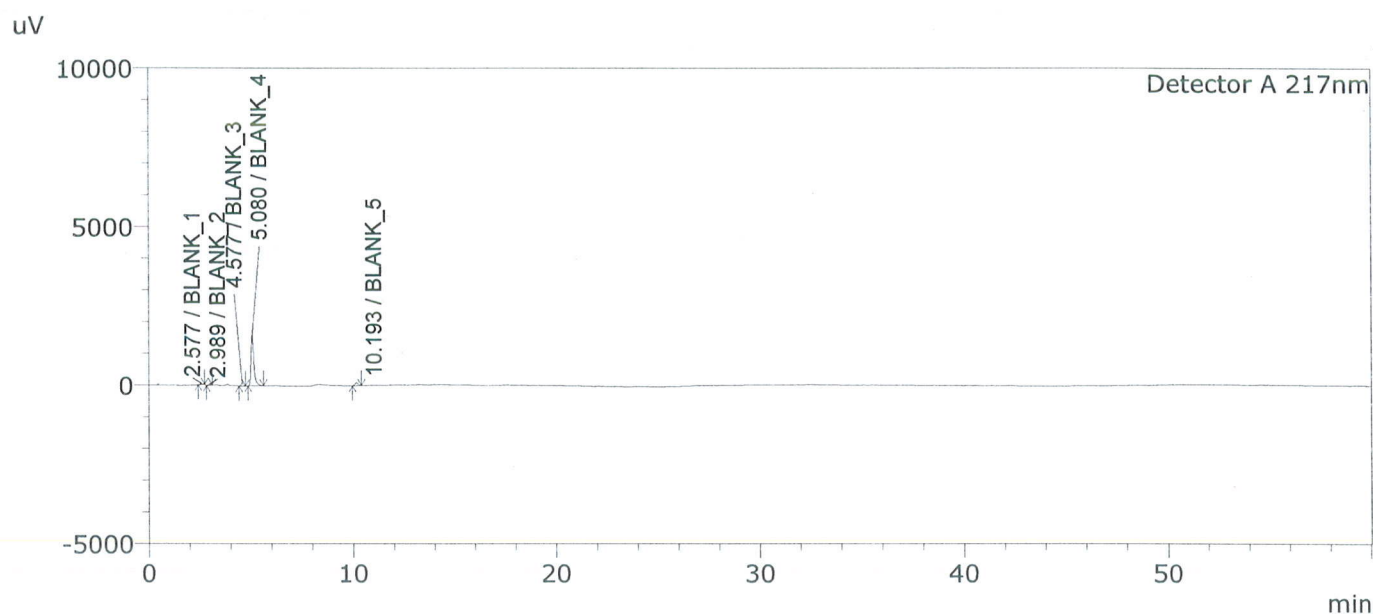
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-LWL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-09.lcd
 Method Filename : GRIPEX-SACH-LWL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 2:29:05 AM
 Date Processed : 1/22/2024 12:39:24 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 217nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.58	332	1.84	2428	1.166	--	--
2	BLANK_2	2.99	325	1.80	2627	1.018	1.859	--
3	BLANK_3	4.58	663	3.67	10025	1.171	7.635	--
4	BLANK_4	5.08	15735	87.04	6558	1.626	2.318	--
5	BLANK_5	10.19	1024	5.66	18123	1.086	18.466	--
Total			18079	100.00				

22/01/24

Analysed By

23/01/2024

Checked By



GENERIC HEALTHCARE PVT. LTD.

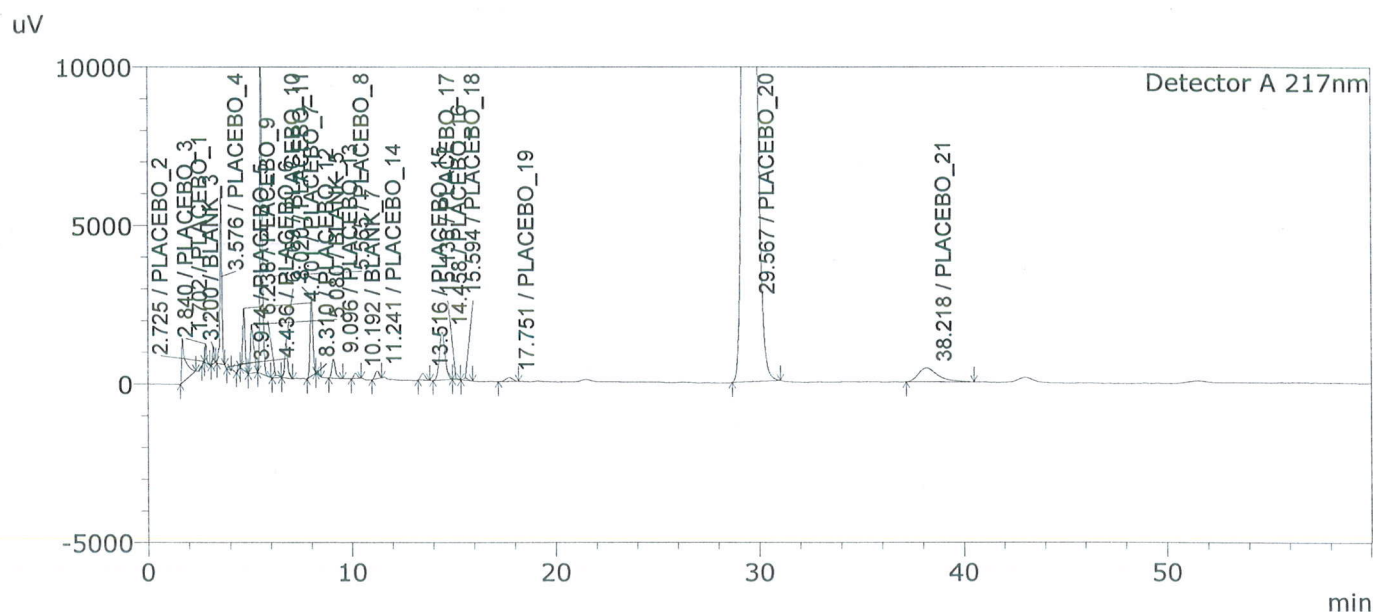
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PLACEBO-LWL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-10.lcd
 Method Filename : GRIPEX-SACH-LWL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 3:29:46 AM
 Date Processed : 1/22/2024 11:49:40 AM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 217nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	19029	1.01	839	4.759	--	--
2	PLACEBO_2	2.73	268	0.01	11953	0.826	6.114	--
3	PLACEBO_3	2.84	2852	0.15	6188	1.432	0.945	--
4	BLANK_3	3.20	2714	0.14	7470	1.111	2.459	--
5	PLACEBO_4	3.58	33417	1.77	6997	0.856	2.355	--
6	PLACEBO_5	3.91	519	0.03	4660	1.554	1.691	--
7	PLACEBO_6	4.44	930	0.05	14242	0.949	2.761	--
8	PLACEBO_7	4.70	15015	0.80	7924	1.040	1.474	--
9	BLANK_5	5.08	17307	0.92	4902	1.525	1.512	--
10	PLACEBO_8	5.56	82089	4.36	10604	1.168	1.914	--
11	PLACEBO_9	6.24	1272	0.07	3939	1.476	2.195	--
12	PLACEBO_10	6.77	11634	0.62	9764	1.254	1.581	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	8.02	24421	1.30	14546	1.025	4.631	--
14	PLACEBO_12	8.31	340	0.02	32018	1.459	1.285	--
15	PLACEBO_13	9.10	7328	0.39	13569	1.437	3.154	--
16	BLANK_7	10.19	2024	0.11	16133	1.146	3.462	--
17	PLACEBO_14	11.24	3044	0.16	15667	1.045	3.084	--
18	PLACEBO_15	13.52	3403	0.18	15918	1.144	5.776	--
19	PLACEBO_16	14.46	28906	1.53	13092	1.093	2.018	--
20	PLACEBO_17	15.14	491	0.03	32153	1.100	1.607	--
21	PLACEBO_18	15.59	1134	0.06	24611	1.247	1.246	--
22	PLACEBO_19	17.75	3049	0.16	12219	0.914	4.148	--
23	PLACEBO_20	29.57	1594425	84.61	18339	1.129	15.592	--
24	PLACEBO_21	38.22	28857	1.53	8604	1.492	6.862	--
Total			1884468	100.00				

Analysed By

22/10/24

Checked By

25/10/24



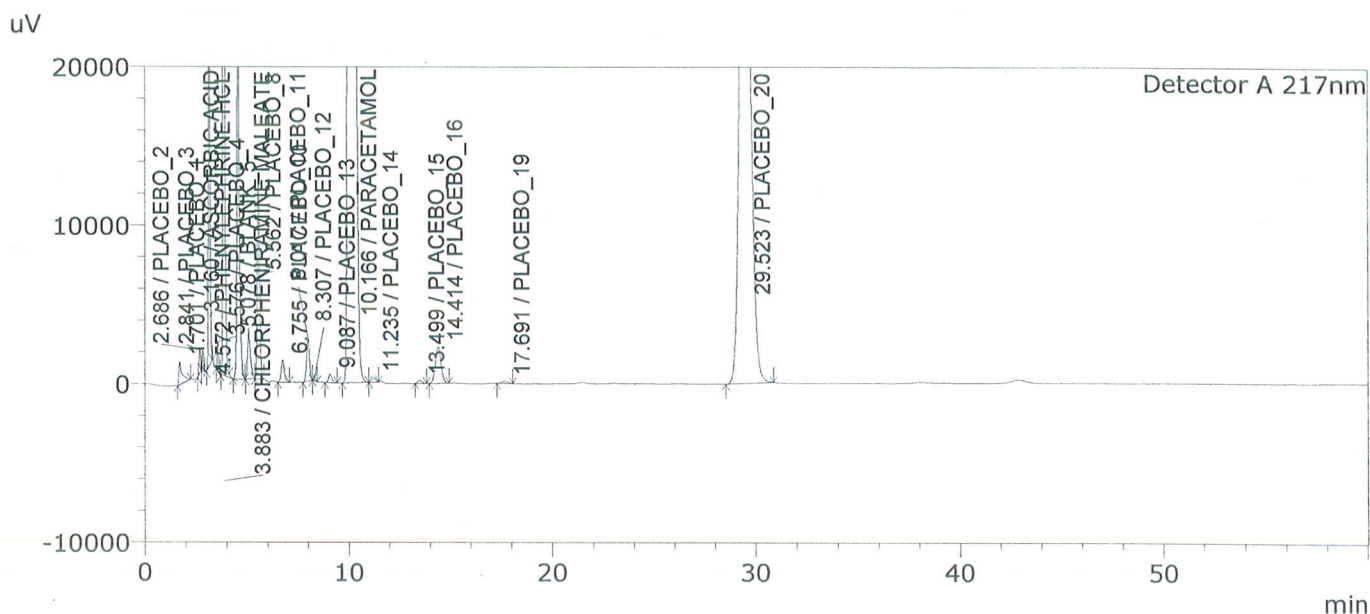
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : GRIPEX-1228-LWL-RS-SPL
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-11.lcd
 Method Filename : GRIPEX-SACH-LWL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 4:31:11 AM
 Date Processed : 1/22/2024 11:45:51 AM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 217nm

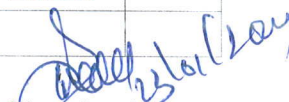
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16724	0.11	1001	3.992	--	--
2	PLACEBO_2	2.69	7884	0.05	4978	1.048	5.365	--
3	PLACEBO_3	2.84	5248	0.03	7790	1.222	1.102	--
4	ASCORBIC ACID	3.16	125238	0.83	6650	1.175	2.249	--
5	PLACEBO_4	3.58	10021	0.07	8056	1.245	2.644	--
6	CHLORPHENIRAMINE MALEATE	3.88	328719	2.19	8896	1.207	1.896	--
7	PHENYLEPHRINE HCL	4.57	189963	1.26	8502	1.386	3.799	--
8	BLANK_5	5.08	28995	0.19	5976	1.500	2.195	--
9	PLACEBO_8	5.56	96033	0.64	10830	1.118	2.027	--
10	PLACEBO_10	6.76	15529	0.10	8946	1.156	4.781	--
11	PLACEBO_11	8.02	26496	0.18	14083	0.965	4.540	--
12	PLACEBO_12	8.31	470	0.00	30331	1.493	1.255	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_13	9.09	6159	0.04	13541	1.163	3.101	--
14	PARACETAMOL	10.17	12623307	83.98	14674	1.086	3.330	--
15	PLACEBO_14	11.24	3588	0.02	16951	1.020	3.142	--
16	PLACEBO_15	13.50	2901	0.02	16449	1.213	5.908	--
17	PLACEBO_16	14.41	44291	0.29	12883	1.081	1.970	--
18	PLACEBO_19	17.69	2758	0.02	14712	1.020	6.006	--
19	PLACEBO_20	29.52	1497596	9.96	17854	1.092	16.128	--
Total			15031919	100.00				

Analysed By


22/01/24

Checked By


23/01/24



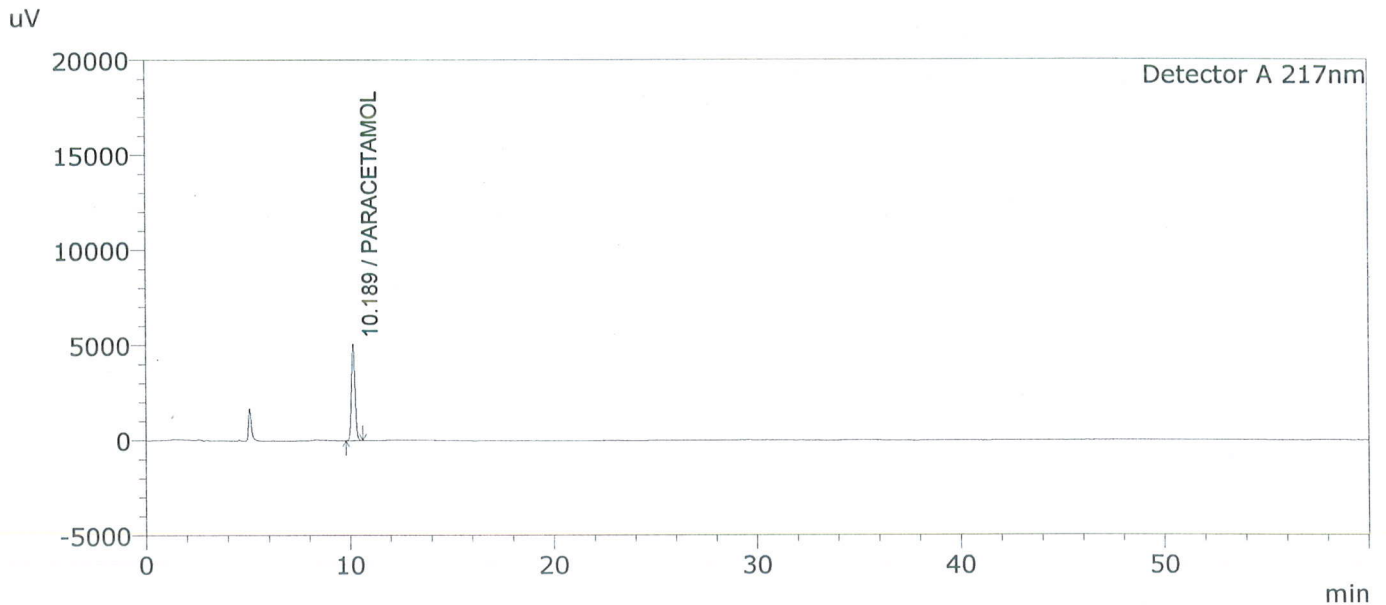
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-LWL-STD-BKT
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-12.lcd
 Method Filename : GRIPEX-SACH-LWL-RS_P.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 5:31:06 AM
 Date Processed : 1/22/2024 12:37:48 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 217nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	62996	100.00	15083	1.065	--	--
Total			62996	100.00				

Analysed By

Checked By



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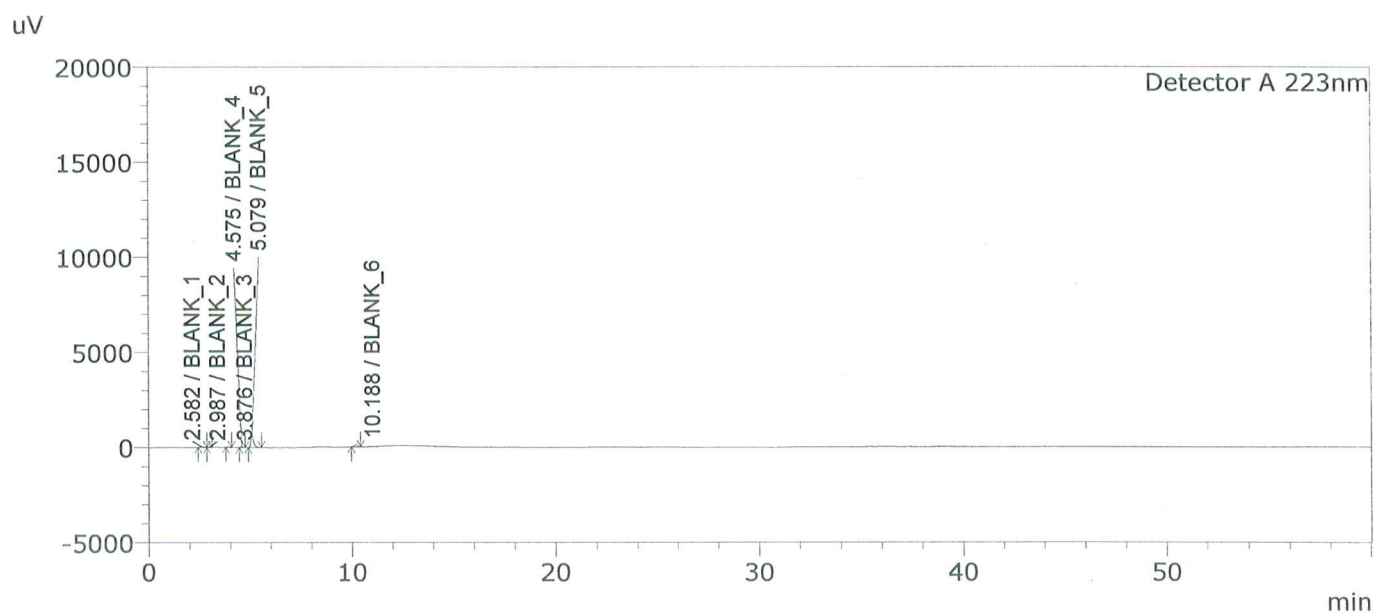
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-HWL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-13.lcd
 Method Filename : GRIPEX-SACH-HWL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 6:31:51 AM
 Date Processed : 1/22/2024 12:44:07 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 223nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.58	634	7.06	337	1.569	--	--
2	BLANK_2	2.99	220	2.45	3669	1.070	1.065	--
3	BLANK_3	3.88	216	2.40	8276	1.670	4.837	--
4	BLANK_4	4.58	428	4.76	9047	1.146	3.853	--
5	BLANK_5	5.08	6180	68.80	6580	1.598	2.274	--
6	BLANK_6	10.19	1305	14.53	17461	1.080	18.284	--
Total			8983	100.00				

Analysed By

Checked By



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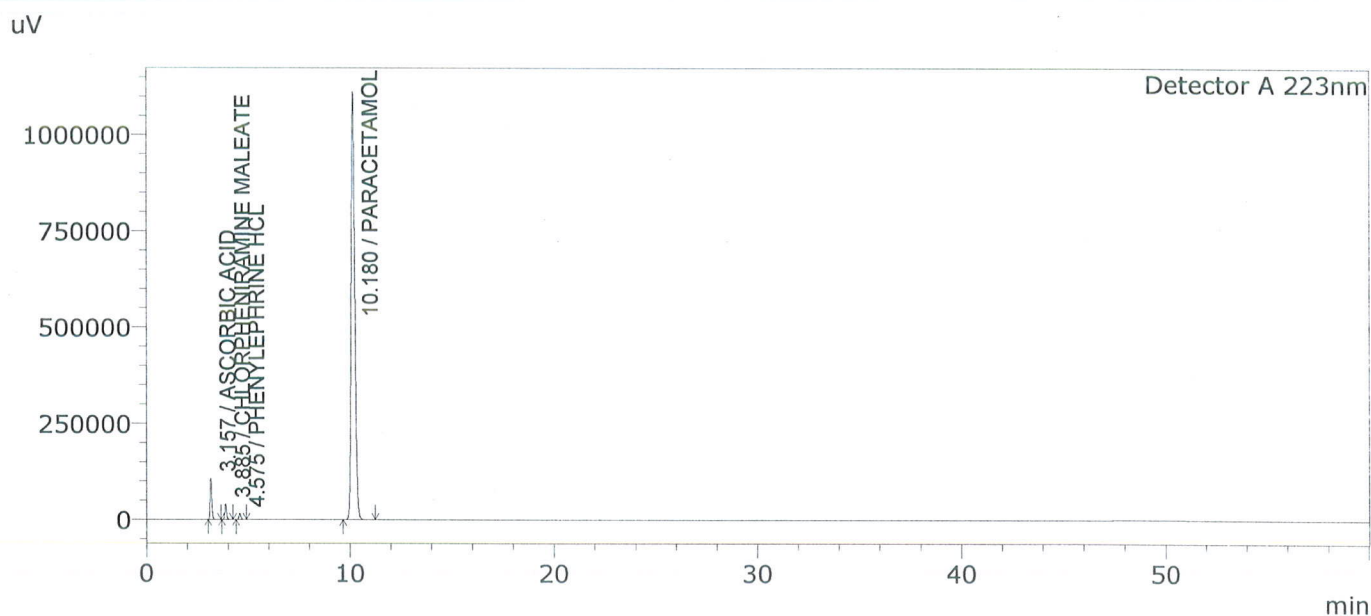
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : RESOLUTION SOLUTION-HWL
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-14.lcd
 Method Filename : GRIPEX-SACH-HWL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 7:32:31 AM
 Date Processed : 1/22/2024 12:45:31 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 223nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	3.16	615901	4.11	6124	1.258	--	--
2	CHLORPHENIRAMINE MALEATE	3.88	239090	1.60	8651	1.218	4.434	--
3	PHENYLEPHRINE HCL	4.58	111734	0.75	8976	1.169	3.834	--
4	PARACETAMOL	10.18	14014489	93.55	14645	1.109	21.164	--
Total			14981215	100.00				

Analysed By

Checked By



GENERIC HEALTHCARE PVT. LTD.

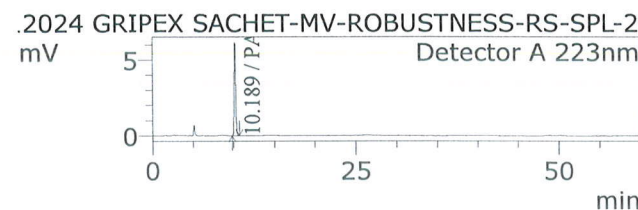
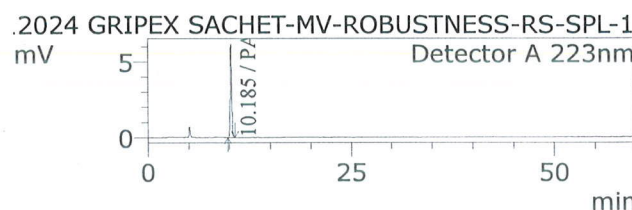
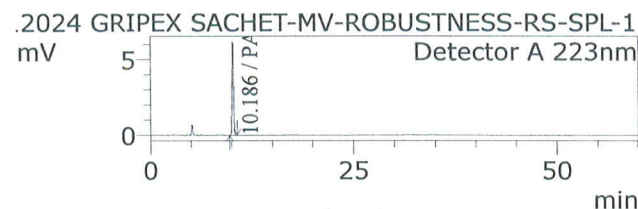
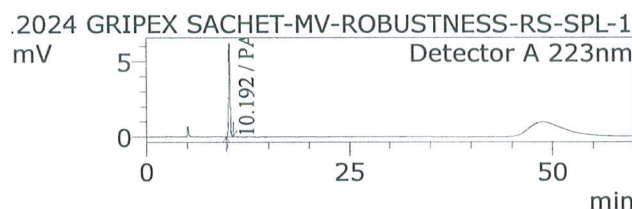
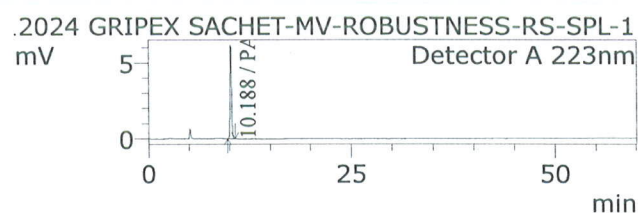
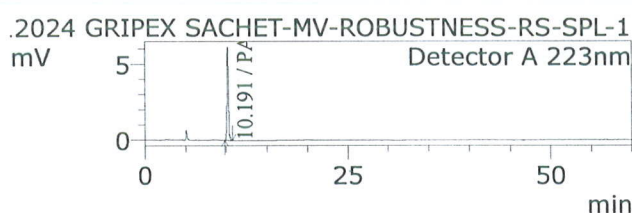
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-HWL-STD-01
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-15.lcd
 Method Filename : GRIPEX-SACH-HWL-RS_P.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 8:33:10 AM
 Date Processed : 1/22/2024 12:42:33 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID# 1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-15.lcd	PARACETAMOL-RS-HWL-STD-01	10.19	76700	14953	1.06
3	RS-SPL-16.lcd	PARACETAMOL-RS-HWL-STD-02	10.19	77019	14862	1.06
3	RS-SPL-17.lcd	PARACETAMOL-RS-HWL-STD-03	10.19	77227	14997	1.06
3	RS-SPL-18.lcd	PARACETAMOL-RS-HWL-STD-04	10.19	77160	15052	1.06
3	RS-SPL-19.lcd	PARACETAMOL-RS-HWL-STD-05	10.19	76997	15005	1.06
3	RS-SPL-20.lcd	PARACETAMOL-RS-HWL-STD-06	10.19	76839	15017	1.06
	Average		10.19	76990	14981	1.06
	%RSD		0.026	0.255	0.444	0.119

Analysed By

Checked By


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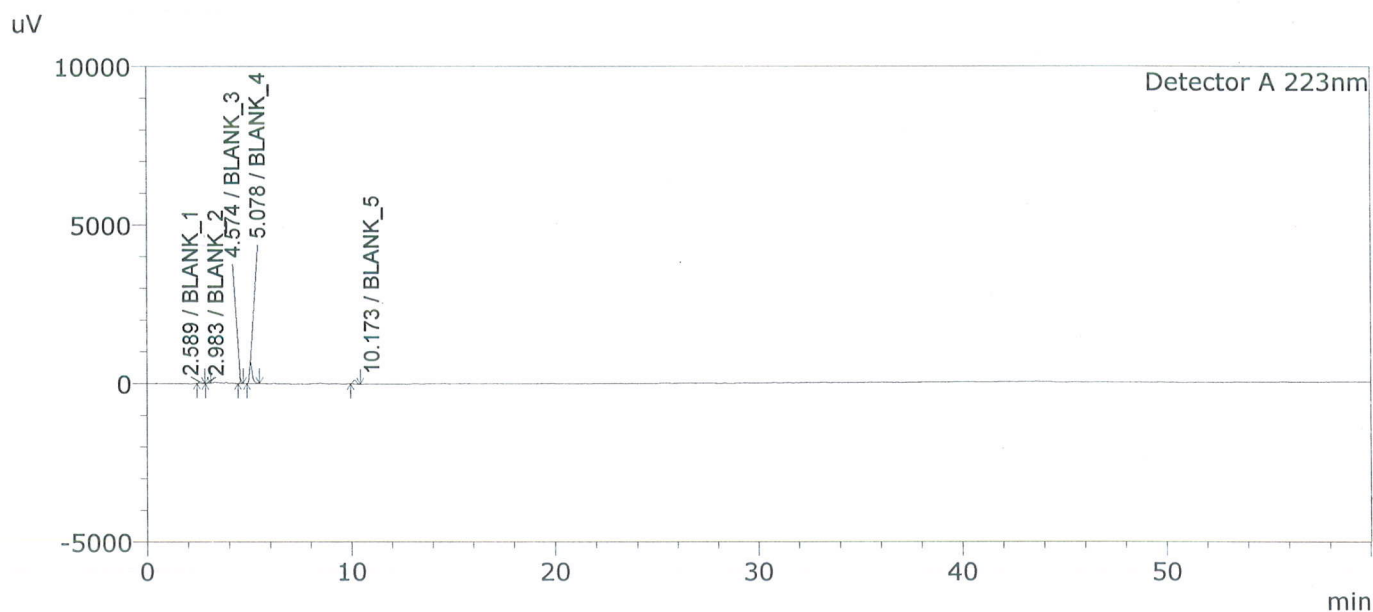
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-HWL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-21.lcd
 Method Filename : GRIPEX-SACH-HWL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 2:37:09 PM
 Date Processed : 1/22/2024 12:46:24 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 223nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.59	580	6.52	574	1.624	--	--
2	BLANK_2	2.98	239	2.68	3523	1.122	1.244	--
3	BLANK_3	4.57	376	4.22	10460	1.110	8.375	--
4	BLANK_4	5.08	6334	71.22	6710	1.579	2.361	--
5	BLANK_5	10.17	1365	15.35	16157	1.076	17.939	--
Total			8893	100.00				

22/01/24

Analysed By

22/01/2024

Checked By



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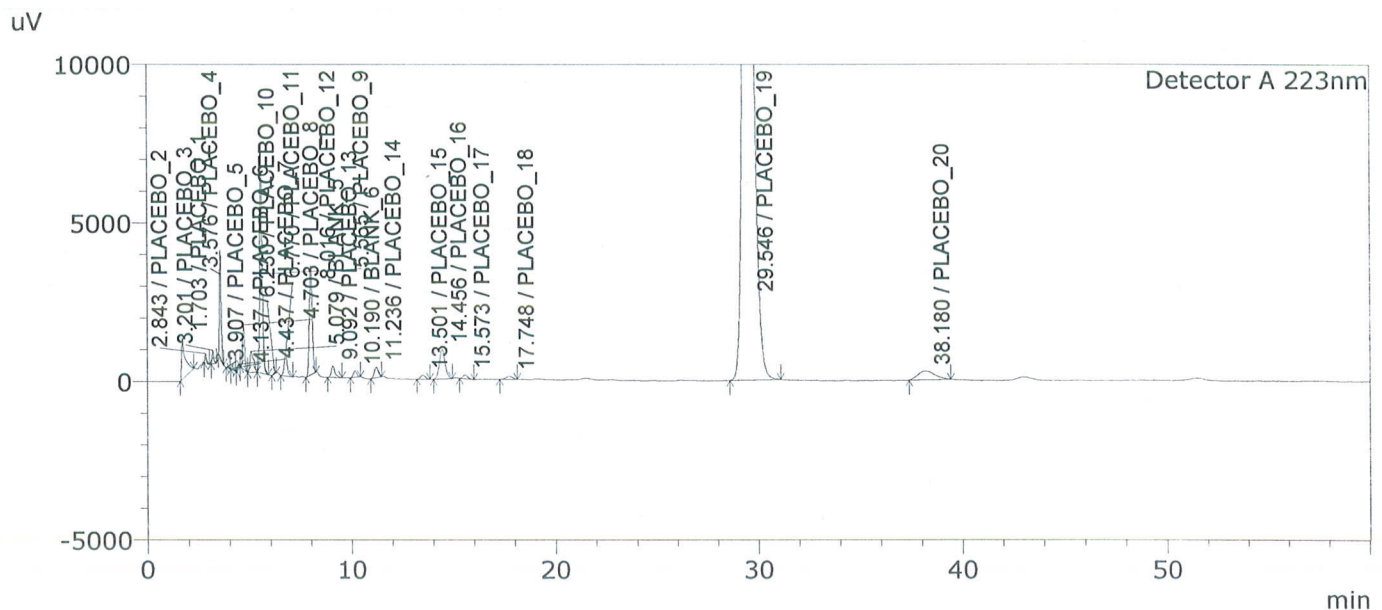
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PLACEBO-HWL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-22.lcd
 Method Filename : GRIPEX-SACH-HWL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 3:37:48 PM
 Date Processed : 1/22/2024 1:34:26 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



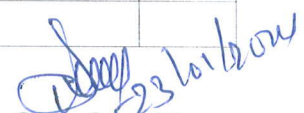
<Peak Table>

Detector A 223nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	16931	1.51	883	4.304	--	--
2	PLACEBO_2	2.84	1565	0.14	5963	1.480	6.058	--
3	PLACEBO_3	3.20	2293	0.20	6830	1.362	2.367	--
4	PLACEBO_4	3.58	18925	1.68	7740	1.161	2.365	--
5	PLACEBO_5	3.91	276	0.02	6607	1.634	1.865	--
6	PLACEBO_6	4.14	280	0.02	8293	1.657	1.229	--
7	PLACEBO_7	4.44	734	0.07	13357	1.003	1.792	--
8	PLACEBO_8	4.70	10355	0.92	8336	1.119	1.474	--
9	BLANK_5	5.08	8404	0.75	3096	1.503	1.317	--
10	PLACEBO_9	5.57	57628	5.13	10473	1.170	1.670	--
11	PLACEBO_10	6.23	315	0.03	18256	0.806	3.308	--
12	PLACEBO_11	6.77	7370	0.66	9841	1.177	2.363	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.02	33611	2.99	14359	1.029	4.608	--
14	PLACEBO_13	9.09	4649	0.41	13006	1.413	3.669	--
15	BLANK_6	10.19	2456	0.22	16239	1.110	3.438	--
16	PLACEBO_14	11.24	4507	0.40	14691	1.029	3.029	--
17	PLACEBO_15	13.50	2238	0.20	15079	1.139	5.588	--
18	PLACEBO_16	14.46	18355	1.63	12608	1.089	2.001	--
19	PLACEBO_17	15.57	1950	0.17	20866	1.210	2.360	--
20	PLACEBO_18	17.75	2263	0.20	12753	0.956	4.104	--
21	PLACEBO_19	29.55	912664	81.20	18042	1.127	15.642	--
22	PLACEBO_20	38.18	16177	1.44	11204	1.272	7.434	--
Total			1123945	100.00				

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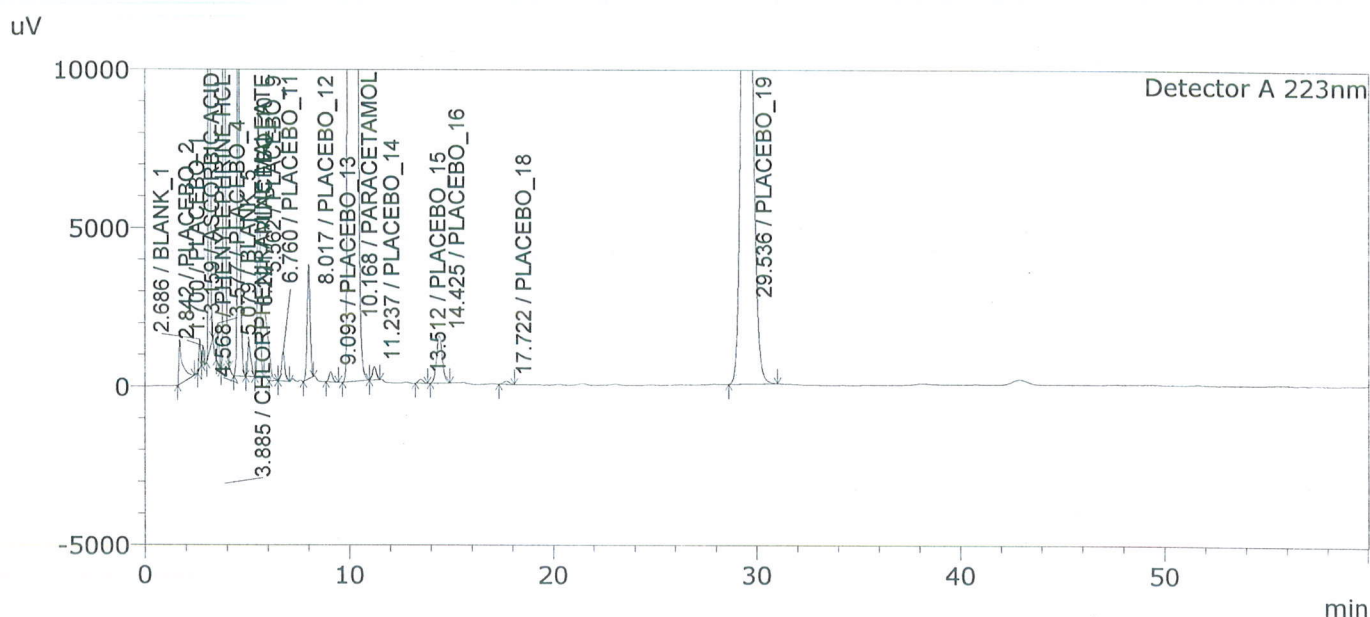
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : GRIPEX-1228-HWL-RS-SPL
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-23.lcd
 Method Filename : GRIPEX-SACH-HWL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 4:38:38 PM
 Date Processed : 1/22/2024 1:33:34 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 223nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	18394	0.11	950	5.018	--	--
2	BLANK_1	2.69	4947	0.03	4991	1.059	5.285	--
3	PLACEBO_2	2.84	2480	0.01	8572	1.206	1.136	--
4	ASCORBIC ACID	3.16	181938	1.08	6653	1.182	2.285	--
5	PLACEBO_4	3.58	7098	0.04	7531	1.286	2.613	--
6	CHLORPHENIRAMINE MALEATE	3.88	213498	1.26	8857	1.197	1.868	--
7	PHENYLEPHRINE HCL	4.57	126738	0.75	8458	1.411	3.755	--
8	BLANK_5	5.08	11878	0.07	5246	1.526	2.131	--
9	PLACEBO_9	5.56	67120	0.40	10734	1.121	1.954	--
10	PLACEBO_10	6.22	1724	0.01	8003	1.539	2.674	--
11	PLACEBO_11	6.76	9815	0.06	8923	1.107	1.910	--
12	PLACEBO_12	8.02	36047	0.21	13962	0.980	4.508	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_13	9.09	3851	0.02	13076	1.163	3.650	--
14	PARACETAMOL	10.17	15330634	90.65	14449	1.090	3.275	--
15	PLACEBO_14	11.24	5409	0.03	15782	1.026	3.070	--
16	PLACEBO_15	13.51	1921	0.01	15436	1.092	5.739	--
17	PLACEBO_16	14.43	28919	0.17	12628	1.079	1.927	--
18	PLACEBO_18	17.72	2043	0.01	15163	0.959	6.054	--
19	PLACEBO_19	29.54	856646	5.07	17739	1.097	16.154	--
Total			16911099	100.00				

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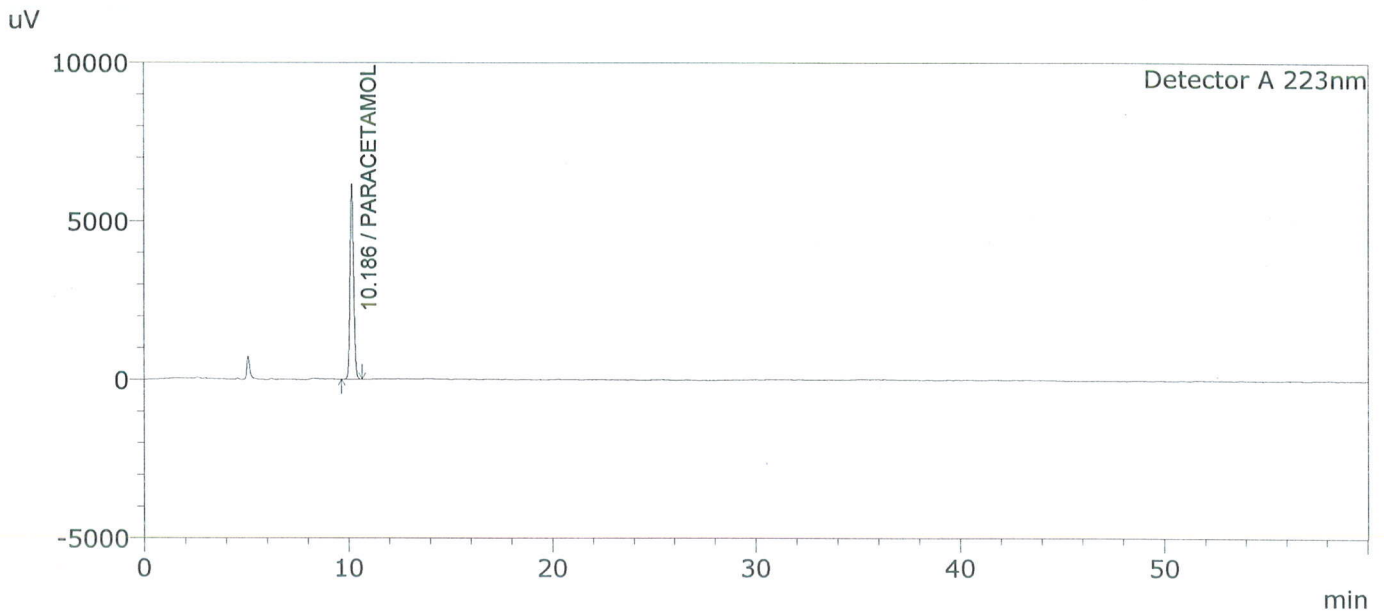
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-HWL-STD-BKT
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-24.lcd
 Method Filename : GRIPEX-SACH-HWL-RS_P.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 5:39:08 PM
 Date Processed : 1/22/2024 12:42:34 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 223nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.19	76849	100.00	15012	1.058	--	--
Total			76849	100.00				

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23/01/2024

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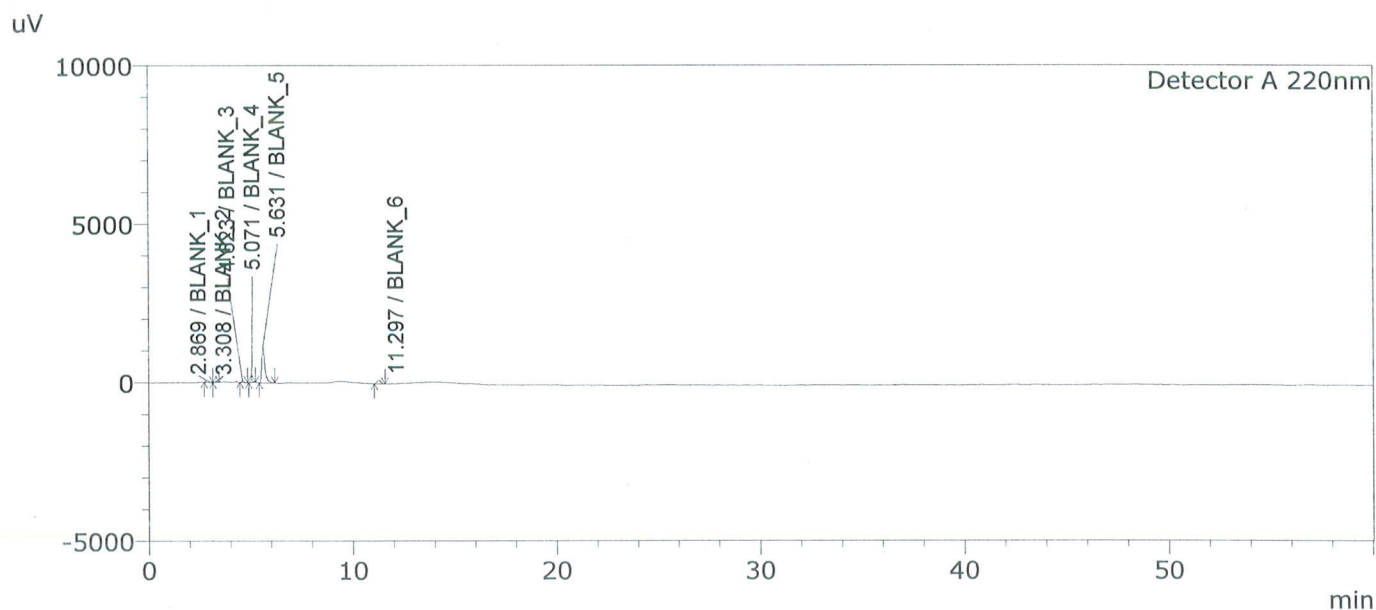
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-LFL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-25.lcd
 Method Filename : GRIPEX-SACH-LFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 6:39:52 PM
 Date Processed : 1/22/2024 10:19:32 AM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.87	749	4.80	892	1.646	--	--
2	BLANK_2	3.31	300	1.92	3274	1.060	1.427	--
3	BLANK_3	4.62	359	2.30	4842	1.402	5.289	--
4	BLANK_4	5.07	650	4.17	9800	1.156	1.906	--
5	BLANK_5	5.63	12111	77.67	6876	1.663	2.348	--
6	BLANK_6	11.30	1425	9.14	16380	1.099	18.141	--
Total			15593	100.00				

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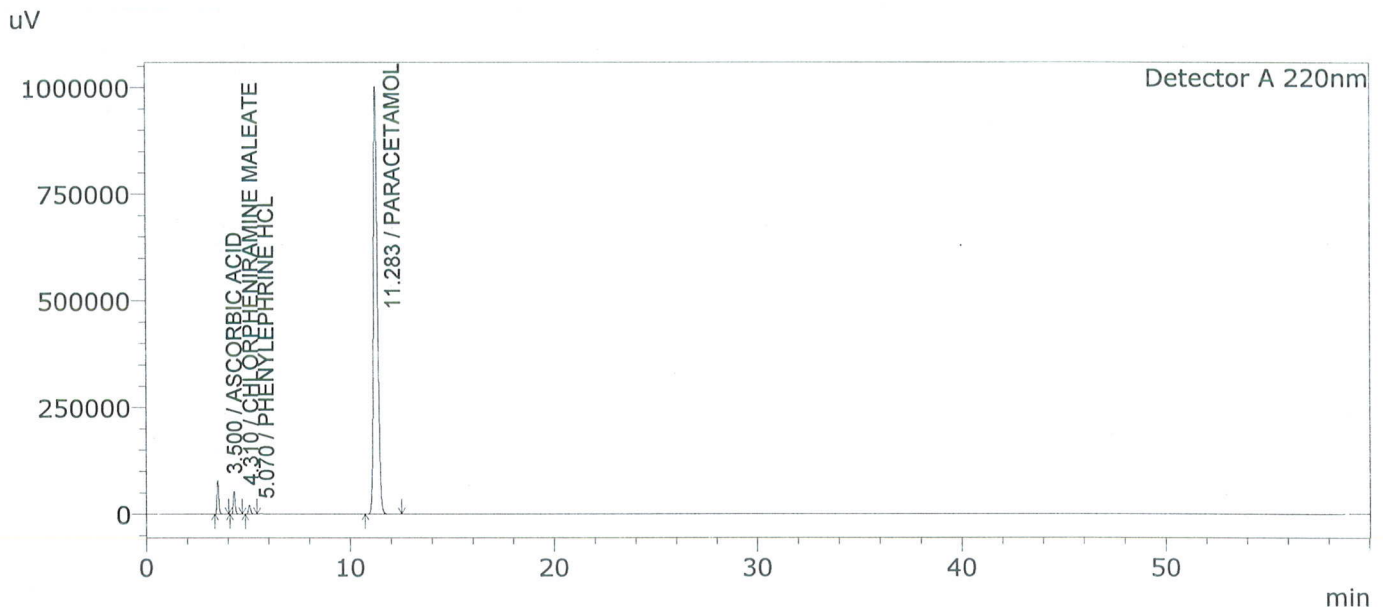
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : RESOLUTION SOLUTION-LFL
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-26.lcd
 Method Filename : GRIPEX-SACH-LFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 7:40:31 PM
 Date Processed : 1/22/2024 10:21:40 AM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	3.50	481137	3.28	6705	1.255	--	--
2	CHLORPHENIRAMINE MALEATE	4.31	336474	2.29	9493	1.212	4.659	--
3	PHENYLEPHRINE HCL	5.07	159751	1.09	9721	1.165	3.969	--
4	PARACETAMOL	11.28	13693575	93.34	15387	1.108	21.818	--
Total			14670937	100.00				

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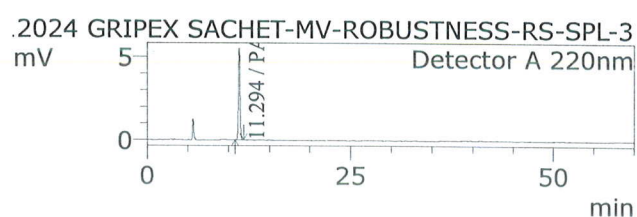
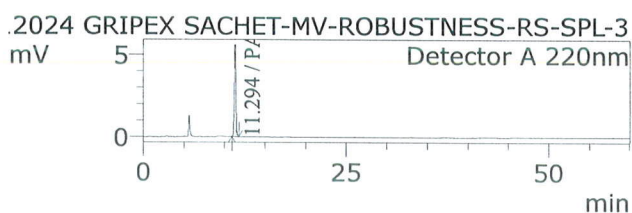
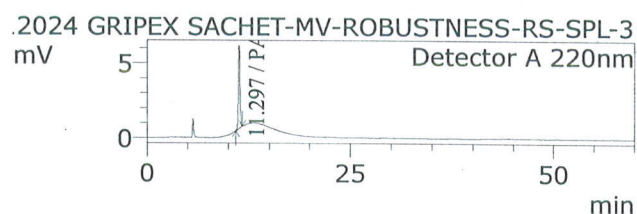
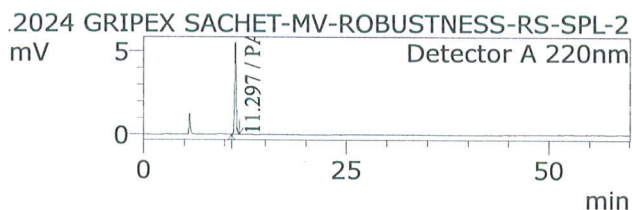
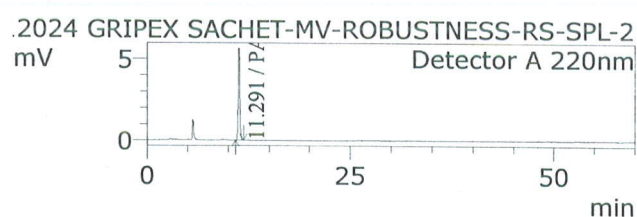
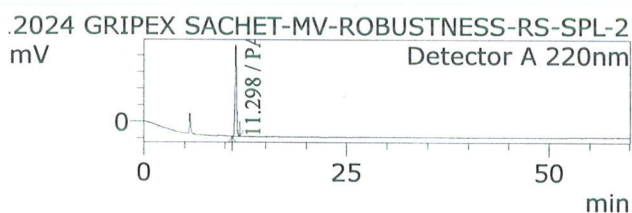
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Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-LFL-STD-01
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-27.lcd
 Method Filename : GRIPEX-SACH-LFL-RS_P.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 µL
 Date Acquired : 1/19/2024 8:41:12 PM
 Date Processed : 1/22/2024 1:39:15 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-27.lcd	PARACETAMOL-RS-LFL-STD-01	11.30	74944	15671	1.06
3	RS-SPL-28.lcd	PARACETAMOL-RS-LFL-STD-02	11.29	76297	15677	1.05
3	RS-SPL-29.lcd	PARACETAMOL-RS-LFL-STD-03	11.30	75036	15605	1.06
3	RS-SPL-30.lcd	PARACETAMOL-RS-LFL-STD-04	11.30	74954	15590	1.05
3	RS-SPL-31.lcd	PARACETAMOL-RS-LFL-STD-05	11.29	75527	15574	1.06
3	RS-SPL-32.lcd	PARACETAMOL-RS-LFL-STD-06	11.29	74975	15554	1.05
	Average		11.30	75289	15612	1.06
	%RSD		0.025	0.719	0.326	0.199

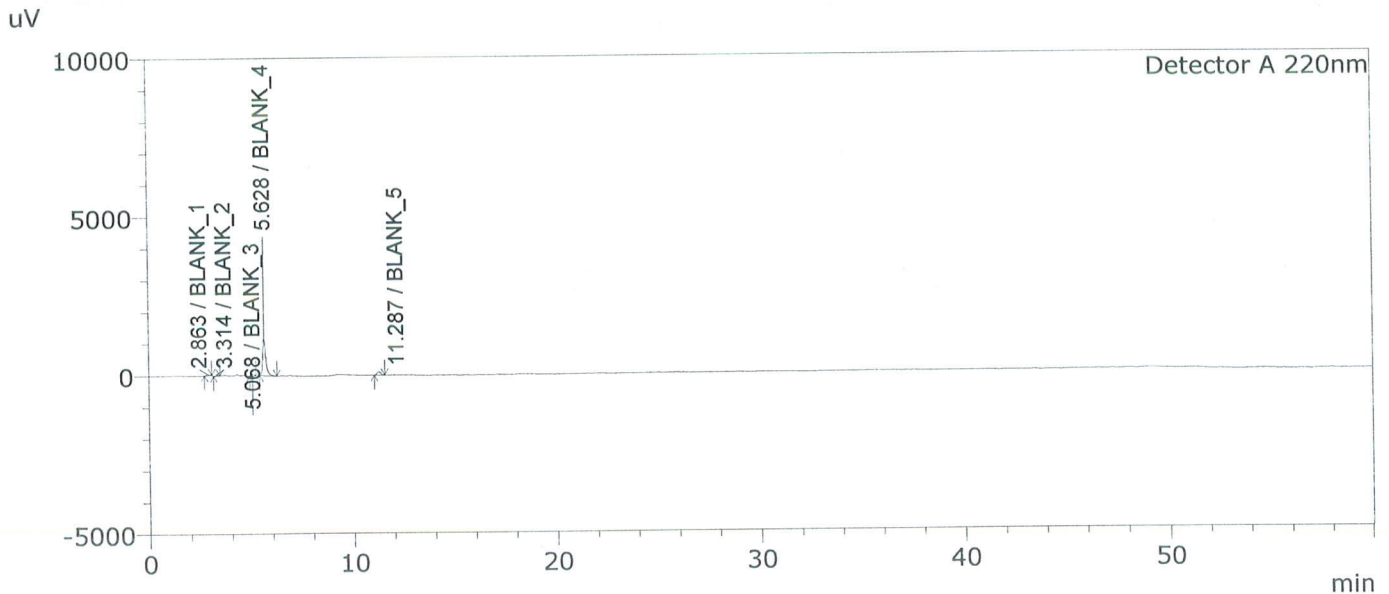
Analysed By

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Analysis Report
<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-LFL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-33.lcd
 Method Filename : GRIPEX-SACH-LFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 2:45:12 AM
 Date Processed : 1/22/2024 10:22:52 AM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.86	375	2.52	2226	1.441	--	--
2	BLANK_2	3.31	366	2.46	2747	1.016	1.817	--
3	BLANK_3	5.07	474	3.18	11080	1.068	7.877	--
4	BLANK_4	5.63	12365	82.99	6869	1.610	2.412	--
5	BLANK_5	11.29	1319	8.85	15924	1.063	17.982	--
Total			14899	100.00				

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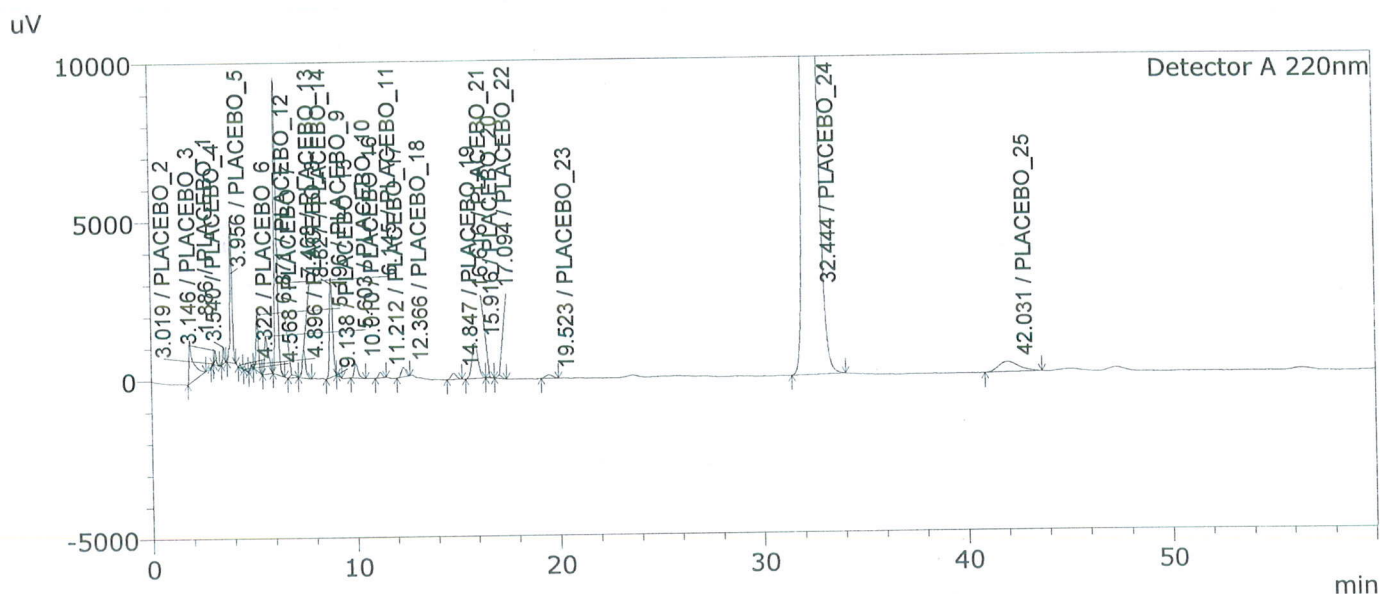
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PLACEBO-LFL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-34.lcd
 Method Filename : GRIPEX-SACH-LFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 9:09:19 AM
 Date Processed : 1/22/2024 1:46:03 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.89	21022	1.33	898	5.111	--	--
2	PLACEBO_2	3.02	222	0.01	12379	0.782	6.289	--
3	PLACEBO_3	3.15	2392	0.15	6809	1.553	0.973	--
4	PLACEBO_4	3.54	2891	0.18	7656	1.099	2.505	--
5	PLACEBO_5	3.96	31283	1.98	7555	0.829	2.421	--
6	PLACEBO_6	4.32	509	0.03	6057	1.752	1.812	--
7	PLACEBO_7	4.57	230	0.01	9438	1.812	1.197	--
8	PLACEBO_8	4.90	977	0.06	13635	1.003	1.841	--
9	PLACEBO_9	5.20	14373	0.91	8701	1.109	1.539	--
10	PLACEBO_10	5.60	15343	0.97	5210	1.567	1.527	--
11	PLACEBO_11	6.14	80482	5.10	11059	1.144	1.990	--
12	PLACEBO_12	6.87	1654	0.10	4043	1.439	2.182	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_13	7.47	9976	0.63	10354	1.195	1.645	--
14	PLACEBO_14	8.83	33190	2.10	14730	1.011	4.651	--
15	PLACEBO_15	9.14	321	0.02	36546	1.688	1.288	--
16	PLACEBO_16	10.01	6022	0.38	13734	1.435	3.272	--
17	PLACEBO_17	11.21	2289	0.15	16970	1.137	3.506	--
18	PLACEBO_18	12.37	4364	0.28	14748	1.037	3.071	--
19	PLACEBO_19	14.85	3580	0.23	14149	1.106	5.473	--
20	PLACEBO_20	15.92	23239	1.47	13269	1.054	2.031	--
21	PLACEBO_21	16.62	399	0.03	34515	1.105	1.538	--
22	PLACEBO_22	17.09	1534	0.10	25169	1.194	1.213	--
23	PLACEBO_23	19.52	2631	0.17	13703	1.098	4.424	--
24	PLACEBO_24	32.44	1294906	82.12	17951	1.105	15.798	--
25	PLACEBO_25	42.03	22931	1.45	8492	1.265	6.865	--
Total			1576760	100.00				

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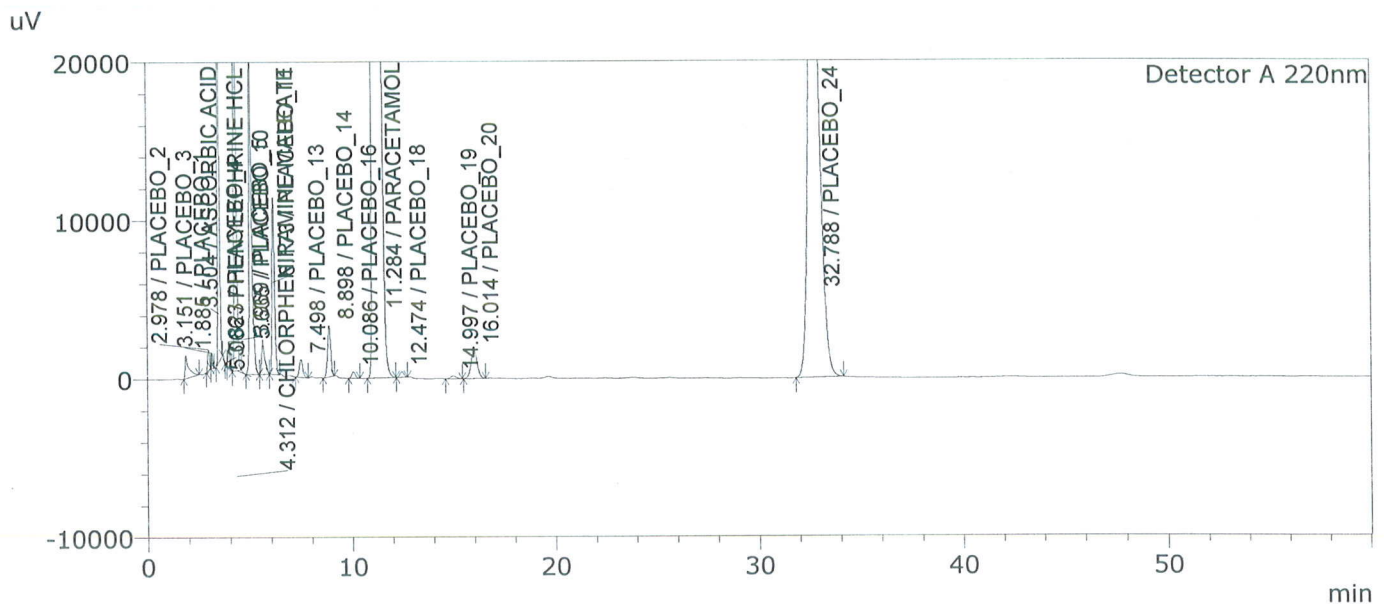
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : GRIPEX-1228-LFL-RS-SPL
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-35.lcd
 Method Filename : GRIPEX-SACH-LFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 10:09:46 AM
 Date Processed : 1/22/2024 2:49:09 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



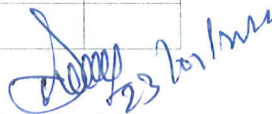
<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.89	18645	0.11	1013	4.105	--	--
2	PLACEBO_2	2.98	7529	0.04	5070	1.092	5.407	--
3	PLACEBO_3	3.15	4180	0.02	8625	1.206	1.145	--
4	ASCORBIC ACID	3.50	159097	0.93	7126	1.178	2.334	--
5	PLACEBO_4	3.82	327	0.00	31067	1.144	2.530	--
6	PLACEBO_5	3.97	9539	0.06	8452	1.270	1.120	--
7	CHLORPHENIRAMINE MALEATE	4.31	302769	1.77	9536	1.204	1.965	--
8	PHENYLEPHRINE HCL	5.07	180338	1.05	9137	1.430	3.883	--
9	PLACEBO_10	5.63	21272	0.12	5773	1.533	2.235	--
10	PLACEBO_11	6.17	94320	0.55	11379	1.123	2.037	--
11	PLACEBO_13	7.50	13318	0.08	9293	1.128	4.886	--
12	PLACEBO_14	8.90	35240	0.21	14574	0.973	4.621	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_16	10.09	5061	0.03	14073	1.116	3.740	--
14	PARACETAMOL	11.28	14998919	87.64	15146	1.093	3.390	--
15	PLACEBO_18	12.47	5003	0.03	16591	1.024	3.157	--
16	PLACEBO_19	15.00	3351	0.02	14258	1.135	5.671	--
17	PLACEBO_20	16.01	38445	0.22	13152	1.074	1.918	--
18	PLACEBO_24	32.79	1216031	7.11	17997	1.100	21.838	--
Total			17113383	100.00				

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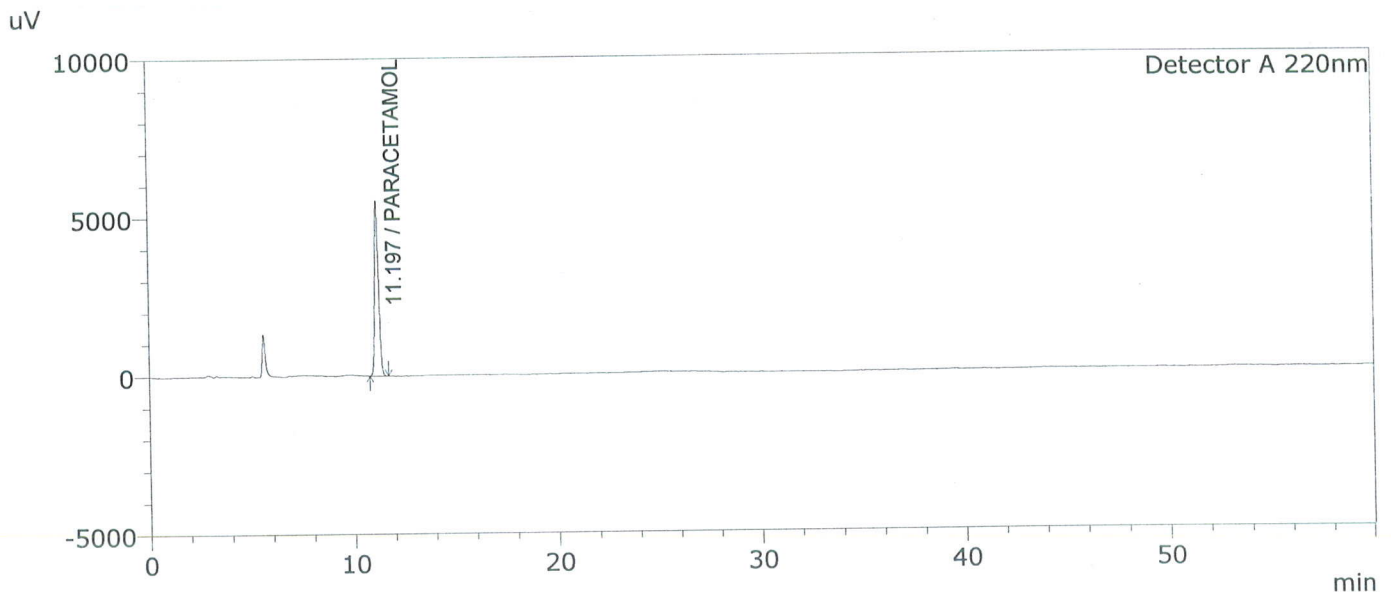
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-LFL-STD-BKT
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-36.lcd
 Method Filename : GRIPEX-SACH-LFL-RS_P.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 11:10:43 AM
 Date Processed : 1/22/2024 1:39:19 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	11.20	75350	100.00	15207	1.044	--	--
Total			75350	100.00				

16/22/01/24

Analysed By

16/22/01/24

Checked By


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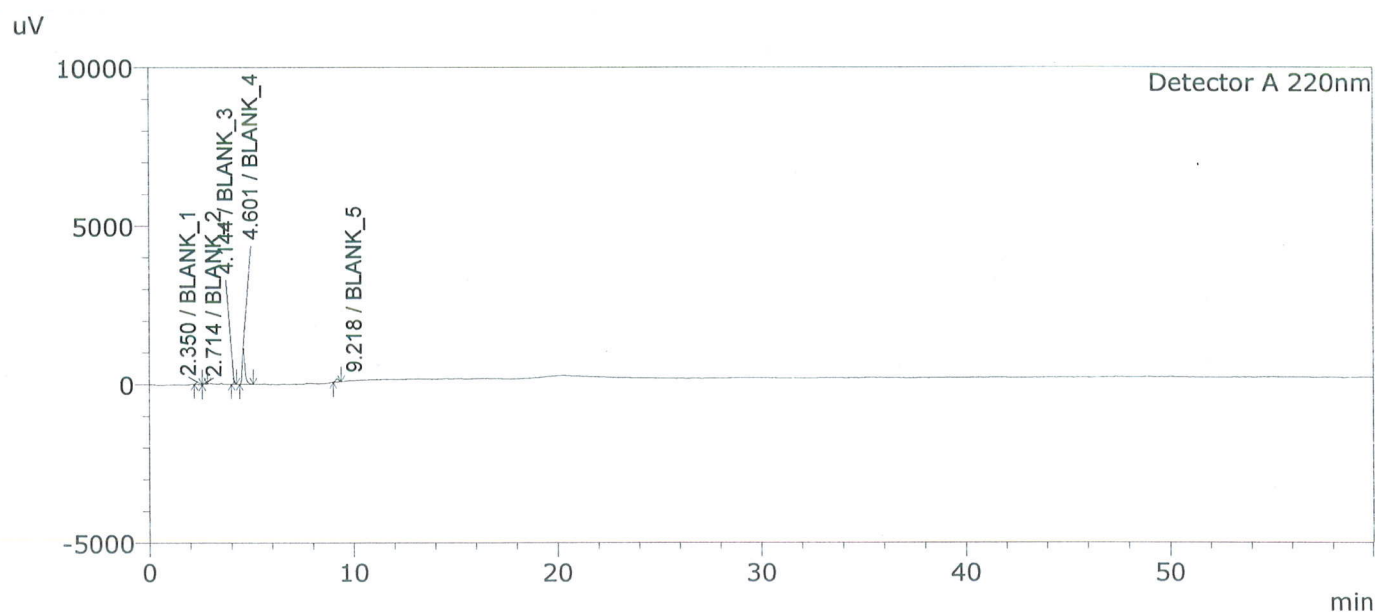
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-HFL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-37.lcd
 Method Filename : GRIPEX-SACH-HFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 12:11:27 PM
 Date Processed : 1/22/2024 2:51:47 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.35	787	6.07	565	1.481	--	--
2	BLANK_2	2.71	265	2.04	2340	1.061	1.175	--
3	BLANK_3	4.14	409	3.16	9408	1.057	7.232	--
4	BLANK_4	4.60	10414	80.30	6195	1.571	2.260	--
5	BLANK_5	9.22	1094	8.43	14964	1.007	17.250	--
Total			12970	100.00				

Analysed By

Checked By



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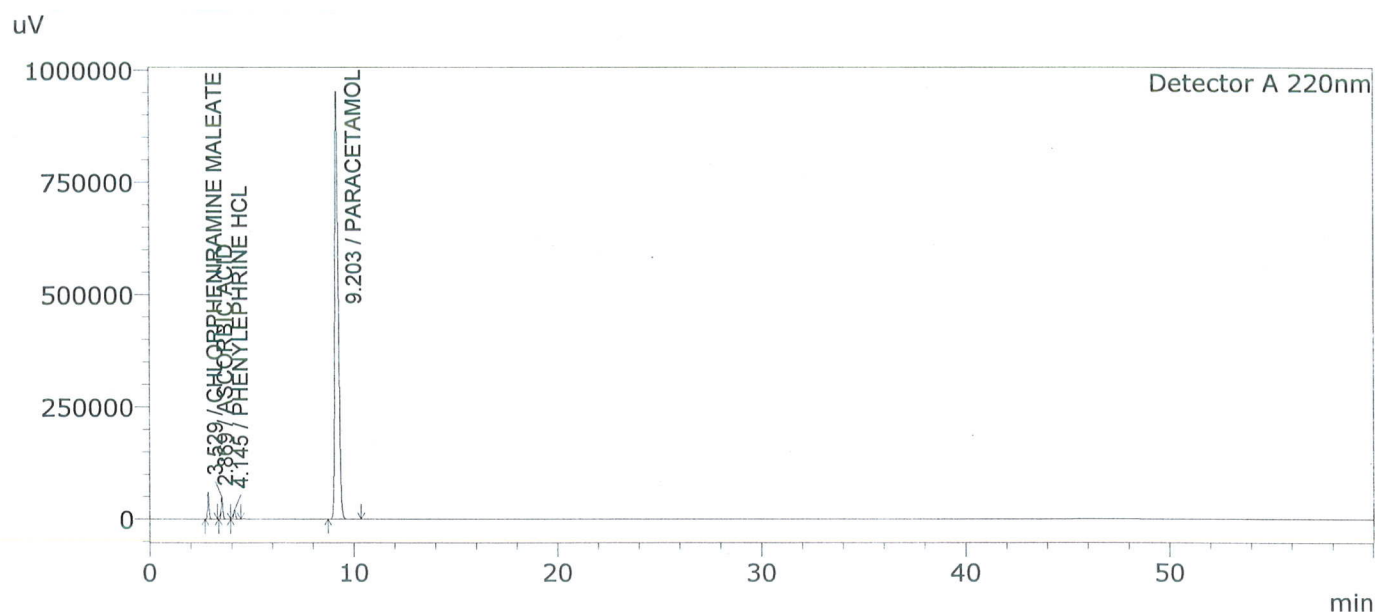
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : RESOLUTION SOLUTION-HFL
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-38.lcd
 Method Filename : GRIPEX-SACH-HFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 1:12:06 PM
 Date Processed : 1/22/2024 2:53:46 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	2.87	317570	2.66	5725	1.256	--	--
2	CHLORPHENIRAMINE MALEATE	3.53	274644	2.30	7985	1.217	4.263	--
3	PHENYLEPHRINE HCL	4.15	130272	1.09	8346	1.162	3.634	--
4	PARACETAMOL	9.20	11223193	93.95	13566	1.088	20.331	--
Total			11945678	100.00				


 22/01/24
 Analysed By


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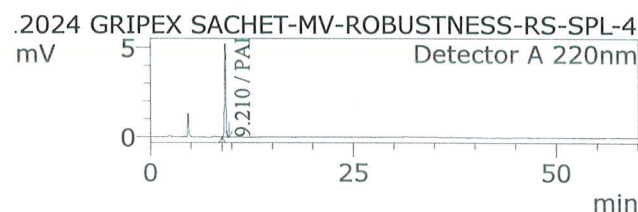
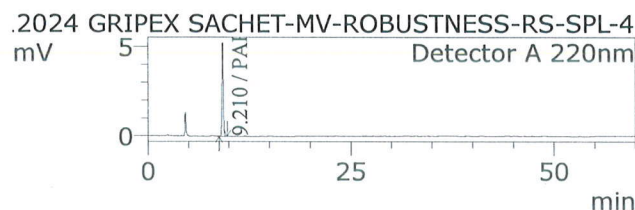
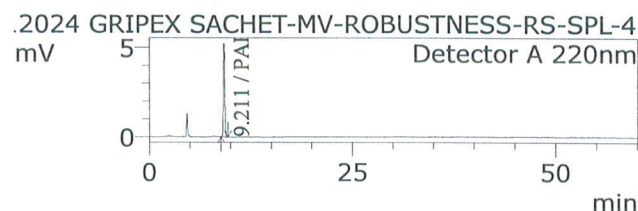
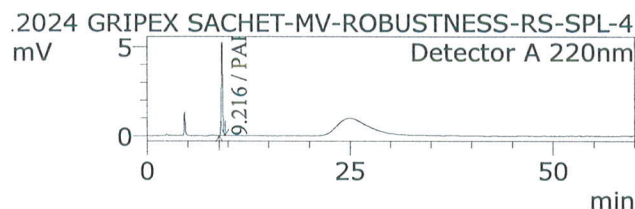
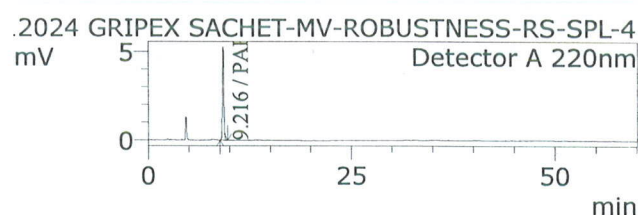
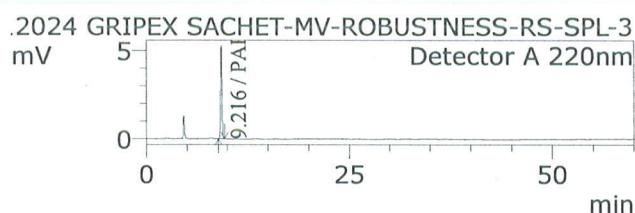
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-HFL-STD-01
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-39.lcd
 Method Filename : GRIPEX-SACH-HFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 2:12:46 PM
 Date Processed : 1/22/2024 2:55:47 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-39.lcd	PARACETAMOL-RS-HFL-STD-01	9.22	61650	13742	1.05
3	RS-SPL-40.lcd	PARACETAMOL-RS-HFL-STD-02	9.22	62135	13582	1.05
3	RS-SPL-41.lcd	PARACETAMOL-RS-HFL-STD-03	9.22	61860	13596	1.05
3	RS-SPL-42.lcd	PARACETAMOL-RS-HFL-STD-04	9.21	61618	13610	1.05
3	RS-SPL-43.lcd	PARACETAMOL-RS-HFL-STD-05	9.21	61781	13565	1.05
3	RS-SPL-44.lcd	PARACETAMOL-RS-HFL-STD-06	9.21	61876	13479	1.05
	Average		9.21	61820	13595	1.05
	%RSD		0.034	0.303	0.627	0.151

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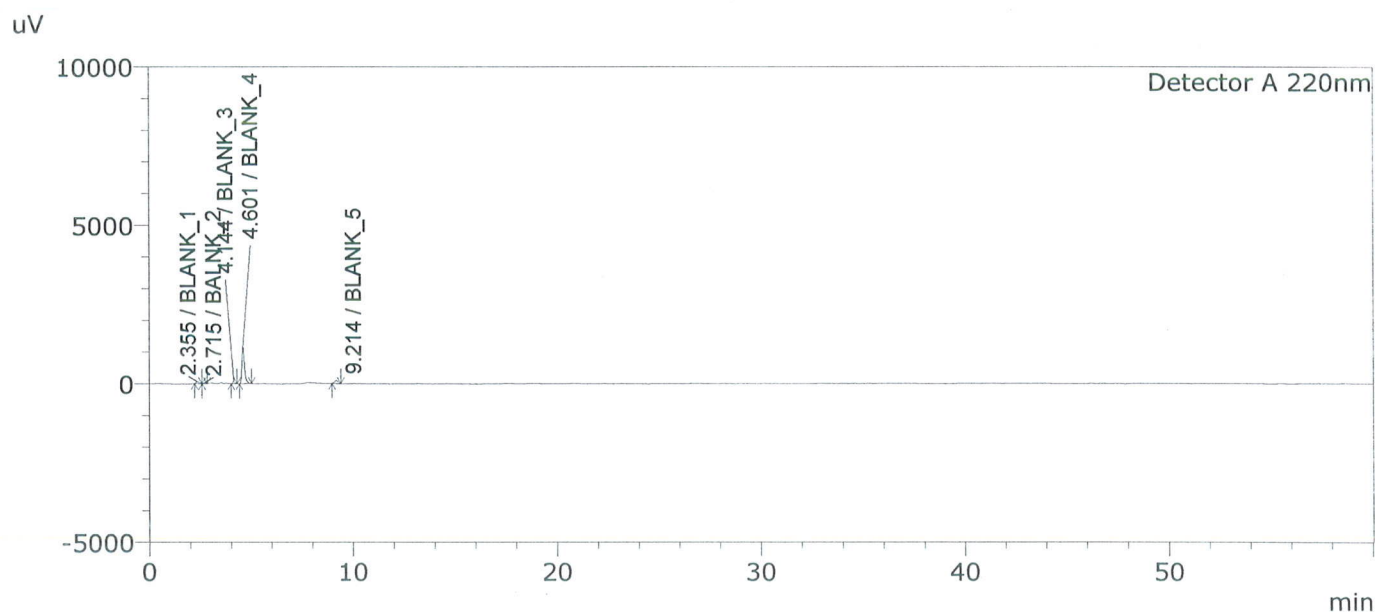
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-HFL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-45.lcd
 Method Filename : GRIPEX-SACH-HFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 8:16:47 PM
 Date Processed : 1/22/2024 2:57:35 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.35	759	5.87	791	1.539	--	--
2	BALNK_2	2.71	253	1.96	2415	1.027	1.296	--
3	BLANK_3	4.14	402	3.11	9492	1.170	7.305	--
4	BLANK_4	4.60	10442	80.86	6129	1.542	2.258	--
5	BLANK_5	9.21	1057	8.19	14565	1.058	17.070	--
Total			12913	100.00				

32/01/24

Analysed By

 23/01/2024
Checked By



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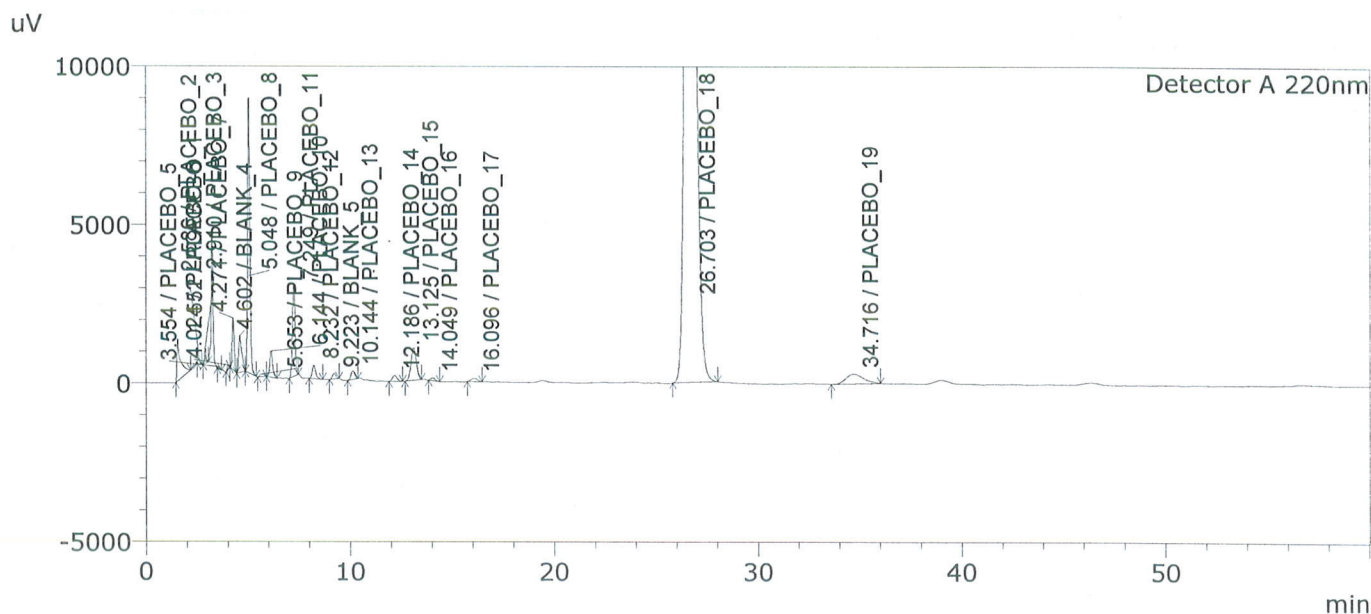
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PLACEBO-HFL-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-46.lcd
 Method Filename : GRIPEX-SACH-HFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 9:17:27 PM
 Date Processed : 1/22/2024 3:03:14 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

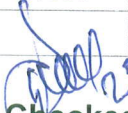
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.55	17074	1.35	858	4.972	--	--
2	PLACEBO_2	2.59	1899	0.15	5809	1.443	5.950	--
3	PLACEBO_3	2.91	2537	0.20	6237	1.349	2.285	--
4	PLACEBO_5	3.55	320	0.03	6525	1.647	3.984	--
5	PLACEBO_6	4.02	772	0.06	11312	0.992	2.876	--
6	PLACEBO_7	4.27	11420	0.90	7526	1.120	1.417	--
7	BLANK_4	4.60	12456	0.99	4680	1.553	1.421	--
8	PLACEBO_8	5.05	65700	5.21	9434	1.156	1.870	--
9	PLACEBO_9	5.65	1281	0.10	3860	1.408	2.116	--
10	PLACEBO_10	6.14	8007	0.63	9082	1.174	1.577	--
11	PLACEBO_11	7.25	26877	2.13	12967	1.019	4.315	--
12	PLACEBO_12	8.23	4974	0.39	12092	1.352	3.547	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	BLANK_5	9.22	1930	0.15	14495	1.075	3.272	--
14	PLACEBO_13	10.14	3353	0.27	14199	1.039	2.847	--
15	PLACEBO_14	12.19	2975	0.24	12830	1.209	5.298	--
16	PLACEBO_15	13.13	18667	1.48	11647	1.018	2.049	--
17	PLACEBO_16	14.05	1236	0.10	20866	1.251	2.109	--
18	PLACEBO_17	16.10	2166	0.17	12063	1.056	4.199	--
19	PLACEBO_18	26.70	1059615	83.96	16453	1.113	14.950	--
20	PLACEBO_19	34.72	18776	1.49	7467	1.234	6.569	--
Total			1262036	100.00				

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 22/01/24

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 23/01/24



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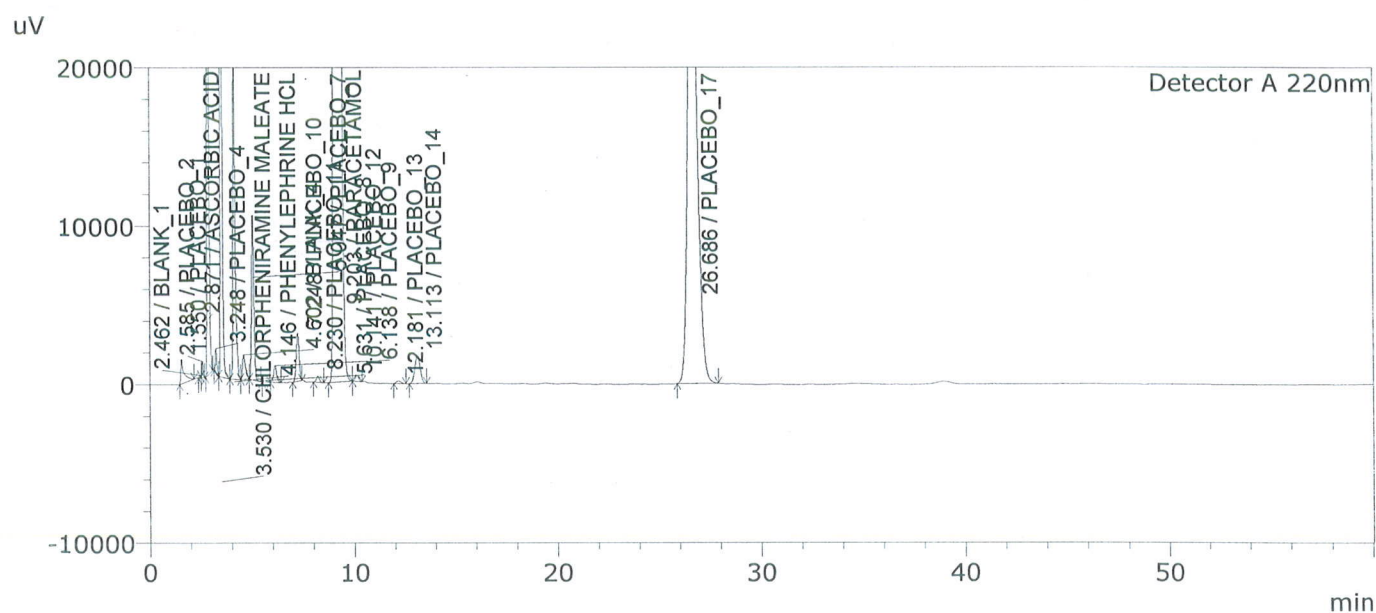
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : GRIPEX-1228-HFL-RS-SPL
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-47.lcd
 Method Filename : GRIPEX-SACH-HFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 10:18:06 PM
 Date Processed : 1/22/2024 3:19:14 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

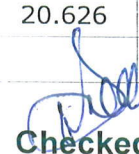
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.55	17707	0.12	963	4.697	--	--
2	BLANK_1	2.46	592	0.00	6099	0.852	5.597	--
3	PLACEBO_2	2.58	4063	0.03	6748	1.145	0.976	--
4	ASCORBIC ACID	2.87	335181	2.35	5789	1.238	2.064	--
5	PLACEBO_4	3.25	7774	0.05	7137	1.222	2.477	--
6	CHLORPHENIRAMINE MALEATE	3.53	255632	1.79	7901	1.213	1.805	--
7	PHENYLEPHRINE HCL	4.15	149777	1.05	7528	1.396	3.520	--
8	BLANK_4	4.60	15430	0.11	5112	1.553	2.034	--
9	PLACEBO_7	5.05	78069	0.55	9555	1.141	1.918	--
10	PLACEBO_8	5.63	1184	0.01	6294	1.607	2.380	--
11	PLACEBO_9	6.14	10288	0.07	8740	1.126	1.856	--
12	PLACEBO_10	7.25	28470	0.20	12647	0.985	4.264	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	8.23	4116	0.03	12494	1.081	3.557	--
14	PARACETAMOL	9.20	12341108	86.39	13139	1.096	3.161	--
15	PLACEBO_12	10.14	4316	0.03	15323	1.046	2.890	--
16	PLACEBO_13	12.18	2522	0.02	14071	1.285	5.525	--
17	PLACEBO_14	13.11	31569	0.22	11767	1.053	2.086	--
18	PLACEBO_17	26.69	998106	6.99	16441	1.112	20.626	--
Total			14285902	100.00				

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22/10/24

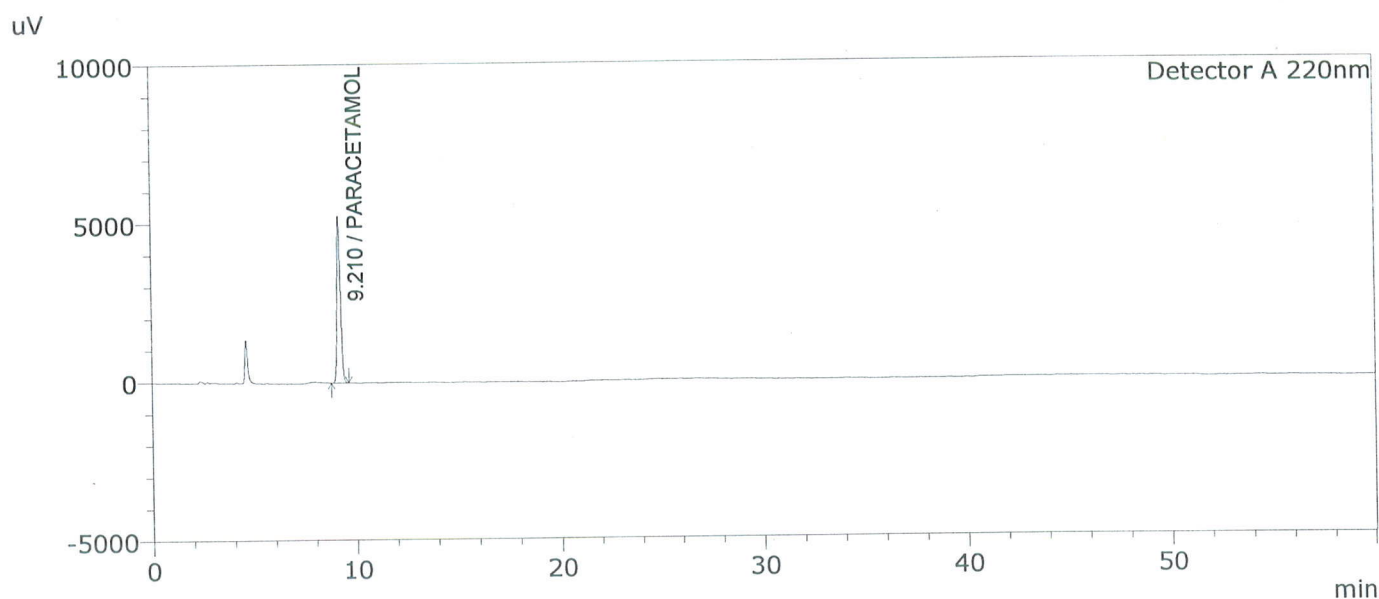
Checked By


23/10/24


GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-HFL-STD-BKT
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-48.lcd
 Method Filename : GRIPEX-SACH-HFL-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 11:18:46 PM
 Date Processed : 1/22/2024 2:55:51 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	9.21	62434	100.00	13378	1.047	--	--
Total			62434	100.00				

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23/01/2024
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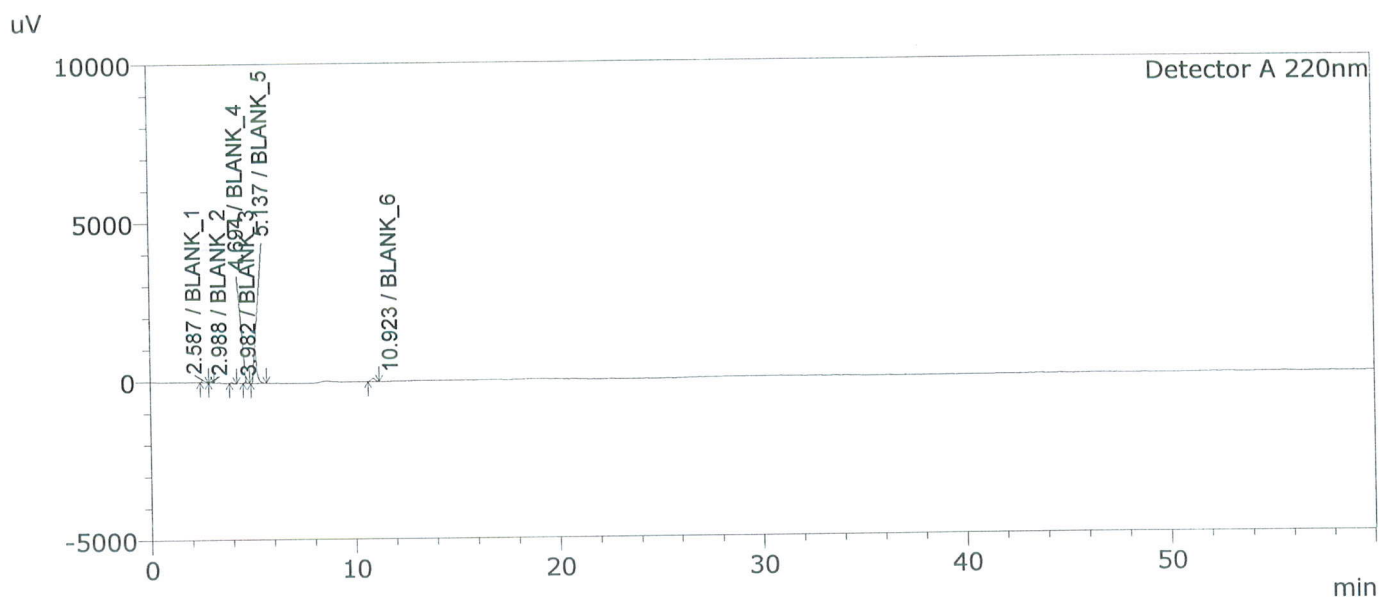
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-LTM-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-49.lcd
 Method Filename : GRIPEX-SACH-LTM-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 12:27:01 AM
 Date Processed : 1/22/2024 3:21:00 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.59	921	6.18	1152	1.674	--	--
2	BLANK_2	2.99	345	2.31	2170	1.104	1.427	--
3	BLANK_3	3.98	252	1.69	4990	1.470	4.122	--
4	BLANK_4	4.69	418	2.80	5764	1.011	3.013	--
5	BLANK_5	5.14	11557	77.52	5914	1.563	1.724	--
6	BLANK_6	10.92	1415	9.49	12322	1.106	17.513	--
Total			14907	100.00				

Analysed By

Checked By



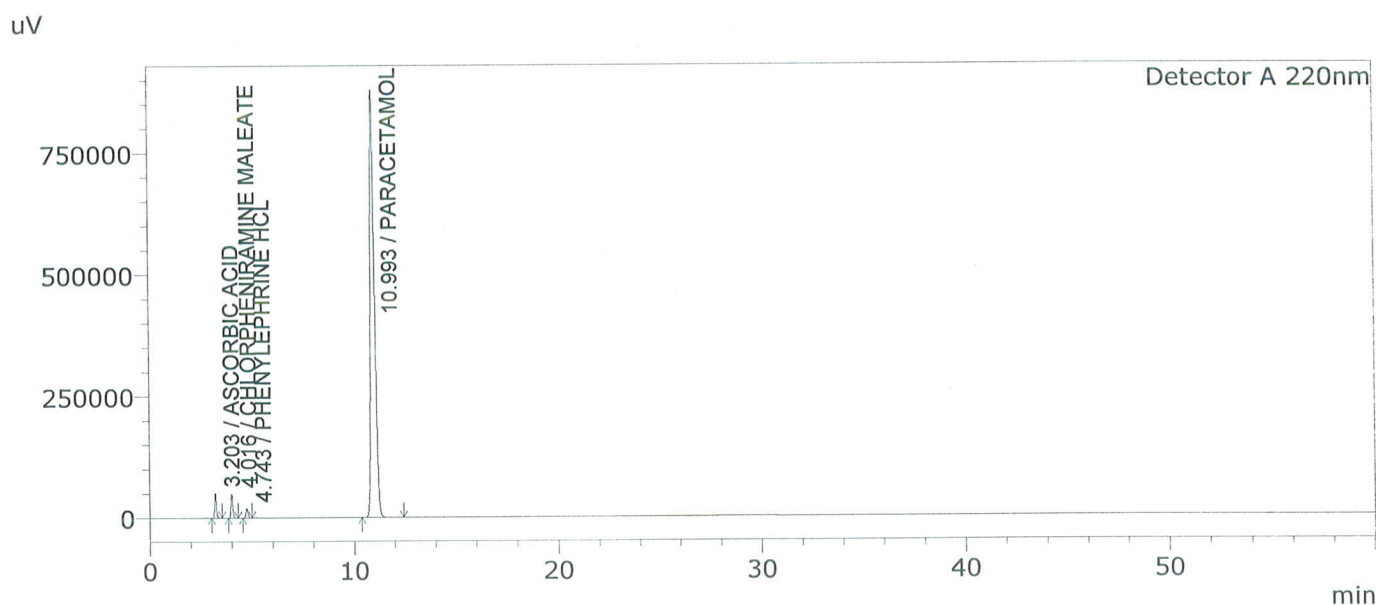
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : RESOLUTION SOLUTION-LTM
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-50.lcd
 Method Filename : GRIPEX-SACH-LTM-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 1:27:41 AM
 Date Processed : 1/22/2024 3:24:46 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	3.20	297951	2.27	6133	1.251	--	--
2	CHLORPHENIRAMINE MALEAT	4.02	300333	2.29	8688	1.201	4.844	--
3	PHENYLEPHRINE HCL	4.74	142244	1.08	8832	1.144	3.884	--
4	PARACETAMOL	10.99	12390011	94.36	13732	1.111	21.659	--
Total			13130540	100.00				

22/01/24

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22/01/24

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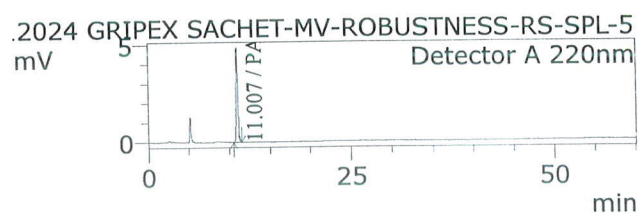
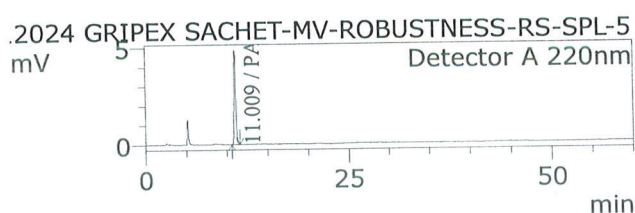
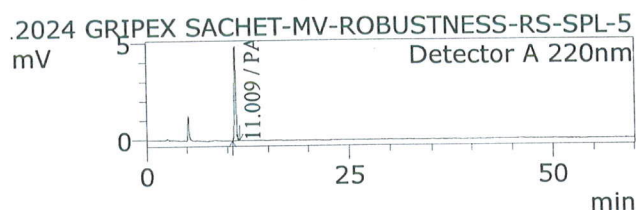
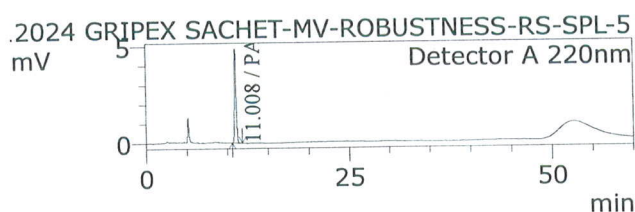
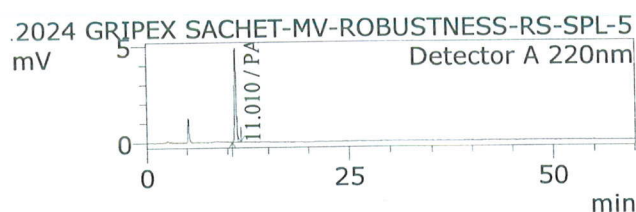
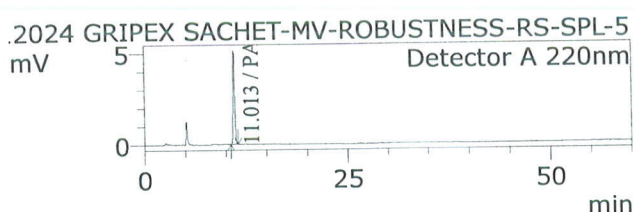
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-LTM-STD-01
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-51.lcd
 Method Filename : GRIPEX-SACH-LTM-RS_P.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 2:28:21 AM
 Date Processed : 1/22/2024 4:40:02 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-51.lcd	PARACETAMOL-RS-LTM-STD-01	11.01	71675	13973	1.06
3	RS-SPL-52.lcd	PARACETAMOL-RS-LTM-STD-02	11.01	67992	14015	1.06
3	RS-SPL-53.lcd	PARACETAMOL-RS-LTM-STD-03	11.01	68689	13940	1.06
3	RS-SPL-54.lcd	PARACETAMOL-RS-LTM-STD-04	11.01	68244	13941	1.06
3	RS-SPL-55.lcd	PARACETAMOL-RS-LTM-STD-05	11.01	68237	13889	1.06
3	RS-SPL-56.lcd	PARACETAMOL-RS-LTM-STD-06	11.01	68200	13866	1.06
	Average		11.01	68839	13937	1.06
	%RSD		0.020	2.045	0.390	0.156

Analysed By

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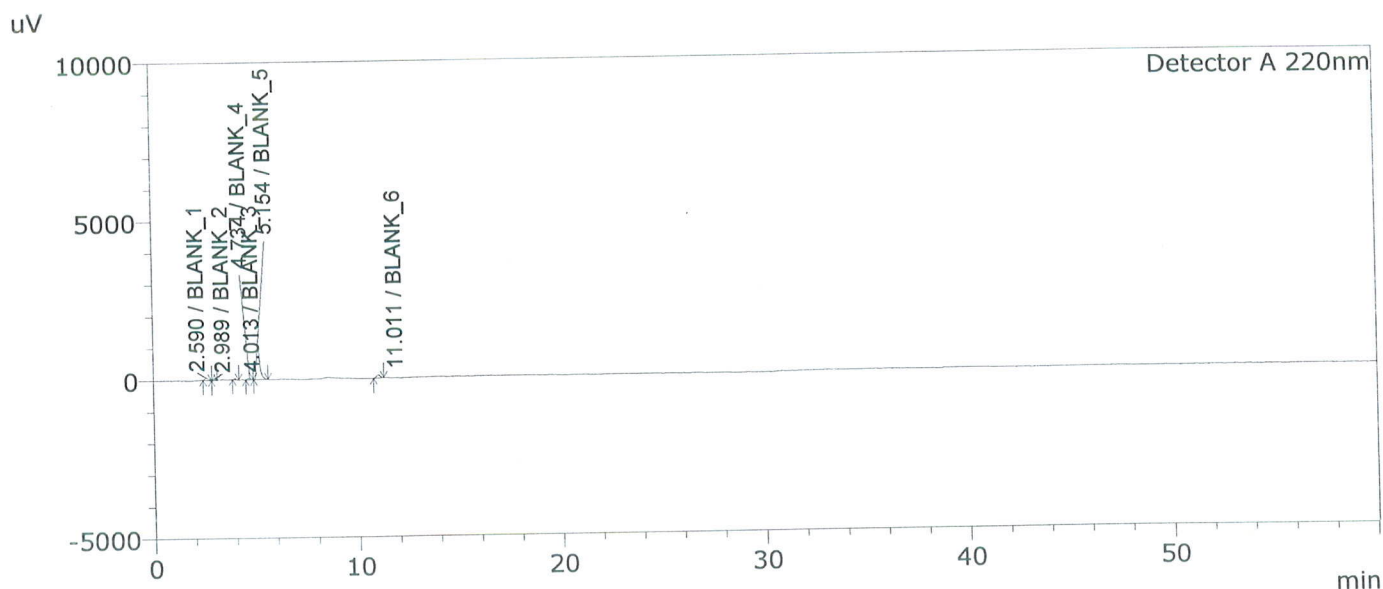
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-LTM-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-57.lcd
 Method Filename : GRIPEX-SACH-LTM-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 8:32:20 AM
 Date Processed : 1/22/2024 3:28:50 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.59	952	6.33	560	1.665	--	--
2	BLANK_2	2.99	369	2.45	2340	1.102	1.163	--
3	BLANK_3	4.01	275	1.82	5229	1.324	4.366	--
4	BLANK_4	4.73	527	3.50	4316	0.895	2.827	--
5	BLANK_5	5.15	11658	77.45	5792	1.615	1.500	--
6	BLANK_6	11.01	1271	8.44	14398	1.113	18.363	--
Total			15052	100.00				

Analysed By

Checked By



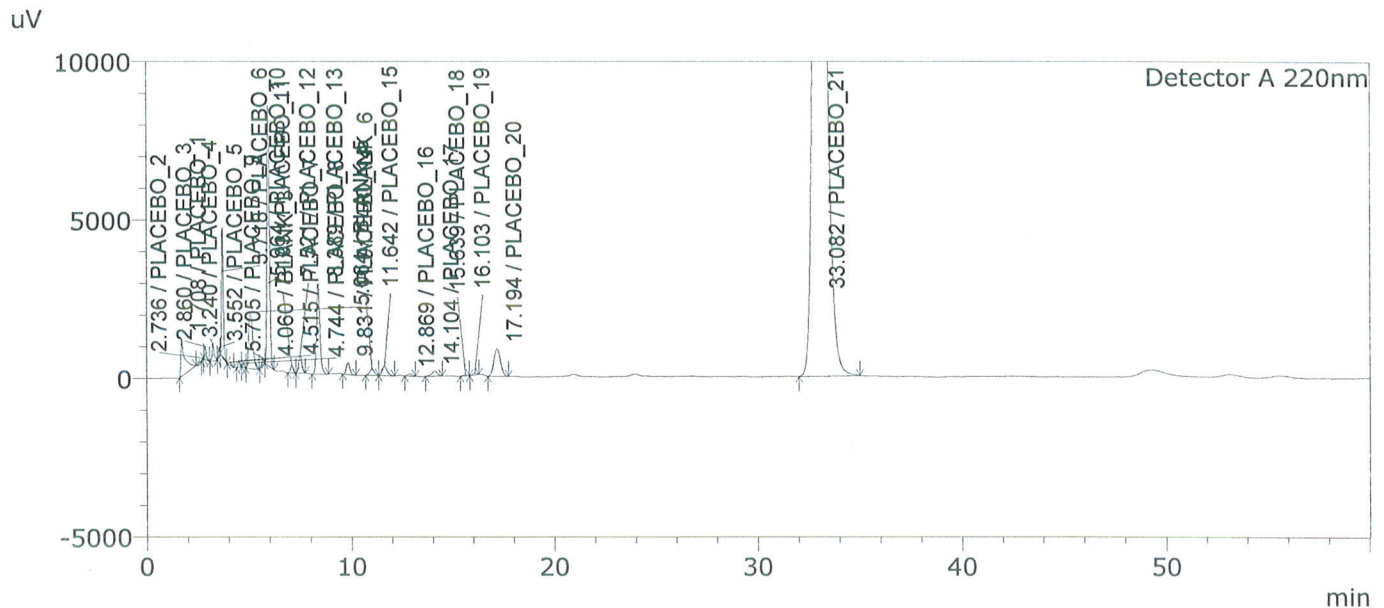
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PLACEBO-LTM-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-58.lcd
 Method Filename : GRIPEX-SACH-LTM-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 9:32:59 AM
 Date Processed : 1/22/2024 3:38:50 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

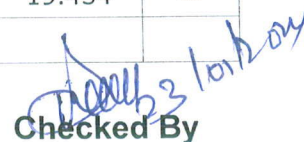
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.71	16878	1.21	878	5.114	--	--
2	PLACEBO_2	2.74	217	0.02	11563	0.873	6.190	--
3	PLACEBO_3	2.86	2248	0.16	5636	1.716	0.975	--
4	PLACEBO_4	3.24	3973	0.29	4916	1.279	2.250	--
5	PLACEBO_5	3.55	1267	0.09	12055	0.855	1.988	--
6	PLACEBO_6	3.72	24593	1.77	7432	1.205	1.097	--
7	BLANK_3	4.06	614	0.04	4292	1.324	1.628	--
8	PLACEBO_7	4.52	1278	0.09	9898	1.170	2.122	--
9	PLACEBO_8	4.74	681	0.05	13215	1.068	1.319	--
10	BLANK_5	5.06	24480	1.76	3151	1.569	1.216	--
11	PLACEBO_9	5.70	1585	0.11	12625	0.795	2.273	--
12	PLACEBO_10	5.96	68831	4.94	10631	1.129	1.196	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	7.10	2206	0.16	11016	1.027	4.536	--
14	PLACEBO_12	7.52	6149	0.44	10243	1.065	1.471	--
15	PLACEBO_13	8.39	33058	2.37	12399	1.183	2.902	--
16	PLACEBO_14	9.83	4657	0.33	13768	1.154	4.531	--
17	BLANK_6	11.02	3027	0.22	10588	1.068	3.105	--
18	PLACEBO_15	11.64	4838	0.35	11914	1.308	1.464	--
19	PLACEBO_16	12.87	992	0.07	17087	1.158	2.989	--
20	PLACEBO_17	14.10	2935	0.21	13721	0.907	2.822	--
21	PLACEBO_18	15.64	487	0.03	28169	0.896	3.593	--
22	PLACEBO_19	16.10	835	0.06	29684	0.908	1.243	--
23	PLACEBO_20	17.19	19670	1.41	12948	1.077	2.231	--
24	PLACEBO_21	33.08	1167775	83.82	16486	1.161	19.434	--
Total			1393273	100.00				

Analysed By


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 23/01/24



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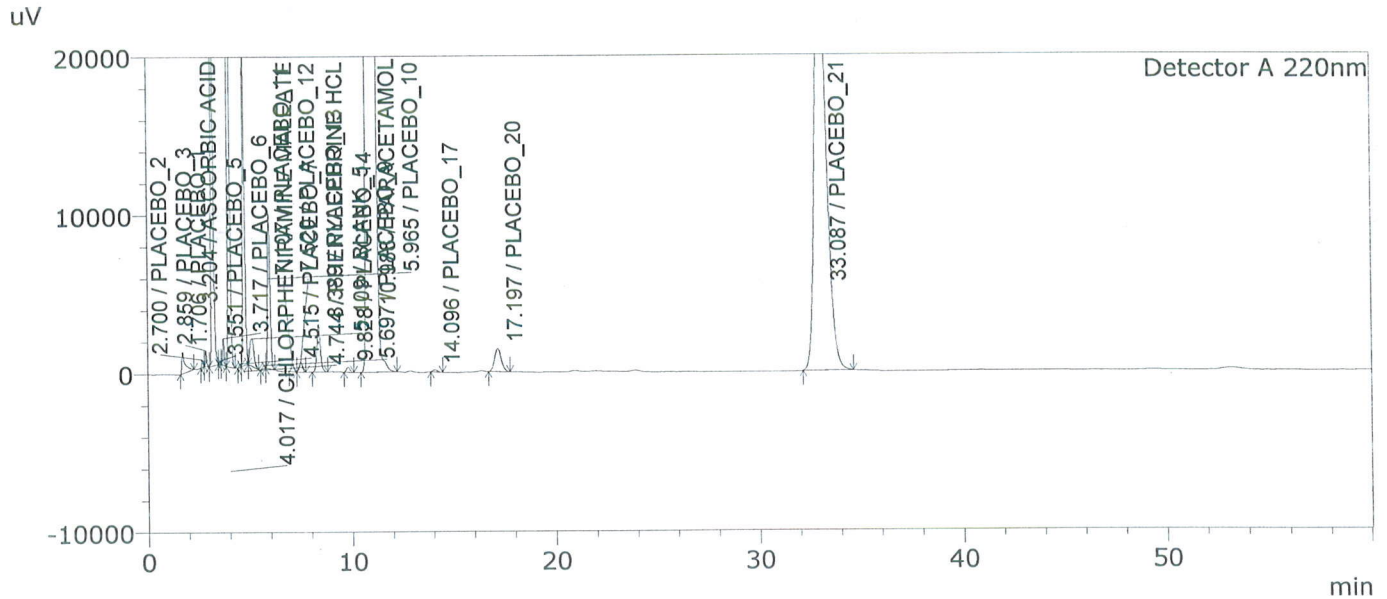
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : GRIPEX-1228-LTM-RS-SPL
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-59.lcd
 Method Filename : GRIPEX-SACH-LTM-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 10:33:38 AM
 Date Processed : 1/22/2024 4:36:59 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

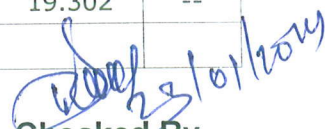
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.71	15778	0.10	992	4.167	--	--
2	PLACEBO_2	2.70	2433	0.02	4770	1.004	5.329	--
3	PLACEBO_3	2.86	4771	0.03	6792	1.591	1.082	--
4	ASCORBIC ACID	3.20	288845	1.85	6121	1.257	2.280	--
5	PLACEBO_5	3.55	787	0.01	13640	0.997	2.431	--
6	PLACEBO_6	3.72	9238	0.06	8289	1.120	1.161	--
7	CHLORPHENIRAMINE MALEATE	4.02	277360	1.78	8645	1.207	1.788	--
8	PLACEBO_7	4.52	1071	0.01	16114	0.916	3.160	--
9	PHENYLEPHRINE HCL	4.74	142569	0.91	8866	1.127	1.329	--
10	BLANK_5	5.11	23188	0.15	3629	1.221	1.349	--
11	PLACEBO_9	5.70	1578	0.01	11342	0.794	2.127	--
12	PLACEBO_10	5.96	83114	0.53	10526	1.127	1.200	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	7.11	3677	0.02	12168	1.038	4.661	--
14	PLACEBO_12	7.52	6459	0.04	10292	1.065	1.487	--
15	PLACEBO_13	8.39	35036	0.22	12132	1.118	2.892	--
16	PLACEBO_14	9.83	3847	0.02	14616	1.084	4.571	--
17	PARACETAMOL	10.99	13592867	87.00	13513	1.117	3.299	--
18	PLACEBO_17	14.10	2065	0.01	17617	1.262	7.740	--
19	PLACEBO_20	17.20	33719	0.22	12481	1.100	5.960	--
20	PLACEBO_21	33.09	1094987	7.01	16485	1.161	19.302	--
Total			15623390	100.00				

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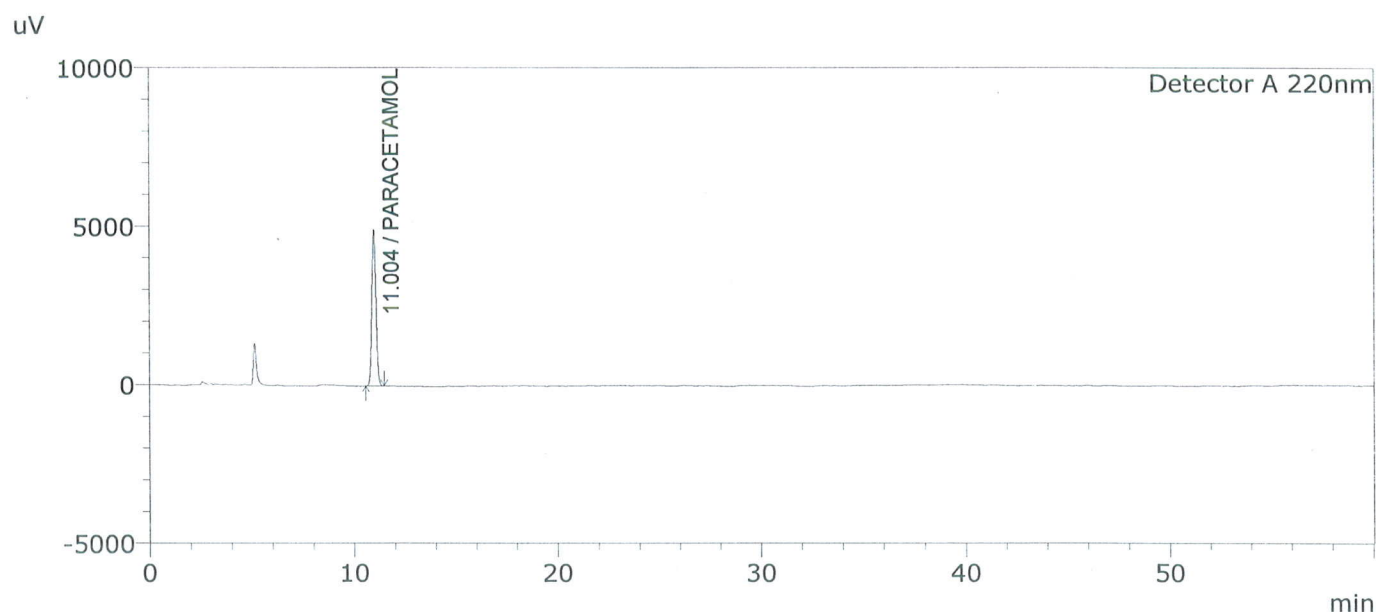
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-LTM-STD-BKT
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-60.lcd
 Method Filename : GRIPEX-SACH-LTM-RS_P.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 11:34:18 AM
 Date Processed : 1/22/2024 4:40:05 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	11.00	69221	100.00	13841	1.059	--	--
Total			69221	100.00				

22/01/24

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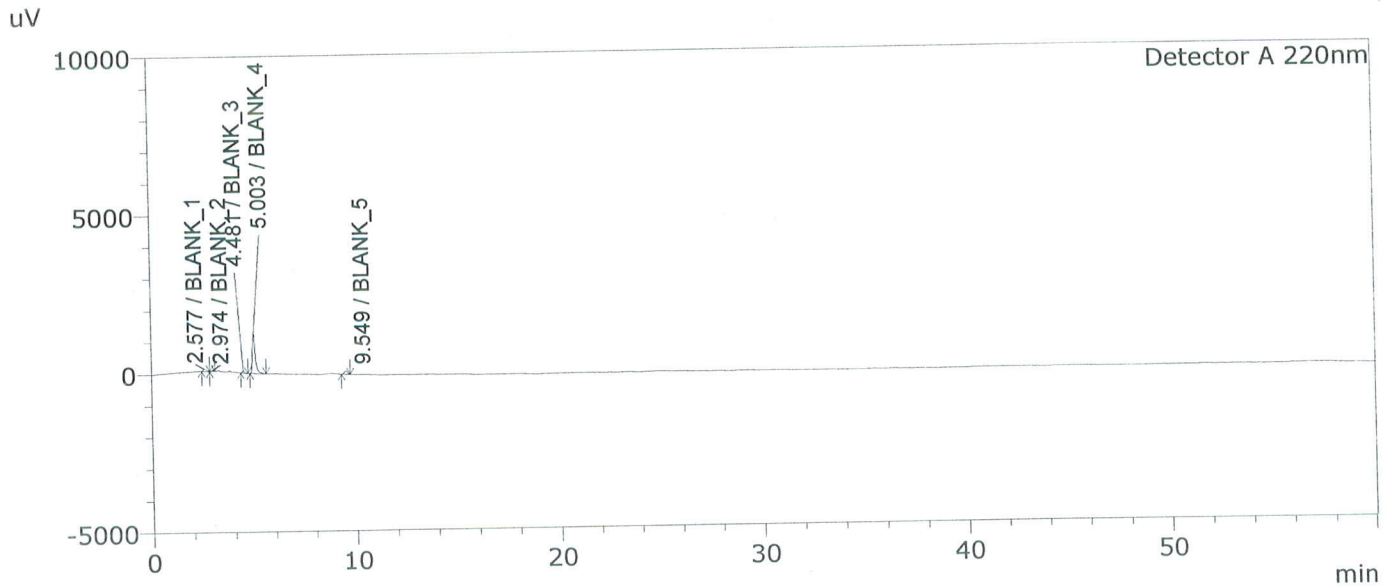
22/01/2024

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Analysis Report
<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-HTM-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-61.lcd
 Method Filename : GRIPEX-SACH-HTM-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 12:38:40 PM
 Date Processed : 1/22/2024 4:46:58 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.58	808	5.45	845	1.719	--	--
2	BLANK_2	2.97	302	2.04	2560	1.020	1.347	--
3	BLANK_3	4.48	412	2.78	7339	1.091	6.784	--
4	BLANK_4	5.00	12071	81.47	6633	1.557	2.291	--
5	BLANK_5	9.55	1225	8.26	14580	0.976	16.180	--
Total			14817	100.00				

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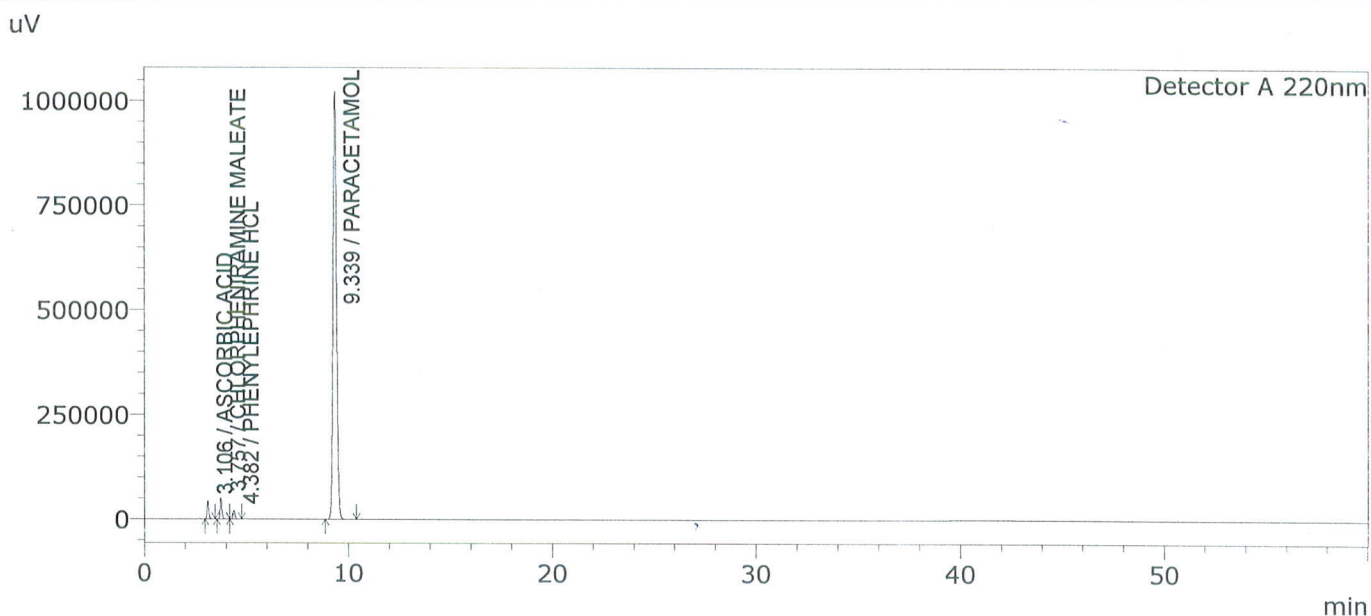
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : RESOLUTION SOLUTION-HTM
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-62.lcd
 Method Filename : GRIPEX-SACH-HTM-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 1:39:19 PM
 Date Processed : 1/22/2024 4:49:03 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	3.11	248137	1.90	6020	1.232	--	--
2	CHLORPHENIRAMINE MALEATE	3.76	300803	2.31	8200	1.206	3.989	--
3	PHENYLEPHRINE HCL	4.38	142465	1.09	8426	1.156	3.506	--
4	PARACETAMOL	9.34	12345525	94.70	13239	1.087	19.226	--
Total			13036931	100.00				

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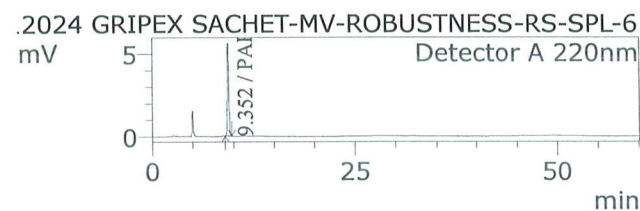
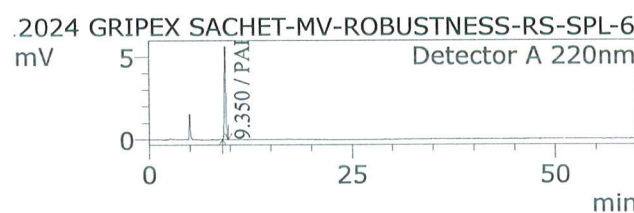
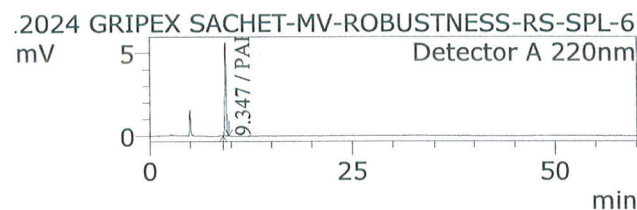
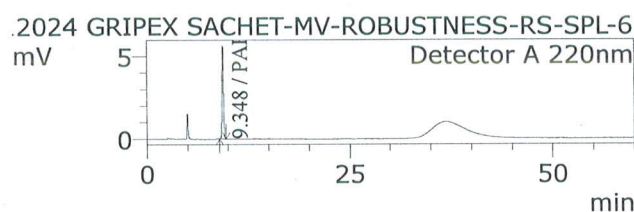
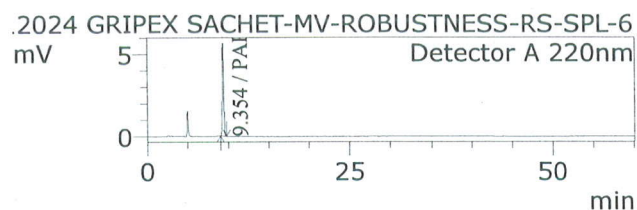
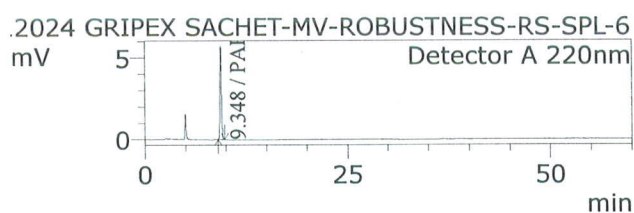
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-HTM-STD-01
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-63.lcd
 Method Filename : GRIPEX-SACH-HTM-RS_P.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 2:39:59 PM
 Date Processed : 1/22/2024 4:44:32 PM
 Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<< Detector A >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-63.lcd	PARACETAMOL-RS-HTM-STD-01	9.35	68279	13463	1.05
3	RS-SPL-64.lcd	PARACETAMOL-RS-HTM-STD-02	9.35	67834	13375	1.05
3	RS-SPL-65.lcd	PARACETAMOL-RS-HTM-STD-03	9.35	67855	13369	1.05
3	RS-SPL-66.lcd	PARACETAMOL-RS-HTM-STD-04	9.35	67687	13374	1.05
3	RS-SPL-67.lcd	PARACETAMOL-RS-HTM-STD-05	9.35	67714	13343	1.05
3	RS-SPL-68.lcd	PARACETAMOL-RS-HTM-STD-06	9.35	67684	13326	1.05
	Average		9.35	67842	13375	1.05
	%RSD		0.028	0.334	0.354	0.115

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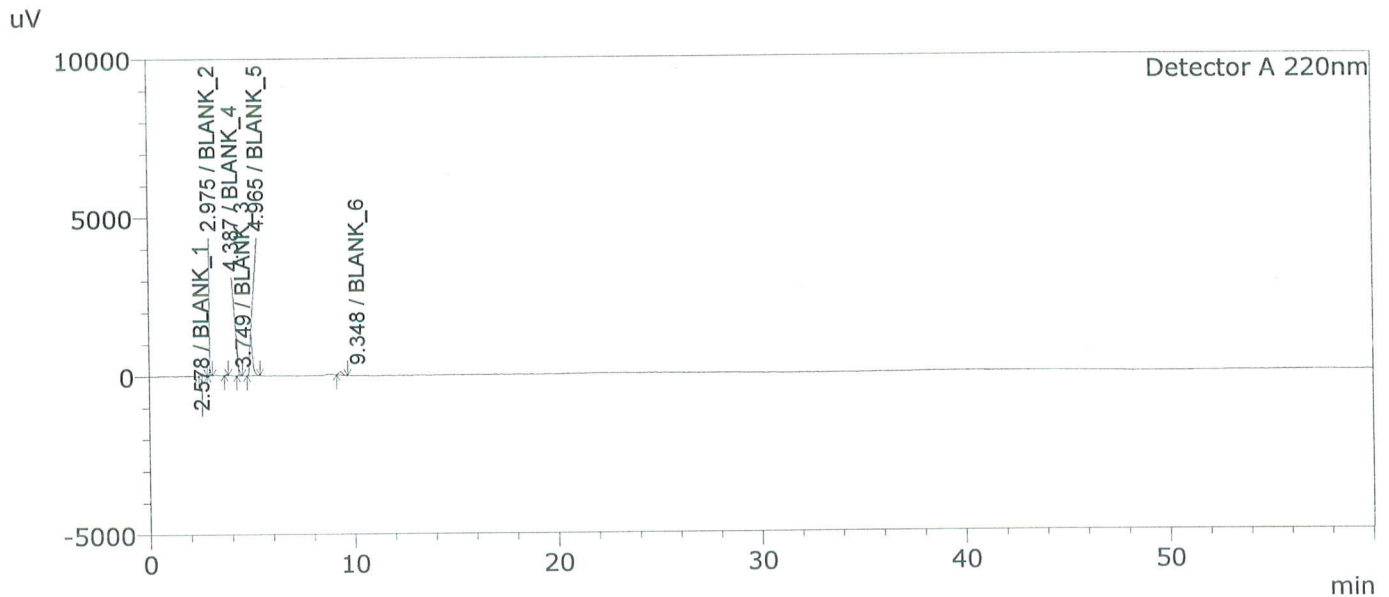
Checked By

22/01/2024


GENERIC HEALTHCARE PVT. LTD.
Analysis Report
<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : BLANK-HTM-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-69.lcd
 Method Filename : GRIPEX-SACH-HTM-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 8:43:53 PM
 Date Processed : 1/22/2024 5:01:11 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>

<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	2.58	888	5.94	706	1.484	--	--
2	BLANK_2	2.97	304	2.04	2461	1.028	1.264	--
3	BLANK_3	3.75	190	1.27	9435	1.145	3.928	--
4	BLANK_4	4.39	314	2.10	5465	1.397	3.256	--
5	BLANK_5	4.97	11959	80.05	6853	1.506	2.425	--
6	BLANK_6	9.35	1284	8.59	14066	1.206	15.786	--
Total			14939	100.00				

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Checked By



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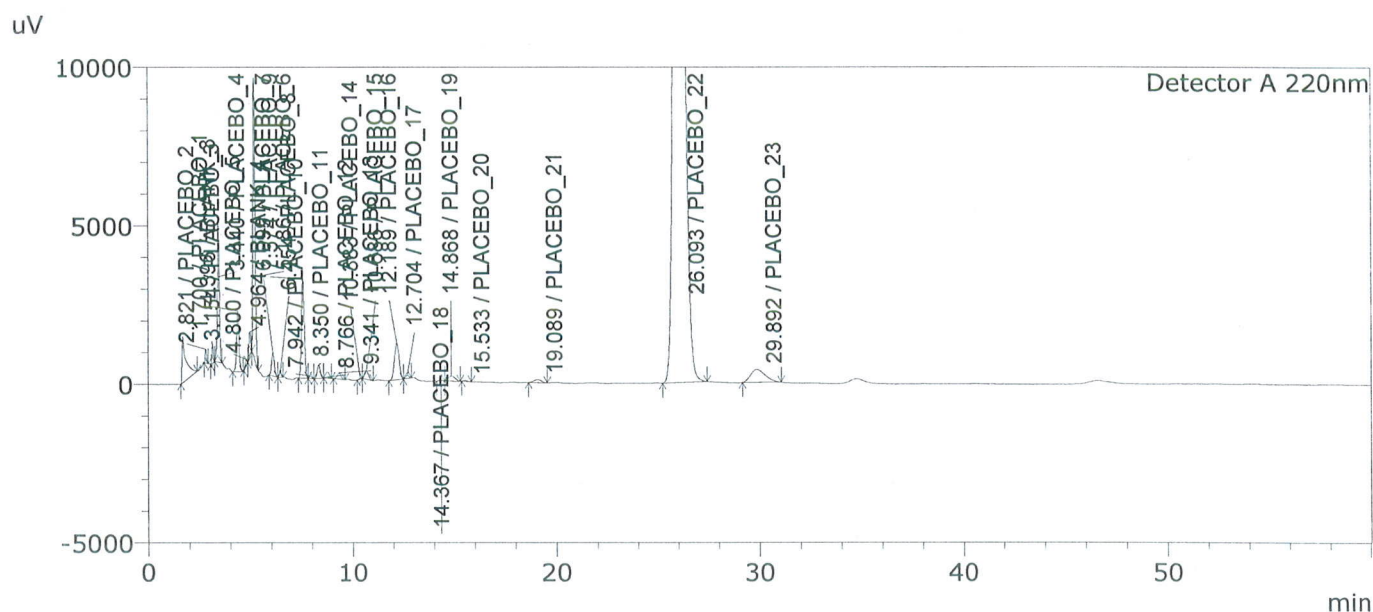
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PLACEBO-HTM-RS
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-70.lcd
 Method Filename : GRIPEX-SACH-HTM-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 9:44:32 PM
 Date Processed : 1/22/2024 5:07:49 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

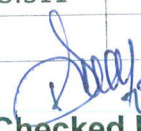
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	20336	1.45	869	4.950	--	--
2	PLACEBO_2	2.82	2065	0.15	6429	1.245	6.041	--
3	PLACEBO_3	3.15	2534	0.18	7586	1.070	2.328	--
4	PLACEBO_4	3.44	28767	2.05	6223	0.916	1.792	--
5	BLANK_3	4.40	15451	1.10	6629	0.997	4.901	--
6	PLACEBO_5	4.80	1035	0.07	16064	0.761	2.199	--
7	BLANK_4	4.96	4408	0.31	14648	0.947	1.038	--
8	PLACEBO_6	5.19	65196	4.64	10084	1.129	1.196	--
9	PLACEBO_7	6.10	6701	0.48	9147	1.083	3.954	--
10	PLACEBO_8	6.45	1087	0.08	16500	1.048	1.559	--
11	PLACEBO_9	7.57	30473	2.17	12934	1.054	4.793	--
12	PLACEBO_10	7.94	618	0.04	20727	1.095	1.509	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_11	8.35	4413	0.31	13693	1.026	1.612	--
14	PLACEBO_12	8.77	512	0.04	9877	1.060	1.306	--
15	PLACEBO_13	9.34	2491	0.18	12744	0.970	1.682	--
16	PLACEBO_14	10.38	250	0.02	36022	0.894	3.790	--
17	PLACEBO_15	10.69	3565	0.25	14090	1.220	1.046	--
18	PLACEBO_16	12.19	18557	1.32	12351	1.002	3.763	--
19	PLACEBO_17	12.70	1188	0.08	25228	1.053	1.358	--
20	PLACEBO_18	14.37	420	0.03	23724	0.863	4.800	--
21	PLACEBO_19	14.87	3508	0.25	9746	1.168	1.026	--
22	PLACEBO_20	15.53	337	0.02	28463	1.495	1.369	--
23	PLACEBO_21	19.09	2465	0.18	12303	1.002	6.732	--
24	PLACEBO_22	26.09	1167133	83.12	15768	1.097	9.217	--
25	PLACEBO_23	29.89	20595	1.47	8042	1.274	3.511	--
Total			1404108	100.00				

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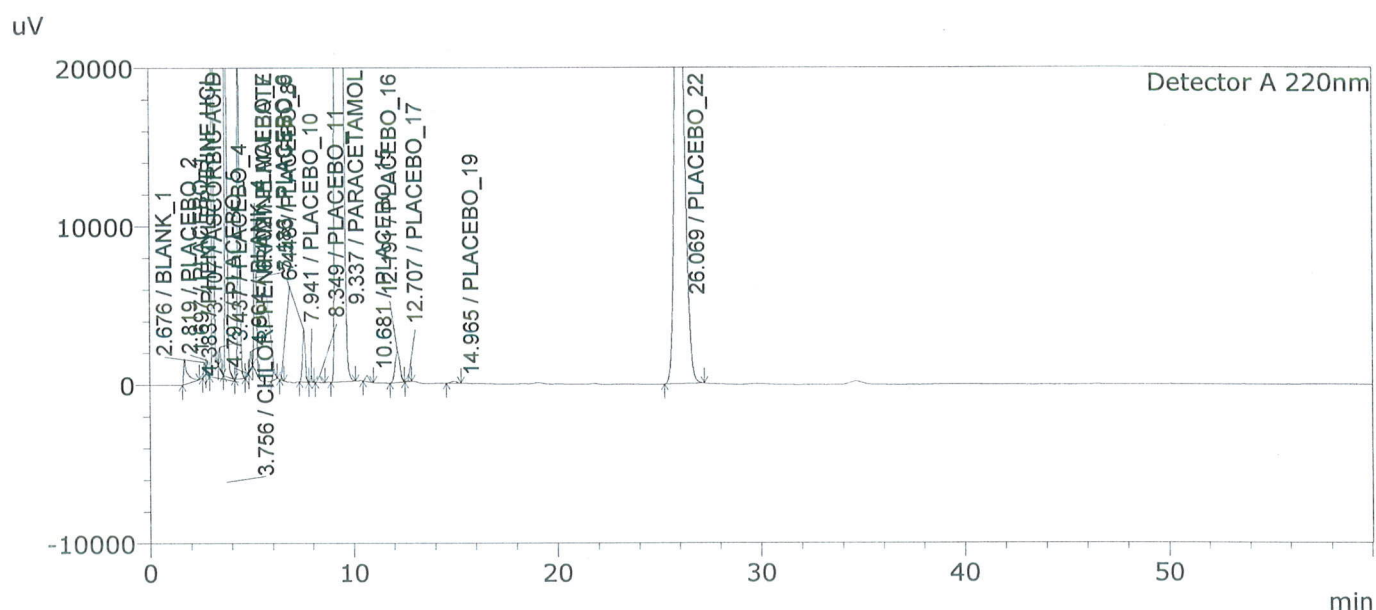
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : GRIPEX-1228-HTM-RS-SPL
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-71.lcd
 Method Filename : GRIPEX-SACH-HTM-RS.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 10:45:11 PM
 Date Processed : 1/22/2024 5:15:55 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

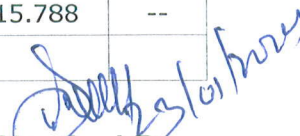
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.70	20654	0.13	969	4.891	--	--
2	BLANK_1	2.68	4137	0.03	5375	0.998	5.377	--
3	PLACEBO_2	2.82	3637	0.02	8398	1.198	1.062	--
4	ASCORBIC ACID	3.11	213230	1.38	5997	1.182	2.033	--
5	PLACEBO_4	3.44	6612	0.04	8815	1.168	2.150	--
6	CHLORPHENIRAMINE MALEATE	3.76	276278	1.79	8138	1.208	2.034	--
7	PHENYLEPHRINE HCL	4.38	161561	1.04	7993	1.144	3.458	--
8	PLACEBO_5	4.80	663	0.00	20614	0.731	2.511	--
9	BLANK_4	4.96	6765	0.04	13832	0.939	1.105	--
10	PLACEBO_6	5.19	77253	0.50	10165	1.132	1.187	--
11	PLACEBO_7	6.10	5492	0.04	11417	0.993	4.218	--
12	PLACEBO_8	6.45	677	0.00	23721	1.173	1.747	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_9	7.57	32300	0.21	12672	1.028	5.156	--
14	PLACEBO_10	7.94	699	0.00	20586	1.079	1.502	--
15	PLACEBO_11	8.35	4187	0.03	13238	1.035	1.595	--
16	PARACETAMOL	9.34	13516605	87.38	12981	1.093	3.197	--
17	PLACEBO_15	10.68	4703	0.03	15191	1.207	3.983	--
18	PLACEBO_16	12.19	31933	0.21	11951	1.003	3.810	--
19	PLACEBO_17	12.71	836	0.01	30742	0.989	1.402	--
20	PLACEBO_19	14.97	2638	0.02	10738	0.943	5.207	--
21	PLACEBO_22	26.07	1097550	7.10	15825	1.097	15.788	--
Total			15468411	100.00				

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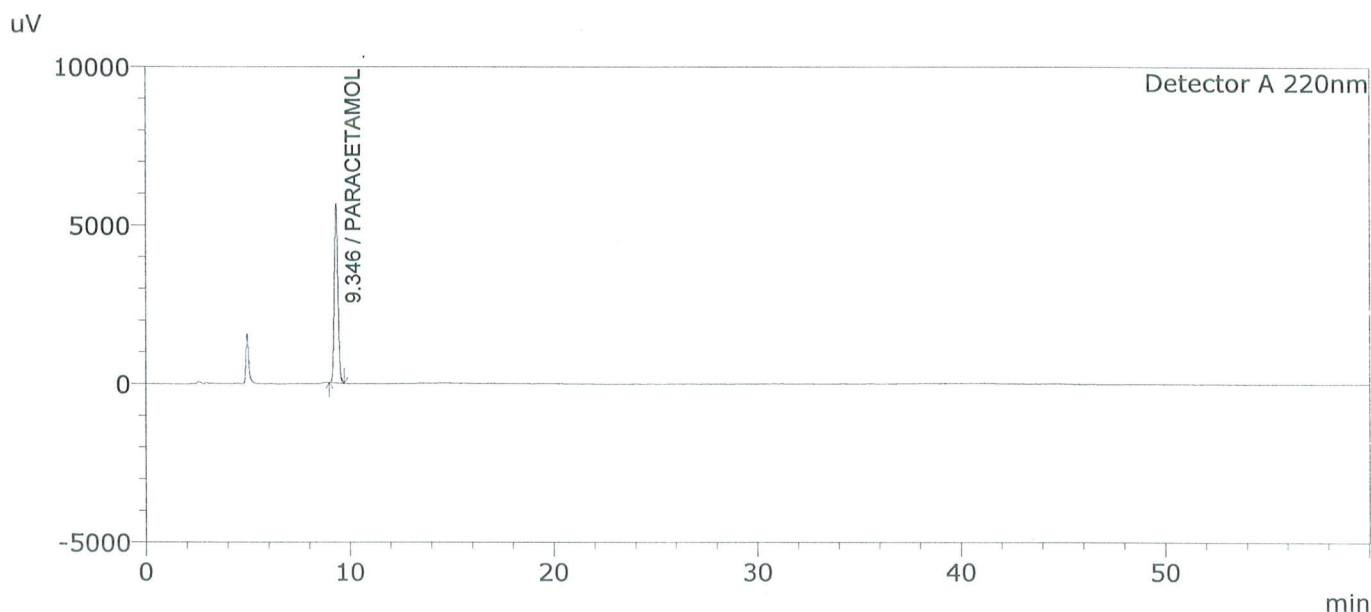
Analysis Report

<Sample Information>

Sample Name : ROBUSTNESS-RS
 Sample ID : PARACETAMOL-RS-HTM-STD-BKT
 Data Filename : 18012024 GRIPEX SACHET-MV-ROBUSTNESS-RS-SPL-72.lcd
 Method Filename : GRIPEX-SACH-HTM-RS_P.lcm
 Batch Filename : 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/21/2024 11:45:50 PM
 Date Processed : 1/22/2024 4:44:36 PM

Acquired by : E.MEENA
 Processed by : C.K.SARAVANAN.

<Chromatogram>



<Peak Table>

Detector A 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	9.35	68099	100.00	13272	1.054	--	--
Total			68099	100.00				

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Batch Table

Batch Table 18012024 GRIPEX SACHET-MV-RS-ROBUSTNESS.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	1	ROBUSTNESS-RS	BLANK-LWL-RS	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-01.lcd	10.0	QC/CL/23/033
2	1	ROBUSTNESS-RS	RESOLUTION SOLUTION-LWL	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-02.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LWL-STD-01	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-03.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LWL-STD-02	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-04.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LWL-STD-03	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-05.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LWL-STD-04	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-06.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LWL-STD-05	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-07.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LWL-STD-06	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-08.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-LWL-RS	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-09.lcd	10.0	QC/CL/23/033
4	1	ROBUSTNESS-RS	PLACEBO-LWL-RS	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-10.lcd	10.0	QC/CL/23/033
5	1	ROBUSTNESS-RS	GRIPEX-1228-LWL-RS-SPL	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-11.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LWL-STD-BKT	IPEX-SACH-LWL-RS.lcm	NESS-RS-SPL-12.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-HWL-RS	IPEX-SACH-HWL-RS.lcm	NESS-RS-SPL-13.lcd	10.0	QC/CL/23/033
2	1	ROBUSTNESS-RS	RESOLUTION SOLUTION-HWL	IPEX-SACH-HWL-RS.lcm	NESS-RS-SPL-14.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HWL-STD-01	IPEX-SACH-HWL-RS.lcm	NESS-RS-SPL-15.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HWL-STD-02	IPEX-SACH-HWL-RS.lcm	NESS-RS-SPL-16.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HWL-STD-03	IPEX-SACH-HWL-RS.lcm	NESS-RS-SPL-17.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HWL-STD-04	IPEX-SACH-HWL-RS.lcm	NESS-RS-SPL-18.lcd	10.0	QC/CL/23/033

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HWL-STD-05	IPEX-SACH-HWL-RS.lcm	TNESS-RS-SPL-19.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HWL-STD-06	IPEX-SACH-HWL-RS.lcm	TNESS-RS-SPL-20.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-HWL-RS	IPEX-SACH-HWL-RS.lcm	TNESS-RS-SPL-21.lcd	10.0	QC/CL/23/033
4	1	ROBUSTNESS-RS	PLACEBO-HWL-RS	IPEX-SACH-HWL-RS.lcm	TNESS-RS-SPL-22.lcd	10.0	QC/CL/23/033
5	1	ROBUSTNESS-RS	GRIPEX-1228-HWL-RS-SPL	IPEX-SACH-HWL-RS.lcm	TNESS-RS-SPL-23.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HWL-STD-BKT	IPEX-SACH-HWL-RS.lcm	TNESS-RS-SPL-24.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-LFL-RS	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-25.lcd	10.0	QC/CL/23/033
2	1	ROBUSTNESS-RS	RESOLUTION SOLUTION-LFL	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-26.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LFL-STD-01	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-27.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LFL-STD-02	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-28.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LFL-STD-03	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-29.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LFL-STD-04	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-30.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LFL-STD-05	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-31.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LFL-STD-06	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-32.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-LFL-RS	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-33.lcd	10.0	QC/CL/23/033
4	1	ROBUSTNESS-RS	PLACEBO-LFL-RS	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-34.lcd	10.0	QC/CL/23/033
5	1	ROBUSTNESS-RS	GRIPEX-1228-LFL-RS-SPL	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-35.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LFL-STD-BKT	RIPEX-SACH-LFL-RS.lcm	TNESS-RS-SPL-36.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-HFL-RS	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-37.lcd	10.0	QC/CL/23/033
2	1	ROBUSTNESS-RS	RESOLUTION SOLUTION-HFL	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-38.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HFL-STD-01	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-39.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HFL-STD-02	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-40.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HFL-STD-03	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-41.lcd	10.0	QC/CL/23/033

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HFL-STD-04	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-42.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HFL-STD-05	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-43.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HFL-STD-06	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-44.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-HFL-RS	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-45.lcd	10.0	QC/CL/23/033
4	1	ROBUSTNESS-RS	PLACEBO-HFL-RS	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-46.lcd	10.0	QC/CL/23/033
5	1	ROBUSTNESS-RS	GRIPEX-1228-HFL-RS-SPL	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-47.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HFL-STD-BKT	RIPEX-SACH-HFL-RS.lcm	TNESS-RS-SPL-48.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-LTM-RS	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-49.lcd	10.0	QC/CL/23/033
2	1	ROBUSTNESS-RS	RESOLUTION SOLUTION-LTM	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-50.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LTM-STD-01	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-51.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LTM-STD-02	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-52.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LTM-STD-03	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-53.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LTM-STD-04	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-54.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LTM-STD-05	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-55.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LTM-STD-06	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-56.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-LTM-RS	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-57.lcd	10.0	QC/CL/23/033
4	1	ROBUSTNESS-RS	PLACEBO-LTM-RS	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-58.lcd	10.0	QC/CL/23/033
5	1	ROBUSTNESS-RS	GRIPEX-1228-LTM-RS-SPL	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-59.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-LTM-STD-BKT	RIPEX-SACH-LTM-RS.lcm	TNESS-RS-SPL-60.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-HTM-RS	IPEX-SACH-HTM-RS.lcm	TNESS-RS-SPL-61.lcd	10.0	QC/CL/23/033
2	1	ROBUSTNESS-RS	RESOLUTION SOLUTION-HTM	IPEX-SACH-HTM-RS.lcm	TNESS-RS-SPL-62.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HTM-STD-01	IPEX-SACH-HTM-RS.lcm	TNESS-RS-SPL-63.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HTM-STD-02	IPEX-SACH-HTM-RS.lcm	TNESS-RS-SPL-64.lcd	10.0	QC/CL/23/033

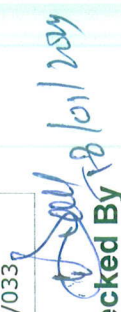
Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HTM-STD-03	IPEX-SACH-HTM-RS.lcm	NESS-RS-SPL-65.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HTM-STD-04	IPEX-SACH-HTM-RS.lcm	NESS-RS-SPL-66.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HTM-STD-05	IPEX-SACH-HTM-RS.lcm	NESS-RS-SPL-67.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HTM-STD-06	IPEX-SACH-HTM-RS.lcm	NESS-RS-SPL-68.lcd	10.0	QC/CL/23/033
1	1	ROBUSTNESS-RS	BLANK-HTM-RS	IPEX-SACH-HTM-RS.lcm	NESS-RS-SPL-69.lcd	10.0	QC/CL/23/033
4	1	ROBUSTNESS-RS	PLACEBO-HTM-RS	IPEX-SACH-HTM-RS.lcm	NESS-RS-SPL-70.lcd	10.0	QC/CL/23/033
5	1	ROBUSTNESS-RS	GRIPEX-1228-HTM-RS-SPL	IPEX-SACH-HTM-RS.lcm	NESS-RS-SPL-71.lcd	10.0	QC/CL/23/033
3	1	ROBUSTNESS-RS	PARACETAMOL-RS-HTM-STD-BKT	IPEX-SACH-HTM-RS.lcm	NESS-RS-SPL-72.lcd	10.0	QC/CL/23/033
-1	1	ROBUSTNESS-RS	WASH	WASHING METHOD.lcm	NESS-RS-SPL-73.lcd	10.0	QC/CL/23/033
-1	1	ROBUSTNESS-RS	SHUTDWON	HUTDOWN METHOD.lcm	NESS-RS-SPL-74.lcd	10.0	QC/CL/23/033

Analysed By



8/10/24

Checked By



8/10/24

**GENERIC HEALTHCARE PVT.LTD****QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET****Title****RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET**

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Parameter :	INTERFERENCE FROM DEGRADANTS	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:

Paracetamol BP ----- 650 mg

Chlorphenamine Maleate BP ----- 20 mg

Phenylephrine Hydrochloride BP ----- 10 mg

Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QC/EQ/039	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.02	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.001	5	ml to --->	50	ml to --->	1	ml to --->	1

(Acid)Test dilution .:	415.16	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.6755	1	ml to --->	1	ml to --->	1	ml to --->	1

(Alkali)Test dilution .:	415.26	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.82	1	ml to --->	1	ml to --->	1	ml to --->	1

(H2O2)Test dilution .:	415.27	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.8344	1	ml to --->	1	ml to --->	1	ml to --->	1

S.No	Sample Name	Single Maximum Unknown Imp	Total Impurities	Peak Name	Peak purity
1	Acid Degradation	0.02	0.06	Paracetamol	1.000
2	Alkali Degradation	0.98	2.47	Paracetamol	1.000
3	Peroxide Degradation	0.03	0.03	Paracetamol	1.000

Results :

1) There is no any interference due to degradants with analyte in Stressed Samples.

2) Peak purity was passed 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 oxidative 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 :

S.ELAVARASAN

Date :

25-01-2024

Checked by :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	INTERFERENCE FROM DEGRADANTS -ACID DEGRADATION	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QC/EQ/039	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.02	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.001	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.16	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.67	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000	
Labelled content :	650	mg
Average weight :	4500.0	mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	65494	64003	65312	65566	64150	65322	64975	704.0	1.083
With Bracketing std.	65479						65047	670.3	1.031

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.	7.435		2093	2437
UNKNOWN Imp.	7.801		2234	
UNKNOWN Imp.	8.553		687	
UNKNOWN Imp.	11.352		981	
UNKNOWN Imp.	11.597		2437	
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			8432	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.012
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.656
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.167

SINGLE MAXIMUM UNKNOWN IMPURITY

Limit: NMT 0.50%

Calculation formula :

Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

2437
64975
0.02

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :

Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

8432
64975
0.06

Analysed by : S.ELAVARASAN

Date : 25-01-2024

Checked by :

Date :

25/01/2024



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	INTERFERENCE FROM DEGRADANTS -ALKALI DEGRADATION	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QC/EQ/039	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
Standard dilution.:	60.02	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.001	5	ml to --->	50	ml to --->	1	ml to --->	1
Test dilution.:	415.26	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.82	1	ml to --->	1	ml to --->	1	ml to --->	1
Conversion factor :	1.0000						
Labelled content :	650	mg					
Average weight :	4500.0	mg					

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	65494	64003	65312	65566	64150	65322	64975	704.0	1.083
With Bracketing std.	65479						65047	670.3	1.031

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.	5.330		2751	127856
UNKNOWN Imp.	6.160		1616	
UNKNOWN Imp.	11.308		13970	
UNKNOWN Imp.	11.950		27947	
UNKNOWN Imp.	12.472		15632	
UNKNOWN Imp.	13.106		15502	
UNKNOWN Imp.	14.041		15414	
UNKNOWN Imp.	17.389		127856	
UNKNOWN Imp.	18.643		35170	
UNKNOWN Imp.	19.472		12637	
UNKNOWN Imp.	20.007		52523	
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			321018	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.012
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.656
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.167

SINGLE MAXIMUM UNKNOWN IMPURITIV

Limit: NMT 0.50%

Calculation formula :

Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

127856
64975

0.98

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :

Total impurities in%	Total impurity area x Std.dilution X Purity % (aib)x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

321018
64975

2.47

Analysed by :

S.ELAVARASAN

Date :

25-01-2024

Checked by :

Date :



GENERIC HEALTHCARE PVT.LTD

QUALITY CONTROL ANALYTICAL METHOD VALIDATION CALCULATION SHEET

Title

RELATED SUBSTANCE OF PARACETAMOL IN GRIPEX SACHET

Product Name :	GRIPEX	Batch size :	Not applicable
Batch Number :	G17231228	Mfg.Date :	Dec-23
Stage :	INTERFERENCE FROM DEGRADANTS -OXIDATIVE DEGRADATION	Exp.Date :	Nov-26

Each 4.5 gm sachet contains:
Paracetamol BP ----- 650 mg
Chlorphenamine Maleate BP ----- 20 mg
Phenylephrine Hydrochloride BP ----- 10 mg
Ascorbic Acid BP----- 50 mg

RELATED SUBSTANCE OF PARACETAMOL

Instrument ID:	ST/QC/EQ/039	Balance ID:	ST/QC/EQ/041	WS No.:	ST/WS/23/012	% Purity (aib)	99.9
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Standard dilution.:	60.02	mg to --->	100	ml to --->	5	ml to --->	100
Std.conc (in ppm)-3.001	5	ml to --->	50	ml to --->	1	ml to --->	1

Test dilution.:	415.27	mg to --->	100	ml to --->	1	ml to --->	1
Test.conc (in ppm)-599.834	1	ml to --->	1	ml to --->	1	ml to --->	1

Conversion factor :	1.0000
Labelled content :	650
Average weight :	4500.0

mg

mg

System suitability	1	2	3	4	5	6	MEAN	S.D	RSD in %
Paracetamol	65494	64003	65312	65566	64150	65322	64975	704.0	1.083
With Bracketing std.	65479						65047	670.3	1.031

Name of the Peaks	RT	RRT	Individual Impurity Peak areas	Maximum Impurity Area
UNKNOWN Imp.	11.617		3766	3766
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
UNKNOWN Imp.				
Total Impurity Area			3766	

SYSTEM SUITABILITY	Resolution between peak due to Ascorbic acid and Chlorpheniramine peak NLT 2.0	4.012
	Resolution between peak due to Chlorpheniramine and Phenylephrine peak NLT 2.0	3.656
	Resolution between peak due to Phenylephrine and Paracetamol peak NLT 2.0	20.167

SINGLE MAXIMUM UNKNOWN IMPURITIY

Limit: NMT 0.50%

Calculation formula :

Any individual impurity in%	Max.impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

0.03

TOTAL IMPURITIES

Limit: NMT 1.00%

Calculation formula :

Total impurities in%	Total impurity area x Std.dilution X Purity % (aib) x conversion factor x avg.weight x100
	Standard area x sample dilution X Label claim x 100

ND

0.03

Analysed by :

S.ELAVARASAN

Date :

25-01-2024

Checked by :

Date :



GENERIC HEALTHCARE PVT. LTD.

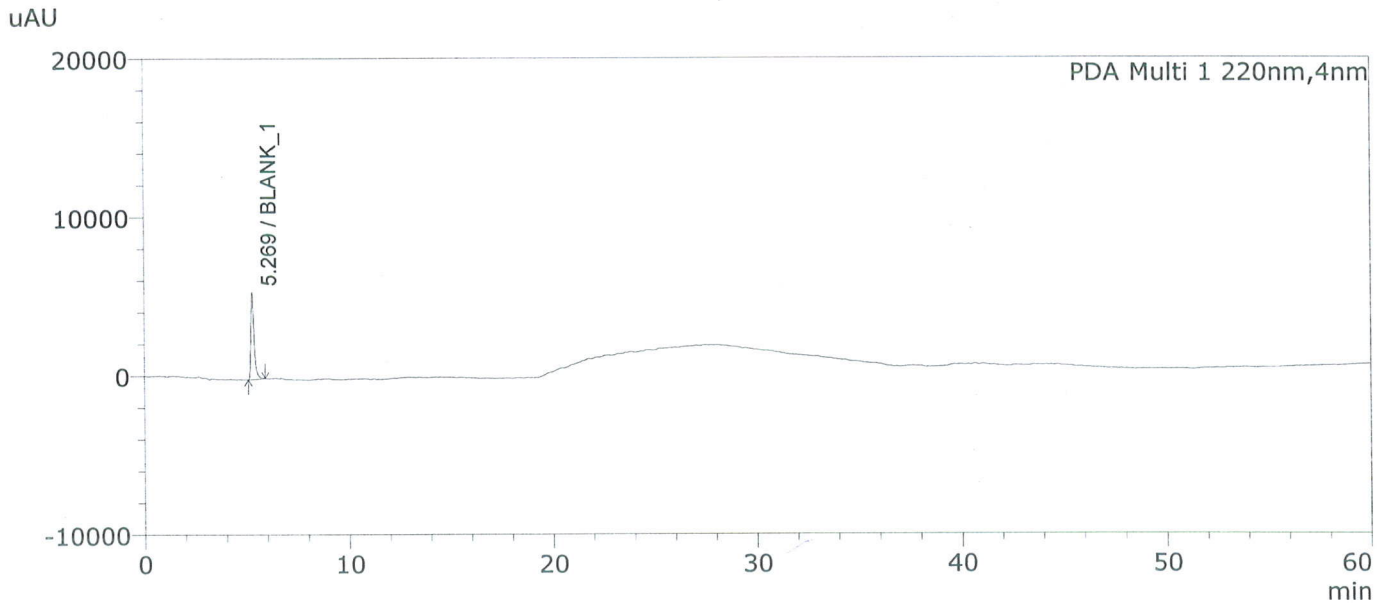
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : BLANK-RS
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-01.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 3:24:42 PM
 Date Processed : 1/25/2024 11:42:09 AM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	5.27	58974	100.00	5691	1.623	--	--
Total			58974	100.00				

Analysed By

[Signature]
25/01/2024

Checked By

[Signature]
25/01/2024



GENERIC HEALTHCARE PVT. LTD.

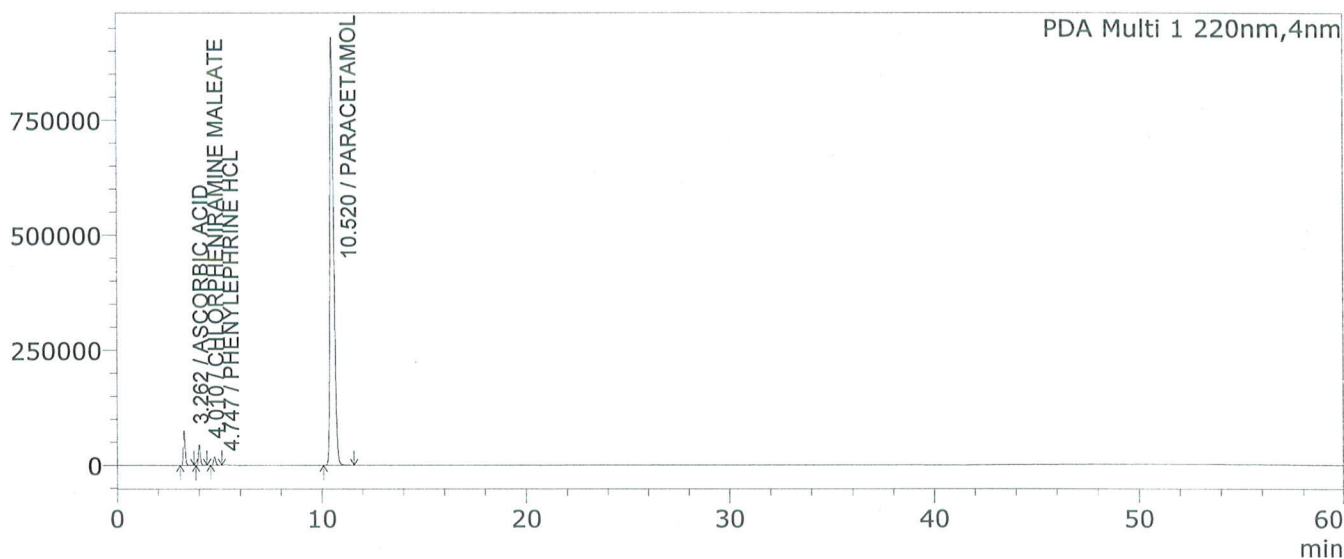
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : RESOLUTION SOLUTION
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-02.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-2
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 4:25:12 PM
 Date Processed : 1/25/2024 11:45:43 AM
 Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>

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<Peak Table>

PDA Ch1 220nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	ASCORBIC ACID	3.26	478908	3.59	5030	1.352	--	--
2	CHLORPHENIRAMINE MALEATE	4.01	295029	2.21	7193	1.314	4.012	--
3	PHENYLEPHRINE HCL	4.75	138100	1.03	7904	1.265	3.656	--
4	PARACETAMOL	10.52	12436699	93.17	13739	1.182	20.167	--
Total			13348736	100.00				

Analysed By

Checked By



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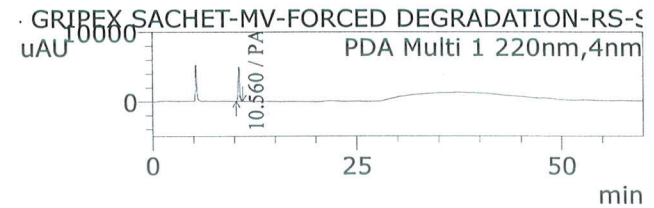
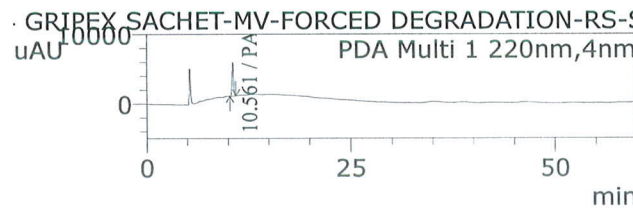
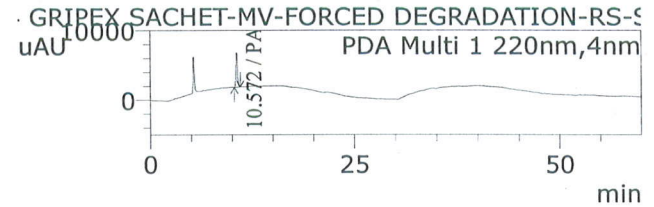
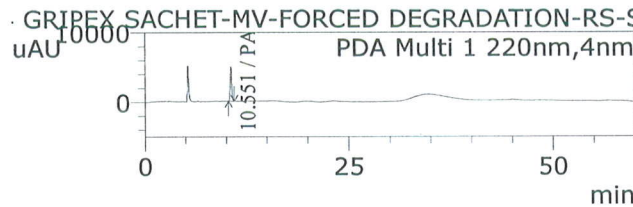
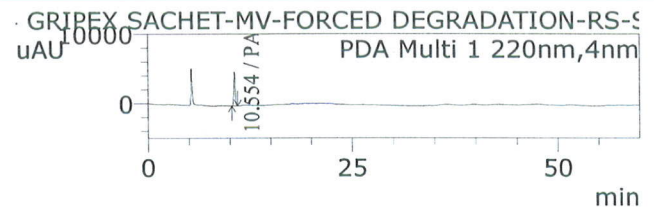
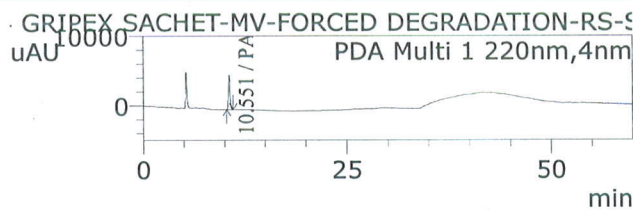
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : PARACETAMOL-RS-STD-01
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-03.lcd
 Method Filename : GRIPEX-SACH-RS-STD_P.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 5:25:44 PM
 Date Processed : 1/25/2024 12:59:12 PM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



<< PDA >>

ID#1 Compound Name: PARACETAMOL

Vial#	Title	Sample ID	R.Time	Area	T. Plate	T.Factor
3	RS-SPL-03.lcd	PARACETAMOL-RS-STD-01	10.55	65494	14296	1.14
3	RS-SPL-04.lcd	PARACETAMOL-RS-STD-02	10.55	64003	14397	1.13
3	RS-SPL-05.lcd	PARACETAMOL-RS-STD-03	10.55	65312	14164	1.14
3	RS-SPL-06.lcd	PARACETAMOL-RS-STD-04	10.57	65566	14141	1.13
3	RS-SPL-07.lcd	PARACETAMOL-RS-STD-05	10.56	64150	14199	1.12
3	RS-SPL-08.lcd	PARACETAMOL-RS-STD-06	10.56	65322	14203	1.14
Average			10.56	64975	14233	1.13
%RSD			0.077	1.084	0.676	0.960

Analysed By

Signature
15/01/2024

Checked By

Signature
16/01/2024



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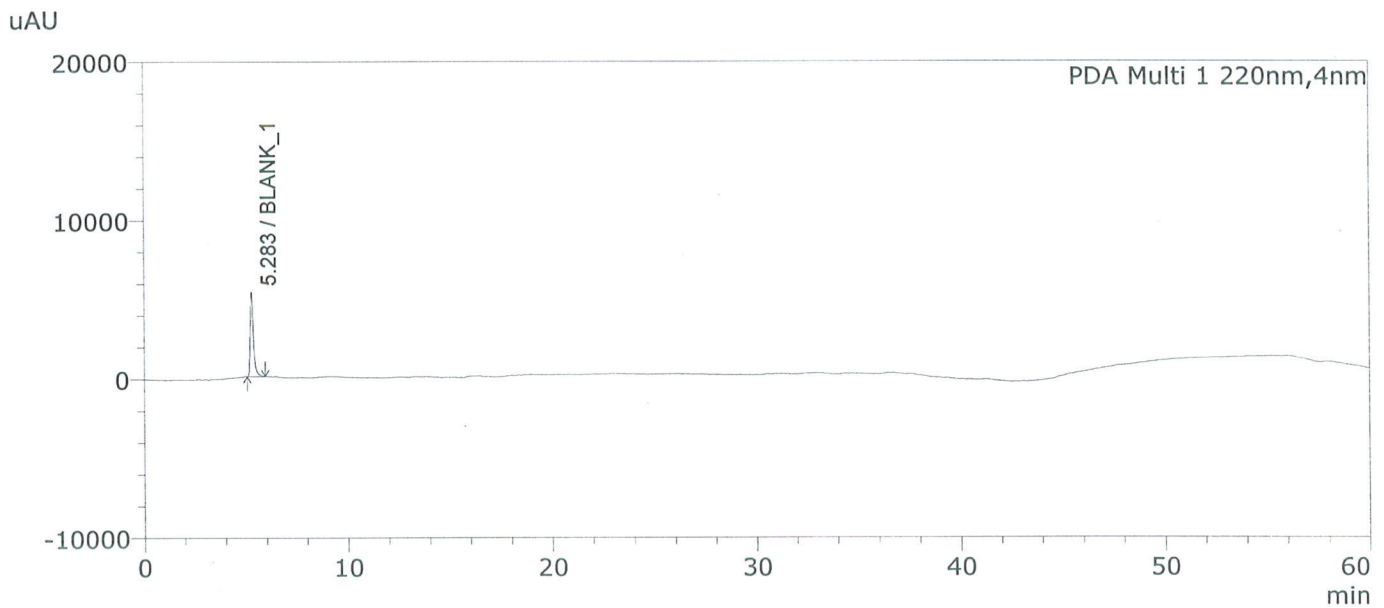
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : BLANK-RS
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-09.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-1
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 11:28:51 PM
 Date Processed : 1/25/2024 11:47:01 AM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	5.28	57340	100.00	5754	1.669	--	--
Total			57340	100.00				

Analysed By

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25/01/2024

Checked By

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25/01/2024



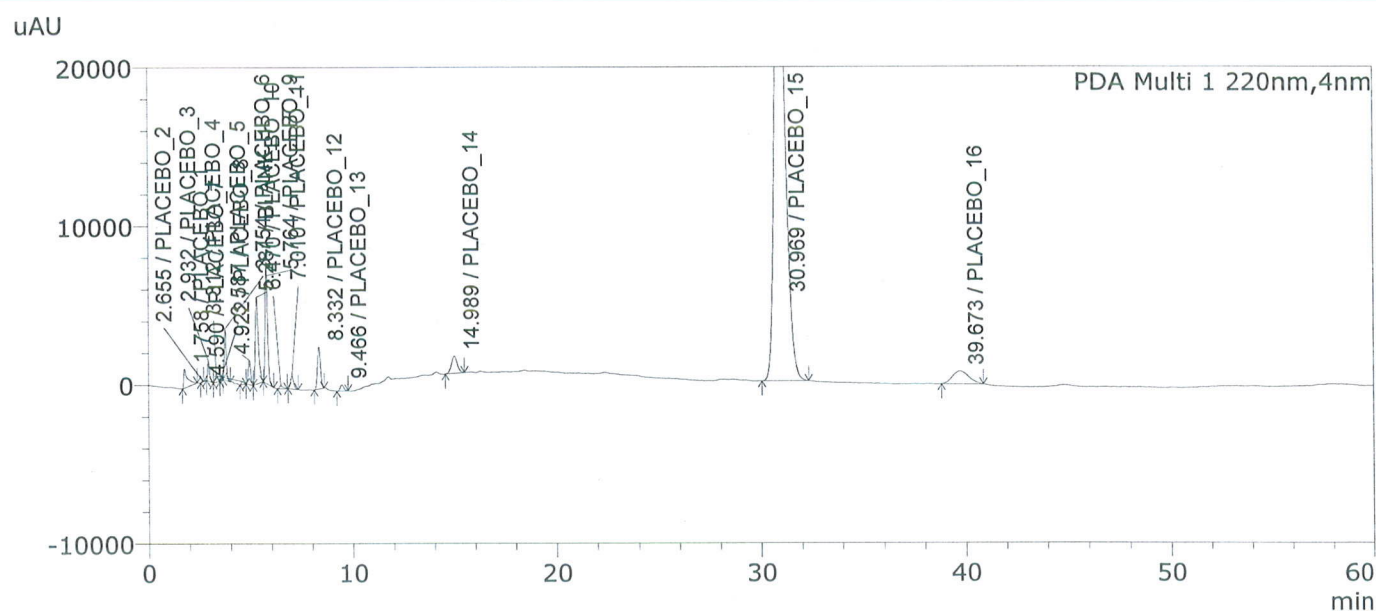
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : PLACEBO-RS
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-10.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-4
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 12:29:22 AM
 Date Processed : 1/25/2024 12:05:37 PM
 Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



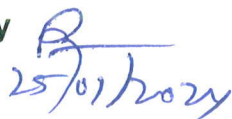
<Peak Table>

PDA Ch1 220nm

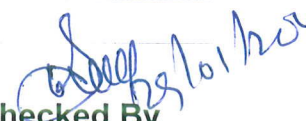
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.76	16743	1.16	719	4.473	--	--
2	PLACEBO_2	2.65	259	0.02	6115	0.739	4.508	--
3	PLACEBO_3	2.93	7477	0.52	4647	1.658	1.803	--
4	PLACEBO_4	3.31	3833	0.27	4428	1.205	2.048	--
5	PLACEBO_5	3.59	1353	0.09	10943	0.901	1.637	--
6	PLACEBO_6	3.75	20062	1.39	6675	1.288	1.041	--
7	PLACEBO_7	4.59	1645	0.11	5526	1.211	3.881	--
8	PLACEBO_8	4.92	12418	0.86	7283	1.143	1.390	--
9	BLANK_1	5.28	57013	3.95	5832	1.584	1.415	--
10	PLACEBO_9	5.76	63753	4.41	9813	1.242	1.897	--
11	PLACEBO_10	6.47	2303	0.16	8690	1.485	2.765	--
12	PLACEBO_11	7.01	8507	0.59	9735	1.304	1.923	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.33	27199	1.88	13564	1.107	4.634	--
14	PLACEBO_13	9.47	4721	0.33	13503	1.159	3.706	--
15	PLACEBO_14	14.99	21150	1.46	13776	1.127	13.203	--
16	PLACEBO_15	30.97	1150961	79.66	17150	1.165	21.940	--
17	PLACEBO_16	39.67	45424	3.14	11683	1.224	7.211	--
Total			1444821	100.00				

Analysed By


25/01/2024

Checked By


25/01/2024



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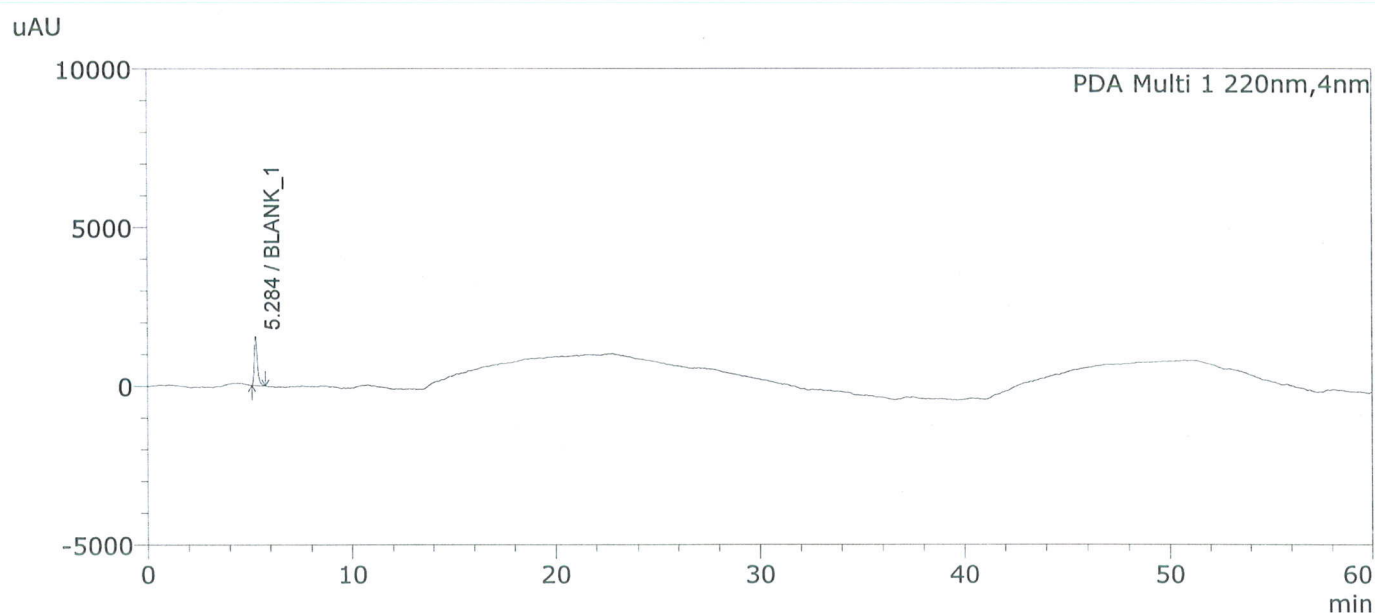
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : ACID-BLANK-RS
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-11.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-5
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 1:29:54 AM
 Date Processed : 1/25/2024 12:06:45 PM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	5.28	16569	100.00	5663	1.637	--	--
Total			16569	100.00				

Analysed By

[Signature]
25/01/2024

Checked By

[Signature]
25/01/2024



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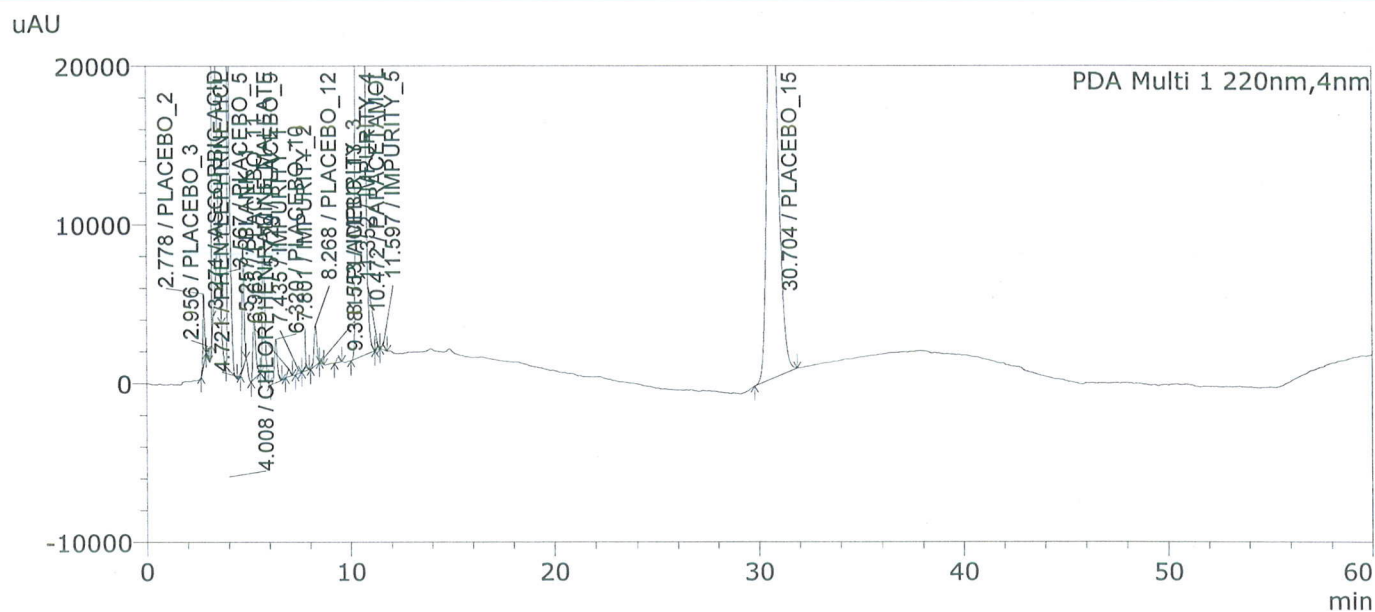
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : GRIPEX-1228-ACID-RS-SPL-1
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-12.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-6
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 9:35:54 AM
 Date Processed : 1/25/2024 12:16:52 PM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

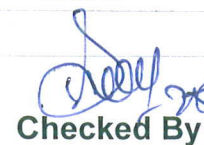
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_2	2.78	25561	0.18	4571	1.069	--	--
2	PLACEBO_3	2.96	2558	0.02	8533	1.305	1.218	--
3	ASCORBIC ACID	3.27	2246460	15.94	6017	1.388	2.122	--
4	PLACEBO_5	3.57	10037	0.07	12495	1.835	1.998	--
5	CHLORPHENIRAMINE MALEATE	4.01	257167	1.83	6692	1.690	2.727	--
6	PHENYLEPHRINE HCL	4.72	51238	0.36	9639	1.134	3.671	--
7	BLANK_1	5.26	37565	0.27	6506	1.597	2.366	--
8	PLACEBO_9	5.73	78052	0.55	9724	1.201	1.916	--
9	PLACEBO_10	6.32	26123	0.19	9433	1.169	2.398	--
10	PLACEBO_11	6.97	4369	0.03	10741	1.014	2.440	--
11	IMPURITY_1	7.43	2093	0.01	13227	1.072	1.779	--
12	IMPURITY_2	7.80	2234	0.02	12087	0.908	1.352	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PLACEBO_12	8.27	25026	0.18	14226	1.062	1.661	--
14	IMPURITY_3	8.55	687	0.00	31180	1.395	1.212	--
15	PLACEBO_13	9.38	3536	0.03	16406	1.042	3.403	--
16	PARACETAMOL	10.47	10303065	73.12	13684	1.184	3.349	--
17	IMPURITY_4	11.35	981	0.01	45411	0.850	3.083	--
18	IMPURITY_5	11.60	2437	0.02	23991	1.134	0.955	--
19	PLACEBO_15	30.70	1011154	7.18	16806	1.170	30.649	--
Total			14090344	100.00				

Analysed By


25/01/2024

Checked By


25/01/2024
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25/01/2024
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GENERIC HEALTHCARE PVT. LTD.

Analysis Report

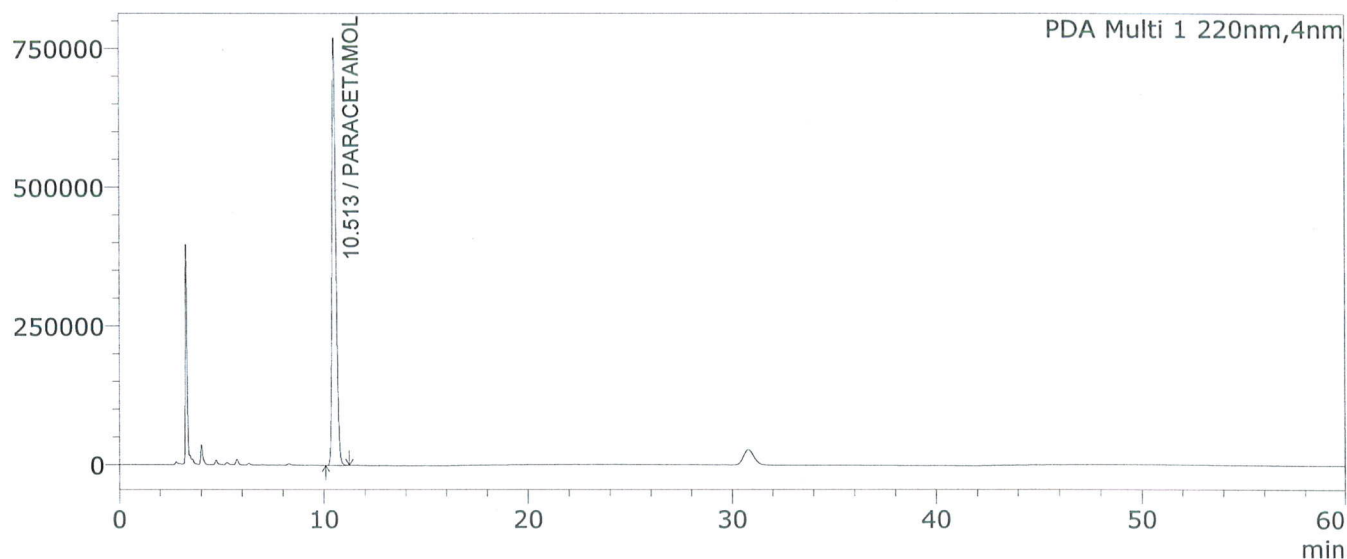
<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : GRIPEX-1228-ACID-RS-SPL-2
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-13.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-6
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 10:36:27 AM
 Date Processed : 1/25/2024 12:19:00 PM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>

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<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.51	10277494	100.00	13804	1.175	--	--
Total			10277494	100.00				

Analysed By

25/01/2024

Checked By

22/01/2024



GENERIC HEALTHCARE PVT. LTD.

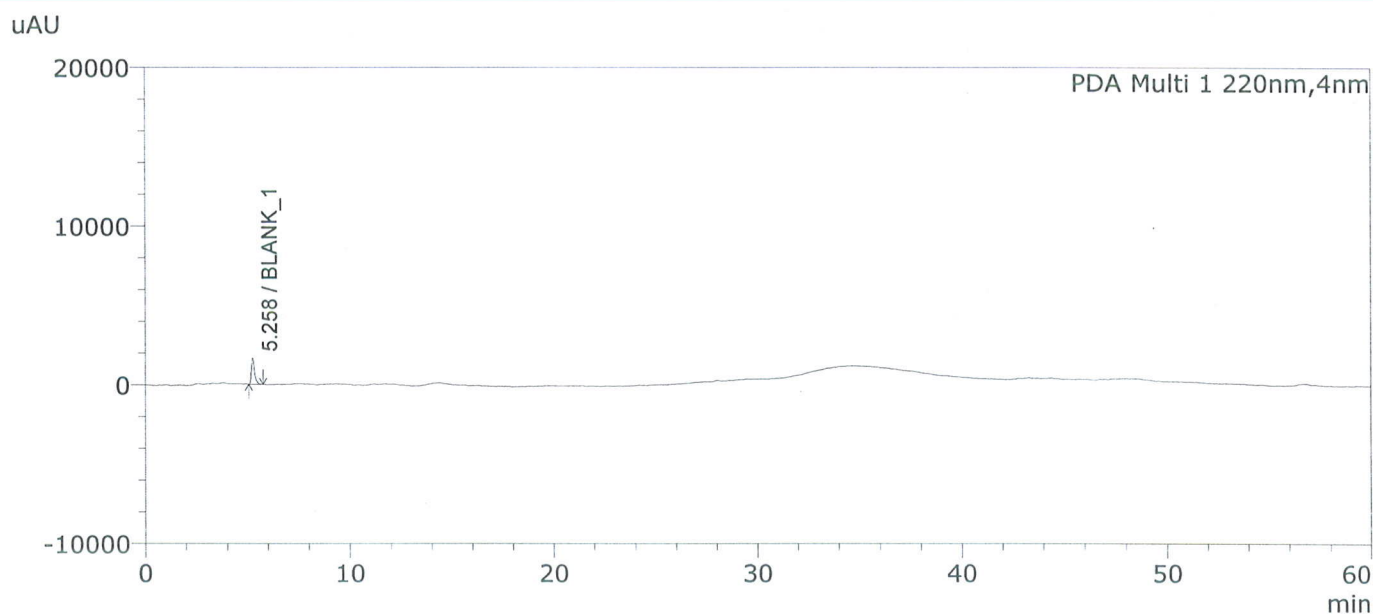
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : ALKALI-BLANK-RS
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-14.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-7
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 11:36:59 AM
 Date Processed : 1/25/2024 12:21:17 PM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	5.26	18020	100.00	5627	1.633	--	--
Total			18020	100.00				

Analysed By

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25/01/2024

Checked By

7/2/2024



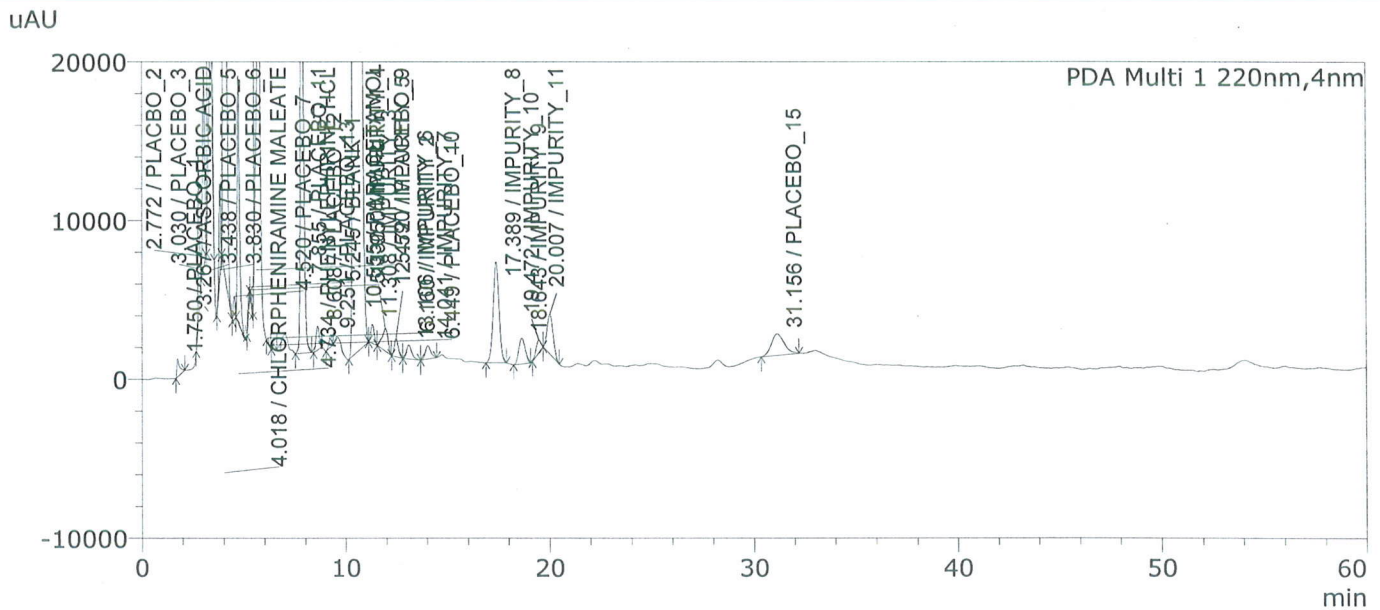
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : GRIPEX-1228-ALKALI-RS-SPL-1
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-15.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-8
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 12:37:30 PM
 Date Processed : 1/25/2024 12:34:27 PM
 Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



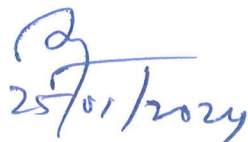
<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.75	11378	0.08	869	2.866	--	--
2	PLACBO_2	2.77	53736	0.37	5520	1.284	5.286	--
3	PLACEBO_3	3.03	87501	0.60	3583	1.045	1.471	--
4	ASCORBIC ACID	3.27	869048	5.92	6793	1.245	1.312	--
5	PLACEBO_5	3.44	38082	0.26	10500	1.552	1.168	--
6	PLACEBO_6	3.83	34572	0.24	8573	0.860	2.616	--
7	CHLORPHENIRAMINE MALEATE	4.02	418862	2.86	5383	2.033	0.980	--
8	PLACEBO_7	4.52	8805	0.06	10011	1.023	2.510	--
9	PHENYLEPHRINE HCL	4.73	118606	0.81	7977	1.500	1.088	--
10	BLANK_1	5.25	7085	0.05	22270	0.731	2.903	--
11	IMPURITY_1	5.33	2751	0.02	30117	1.645	0.641	--
12	PLACEBO_9	5.59	443318	3.02	12149	1.015	1.597	--

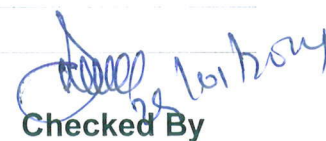
Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	IMPURITY_2	6.16	1616	0.01	21274	1.611	3.066	--
14	PLACEBO_10	6.45	2292	0.02	12270	1.199	1.437	--
15	PLACEBO_11	7.86	327083	2.23	13482	1.181	5.588	--
16	PLACEBO_12	8.61	16581	0.11	12495	1.095	2.602	--
17	PLACEBO_13	9.25	7422	0.05	20045	0.837	2.257	--
18	PARACETAMOL	10.55	11842394	80.74	13905	1.170	4.211	--
19	IMPURITY_3	11.31	13970	0.10	18997	1.135	2.196	--
20	IMPURITY_4	11.95	27947	0.19	8261	0.864	1.503	--
21	IMPURITY_5	12.47	15632	0.11	16800	1.221	1.145	--
22	IMPURITY_6	13.11	15502	0.11	12070	1.374	1.472	--
23	IMPURITY_7	14.04	15414	0.11	13084	1.218	1.930	--
24	IMPURITY_8	17.39	127856	0.87	16915	1.007	6.528	--
25	IMPURITY_9	18.64	35170	0.24	15730	1.067	2.221	--
26	IMPURITY_10	19.47	12637	0.09	32883	0.838	1.618	--
27	IMPURITY_11	20.01	52523	0.36	19259	1.134	1.065	--
28	PLACEBO_15	31.16	60015	0.41	11452	1.201	12.805	--
Total			14667798	100.00				

Analysed By



25/01/2024

Checked By



25/01/2024


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Analysis Report

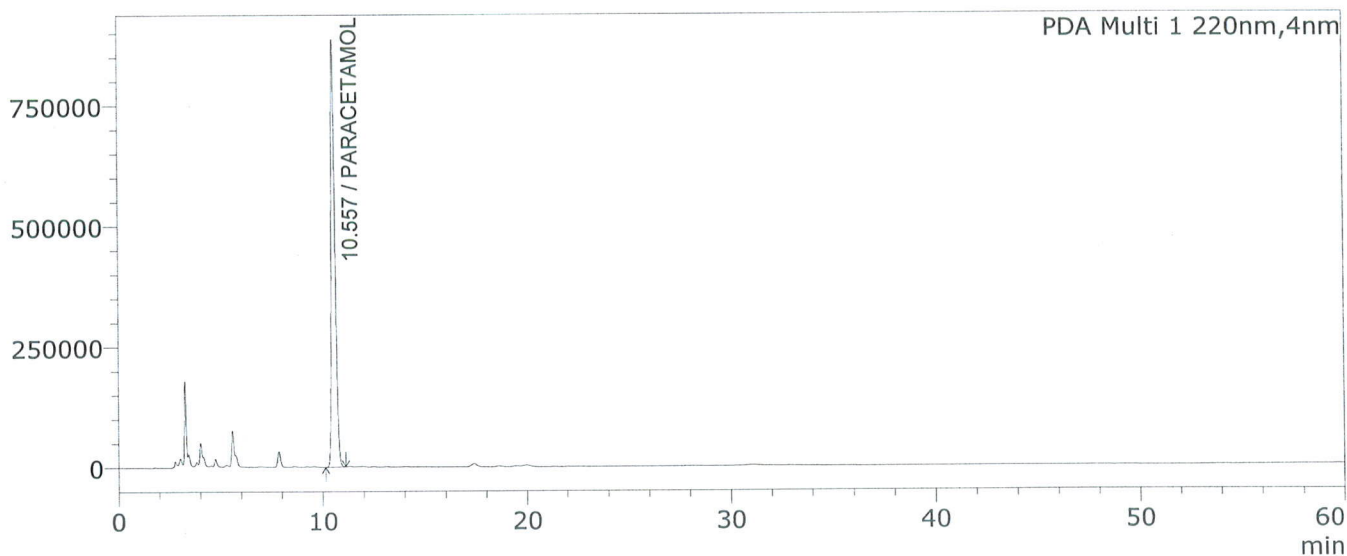
<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : GRIPEX-1228-ALKALI-RS-SPL-2
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-16.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-8
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 1:38:03 PM
 Date Processed : 1/25/2024 12:43:12 PM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>

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<Peak Table>

PDA Ch1 220nm

Peak #	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.56	11846347	100.00	13778	1.150	--	--
Total			11846347	100.00				

Analysed By

25/01/2024

Checked By

25/01/2024



GENERIC HEALTHCARE PVT. LTD.

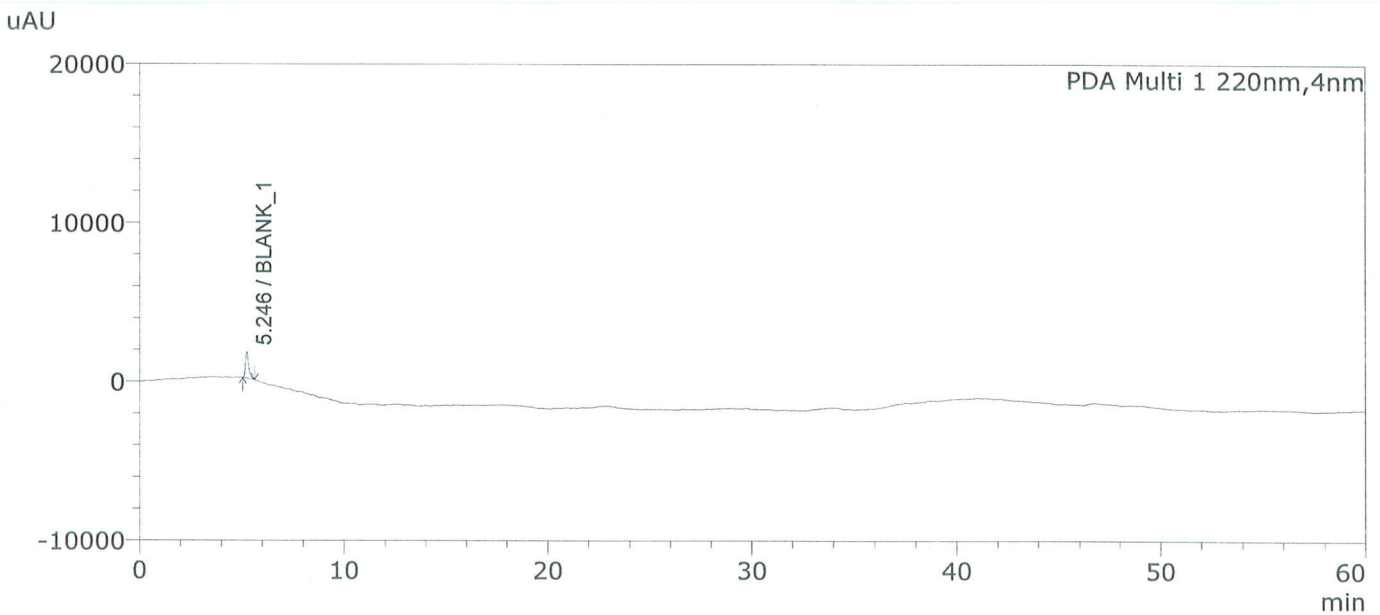
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : PEROXIDE-BLANK-RS
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-17.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-9
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 2:38:34 PM
 Date Processed : 1/25/2024 12:45:06 PM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	BLANK_1	5.25	17859	100.00	5460	1.541	--	--
Total			17859	100.00				

Analysed By

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23/01/2024

Checked By

[Signature]
23/01/2024



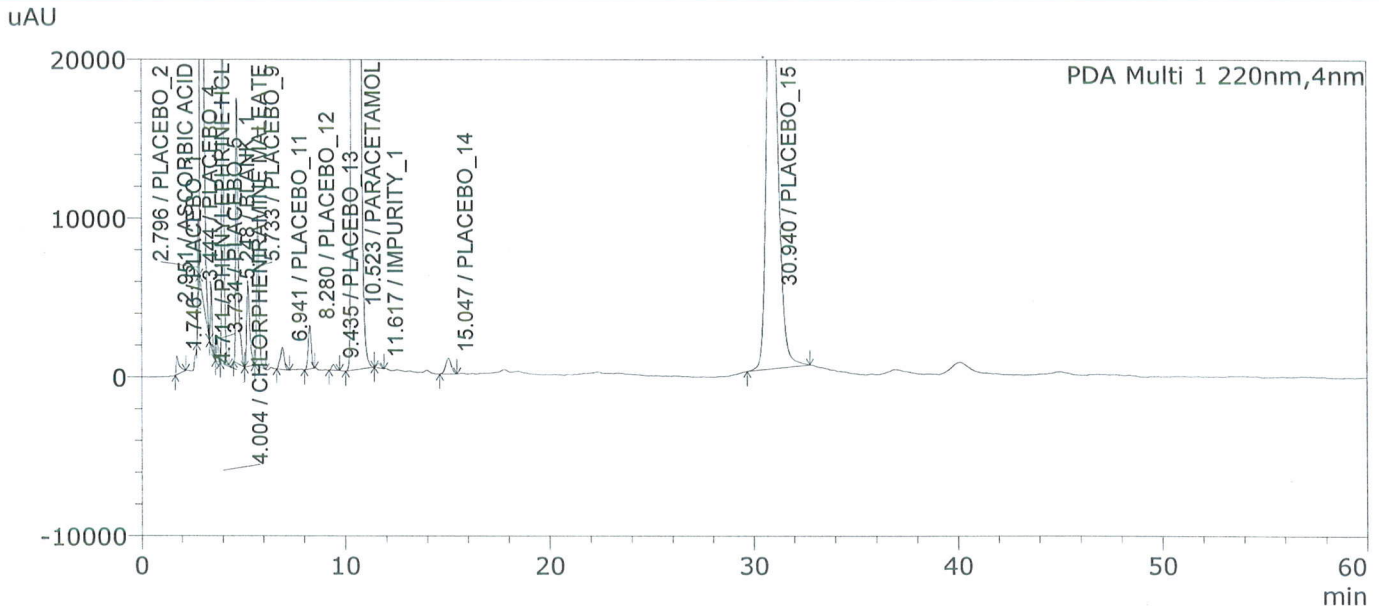
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : GRIPEX-1228-PEROXIDE-RS-SPL-1
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-18.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-10
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 3:39:06 PM
 Date Processed : 1/25/2024 12:50:09 PM
 Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PLACEBO_1	1.75	12939	0.06	809	3.325	--	--
2	PLACEBO_2	2.80	22875	0.10	9211	0.875	5.802	--
3	ASCORBIC ACID	2.95	7257443	32.60	5085	1.357	1.099	--
4	PLACEBO_4	3.44	21686	0.10	6359	1.491	2.914	--
5	PLACEBO_5	3.73	8165	0.04	6999	1.281	1.649	--
6	CHLORPHENIRAMINE MALEATE	4.00	181397	0.81	7106	1.444	1.463	--
7	PHENYLEPHRINE HCL	4.71	135179	0.61	7857	1.736	3.516	--
8	BLANK_1	5.25	53047	0.24	5728	1.593	2.191	--
9	PLACEBO_9	5.73	79070	0.36	9726	1.228	1.902	--
10	PLACEBO_11	6.94	18811	0.08	6055	0.931	4.100	--
11	PLACEBO_12	8.28	28571	0.13	13181	1.053	4.147	--
12	PLACEBO_13	9.43	4502	0.02	12605	1.199	3.699	--

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
13	PARACETAMOL	10.52	13295679	59.73	13576	1.154	3.121	--
14	IMPURITY_1	11.62	3766	0.02	17682	1.185	3.079	--
15	PLACEBO_14	15.05	19339	0.09	13400	1.058	7.890	--
16	PLACEBO_15	30.94	1118467	5.02	16483	1.164	21.420	--
Total			22260935	100.00				

Analysed By


25/01/2024

Checked By


25/01/2024


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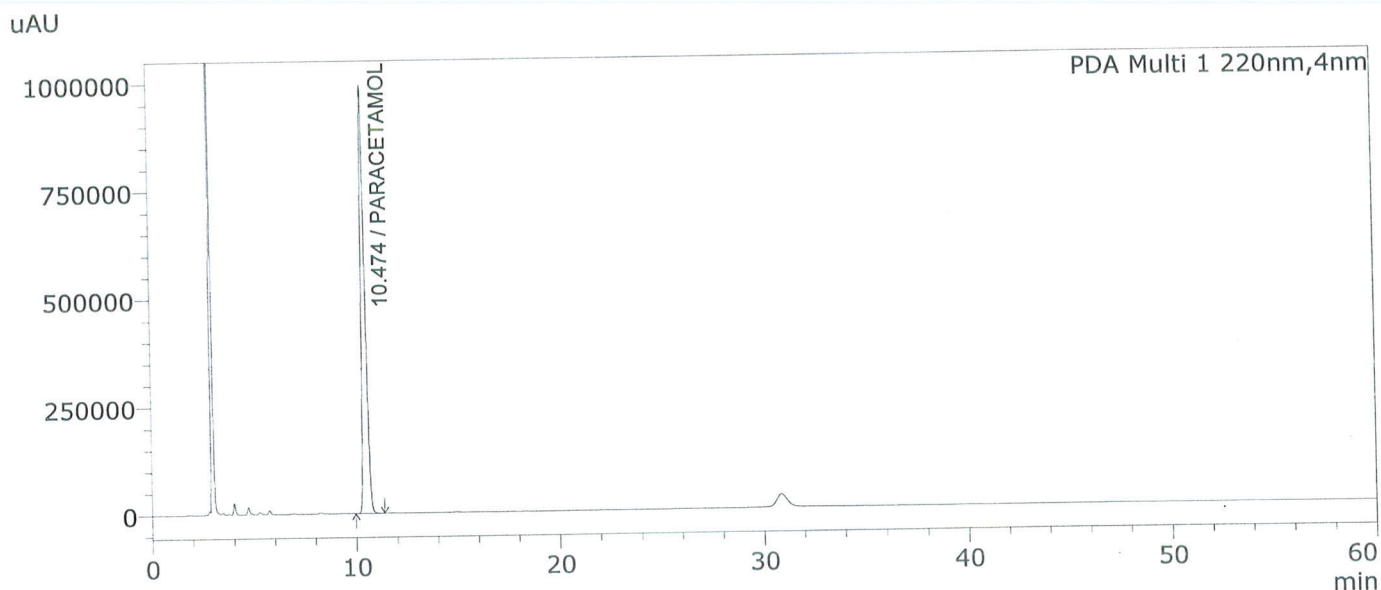
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : GRIPEX-1228-PEROXIDE-RS-SPL-2
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-19.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-10
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 4:39:39 PM
 Date Processed : 1/25/2024 12:51:46 PM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.47	13301206	100.00	13493	1.187	--	--
Total			13301206	100.00				

Analysed By

Checked By


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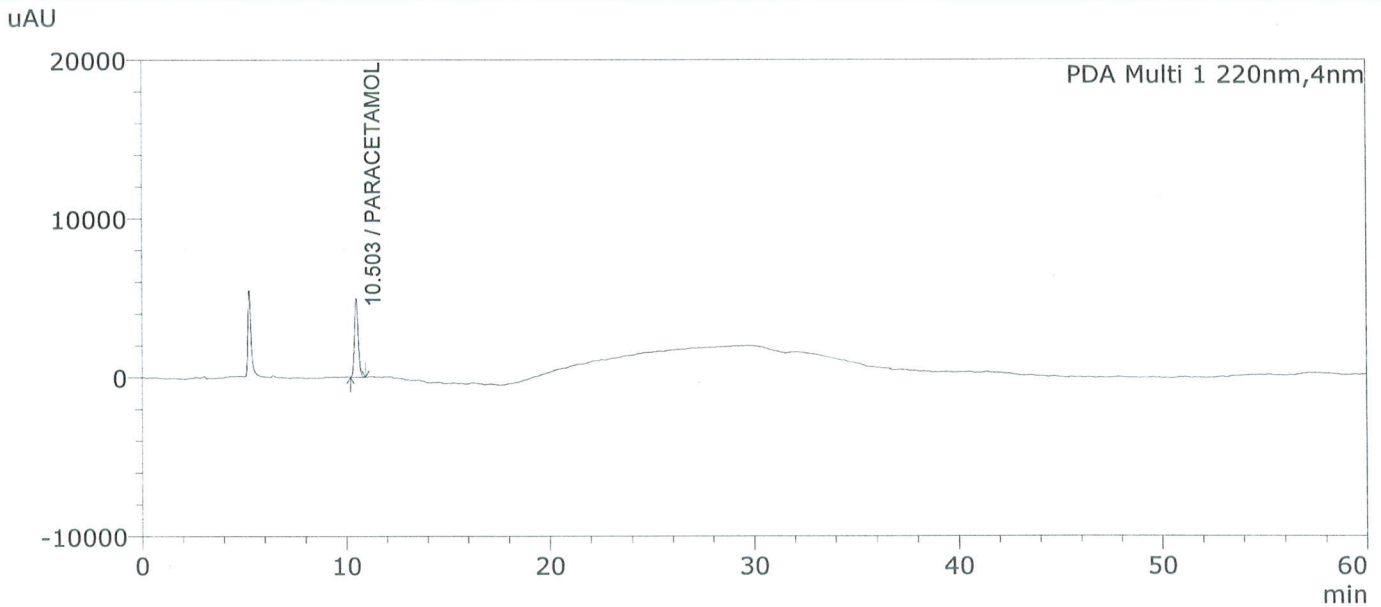
Analysis Report

<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : PARACETAMOL-RS-STD-BKT
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-20.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-3
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 5:40:10 PM
 Date Processed : 1/25/2024 12:53:14 PM

Acquired by : ELAVARASAN.S
 Processed by : C.Albinjose

<Chromatogram>



<Peak Table>

PDA Ch1 220nm

Peak#	Name	R.Time	Area	Area%	T. Plate	T.Factor	Resolution	R.R.T
1	PARACETAMOL	10.50	65479	100.00	14126	1.135	--	--
Total			65479	100.00				

Analysed By

25/01/2024

Checked By

25/01/2024



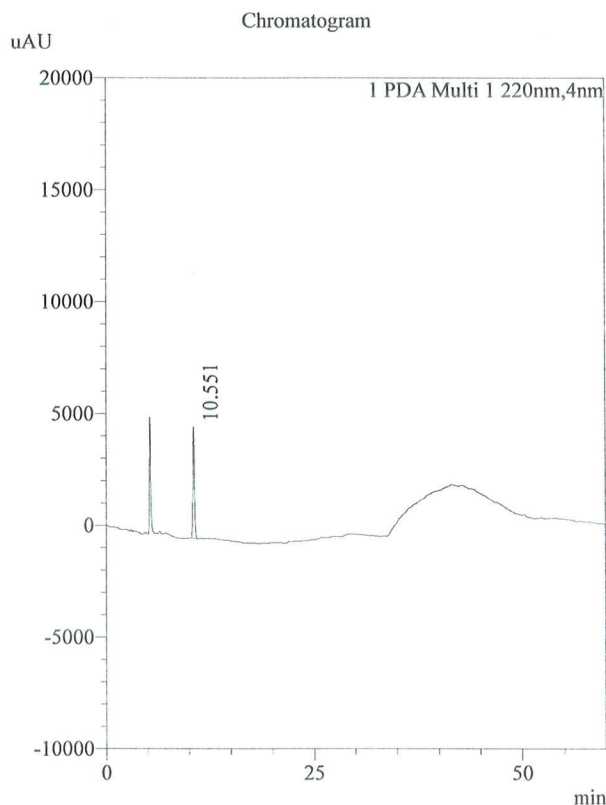
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

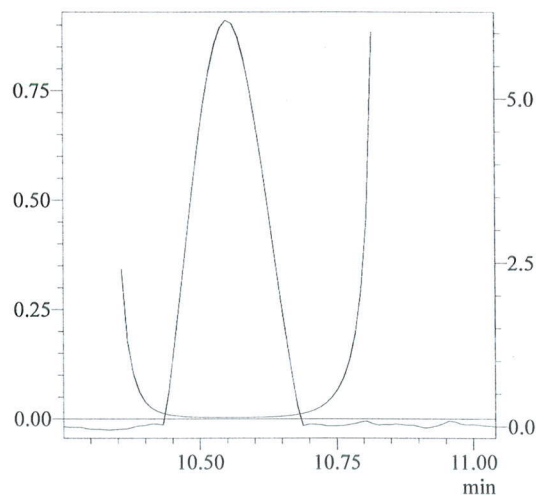
<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : PARACETAMOL-RS-STD-01
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-03.lcd
 Method Filename : GRIPEX-SACH-RS-STD_P.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-3 Sample Type : Unknown
 Injection Volume : 10 uL
 Date Acquired : 1/19/2024 5:25:44 PM Acquired by : ELAVARASAN.S
 Date Processed : 1/25/2024 12:59:12 PM Processed by : C.Albinjose

<Peak Purity>



ID# : 1
 Retention Time : 10.551 min
 Compound Name : PARACETAMOL



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.996780
 Minimum peak purity index : 3220

PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	10.551	1.000	0.996780	PARACETAMOL
Total				

Analysed By

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25/01/2024

Checked By

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25/01/2024



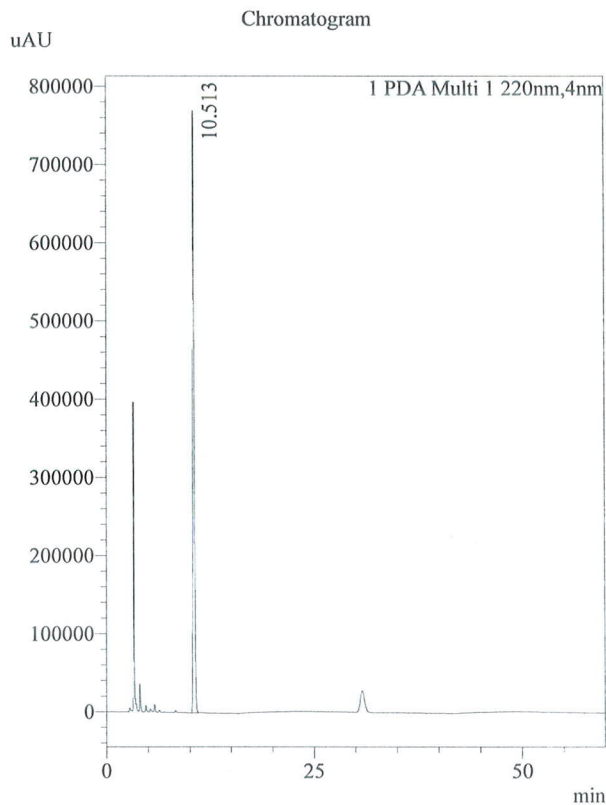
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

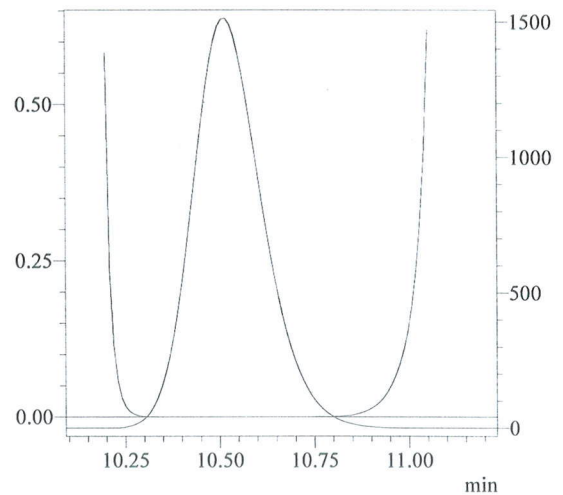
<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : GRIPEX-1228-ACID-RS-SPL-2
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-13.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-6 Sample Type : Unknown
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 10:36:27 AM Acquired by : ELAVARASAN.S
 Date Processed : 1/25/2024 12:19:00 PM Processed by : C.Albinjose

<Peak Purity>



ID# : 1
 Retention Time : 10.513 min
 Compound Name : PARACETAMOL



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999993
 Minimum peak purity index : 6

PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	10.513	1.000	0.999993	PARACETAMOL
Total				

Analysed By

25/01/2024

Checked By

25/01/2024



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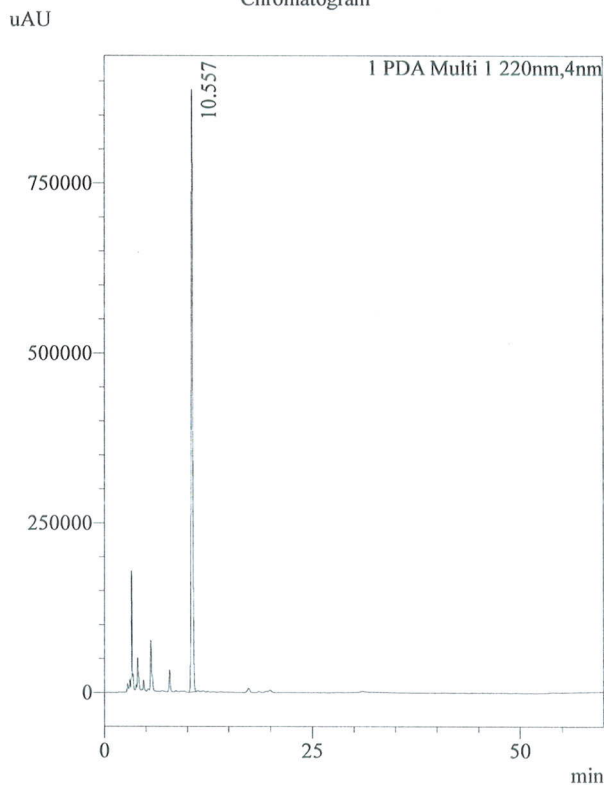
Analysis Report

<Sample Information>

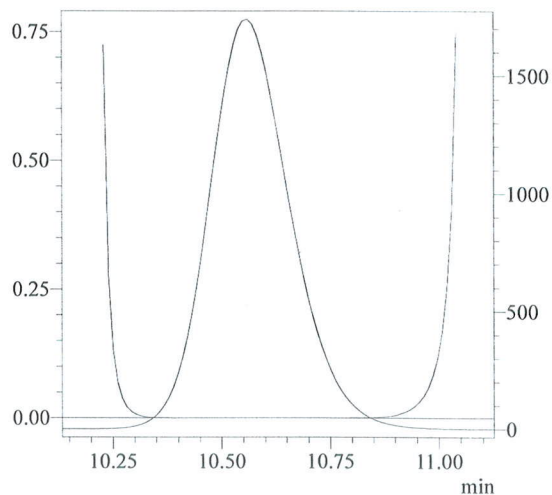
Sample Name : FORCED DEGRADATION-RS
 Sample ID : GRIPEX-1228-ALKALI-RS-SPL-2
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-16.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-8 Sample Type : Unknown
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 1:38:03 PM Acquired by : ELAVARASAN.S
 Date Processed : 1/25/2024 12:43:12 PM Processed by : C.Albinjose

<Peak Purity>

Chromatogram



ID# : 1
 Retention Time : 10.557 min
 Compound Name : PARACETAMOL



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999966
 Minimum peak purity index : 33

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	10.557	1.000	0.999966	PARACETAMOL
Total				

Analysed By

25/1/2024

Checked By

Supriya


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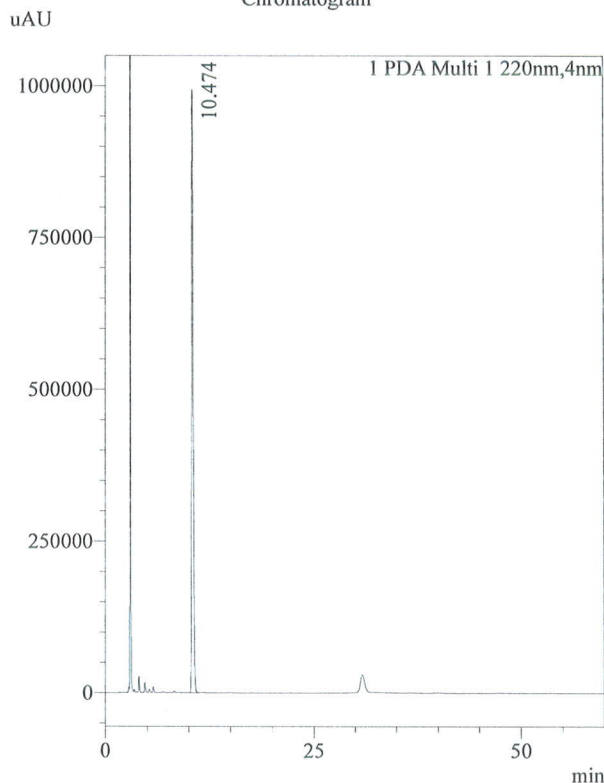
Analysis Report

<Sample Information>

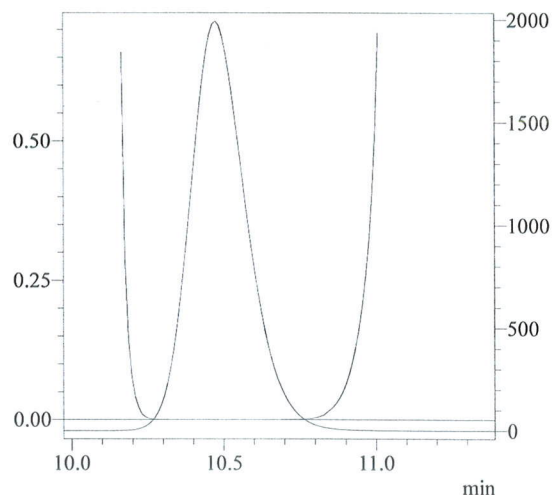
Sample Name : FORCED DEGRADATION-RS
 Sample ID : GRIPEX-1228-PEROXIDE-RS-SPL-2
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-19.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-10 Sample Type : Unknown
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 4:39:39 PM Acquired by : ELAVARASAN.S
 Date Processed : 1/25/2024 12:51:46 PM Processed by : C.Albinjose

<Peak Purity>

Chromatogram



ID# : 1
 Retention Time : 10.474 min
 Compound Name : PARACETAMOL



Impurity : Not Detected
 Peak purity index : 1.000000
 Single point threshold : 0.999939
 Minimum peak purity index : 61

PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	10.474	1.000	0.999939	PARACETAMOL
Total				

Analysed By

Checked By



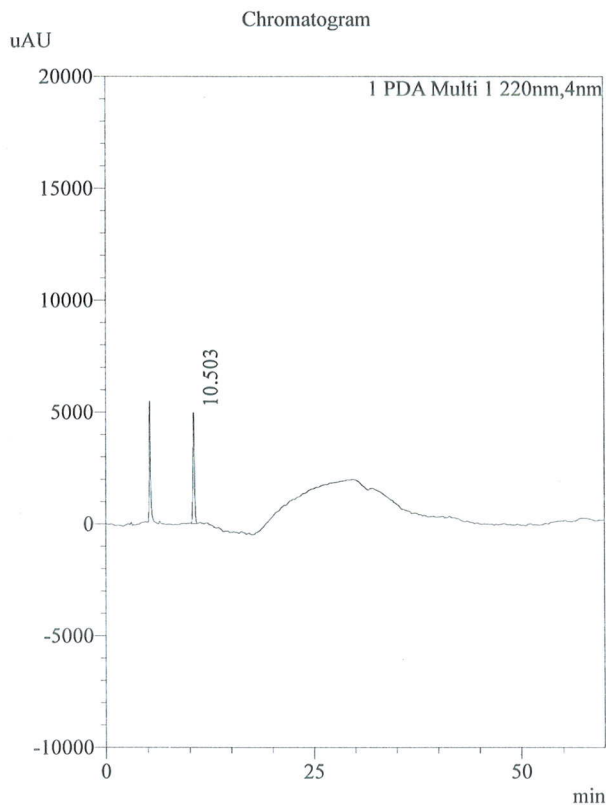
GENERIC HEALTHCARE PVT. LTD.

Analysis Report

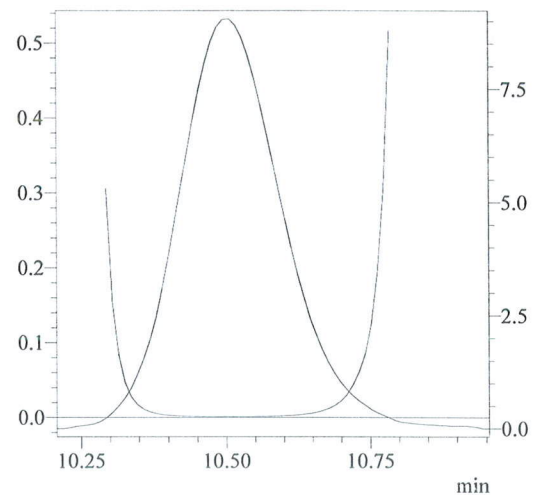
<Sample Information>

Sample Name : FORCED DEGRADATION-RS
 Sample ID : PARACETAMOL-RS-STD-BKT
 Data Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS-SPL-20.lcd
 Method Filename : GRIPEX-SACH-RS.lcm
 Batch Filename : 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb
 Vial # : 1-3 Sample Type : Unknown
 Injection Volume : 10 uL
 Date Acquired : 1/20/2024 5:40:10 PM Acquired by : ELAVARASAN.S
 Date Processed : 1/25/2024 12:53:14 PM Processed by : C.Albinjose

<Peak Purity>



ID# : 1
 Retention Time : 10.503 min
 Compound Name : PARACETAMOL



Impurity : Not Detected
 Peak purity index : 0.999999
 Single point threshold : 0.998758
 Minimum peak purity index : 1241

PDA Ch1 220nm

Peak Table

Peak#	Ret. Time	Peak Purity Index	Single Point Threshold	Name
1	10.503	1.000	0.998758	PARACETAMOL
Total				

Analysed By

[Signature]
25/01/2024

Checked By

[Signature]
26/01/2024



GENERIC HEALTHCARE PVT. LTD.

Batch Table

Batch Table 19012024 GRIPEX SACHET-MV-FORCED DEGRADATION-RS.lcb

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
1	1	FORCED DEGRADATION-RS	BLANK-RS	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-01.lcd	10.0	QC/CL/23/032
2	1	FORCED DEGRADATION-RS	RESOLUTION SOLUTION	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-02.lcd	10.0	QC/CL/23/032
3	1	FORCED DEGRADATION-RS	PARACETAMOL-RS-STD-01	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-03.lcd	10.0	QC/CL/23/032
3	1	FORCED DEGRADATION-RS	PARACETAMOL-RS-STD-02	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-04.lcd	10.0	QC/CL/23/032
3	1	FORCED DEGRADATION-RS	PARACETAMOL-RS-STD-03	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-05.lcd	10.0	QC/CL/23/032
3	1	FORCED DEGRADATION-RS	PARACETAMOL-RS-STD-04	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-06.lcd	10.0	QC/CL/23/032
3	1	FORCED DEGRADATION-RS	PARACETAMOL-RS-STD-05	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-07.lcd	10.0	QC/CL/23/032
3	1	FORCED DEGRADATION-RS	PARACETAMOL-RS-STD-06	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-08.lcd	10.0	QC/CL/23/032
1	1	FORCED DEGRADATION-RS	BLANK-RS	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-09.lcd	10.0	QC/CL/23/032
4	1	FORCED DEGRADATION-RS	PLACEBO-RS	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-10.lcd	10.0	QC/CL/23/032
5	1	FORCED DEGRADATION-RS	ACID-BLANK-RS	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-11.lcd	10.0	QC/CL/23/032
6	1	FORCED DEGRADATION-RS	GRIPEX-1228-ACID-RS-SPL-1	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-12.lcd	10.0	QC/CL/23/032
6	1	FORCED DEGRADATION-RS	GRIPEX-1228-ACID-RS-SPL-2	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-13.lcd	10.0	QC/CL/23/032
7	1	FORCED DEGRADATION-RS	ALKALI-BLANK-RS	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-14.lcd	10.0	QC/CL/23/032
8	1	FORCED DEGRADATION-RS	GRIPEX-1228-ALKALI-RS-SPL-1	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-15.lcd	10.0	QC/CL/23/032
8	1	FORCED DEGRADATION-RS	GRIPEX-1228-ALKALI-RS-SPL-2	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-16.lcd	10.0	QC/CL/23/032
9	1	FORCED DEGRADATION-RS	PEROXIDE-BLANK-RS	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-17.lcd	10.0	QC/CL/23/032
10	1	FORCED DEGRADATION-RS	GRIPEX-1228-PEROXIDE-RS-SPL-1	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-18.lcd	10.0	QC/CL/23/032

Vial#	Tray Name	Sample Name	Sample ID	Method File	Data File	Inj. Volume	Data Comment
10	1	FORCED DEGRADATION-RS	GRIPEX-1228-PEROXIDE-RS-SPL-2	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-19.lcd	10.0	QC/CL/23/032
3	1	FORCED DEGRADATION-RS	PARACETAMOL-RS-STD-BKT	GRIPEX-SACH-RS.lcm	ATION-RS-SPL-20.lcd	10.0	QC/CL/23/032
-1	1	FORCED DEGRADATION-RS	WASH	WASH METHOD.lcm	ATION-RS-SPL-21.lcd	10.0	QC/CL/23/032
-1	1	FORCED DEGRADATION-RS	SHUTDOWN	SHUT DOWN .lcm	ATION-RS-SPL-22.lcd	10.0	QC/CL/23/032

Analysed By


 19/01/2024

Checked By


 19/01/2024