

|                                                                                                                               |                                                                                                                                                     |                               |                                      |
|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------------------------|
| <br><b>SAI PRIMUS</b><br>LIFE BIOTECH PVT LTD | <b>SAI PRIMUS LIFE BIOTECH PVT LTD</b><br>Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur<br>Commune, Puducherry-605009. |                               | Page 1 of 36                         |
|                                                                                                                               | <b>BATCH MANUFACTURING RECORD</b>                                                                                                                   | <b>Product Code: R09</b>      | <b>Batch Size: 6,00,000 Tablets</b>  |
| <b>Product</b>                                                                                                                | <b>RAMITHIAZIDE 5/12.5</b>                                                                                                                          | <b>BMR. No.: BMR/T/134-00</b> | <b>Batch No.: GF201004</b>           |
|                                                                                                                               |                                                                                                                                                     | <b>Customer:</b>              | <b>Generic Health Care Pvt. Ltd.</b> |

### BATCH MANUFACTURING RECORD COVER SHEET

**PRODUCT NAME** : RAMITHIAZIDE 5/12.5  
**GENERIC NAME** : Ramipril and Hydrochlorothiazide Tablets  
 Each Uncoated tablet contains:  
 Ramipril BP.....5 mg  
**LABEL CLAIM** : Hydrochlorothiazide BP.....12.5 mg  
 Excipients.....q.s.  
 Colour: Erythrosine Supra  
**MFR No. / Reference Document No.** : MFR/T/058-00  
**BMR No.** : BMR/T/134-00  
**REVISION No.** : 00  
**SUPERSEDES No.** : NIL  
**BMR EFFECTIVE BATCH NUMBER/DATE** : GF201004 / 26/10/2020  
**MFG.LIC No.** : PON/DRUGS/19 13 4323  
**STORAGE** : Store in cool and dry place. Protect from light and moisture.  
**BMR ISSUED BY/DATE (QA)** :  26/10/2020  
**BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)** :  26/10/2020  
**SHELF LIFE** : 36 Months  
**BATCH SIZE** : 6,00,000 Tablets (120.210 Kg)  
**MFG. DATE:** 10/2020 **EXP. DATE:** 09/2023

### RECOVERY ADDITION RECORD

| BATCH NO | MFG | EXP | QUANTITY | REVISED BATCH SIZE |
|----------|-----|-----|----------|--------------------|
|          |     | NA  |          |                    |

**ALLOTTED BY:**  **QA SIGN/DATE:** 26/10/2020  
**COUNTER CHECKED BY:**  **QA SIGN/DATE:** 26/10/2020  
**DATE OF COMMENCEMENT:** 26/10/2020 **DATE OF COMPLETION:** 11/11/2020  
**RELEASED QUANTITY OF TABLETS FOR PACKING** : 576000 NOS  
**RELEASE FOR PACKING STAGE**  
**HEAD OF QA SIGN/DATE:**  11/11/2020

This BMR contains 36 Pages + 01 Additional Pages

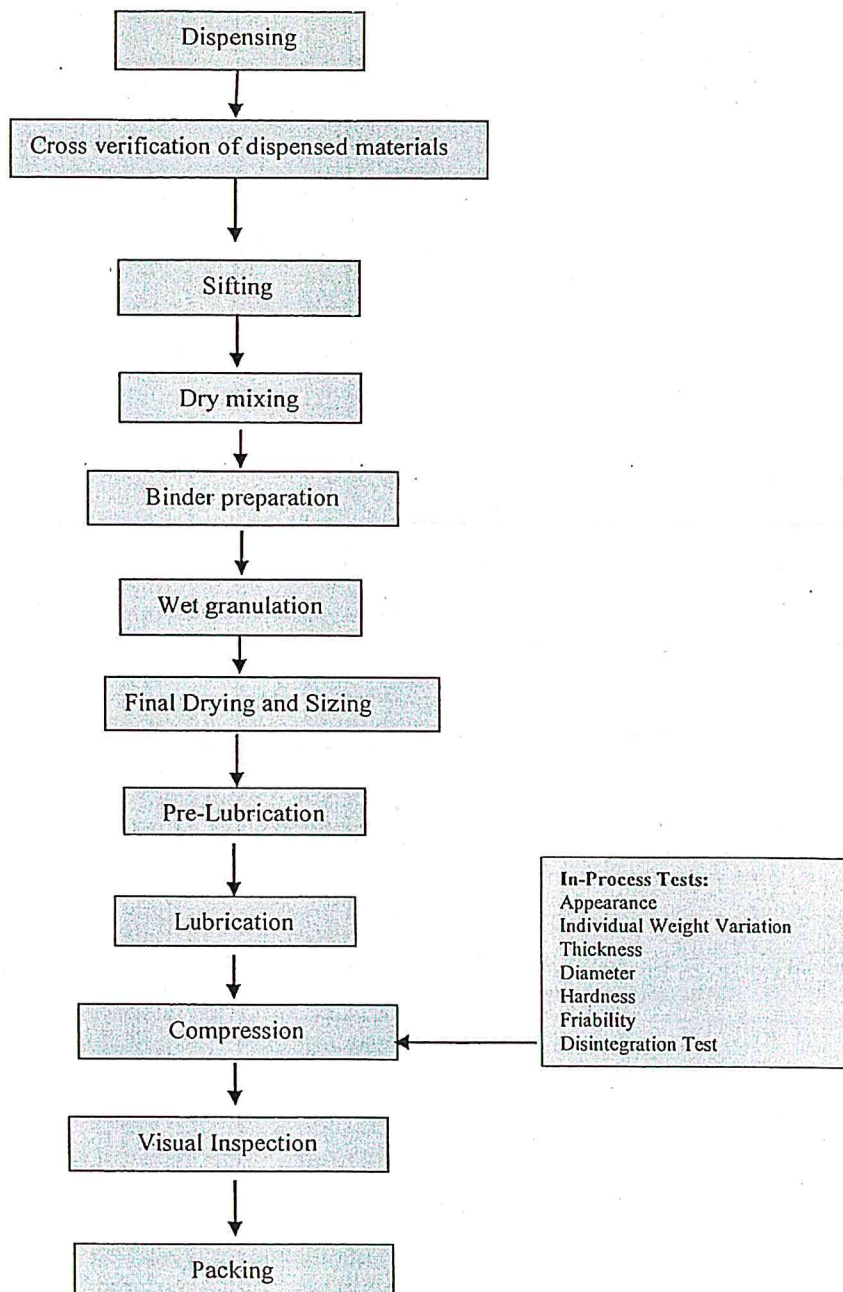
| Prepared by: |                                                                                     | Checked by:                                                                         |                                                                                     | Approved By:                                                                          |
|--------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Dept.        | Production                                                                          | Production                                                                          | Quality Assurance                                                                   | Head Quality Assurance                                                                |
| Sign.        |  |  |  |  |
| Date         | 26/10/2020                                                                          | 26/10/2020                                                                          | 26/10/2020                                                                          | 26/10/2020                                                                            |

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|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------------------------|
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|                                                                                                                               | <b>BATCH MANUFACTURING RECORD</b>                                                                                                                   | <b>Product Code: R09</b>     | <b>Batch Size: 6,00,000 Tablets</b>  |
| <b>Product</b>                                                                                                                | <b>RAMITHIAZIDE 5/12.5</b>                                                                                                                          | <b>BMR. No.: BMRT/134-00</b> | <b>Batch No.: GF 201004</b>          |
|                                                                                                                               |                                                                                                                                                     | <b>Customer:</b>             | <b>Generic Health Care Pvt. Ltd.</b> |

## 2.0 PROCESS FLOW CHART



| Prepared by: |            | Checked by: |                   | Approved By:           |
|--------------|------------|-------------|-------------------|------------------------|
| Dept.        | Production | Production  | Quality Assurance | Head Quality Assurance |
| Sign.        | L. Ka      |             |                   |                        |
| Date         | 26/10/2020 | 26/10/2020  | 26/10/2020        | 26/10/2020             |

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|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------------------------------------------------------------------------------------------------|
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|                                                                                                                               | <b>BATCH MANUFACTURING RECORD</b>                                                                                                                   | <b>Product Code: R09</b>   | <b>Batch Size: 6,00,000 Tablets</b>                                                                            |
|                                                                                                                               | <b>Product</b>                                                                                                                                      | <b>RAMITHIAZIDE 5/12.5</b> | <b>BMR. No.: BMR/T/134-00</b><br><b>Batch No.: GF 901004</b><br><b>Customer:</b> Generic Health Care Pvt. Ltd. |

### 3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

| Sr. No.                                              | Name of the Ingredient            | Spec. | Item Code   | Quantity/ Tablets (mg) | Std. quantity per 6,00,000 tablets (kg) | OA/ PL (%) | Req. quantity per 6,00,000 tablets (kg) |
|------------------------------------------------------|-----------------------------------|-------|-------------|------------------------|-----------------------------------------|------------|-----------------------------------------|
| <b>Dry mixing material:</b>                          |                                   |       |             |                        |                                         |            |                                         |
| 1                                                    | Ramipril*                         | BP    | RAI/GH/R001 | 5.000                  | 3.000                                   | 2          | 3.060                                   |
| 2                                                    | Hydrochlorothiazide^              | BP    | RAI/GH/H002 | 12.500                 | 7.500                                   | 2          | 7.650                                   |
| 3                                                    | Dried Maize Starch***^            | BP    | IRM/SP/M001 | 61.400                 | 36.840                                  | -          | 36.840                                  |
| 4                                                    | Lactose Monohydrate               | BP    | REX/SP/L003 | 74.000                 | 44.400                                  | -          | 44.400                                  |
| 5                                                    | Microcrystalline Cellulose PH 102 | BP    | REX/SP/M010 | 30.000                 | 18.000                                  | -          | 18.000                                  |
| <b>Binder Material:</b>                              |                                   |       |             |                        |                                         |            |                                         |
| 6                                                    | Gelatin                           | BP    | REX/SP/G001 | 2.000                  | 1.200                                   | -          | 1.200                                   |
| 7                                                    | Dried Maize Starch                | BP    | IRM/SP/M001 | 5.000                  | 3.000                                   | -          | 3.000                                   |
| 8                                                    | Erythrosine Supra                 | IHS   | REX/SP/E005 | 0.100                  | 0.060                                   | -          | 0.060                                   |
| 9                                                    | Purified Water                    | BP    | NA          | q.s.                   | 30.000                                  | -          | 30.000                                  |
| <b>Theoretical Weight of Dried Granules</b>          |                                   |       |             | <b>190.000</b>         | <b>114.000</b>                          | <b>-</b>   | <b>114.210</b>                          |
| <b>Lubrication Material:</b>                         |                                   |       |             |                        |                                         |            |                                         |
| 10                                                   | Sodium Starch Glycollate          | BP    | REX/SP/S004 | 5.000                  | 3.000                                   | -          | 3.000                                   |
| 11                                                   | Colloidal Silicon Dioxide         | BP    | REX/SP/C001 | 1.000                  | 0.600                                   | -          | 0.600                                   |
| 12                                                   | Magnesium Stearate                | BP    | REX/SP/M011 | 4.000                  | 2.400                                   | -          | 2.400                                   |
| <b>Theoretical Weight of the Lubricated granules</b> |                                   |       |             | <b>200.000</b>         | <b>120.000</b>                          | <b>-</b>   | <b>120.210</b>                          |
| <b>Theoretical weight of Compressed tablet</b>       |                                   |       |             | <b>200.000</b>         | <b>120.000</b>                          | <b>-</b>   | <b>120.210</b>                          |

**NOTE:** \*^API quantity shall be calculated based on potency.

OA: Overages, PL: Process loss

#### Potency calculation:

Theoretical Quantity of Ramipril and Hydrochlorothiazide required in Kg for a batch size of 6,00,000 Tablets are calculated.

\* Excess Quantity shall be compensating from Dried Maize Starch\*\*\*^

| Prepared by: |            | Checked by: |                   | Approved By:           |
|--------------|------------|-------------|-------------------|------------------------|
| Dept.        | Production | Production  | Quality Assurance | Head Quality Assurance |
| Sign.        | L. Ka      | 26/10/2020  | 26/10/2020        | 26/10/2020             |
| Date         | 26/10/2020 | 26/10/2020  | 26/10/2020        | 26/10/2020             |

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