

|                                                                                                                                                               |                                   |                              |                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|------------------------------|----------------------------------------------|
|  <b>PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg</b><br><br><b>B.No. : G1822115</b> | <b>ACCELERATED STABILITY DATA</b> |                              | Page No: Page 1 of 2                         |
|                                                                                                                                                               |                                   |                              | Format No:F/QCGN/034/06                      |
|                                                                                                                                                               |                                   |                              | Storage Condition:40°C ±2°C & 75% RH ± 5%    |
|                                                                                                                                                               | Mfg. Date: SEP-2022               | Batch Size: 6.0 L            | Reason for stability: Validation Batch study |
|                                                                                                                                                               | Exp. Date: AUG-2025               | Pack Size: Alu /Alu (3x10'S) | Period: 6 Month                              |
| Label Claim: Each uncoated tablet contains:<br><br>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg                                                        |                                   |                              | Date of Loading:26.09.2022                   |

| Tests                                                                                                                | Limits                                                                                                         | Initial<br>26.09.2022                                                        | 3 <sup>rd</sup> Month<br>26.12.2022                            | 6 <sup>th</sup> Month<br>26.03.2023                            |
|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------|
|                                                                                                                      |                                                                                                                | Results                                                                      | Results                                                        | Results                                                        |
| Description                                                                                                          | Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side. | Complies                                                                     | Complies                                                       | Complies                                                       |
| Average Weight                                                                                                       | 200.0 mg ± 5.0%<br>(Limit:190.0mg to 210.0 mg)                                                                 | 198.40 mg                                                                    | 199.05 mg                                                      | 199.52 mg                                                      |
| Hardness                                                                                                             | NLT 3.0 kg/cm <sup>2</sup>                                                                                     | 3.75 kg/cm <sup>2</sup>                                                      | 4.13 kg/cm <sup>2</sup>                                        | 3.90 kg/cm <sup>2</sup>                                        |
| Friability                                                                                                           | NMT 1.0%                                                                                                       | 0.15%                                                                        | 0.12%                                                          | 0.21%                                                          |
| Disintegration Time                                                                                                  | Not more than 15 minutes                                                                                       | 02 min 10 sec                                                                | 02 min 24 sec                                                  | 02 min 18 sec                                                  |
| Dissolution<br>Ramipril BP-5mg                                                                                       | Not less than 75.0 % of labeled amount.                                                                        | Min: 98.94 % to Max: 103.88% Avg: 100.57%                                    | Min: 90.84% to Max:96.12% Avg: 94.14%                          | Min: 93.53% to Max:95.15% Avg: 94.25%                          |
| Hydrochlorothiazide BP-12.5mg                                                                                        | Not less than 75.0 % of labeled amount.                                                                        | Min: 97.40% to Max: 99.75% Avg: 98.55%                                       | Min: 90.78% to Max:101.36% Avg:98.33%                          | Min: 94.91% to Max:96.07% Avg: 95.23%                          |
| Related substances:<br>Impurity A<br>Impurity D<br>Impurity E<br>Single maximum unknown impurity<br>Total impurities | Not more than 2.0%<br>Not more than 6.0%<br>Not more than 2.0%<br>Not more than 0.5%<br>Not more than 6.0%     | Not Detected<br>Not Detected<br>Not Detected<br>Not Detected<br>Not Detected | Not Detected<br>3.75%<br>Not Detected<br>Not Detected<br>3.75% | Not Detected<br>3.82%<br>Not Detected<br>Not Detected<br>3.82% |

|                                                                                                                                                                                |                                                     |                              |                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|------------------------------|----------------------------------------------|
| <br><b>SAI PRIMUS</b><br>LIFE BIOTECH PVT LTD<br><b>PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg</b> | <b>ACCELERATED STABILITY DATA</b>                   |                              | Page No: Page 2 of 2                         |
|                                                                                                                                                                                |                                                     |                              | Format No:F/QCGN/034/06                      |
| B.No. : G1822115                                                                                                                                                               | Mfg. Date: SEP-2022                                 | Batch Size: 6.0 L            | Storage Condition:40°C ±2°C & 75% RH ± 5%    |
|                                                                                                                                                                                | Exp. Date: AUG-2025                                 | Pack Size: Alu /Alu (3x10'S) | Reason for stability: Validation Batch study |
|                                                                                                                                                                                | Label Claim: Each uncoated tablet contains:         |                              | Period: 6 Month                              |
|                                                                                                                                                                                | Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |                              | Date of Loading:26.09.2022                   |

|                                                                                                                                                      |                                                                                                                 |                                                                |          |                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|----------|---------------------------------------------------------------|
| Assay: Each uncoated tablet contains:<br>Ramipril BP -5 mg                                                                                           | Not less than 90.0 % and<br>Not more than 110.0%                                                                | 100.48%                                                        | 100.20%  | 99.80%                                                        |
| Hydrochlorothiazide BP-12.5mg                                                                                                                        | Not less than 90.0 % and<br>Not more than 110.0%                                                                | 100.17%                                                        | 101.76 % | 100.60 %                                                      |
| <b>Microbiological limits:</b><br>Total Aerobic Microbial count<br>Total Yeasts and mould counts<br>E.Coli<br>Salmonella<br>S.aureus<br>P.aeruginosa | NMT 1000 cfu/g<br>NMT 100 cfu/g<br>Should be Absent<br>Should be Absent<br>Should be Absent<br>Should be Absent | <10 cfu/g<br><10 cfu/g<br>Absent<br>Absent<br>Absent<br>Absent | NA       | 30 cfu/g<br><10 cfu/g<br>Absent<br>Absent<br>Absent<br>Absent |

Stability study:

Complete [ ✓ ]

Incomplete [ ✗ ]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for .....<sup>6th</sup> months.

Reference: ICH Guidelines

PREPARED BY: J. Keyl.  
DATE: 01/04/2023

CHECKED BY: J.  
DATE: 01/04/2023

APPROVED BY: H.  
DATE: 01/04/2023

|                                                                                   |                                                     |  |                             |                                              |
|-----------------------------------------------------------------------------------|-----------------------------------------------------|--|-----------------------------|----------------------------------------------|
|  | LONG TERM STABILITY DATA                            |  |                             | Page No: Page 1 of 3                         |
|                                                                                   | PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg               |  |                             | Format No: F/QCGN/034/06                     |
| B.No.: G1822115                                                                   | Mfg. Date: SEP-2022                                 |  | Batch Size: 6.0 L           | Storage Condition: 30°C ± 2°C & 75% RH ± 5%  |
|                                                                                   | Exp. Date: AUG-2025                                 |  | Pack Size: Alu/Alu (3x10'S) | Reason for stability: Validation Batch study |
|                                                                                   | Label Claim: Each uncoated tablet contains:         |  |                             | Period: 36 Month                             |
|                                                                                   | Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |  |                             | Date of Loading: 26.09.2022                  |

| Tests                          | Limits                                                                                                         | Initial<br>26.09.2022                           | 3 <sup>rd</sup> Month<br>26.12.2022           | 6 <sup>th</sup> Month<br>26.03.2023          | 9 <sup>th</sup> Month<br>26.06.2023          | 12 <sup>th</sup> Month<br>26.09.2023         | 18 <sup>th</sup> Month<br>26.03.2024         | 24 <sup>th</sup> Month<br>26.09.2024         |
|--------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------|-----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|
|                                |                                                                                                                | Results                                         | Results                                       | Results                                      | Results                                      | Results                                      | Results                                      | Results                                      |
| Description                    | Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side. | Complies                                        | Complies                                      | Complies                                     | Complies                                     | Complies                                     | Complies                                     | Complies                                     |
| Average Weight                 | 200.0 mg ± 5.0% (Limit: 190.0mg to 210.0 mg)                                                                   | 198.40 mg                                       | 198.21 mg                                     | 199.15 mg                                    | 199.00 mg                                    | 199.49 mg                                    | 200.52 mg                                    | 201.15 mg                                    |
| Hardness                       | NLT 3.0 kg/cm <sup>2</sup>                                                                                     | 3.75 kg/cm <sup>2</sup>                         | 3.95 kg/cm <sup>2</sup>                       | 3.59 kg/cm <sup>2</sup>                      | 3.39 kg/cm <sup>2</sup>                      | 3.16 kg/cm <sup>2</sup>                      | 3.12 kg/cm <sup>2</sup>                      | 3.10 kg/cm <sup>2</sup>                      |
| Friability                     | NMT 1.0%                                                                                                       | 0.15%                                           | 0.11%                                         | 0.18%                                        | 0.29%                                        | 0.31%                                        | 0.35%                                        | 0.37%                                        |
| Disintegration Time            | Not more than 15 minutes                                                                                       | 02 min 10 sec                                   | 02 min 20 sec                                 | 02 min 21 sec                                | 02 min 58 sec                                | 03 min 24 sec                                | 04 min 59 sec                                | 05 min 19 sec                                |
| Dissolution<br>Ramipril BP-5mg | Not less than 75.0 % of labeled amount.                                                                        | Min: 98.94 % to<br>Max: 103.88%<br>Avg: 100.57% | Min: 91.93% to<br>Max: 94.97%<br>Avg: 93.97%  | Min: 93.27% to<br>Max: 94.90%<br>Avg: 94.20% | Min: 93.30% to<br>Max: 94.69%<br>Avg: 94.17% | Min: 92.92% to<br>Max: 94.33%<br>Avg: 93.79% | Min: 92.78% to<br>Max: 93.96%<br>Avg: 93.25% | Min: 86.92% to<br>Max: 91.40%<br>Avg: 89.77% |
| Hydrochlorothiazide BP-12.5mg  | Not less than 75.0 % of labeled amount.                                                                        | Min: 97.40% to<br>Max: 99.75%<br>Avg: 98.55%    | Min: 94.18% to<br>Max: 101.29%<br>Avg: 98.52% | Min: 95.15% to<br>Max: 96.37%<br>Avg: 95.90% | Min: 94.90% to<br>Max: 96.60%<br>Avg: 95.52% | Min: 94.36% to<br>Max: 96.27%<br>Avg: 94.94% | Min: 93.98% to<br>Max: 95.21%<br>Avg: 94.64% | Min: 92.89% to<br>Max: 95.41%<br>Avg: 94.38% |

|                                                                                   |                                                     |                             |                                              |
|-----------------------------------------------------------------------------------|-----------------------------------------------------|-----------------------------|----------------------------------------------|
|  | LONG TERM STABILITY DATA                            |                             | Page No: Page 2 of 3                         |
|                                                                                   | PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg               |                             | Format No: F/QCGN/034/06                     |
| B.No.: G1822115                                                                   | Mfg. Date: SEP-2022                                 | Batch Size: 6.0 L           | Storage Condition: 30°C ± 2°C & 75% RH ± 5%  |
|                                                                                   | Exp. Date: AUG-2025                                 | Pack Size: Alu/Alu (3x10'S) | Reason for stability: Validation Batch study |
|                                                                                   | Label Claim: Each uncoated tablet contains:         |                             | Period: 36 Month                             |
|                                                                                   | Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |                             | Date of Loading: 26.09.2022                  |

|                                              |                                               |              |              |              |              |              |              |              |
|----------------------------------------------|-----------------------------------------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| <b>Related substances:</b>                   |                                               |              |              |              |              |              |              |              |
| Impurity A                                   | Not more than 2.0%                            | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected |
| Impurity D                                   | Not more than 6.0%                            | Not Detected | 3.76%        | 3.84%        | 4.11%        | 4.13%        | 4.56%        | 5.03%        |
| Impurity E                                   | Not more than 2.0%                            | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected |
| Single maximum unknown impurity              | Not more than 0.5%                            | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected |
| Total impurities                             | Not more than 6.0%                            | Not Detected | 3.76%        | 3.84%        | 4.11%        | 4.15%        | 4.56%        | 5.05%        |
| <b>Assay: Each uncoated tablet contains:</b> |                                               |              |              |              |              |              |              |              |
| Ramipril BP -5 mg                            | Not less than 90.0 % and Not more than 110.0% | 100.48%      | 101.00%      | 100.30%      | 101.60%      | 100.74%      | 99.78%       | 98.90%       |
| Hydrochlorothiazide BP-12.5mg                | Not less than 90.0 % and Not more than 110.0% | 100.17%      | 101.60 %     | 102.00 %     | 100.88%      | 100.21%      | 99.54%       | 97.55%       |
| <b>Microbiological limits:</b>               |                                               |              |              |              |              |              |              |              |
| Total Aerobic Microbial count                | NMT 1000 cfu/g                                | <10 cfu/g    |              |              |              |              |              |              |
| Total Yeasts and mould counts                | NMT 100 cfu/g                                 | <10 cfu/g    | NA           | NA           | NA           | NA           | NA           | NA           |
| E. Coli                                      | Should be Absent                              | Absent       |              |              |              |              |              |              |
| Salmonella                                   | Should be Absent                              | Absent       |              |              |              |              |              |              |
| S. aureus                                    | Should be Absent                              | Absent       |              |              |              |              |              |              |
| P. aeruginosa                                | Should be Absent                              | Absent       |              |              |              |              |              |              |

|                                                                                   |                                                     |                             |                                              |
|-----------------------------------------------------------------------------------|-----------------------------------------------------|-----------------------------|----------------------------------------------|
|  | LONG TERM STABILITY DATA                            |                             | Page No: Page 3 of 3                         |
|                                                                                   |                                                     |                             | Format No: F/QCGN/034/06                     |
| PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg                                             |                                                     |                             | Storage Condition: 30°C ± 2°C & 75% RH ± 5%  |
| B.No.: G1822115                                                                   | Mfg. Date: SEP-2022                                 | Batch Size: 6.0 L           | Reason for stability: Validation Batch study |
|                                                                                   | Exp. Date: AUG-2025                                 | Pack Size: Alu/Alu (3x10'S) | Period: 36 Month                             |
|                                                                                   | Label Claim: Each uncoated tablet contains:         |                             | Date of Loading: 26.09.2022                  |
|                                                                                   | Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |                             |                                              |

Stability study:

Complete [ X ]

Incomplete [ ✓ ]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for ..... 24<sup>th</sup> months.

Reference: ICH Guidelines

PREPARED BY: Suba  
DATE: 19/10/2024

CHECKED BY: J. K. S.  
DATE: 19/10/2024

APPROVED BY: [Signature]  
DATE: 18/10/24



# ACCELERATED STABILITY DATA

Page No: Page 1 of 2

Foramt No:F/QCGN/034/06

PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg

Storage Condition:40°C ±2°C & 75% RH ± 5%

B.No. : GF201004

Mfg. Date: OCT-2020

Batch Size: 6.0 L

Reason for stability: Validataion Batch study

Exp. Date: SEP-2023

Pack Size: Alu Alu (3x10'S)

Period: 6 Month

Label Claim: Each uncoated tablet contains:  
Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg

Date of Loading:16.11.2020

| Tests                                                                                                                | Limits                                                                                                         | Initial<br>23.11.2020                                            | 3 <sup>rd</sup> Month<br>16.02.2021                              | 6 <sup>th</sup> Month<br>16.05.2021                              |
|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------|
|                                                                                                                      |                                                                                                                | Results                                                          | Results                                                          | Results                                                          |
| Description                                                                                                          | Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side. | Complies                                                         | Complies                                                         | Complies                                                         |
| Average Weight                                                                                                       | 200.0 mg ± 5.0%<br>(Limit:190.0 mg to 210.0 mg)                                                                | 200.35 mg                                                        | 199.80 mg                                                        | 199.95 mg                                                        |
| Disintegration Time                                                                                                  | Not more than 15 minutes                                                                                       | 01 min 25 sec                                                    | 01 min 56 sec                                                    | 02 min 40 sec                                                    |
| Dissolution<br>Ramipril BP-5mg                                                                                       | Not less than 75.0 % of labeled amount.                                                                        | Min: 97.73 % to Max: 103.76%<br>Avg: 100.44%                     | Min: 95.12% to Max:98.48%<br>Avg: 96.38%                         | Min: 95.15% to Max:97.20%<br>Avg: 95.91%                         |
| Hydrochlorothiazide BP-12.5mg                                                                                        | Not less than 75.0 % of labeled amount.                                                                        | Min: 93.72% to Max: 102.01%<br>Avg: 99.59%                       | Min: 96.18% to Max:102.65%<br>Avg: 100.34%                       | Min: 97.50% to Max:101.97%<br>Avg: 100.77%                       |
| Related substances:<br>Impurity A<br>Impurity D<br>Impurity E<br>Single maximum unknown impurity<br>Total impurities | Not more than 2.0%<br>Not more than 6.0%<br>Not more than 2.0%<br>Not more than 0.5%<br>Not more than 6.0%     | Not Detected<br>0.24 %<br>Not Detected<br>Not Detected<br>0.24 % | Not Detected<br>0.27 %<br>Not Detected<br>Not Detected<br>0.27 % | Not Detected<br>0.28 %<br>Not Detected<br>Not Detected<br>0.28 % |
| Assay: Each uncoated tablet contains:<br>Ramipril BP -5 mg                                                           | Not less than 90.0 % and Not more than 110.0%                                                                  | 101.59%                                                          | 99.05%                                                           | 98.88%                                                           |
| Hydrochlorothiazide BP-12.5mg                                                                                        | Not less than 90.0 % and Not more than 110.0%                                                                  | 101.18%                                                          | 99.53%                                                           | 100.11%                                                          |

|                                                                                   |                                                                                                            |                                   |                                    |                                |                                                      |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------|--------------------------------|------------------------------------------------------|
|  |                                                                                                            | <b>ACCELERATED STABILITY DATA</b> |                                    | <b>Page No: Page 2 of 2</b>    |                                                      |
| <b>PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg</b>                                      |                                                                                                            |                                   |                                    | <b>Foramt No:F/QCGN/034/06</b> |                                                      |
| <b>B.No. : GF201004</b>                                                           | <b>Mfg. Date: OCT-2020</b>                                                                                 |                                   | <b>Batch Size: 6.0 L</b>           |                                | <b>Reason for stability: Validataion Batch study</b> |
|                                                                                   | <b>Exp. Date: SEP-2023</b>                                                                                 |                                   | <b>Pack Size: Alu Alu (3x10'S)</b> |                                |                                                      |
|                                                                                   | <b>Label Claim: Each uncoated tablet contains:<br/>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg</b> |                                   |                                    |                                | <b>Date of Loading:16.11.2020</b>                    |
| <b>Microbiological limits:</b>                                                    |                                                                                                            |                                   |                                    |                                |                                                      |
| Total Aerobic Microbial count                                                     | NMT 1000 cfu/g                                                                                             | 10 cfu/g                          | NA                                 |                                | 40 cfu/g                                             |
| Total Yeasts and mould counts                                                     | NMT 100 cfu/g                                                                                              | <10 cfu/g                         | NA                                 |                                | <10 cfu/g                                            |
| E.Coli                                                                            | Should be Absent                                                                                           | Absent                            | NA                                 |                                | Absent                                               |
| Salmonella                                                                        | Should be Absent                                                                                           | Absent                            | NA                                 |                                | Absent                                               |
| S.aureus                                                                          | Should be Absent                                                                                           | Absent                            | NA                                 |                                | Absent                                               |
| P.aeruginosa                                                                      | Should be Absent                                                                                           | Absent                            | NA                                 |                                | Absent                                               |

Stability study:

Complete [ ✓ ]

Incomplete [ ✗ ]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for .....<sup>6<sup>th</sup></sup> months.

Reference: ICH Guidelines

PREPARED BY: J. Jay J

DATE: 21/05/2021

CHECKED BY: JF

DATE: 21/05/2021

APPROVED BY: M

DATE: 21/05/2021

|                                                                                   |                                                                                                    |  |                             |                                              |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|--|-----------------------------|----------------------------------------------|
|  | LONG TEAM STABILITY DATA                                                                           |  |                             | Page No: Page 1 of 2                         |
|                                                                                   |                                                                                                    |  |                             | Foramt No:F/QCGN/034/06                      |
| PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg                                             |                                                                                                    |  |                             | Storage Condition:30°C ±2°C & 75% RH ± 5%    |
| B.No. : GF201004                                                                  | Mfg. Date: OCT-2020                                                                                |  | Batch Size: 6.0 L           | Reason for stability: Validation Batch study |
|                                                                                   | Exp. Date: SEP-2023                                                                                |  | Pack Size: Alu Alu (3x10'S) | Period: 36 Month                             |
|                                                                                   | Label Claim: Each uncoated tablet contains:<br>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |  |                             | Date of Loading:16.11.2020                   |

| Tests                                                                                                                | Limits                                                                                                         | Initial<br>23.11.2020                                                | 3 <sup>rd</sup> Month<br>16.02.2021                                  | 6 <sup>th</sup> Month<br>16.05.2021                                  | 9 <sup>th</sup> Month<br>16.08.2021                                  | 12 <sup>th</sup> Month<br>16.11.2021                                 | 18 <sup>th</sup> Month<br>16.05.2022                                 | 24 <sup>th</sup> Month<br>16.11.2022                                 | 36 <sup>th</sup> Month<br>16.11.2023                                 |
|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|
|                                                                                                                      |                                                                                                                | Results                                                              | Results                                                              | Results                                                              | Results                                                              | Results                                                              | Results                                                              | Results                                                              | Results                                                              |
| Description                                                                                                          | Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side. | Complies                                                             | Complies                                                             | Complies                                                             | Complies                                                             | Complies                                                             | Complies                                                             | Complies                                                             | Complies                                                             |
| Average Weight                                                                                                       | 200.0 mg ± 5.0%<br>(Limit:190.0mg to 210.0 mg)                                                                 | 200.35 mg                                                            | 199.40 mg                                                            | 199.65 mg                                                            | 200.60 mg                                                            | 199.52 mg                                                            | 202.14 mg                                                            | 203.24 mg                                                            | 202.57 mg                                                            |
| Disintegration Time                                                                                                  | Not more than 15 minutes                                                                                       | 01 min 25 sec                                                        | 01 min 40 sec                                                        | 02 min 05 sec                                                        | 02 min 55 sec                                                        | 03 min 16 sec                                                        | 03 min 54 sec                                                        | 05 min 03 sec                                                        | 05 min 06 sec                                                        |
| Dissolution<br>Ramipril BP-5mg                                                                                       | Not less than 75.0 % of labeled amount.                                                                        | Min: 97.73 %<br>Max: 103.76%<br>Avg: 100.44%                         | Min: 94.44%<br>Max:98.29%<br>Avg: 96.29%                             | Min: 94.60%<br>Max:97.06%<br>Avg: 95.81%                             | Min: 95.22%<br>Max:97.99%<br>Avg: 96.80%                             | Min: 96.22%<br>Max:98.99%<br>Avg: 98.52%                             | Min: 94.21%<br>Max:99.45%<br>Avg: 97.46%                             | Min: 91.81%<br>Max:96.61%<br>Avg: 94.26%                             | Min: 90.53%<br>Max:97.18%<br>Avg: 95.11%                             |
| Hydrochlorothiazide BP-12.5mg                                                                                        | Not less than 75.0 % of labeled amount.                                                                        | Min: 93.72%<br>Max: 102.01%<br>Avg: 99.59%                           | Min: 97.81%<br>Max:103.51%<br>Avg: 101.16%                           | Min: 94.20%<br>Max:101.13%<br>Avg: 99.67%                            | Min: 95.20%<br>Max:100.13%<br>Avg: 99.81%                            | Min: 94.21%<br>Max:100.52%<br>Avg: 99.02%                            | Min: 92.25%<br>Max:98.26%<br>Avg: 96.15%                             | Min: 92.69%<br>Max:98.13%<br>Avg: 95.40%                             | Min: 91.58%<br>Max:98.10%<br>Avg: 96.34%                             |
| Related substances:<br>Impurity A<br>Impurity D<br>Impurity E<br>Single maximum unknown impurity<br>Total impurities | Not more than 2.0%<br>Not more than 6.0%<br>Not more than 2.0%<br><br>Not more than 0.5%<br>Not more than 6.0% | Not Detected<br>0.24 %<br>Not Detected<br><br>Not Detected<br>0.24 % | Not Detected<br>0.25 %<br>Not Detected<br><br>Not Detected<br>0.25 % | Not Detected<br>0.26 %<br>Not Detected<br><br>Not Detected<br>0.26 % | Not Detected<br>0.42 %<br>Not Detected<br><br>Not Detected<br>0.42 % | Not Detected<br>0.65 %<br>Not Detected<br><br>Not Detected<br>0.65 % | Not Detected<br>0.88 %<br>Not Detected<br><br>Not Detected<br>0.88 % | Not Detected<br>1.11 %<br>Not Detected<br><br>Not Detected<br>1.11 % | Not Detected<br>1.15 %<br>Not Detected<br><br>Not Detected<br>1.15 % |

|                                                                                   |                                                                                                    |                             |                                              |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------|
|  | LONG TEAM STABILITY DATA                                                                           |                             | Page No: Page 2 of 2                         |
|                                                                                   |                                                                                                    |                             | Foramt No:F/QCGN/034/06                      |
| PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg                                             |                                                                                                    |                             | Storage Condition:30°C ±2°C & 75% RH ± 5%    |
| B.No. : GF201004                                                                  | Mfg. Date: OCT-2020                                                                                | Batch Size: 6.0 L           | Reason for stability: Validation Batch study |
|                                                                                   | Exp. Date: SEP-2023                                                                                | Pack Size: Alu Alu (3x10'S) | Period: 36 Month                             |
|                                                                                   | Label Claim: Each uncoated tablet contains:<br>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |                             | Date of Loading:16.11.2020                   |

|                                                                                                                                               |                                                                                                                 |                                                               |         |        |         |         |        |        |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|---------|--------|---------|---------|--------|--------|---------------------------------------------------------------|
| Assay: Each uncoated tablet contains:<br>Ramipril BP -5 mg                                                                                    | Not less than 90.0 % and Not more than 110.0%                                                                   | 101.59%                                                       | 99.93%  | 99.52% | 100.04% | 99.55%  | 97.99% | 97.57% | 97.23%                                                        |
| Hydrochlorothiazide BP-12.5mg                                                                                                                 | Not less than 90.0 % and Not more than 110.0%                                                                   | 101.18%                                                       | 100.38% | 99.34% | 99.17%  | 100.05% | 98.86% | 98.53% | 98.06%                                                        |
| Microbiological limits:<br>Total Aerobic Microbial count<br>Total Yeasts and mould counts<br>E.Coli<br>Salmonella<br>S.aureus<br>P.aeruginosa | NMT 1000 cfu/g<br>NMT 100 cfu/g<br>Should be Absent<br>Should be Absent<br>Should be Absent<br>Should be Absent | 10 cfu/g<br><10 cfu/g<br>Absent<br>Absent<br>Absent<br>Absent | NA      | NA     | NA      | NA      | NA     | NA     | 30 cfu/g<br><10 cfu/g<br>Absent<br>Absent<br>Absent<br>Absent |

Stability study:

Complete [ ✓ ]

Incomplete [ ✗ ]

Opinion: Based on the above stability studies, the product is ~~unstable~~/ stable for .....<sup>36<sup>th</sup></sup> months.

Reference: ICH Guidelines

PREPARED BY: J. K. H  
DATE: 22/11/2023

CHECKED BY: B  
DATE: 22/11/23

APPROVED BY: H  
DATE: 22/11/24

|                                                                                   |                                                                                                    |  |                             |                                              |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|--|-----------------------------|----------------------------------------------|
|  | LONG TEAM STABILITY DATA                                                                           |  |                             | Page No: Page 1 of 3                         |
|                                                                                   |                                                                                                    |  |                             | Foramt No:F/QCGN/034/06                      |
| PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg                                             |                                                                                                    |  |                             | Storage Condition:30°C ±2°C & 75% RH ± 5%    |
| B.No. : GF210918                                                                  | Mfg. Date: SEP-2021                                                                                |  | Batch Size: 6.0 L           | Reason for stability: Validation Batch study |
|                                                                                   | Exp. Date: AUG-2024                                                                                |  | Pack Size: Alu Alu (3x10'S) | Period: 36 Month                             |
|                                                                                   | Label Claim: Each uncoated tablet contains:<br>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |  |                             | Date of Loading:03.09.2021                   |

| Tests                          | Limits                                                                                                         | Initial<br>09.09.2021                         | 3 <sup>rd</sup> Month<br>03.12.2021           | 6 <sup>th</sup> Month<br>03.03.2022          | 9 <sup>th</sup> Month<br>03.06.2022         | 12 <sup>th</sup> Month<br>03.09.2022        | 18 <sup>th</sup> Month<br>03.03.2023        | 24 <sup>th</sup> Month<br>03.09.2023        |
|--------------------------------|----------------------------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------------------------------|----------------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------|
|                                |                                                                                                                | Results                                       | Results                                       | Results                                      | Results                                     | Results                                     | Results                                     | Results                                     |
| Description                    | Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side. | Complies                                      | Complies                                      | Complies                                     | Complies                                    | Complies                                    | Complies                                    | Complies                                    |
| Average Weight                 | 200.0 mg ± 5.0%<br>(Limit:190.0mg to 210.0 mg)                                                                 | 199.15 mg                                     | 201.12 mg                                     | 201.58 mg                                    | 202.46 mg                                   | 203.86 mg                                   | 203.22 mg                                   | 203.65 mg                                   |
| Disintegration Time            | Not more than 15 minutes                                                                                       | 01 min 46 sec                                 | 02 min 19 sec                                 | 03 min 55 sec                                | 03 min 23 sec                               | 03 min 42 sec                               | 03 min 52 sec                               | 04 min 16 sec                               |
| Dissolution<br>Ramipril BP-5mg | Not less than 75.0 % of labeled amount.                                                                        | Min: 96.47 % to<br>Max: 98.19%<br>Avg: 97.19% | Min: 94.55% to<br>Max:98.79%<br>Avg: 96.88%   | Min: 95.26% to<br>Max:97.10%<br>Avg: 95.96%  | Min: 92.60% to<br>Max:96.15%<br>Avg: 94.25% | Min: 94.01% to<br>Max:96.28%<br>Avg: 95.30% | Min: 93.03% to<br>Max:95.36%<br>Avg: 94.17% | Min: 92.81% to<br>Max:94.98%<br>Avg: 93.74% |
| Hydrochlorothiazide BP-12.5mg  | Not less than 75.0 % of labeled amount.                                                                        | Min: 98.32% to<br>Max: 100.50%<br>Avg: 99.48% | Min: 96.81% to<br>Max:102.51%<br>Avg: 100.16% | Min: 97.55% to<br>Max:101.47%<br>Avg: 99.77% | Min: 94.45% to<br>Max:99.76%<br>Avg: 97.91% | Min: 92.25% to<br>Max:99.73%<br>Avg: 95.89% | Min: 91.93% to<br>Max:96.08%<br>Avg: 93.78% | Min: 91.38% to<br>Max:95.72%<br>Avg: 93.51% |

|                                                                                   |                                                                                                    |                             |                                              |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------|
|  | LONG TEAM STABILITY DATA                                                                           |                             | Page No: Page 2 of 3                         |
|                                                                                   |                                                                                                    |                             | Foramt No:F/QCGN/034/06                      |
| PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg                                             |                                                                                                    |                             | Storage Condition:30°C ±2°C & 75% RH ± 5%    |
| B.No. : GF210918                                                                  | Mfg. Date: SEP-2021                                                                                | Batch Size: 6.0 L           | Reason for stability: Validation Batch study |
|                                                                                   | Exp. Date: AUG-2024                                                                                | Pack Size: Alu Alu (3x10'S) | Period: 36 Month                             |
|                                                                                   | Label Claim: Each uncoated tablet contains:<br>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |                             | Date of Loading:03.09.2021                   |

|                                              |                                               |              |              |              |              |              |              |              |
|----------------------------------------------|-----------------------------------------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| <b>Related substances:</b>                   |                                               |              |              |              |              |              |              |              |
| Impurity A                                   | Not more than 2.0%                            | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected |
| Impurity D                                   | Not more than 6.0%                            | Not Detected | Not Detected | 0.32%        | 0.53%        | 0.70%        | 0.98%        | 1.06%        |
| Impurity E                                   | Not more than 2.0%                            | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected |
| Single maximum unknown impurity              | Not more than 0.5%                            | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected | Not Detected |
| Total impurities                             | Not more than 6.0%                            | Not Detected | Not Detected | 0.32%        | 0.55%        | 0.70%        | 0.98%        | 1.06%        |
| <b>Assay: Each uncoated tablet contains:</b> |                                               |              |              |              |              |              |              |              |
| Ramipril BP -5 mg                            | Not less than 90.0 % and Not more than 110.0% | 100.65%      | 100.02%      | 100.02%      | 98.79%       | 98.06%       | 97.50%       | 97.19%       |
| Hydrochlorothiazide BP-12.5mg                | Not less than 90.0 % and Not more than 110.0% | 100.40%      | 99.97%       | 99.97%       | 98.45%       | 98.31%       | 97.71%       | 97.48%       |
| <b>Microbiological limits:</b>               |                                               |              |              |              |              |              |              |              |
| Total Aerobic Microbial count                | NMT 1000 cfu/g                                | 20 cfu/g     |              |              |              |              |              |              |
| Total Yeasts and mould counts                | NMT 100 cfu/g                                 | <10 cfu/g    |              |              |              |              |              |              |
| E.Coli                                       |                                               |              | NA           | NA           | NA           | NA           | NA           | NA           |
| Salmonella                                   | Should be Absent                              | Absent       |              |              |              |              |              |              |
| S.aureus                                     | Should be Absent                              | Absent       |              |              |              |              |              |              |
| P.aeruginosa                                 | Should be Absent                              | Absent       |              |              |              |              |              |              |

|                                                                                   |                                                                                                            |                                 |                                    |                                                      |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------|------------------------------------------------------|
|  |                                                                                                            | <b>LONG TEAM STABILITY DATA</b> |                                    | <b>Page No: Page 3 of 3</b>                          |
|                                                                                   |                                                                                                            |                                 |                                    | <b>Foramt No:F/QCGN/034/06</b>                       |
| <b>PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg</b>                                      |                                                                                                            |                                 |                                    | <b>Storage Condition:30°C ±2°C &amp; 75% RH ± 5%</b> |
| <b>B.No. : GF210918</b>                                                           | <b>Mfg. Date: SEP-2021</b>                                                                                 |                                 | <b>Batch Size: 6.0 L</b>           | <b>Reason for stability: Validation Batch study</b>  |
|                                                                                   | <b>Exp. Date: AUG-2024</b>                                                                                 |                                 | <b>Pack Size: Alu Alu (3x10'S)</b> | <b>Period: 36 Month</b>                              |
|                                                                                   | <b>Label Claim: Each uncoated tablet contains:<br/>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg</b> |                                 |                                    | <b>Date of Loading:03.09.2021</b>                    |

Stability study:

Complete [ ☒ ]

Incomplete [ ☐ ]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for .....<sup>th</sup>24..... months.

Reference: ICH Guidelines

PREPARED BY: M. 

DATE:

06/09/2023

CHECKED BY: 

DATE:

06/09/23

APPROVED BY: 

DATE:

06/09/23

|                                                                                  |                                                                                                    |                             |                                               |
|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------|-----------------------------------------------|
|  | ACCELERATED STABILITY DATA                                                                         |                             | Page No: Page 1 of 2                          |
|                                                                                  |                                                                                                    |                             | Foramt No:F/QCGN/034/06                       |
| PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg                                            |                                                                                                    |                             | Storage Condition:40°C ±2°C & 75% RH ± 5%     |
| B.No. : GF210918                                                                 | Mfg. Date: SEP-2021                                                                                | Batch Size: 6.0 L           | Reason for stability: Validataion Batch study |
|                                                                                  | Exp. Date: AUG-2024                                                                                | Pack Size: Alu Alu (3x10'S) | Period: 6 Month                               |
|                                                                                  | Label Claim: Each uncoated tablet contains:<br>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |                             | Date of Loading:03.09.2021                    |

| Tests                                                                                                                | Limits                                                                                                         | Initial<br>09.09.2021                                                        | 3 <sup>rd</sup> Month<br>03.12.2021                                          | 6 <sup>th</sup> Month<br>03.03.2022                                          |
|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------|
|                                                                                                                      |                                                                                                                | Results                                                                      | Results                                                                      | Results                                                                      |
| Description                                                                                                          | Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side. | Complies                                                                     | Complies                                                                     | Complies                                                                     |
| Average Weight                                                                                                       | 200.0 mg ± 5.0%<br>(Limit:190.0mg to 210.0 mg)                                                                 | 199.15 mg                                                                    | 198.89 mg                                                                    | 202.17 mg                                                                    |
| Disintegration Time                                                                                                  | Not more than 15 minutes                                                                                       | 01 min 46 sec                                                                | 02 min 02 sec                                                                | 02 min 25 sec                                                                |
| Dissolution<br>Ramipril BP-5mg                                                                                       | Not less than 75.0 % of labeled amount.                                                                        | Min: 96.47 % to Max: 98.19% Avg: 97.19%                                      | Min: 96.23% to Max:99.45% Avg: 98.08%                                        | Min: 92.49% to Max:95.87% Avg: 94.53%                                        |
| Hydrochlorothiazide BP-12.5mg                                                                                        | Not less than 75.0 % of labeled amount.                                                                        | Min: 98.32% to Max: 100.50% Avg: 99.48%                                      | Min: 99.05% to Max:99.65% Avg: 99.52%                                        | Min: 94.46% to Max:98.85% Avg: 96.45%                                        |
| Related substances:<br>Impurity A<br>Impurity D<br>Impurity E<br>Single maximum unknown impurity<br>Total impurities | Not more than 2.0%<br>Not more than 6.0%<br>Not more than 2.0%<br>Not more than 0.5%<br>Not more than 6.0%     | Not Detected<br>Not Detected<br>Not Detected<br>Not Detected<br>Not Detected | Not Detected<br>Not Detected<br>Not Detected<br>Not Detected<br>Not Detected | Not Detected<br>Not Detected<br>Not Detected<br>Not Detected<br>Not Detected |
| Assay: Each uncoated tablet contains:<br>Ramipril BP -5 mg                                                           | Not less than 90.0 % and<br>Not more than 110.0%                                                               | 100.65%                                                                      | 99.35%                                                                       | 98.81%                                                                       |

|                                                                                                                                                      |                                                                                                            |                                                                                                                 |                                                               |                                                               |                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|
|                                                                      |                                                                                                            | <b>ACCELERATED STABILITY DATA</b>                                                                               |                                                               | <b>Page No: Page 2 of 2</b><br><b>Foramt No:F/QCGN/034/06</b> |                                                               |
| <b>PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg</b>                                                                                                         |                                                                                                            |                                                                                                                 |                                                               | <b>Storage Condition:40°C ±2°C &amp; 75% RH ± 5%</b>          |                                                               |
| <b>B.No. : GF210918</b>                                                                                                                              | <b>Mfg. Date: SEP-2021</b>                                                                                 |                                                                                                                 | <b>Batch Size: 6.0 L</b>                                      |                                                               | <b>Reason for stability: Validataion Batch study</b>          |
|                                                                                                                                                      | <b>Exp. Date: AUG-2024</b>                                                                                 |                                                                                                                 | <b>Pack Size: Alu Alu (3x10'S)</b>                            |                                                               | <b>Period: 6 Month</b>                                        |
|                                                                                                                                                      | <b>Label Claim: Each uncoated tablet contains:<br/>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg</b> |                                                                                                                 |                                                               |                                                               | <b>Date of Loading:03.09.2021</b>                             |
| <b>Hydrochlorothiazide BP-12.5mg</b>                                                                                                                 |                                                                                                            | Not less than 90.0 % and<br>Not more than 110.0%                                                                | 100.40%                                                       | 99.85 %                                                       | 98.45 %                                                       |
| <b>Microbiological limits:</b><br>Total Aerobic Microbial count<br>Total Yeasts and mould counts<br>E.Coli<br>Salmonella<br>S.aureus<br>P.aeruginosa |                                                                                                            | NMT 1000 cfu/g<br>NMT 100 cfu/g<br>Should be Absent<br>Should be Absent<br>Should be Absent<br>Should be Absent | 20 cfu/g<br><10 cfu/g<br>Absent<br>Absent<br>Absent<br>Absent | NA                                                            | 30 cfu/g<br><10 cfu/g<br>Absent<br>Absent<br>Absent<br>Absent |

Stability study:

Complete [ ✓ ]

Incomplete [ ✕ ]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for .....<sup>6th</sup>..... months.

Reference: ICH Guidelines

PREPARED BY: *J. K. S.*  
DATE: 08/03/2022

CHECKED BY: *J. K. S.*  
DATE: 08/03/2022

APPROVED BY: *Ar*  
DATE: 08/03/2022

|                                                                                   |                                       |                                                                                                    |                             |                                              |
|-----------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------|
|  | LONG TEAM STABILITY DATA              |                                                                                                    |                             | Page No: Page 1 of 3                         |
|                                                                                   |                                       |                                                                                                    |                             | Foramt No:F/QCGN/034/06                      |
|                                                                                   | PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg |                                                                                                    |                             | Storage Condition:30°C ±2°C & 75% RH ± 5%    |
|                                                                                   | B.No. : GF210918                      | Mfg. Date: SEP-2021                                                                                | Batch Size: 6.0 L           | Reason for stability: Validation Batch study |
|                                                                                   |                                       | Exp. Date: AUG-2024                                                                                | Pack Size: Alu Alu (3x10'S) | Period: 36 Month                             |
|                                                                                   |                                       | Label Claim: Each uncoated tablet contains:<br>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |                             | Date of Loading:03.09.2021                   |

| Tests                          | Limits                                                                                                         | Initial<br>09.09.2021                        | 3 <sup>rd</sup> Month<br>03.12.2021         | 6 <sup>th</sup> Month<br>03.03.2022         | 9 <sup>th</sup> Month<br>03.06.2022         | 12 <sup>th</sup> Month<br>03.09.2022        | 18 <sup>th</sup> Month<br>03.03.2023        | 24 <sup>th</sup> Month<br>03.09.2023        | 36 <sup>th</sup> Month<br>03.09.2024        |
|--------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------|
|                                |                                                                                                                | Results                                      | Results                                     | Results                                     | Results                                     | Results                                     | Results                                     | Results                                     | Results                                     |
| Description                    | Pink coloured, flat, round, beveled edged uncoated tablet with break line on one side and plain on other side. | Complies                                     | Complies                                    | Complies                                    | Complies                                    | Complies                                    | Complies                                    | Complies                                    | Complies                                    |
| Average Weight                 | 200.0 mg ± 5.0%<br>(Limit:190.0mg to 210.0 mg)                                                                 | 199.15 mg                                    | 201.12 mg                                   | 201.58 mg                                   | 202.46 mg                                   | 203.86 mg                                   | 203.22 mg                                   | 203.65 mg                                   | 205.78 mg                                   |
| Disintegration Time            | Not more than 15 minutes                                                                                       | 01 min 46 sec                                | 02 min 19 sec                               | 03 min 55 sec                               | 03 min 23 sec                               | 03 min 42 sec                               | 03 min 52 sec                               | 04 min 16 sec                               | 05 min 25 sec                               |
| Dissolution<br>Ramipril BP-5mg | Not less than 75.0 % of labeled amount.                                                                        | Min: 96.47 %<br>to Max:98.19%<br>Avg: 97.19% | Min: 94.55%<br>to Max:98.79%<br>Avg: 96.88% | Min: 95.26%<br>to Max:97.10%<br>Avg: 95.96% | Min: 92.60%<br>to Max:96.15%<br>Avg: 94.25% | Min: 94.01%<br>to Max:96.28%<br>Avg: 95.30% | Min: 93.03%<br>to Max:95.36%<br>Avg: 94.17% | Min: 92.81%<br>to Max:94.98%<br>Avg: 93.74% | Min: 92.02%<br>to Max:93.66%<br>Avg: 93.11% |
| Hydrochlorothiazide BP-12.5mg  | Not less than 75.0 % of labeled amount.                                                                        | Min: 98.32%<br>toMax:100.5%<br>Avg: 99.48%   | Min: 96.81%<br>toMax:102.5%<br>Avg:100.16%  | Min: 97.55%<br>toMax:101.4%<br>Avg: 99.77%  | Min: 94.45%<br>to Max:99.76%<br>Avg: 97.91% | Min: 92.25%<br>to Max:99.73%<br>Avg: 95.89% | Min: 91.93%<br>to Max:96.08%<br>Avg: 93.78% | Min: 91.38%<br>to Max:95.72%<br>Avg: 93.51% | Min: 90.85%<br>to Max:94.15%<br>Avg: 92.67% |

|                                                                                   |                                                                                                    |  |                             |                                              |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|--|-----------------------------|----------------------------------------------|
|  | LONG TEAM STABILITY DATA                                                                           |  |                             | Page No: Page 2 of 3                         |
|                                                                                   |                                                                                                    |  |                             | Foramt No:F/QCGN/034/06                      |
| PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg                                             |                                                                                                    |  |                             | Storage Condition:30°C ±2°C & 75% RH ± 5%    |
| B.No. : GF210918                                                                  | Mfg. Date: SEP-2021                                                                                |  | Batch Size: 6.0 L           | Reason for stability: Validation Batch study |
|                                                                                   | Exp. Date: AUG-2024                                                                                |  | Pack Size: Alu Alu (3x10'S) | Period: 36 Month                             |
|                                                                                   | Label Claim: Each uncoated tablet contains:<br>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |  |                             | Date of Loading:03.09.2021                   |

|                                                                                                                                      |                                                                                                            |                                                                              |                                                                              |                                                                |                                                                |                                                                |                                                                |                                                                |                                                                |
|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------|
| <b>Related substances:</b><br>Impurity A<br>Impurity D<br>Impurity E<br>Single maximum unknown impurity<br>Total impurities          | Not more than 2.0%<br>Not more than 6.0%<br>Not more than 2.0%<br>Not more than 0.5%<br>Not more than 6.0% | Not Detected<br>Not Detected<br>Not Detected<br>Not Detected<br>Not Detected | Not Detected<br>Not Detected<br>Not Detected<br>Not Detected<br>Not Detected | Not Detected<br>0.32%<br>Not Detected<br>Not Detected<br>0.32% | Not Detected<br>0.53%<br>Not Detected<br>Not Detected<br>0.55% | Not Detected<br>0.70%<br>Not Detected<br>Not Detected<br>0.70% | Not Detected<br>0.98%<br>Not Detected<br>Not Detected<br>0.98% | Not Detected<br>1.06%<br>Not Detected<br>Not Detected<br>1.06% | Not Detected<br>1.11%<br>Not Detected<br>Not Detected<br>1.11% |
| <b>Assay: Each uncoated tablet contains:</b><br>Ramipril BP -5 mg                                                                    | Not less than 90.0 %<br>and Not more than 110.0%                                                           | 100.65%                                                                      | 100.02%                                                                      | 100.02%                                                        | 98.79%                                                         | 98.06%                                                         | 97.50%                                                         | 97.19%                                                         | 96.65%                                                         |
| Hydrochlorothiazide BP-12.5mg                                                                                                        | Not less than 90.0 %<br>and Not more than 110.0%                                                           | 100.40%                                                                      | 99.97%                                                                       | 99.97%                                                         | 98.45%                                                         | 98.31%                                                         | 97.71%                                                         | 97.48%                                                         | 96.23%                                                         |
| <b>Microbiological limits:</b><br>Total Aerobic Microbial count<br>Total Yeasts and mould counts<br>E.Coli<br>Salmonella<br>S.aureus | NMT 1000 cfu/g<br>NMT 100 cfu/g<br><br>Should be Absent<br>Should be Absent<br>Should be Absent            | 20 cfu/g<br><10 cfu/g<br><br>Absent<br>Absent<br>Absent                      | NA<br><br><br>NA                                                             | NA<br><br><br>NA                                               | NA<br><br><br>NA                                               | NA<br><br><br>NA                                               | NA<br><br><br>NA                                               | NA<br><br><br>NA                                               | 30 cfu/g<br><10 cfu/g<br><br>Absent<br>Absent<br>Absent        |

|                                                                                   |                                                                                                    |                             |                                              |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------|
|  | LONG TEAM STABILITY DATA                                                                           |                             | Page No: Page 3 of 3                         |
|                                                                                   |                                                                                                    |                             | Foramt No:F/QCGN/034/06                      |
| PRODUCT NAME: RAMITHIAZIDE 5mg/12.5mg                                             |                                                                                                    |                             | Storage Condition:30°C ±2°C & 75% RH ± 5%    |
| B.No. : GF210918                                                                  | Mfg. Date: SEP-2021                                                                                | Batch Size: 6.0 L           | Reason for stability: Validation Batch study |
|                                                                                   | Exp. Date: AUG-2024                                                                                | Pack Size: Alu Alu (3x10'S) | Period: 36 Month                             |
|                                                                                   | Label Claim: Each uncoated tablet contains:<br>Ramipril BP 5 mg and Hydrochlorothiazide BP 12.5 mg |                             | Date of Loading:03.09.2021                   |

|                  |                  |                |  |                  |  |  |  |        |
|------------------|------------------|----------------|--|------------------|--|--|--|--------|
| P.aeruginosa     | Should be Absent | Absent         |  |                  |  |  |  | Absent |
| Stability study: |                  | Complete [ ✓ ] |  | Incomplete [ X ] |  |  |  |        |

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for 36<sup>th</sup> months.

Reference: ICH Guidelines

PREPARED BY:

DATE:

*Q.22*  
*16/09/2024*

CHECKED BY:

DATE:

*J. Kemp*  
*16/09/2024*

APPROVED BY:

DATE:

*hr*  
*16/09/2024*