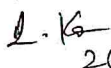


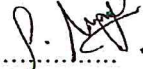
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 1 of 36
	BATCH MANUFACTURING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00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

BATCH MANUFACTURING RECORD COVER SHEET

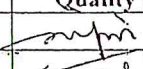
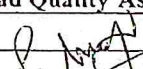
PRODUCT NAME : RAMITHIAZIDE 5/12.5
GENERIC NAME : Ramipril and Hydrochlorothiazide Tablets
 Each Uncoated tablet contains:
 Ramipril BP.....5 mg
LABEL CLAIM : Hydrochlorothiazide BP.....12.5 mg
 Excipients.....q.s.
 Colour: Erythrosine Supra
MFR No. / Reference Document No. : MFR/T/058-00
BMR No. : BMR/T/134-00
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
		N/A		

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 +  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

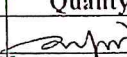
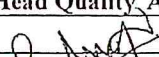
MAST COPY

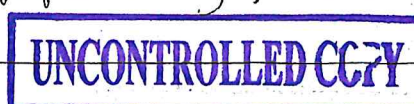
UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 36
	BATCH MANUFACTURING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00	Batch No.: CF201004
		Customer:	Generic Health Care Pvt. Ltd.

1.0 INDEX

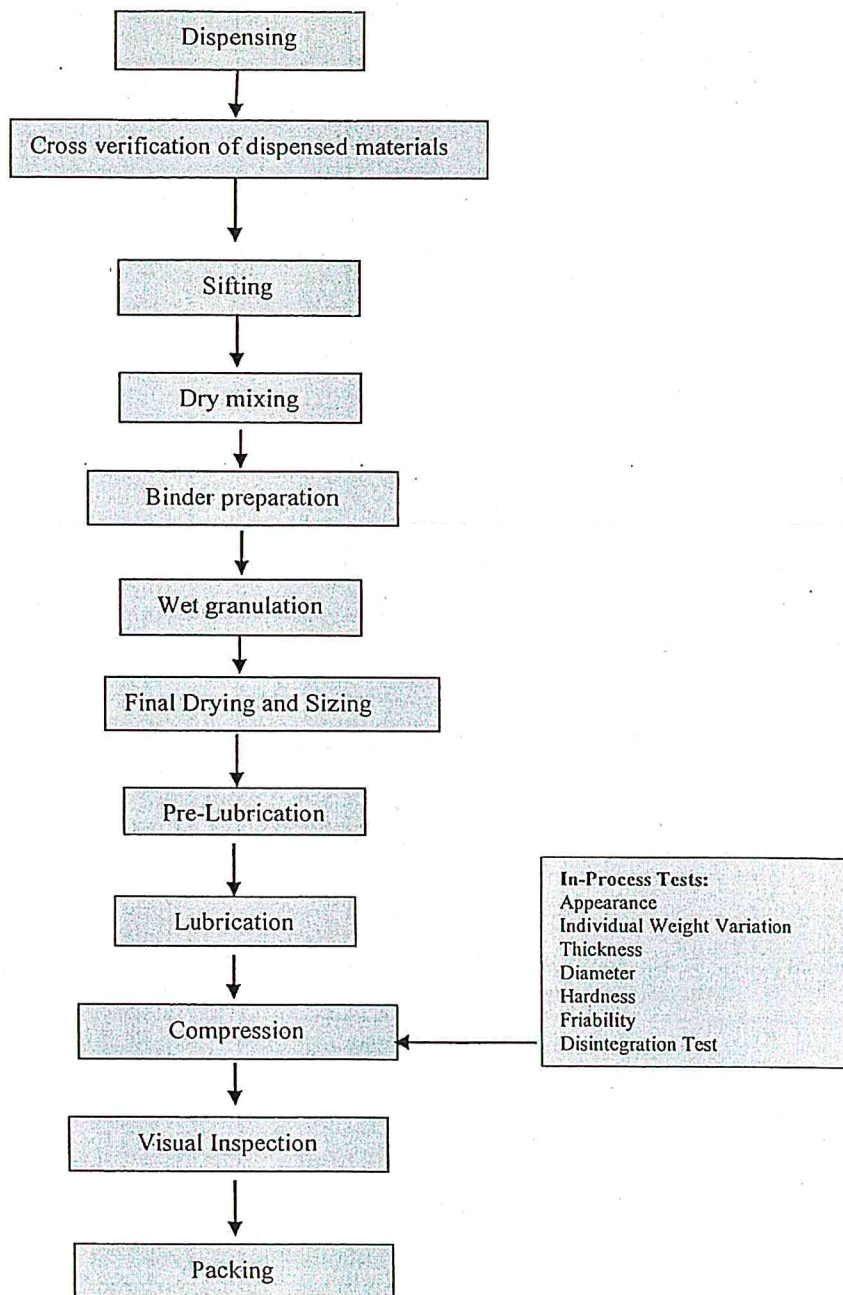
Sr. No.	Content	Page No.
	Batch manufacturing cover sheet	1
1.0	Index	2
2.0	Flow Chart	3
3.0	Indent of active pharmaceutical ingredients & excipients	4
4.0	Calculation	5-6
5.0	Dispensing line clearance checks, Dispensing weighing sheet	7-8
6.0	Line clearance for Sifting and granulation.	9
7.0	Granulation instruction, sieve integrity checks, sifting instruction, wet granulation, drying record, sifting and milling record	10-12
8.0	Blending Line clearance, Blending and Lubrication process, Lubrication material sifting record, Blending and Lubrication records, Weight record, Reconciliation, Release for Compression	13-14
9.0	Compression Line Clearance	15
10.0	Compression instruction, Granules receipt record, compression specification, compression machine running status, initial In-process checks, Compression specification/ Parameters, In-process checks (Production and IPQA), uniformity of weight checks (Production and IPQA), weight record of compressed tablets, Reconciliation	16-33
11.0	Release for Inspection	33
12.0	Inspection Line clearance	34
13.0	Inspection Process instruction, performance checks record for metal detector, tablets visual inspection record, weight record, Reconciliation of inspected tablets	35-36
14.0	Release for Packing	36
15.0	BMR Review details	36
16.0	Revision History	36

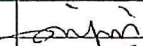
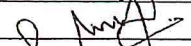
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020



 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 36
Product	BATCH MANUFACTURING RECORD		Batch Size: 6,00,000 Tablets
	RAMITHIAZIDE 5/12.5		Batch No.: GF 201004
	Customer:		Generic Health Care Pvt. Ltd.

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

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 36
	BATCH MANUFACTURING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
	Product	RAMITHIAZIDE 5/12.5	Batch No.: GF901004
		BMR. No.: BMR/T/134-00	Batch No.: GF901004
		Customer:	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)
Dry mixing material:							
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
Binder Material:							
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
Theoretical Weight of Dried Granules				190.000	114.000	-	114.210
Lubrication Material:							
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
Theoretical Weight of the Lubricated granules				200.000	120.000	-	120.210
Theoretical weight of Compressed tablet				200.000	120.000	-	120.210

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

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 5 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 61F201004

Customer:

Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR RAMIPRIL:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Ramipril: 3.060 Kg (A)

Calculation for Ramipril:

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} + \text{Overages} = \frac{5 \times 6,00,000}{1000 \times 1000} + 2\% = 3.060 \text{ kg}$$

1) Calculation for Single A. R. No. RM4/00040, Assay on dried basis: 99.7 w/w, LOD: 0.2 w/w
Exp. Date... 01/2025

$$\text{Actual Quantity (Kg) (B)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{3.060 \times 100 \times 100}{99.7 \times (100 - 0.2)} = \frac{3.060}{0.997} = 3.075 \text{ Kg}$$

2) Calculation for Ramipril Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (C)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
Total Actual Quantity (D)					

Calculation for Remaining Quantity Required (E):

$$\text{Theoretical Qty.} - \text{Actual Quantity (D)} = \text{Kg}$$

AR. No.: _____, Assay on dried basis: _____ w/w, LOD: _____ %w/w, Exp. Date: _____

$$\text{Actual Remaining Quantity (Kg) (F)} = \frac{\text{Remaining qty. required (E)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{X \times 100 \times 100}{X(100 -)} = \text{Kg}$$

$$\text{Total Qty. of Ramipril to be dispensed (G)} = (C) + (F) = \text{Kg}$$

Done By/On (QA):

Checked By/On (Production):

Prepared by:

Checked by:

Approved By:

Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	Vignesh R		
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

MASTRO COPY

UNCONTROLLED CC7Y



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 6 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 26/10/2020

Customer:

Generic Health Care Pvt. Ltd.

4.1 ASSAY AND LOD CALCULATIONS FOR HYDROCHLOROTHIAZIDE:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Hydrochlorothiazide: 7.650 Kg (A)

Standard quantity of Maize Starch (B): 36.840 Kg

Calculation for Hydrochlorothiazide:

1) Calculation for Single A. R. No. RN4/00013, Assay on dried basis: 100.95 w/w, LOD: 0.3 w/w
Exp. Date: 09/12/2024

Actual Quantity (Kg) (C) = $\frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{7.650 \times 100 \times 100}{100 \times (100 - 0.3)} = \underline{7.673} \text{ Kg}$

2) Calculation for Maize Starch (B):

Actual Quantity (Kg) (D) = Standard quantity of Maize Starch - (Excess Calculated quantity of Ramipril + Excess Calculated quantity of Hydrochlorothiazide)

= 36.840 Kg - (0.015 Kg + 0.023 Kg)
= 36.802 Kg.

3) Calculation for Hydrochlorothiazide Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (E)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
1					
2					
3					
Total Actual Quantity (F)					

Calculation for Remaining Quantity Required (G):

Theoretical Qty. - Actual Quantity (F) = _____ Kg

AR. No.: _____, Assay on dried basis: _____ w/w, LOD: _____ %w/w, Exp. Date: _____

Actual Quantity (Kg) (H) = $\frac{\text{Remaining qty. required (G)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{X \times 100 \times 100}{X(100 -)} = \underline{\hspace{2cm}} \text{ Kg.}$

Total Qty. of Hydrochlorothiazide to be dispensed (I) = (E) + (H) = _____ Kg

4) Calculation for Maize Starch (B):

Actual Quantity (Kg) (J) = Standard quantity of Maize Starch - (Excess Calculated quantity of Ramipril + Excess Calculated quantity of Hydrochlorothiazide)

= 36.840 Kg - (_____ Kg + _____ Kg)
= _____ Kg.

Done By/On (QA): 26/10/2020

Checked By/On (Production): 26/10/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>Vignesh T</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>



UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT. LTD.	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 7 of 36
	BATCH MANUFACTURING RECORD	Product Code: R09 Batch Size: 6,00,000 Tablets	Batch No.: 61F201004
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMRT/134-00	Generic Health Care Pvt. Ltd.
		Customer:	

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 26/10/2020 Time: 9.15 AM

Sr. No.	Checks	Observation*	
		Store	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags, documents and scrap from waste bin of previous batch/product are removed from the area.	✓	✓
2	Check and ensure that display stand and weighing balance are clean.	✓	✓
3	Check and ensure that SS scoop, SS spatula and SS trolley are clean.	✓	✓
4	Check and ensure that area (floor, walls, ceiling, doors and windows) are clean.	✓	✓
5	Check and ensure that Magnehelic gauges, tube light fixtures, supply grills, return riser grills and filters, electrical fixture are clean.	✓	✓
6	Check and ensure that all the sides of dispensing booth is clean	✓	✓
7	Check all the gauges of dispensing booth before switching ON.	✓	✓
8	Check and ensure that weighing balances and pressure gauges to be used are within calibration due date.	✓	✓
9	Check that the daily records (Balance Logbook, RH & Temp. record) are updated and signed.	✓	✓
10	Equipment status is updated for Cleaned and Preventive maintenance.	✓	✓

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Dispensing Booth	Weighing Balance	Area
ID No.	85/0001001	85/0001001	85/0001001
Previous Product	Pragmatin Bismut Feeding		
B. No.	PRB 20083		
Cleaned by Sign/Date	AHL 26/10/2020		
Checked by Store Sign/Date	Sey 26/10/2020		
Verified by IPQA Sign/Date	M. Nay 26/10/2020		

ENVIRONMENTAL CONDITIONS: Date: 26/10/2020 Time: 9.15 AM	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	24°C	85/26/10/2020	M. Nay 26/10/2020
Relative Humidity % (Limit: NMT 60%)	60%	85/26/10/2020	M. Nay 26/10/2020
Differential Pressure (NLT 10 Pascal)	11 Pa	85/26/10/2020	M. Nay 26/10/2020
Differential Pressure across the booth Limit: 5 to 20 mm Water	12 mm	85/26/10/2020	M. Nay 26/10/2020

APPROVAL FOR DISPENSING BY IPQA: Sign: M. Nay Date: 26/10/2020

Dispensing start Time: 09.15 End Time: 10.00

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	P. P. P.	Sanjay	S. Nay
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune,
Puducherry-605009.

Page 8 of 36

SAI PRIMUS
LIFE BIOTECH PVT LTD

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF 201004

Customer:

Generic Health Care Pvt. Ltd.

Dispensing Weighing Sheet:

Balance ID: 517324/004, 517324/005, 517324/006 Date: 26/10/2020 Shift: 09:15 Time: 09:15

Sr No	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R No.	Issued Qty.			Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Tare Wt.	Net Wt.			Checked Production (Sign & Date)	Verified IPQA (Sign & Date)

Dry mixing material:

1	Ramipril*	BP	RAU/GH/R001	Kg	3.060		my 00040	3.165	0.090	3.075	26/10/2020	26/10/2020	26/10/2020	26/10/2020
2	Hydrochlorothiazide^	BP	RAU/GH/H002	Kg	7.650		my 00013	7.763	0.090	7.673	26/10/2020	26/10/2020	26/10/2020	26/10/2020
3	Dried Maize Starch***	BP	IRM/SP/M001	Kg	36.840		my 00119/06	37.092	0.290	36.802	26/10/2020	26/10/2020	26/10/2020	26/10/2020
4	Lactose Monohydrate	BP	REX/SP/L003	Kg	44.400	44.400	my 00117	25.220	0.220	25.000	26/10/2020	26/10/2020	26/10/2020	26/10/2020
5	Microcrystalline Cellulose PH 102	BP	REX/SP/M010	Kg	18.000	18.000	my 00040	19.620	0.220	19.400	26/10/2020	26/10/2020	26/10/2020	26/10/2020

Binder Material:

6	Gelatin	BP	REX/SP/G001	Kg	1.200	1.200	my 00037	1.260	0.060	1.200	26/10/2020	26/10/2020	26/10/2020	26/10/2020
7	Dried Maize Starch	BP	IRM/SP/M001	Kg	3.000	3.000	my 00119/06	3.060	0.060	3.000	26/10/2020	26/10/2020	26/10/2020	26/10/2020
8	Erythrosine Supra	IHS	REX/SP/E005	Kg	0.060	0.060	my 00012/01	92.09	32.09	60.00	26/10/2020	26/10/2020	26/10/2020	26/10/2020
9	Purified Water	BP	NA	Kg	30.000	30.000	my 00110/04	32.600	4.600	28.00	26/10/2020	26/10/2020	26/10/2020	26/10/2020

Lubrication Material:

10	Sodium Starch Glycollate	BP	REX/SP/S004	Kg	3.000	3.000	my 000461	3.060	0.060	3.000	26/10/2020	26/10/2020	26/10/2020	26/10/2020
11	Colloidal Silicon Dioxide	BP	REX/SP/C001	Kg	0.600	0.600	my 000359	0.650	0.050	0.600	26/10/2020	26/10/2020	26/10/2020	26/10/2020
12	Magnesium Stearate	BP	REX/SP/M011	Kg	2.400	2.400	my 000255	2.450	0.050	2.400	26/10/2020	26/10/2020	26/10/2020	26/10/2020

Prepared by:

Production

Checked by:

Quality Assurance

Approved By:

Head Quality Assurance

Dept.

Production

Production

Quality Assurance

Head Quality Assurance

Sign.

L.K

26/10/2020

26/10/2020

26/10/2020

Date

26/10/2020

26/10/2020

26/10/2020

26/10/2020

MASTER COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: <u>GR 201004</u> Generic Health Care Pvt. Ltd.

6.0 GRANULATION LINE CLEARANCE CHECKS: Date/Time: 26/10/2020 / 17:00 /

Sr. No.	Checks	*Observations					
		Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.	/	/				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.	/	/				
3	Check and ensure that display, display stand, weighing balance are clean.	/	/				
4	Check and ensure that SS storage Cabinet and Drain point are clean.	/	/				
5	Check and ensure that absence of previous batch/product from area below machine	/	/				
6	Check and ensure that all equipment body and inside the vessel are clean	/	/				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean	/	/				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.	/	/				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.	/	/				
10	Check and ensure that environment condition and record on BMR	/	/				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)	/	/				
12	Equipment status is updated for Cleaned and Preventive maintenance.	/	/				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Sifter	Multimill	Mass Mixer/RMG	FBD/ Tray Drier	Area
EQP. ID No.	PD/VRS/002	PD/MM/009	PD/RMG/001	PD/FBD/001	Granulation II
Previous Product	Pregnare Brex feeding				
Batch No.	PB20075				
Cleaned by	Muthu Vaths				
Checked by	[Signature]				
Verified by	[Signature]				

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 26/10/2020 Time: 17:00			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	[Signature]	AS						
RH % (NMT 60%)	52%	[Signature]	AS						
DP (NLT 10 Pascal)	10 pascals	[Signature]	AS						

APPROVAL FOR SIFTING AND GRANULATION:

Production Sign/Date:	[Signature] 26/10/2020		
IPQA Sign/Date:	[Signature] 26/10/2020		
Start and End Time:	17:10	20:16	

26/10/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

MAILED COPY

UNCONTROLLED COPY

SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 10 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C9F201004

Customer:

Generic Health Care Pvt. Ltd.

7.0 GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: Date: 26/10/2020 Shift: 3

S. No	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by
						From	To			
Dry mixing:										
1	Ramipril*	3.075	40#	PD/305E40/002	OK/Not OK	17.10	17.20	OK/Not OK	Muthu	✓
2	Hydrochlorothiazide^	7.673	40#			17.21	17.30		Muthu	✓
3	Maize Starch***	36.702	40#			17.31	17.35		Muthu	✓
4	Lactose Monohydrate	44.400	40#			17.36	17.40		Muthu	✓
5	Microcrystalline Cellulose PH 102	18.00	40#			17.41	17.45		Muthu	✓
Binder Material:										
6	Gelatin	1.200	NA	NA	NA	16.10	16.20	NA	Vishva	✓
7	Maize Starch	8.000				16.21	16.29		Vishva	✓
8	Erythrosine Supra	60.00(4)				16.30	16.40		Vishva	✓
9	Purified Water	18.00kg				16.40	17.00		Vishva	✓
Lubrication:										
10	Sodium Starch Glycollate	2.000	60#	PD/305E60/001	OK/Not OK	13.01	13.03	OK/Not OK	prabha	✓
11	Colloidal Silicon Dioxide	0.600	30#	PD/305E60/001	OK/Not OK	13.04	13.07	OK/Not OK	prabha	✓
12	Magnesium Stearate	2.400	60#	PD/305E60/001	OK/Not OK	13.08	13.10	OK/Not OK	prabha	✓

7.1 MANUFACTURING PROCESS:

Step No	Process Instructions	Date: 26/10/2020		Done by	Checked by
		Time			
		Started	Completed		
1	Dry mixing: Transfer the sifted material from step 7.0 (1-5) into the RMG/Mass mixer. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>55</u> RPM	17.50	18.00	Vishva	J
2	Binder Preparation: Take Purified Water and mix Maize Starch to form a slurry.	18.01	18.09	Vishva	J
3	Take Purified Water in Paste Kettle and heat till reaches 95°C and dissolve Erythrosine Supra and Gelatin in it to form a solution. Then Immediately add the starch slurry prepared in the above step.	18.10	18.15	Vishva	J
4	Wet Granulation: Binder Addition: Add binder solution into RMG/Mass mixer take 1 min for binder addition with impeller slow speed and Chopper OFF. Impeller Speed: <u>55</u> RPM,	18.16	18.26	Vishva	J
5	After binder addition allow mixing for 1 minutes. If required allow mixing for 1 min or till required consistency of granules obtained with impeller at slow speed and chopper at slow speed. Impeller Speed: <u>155</u> RPM, Chopper Speed: <u>NA</u> RPM Additional quantity of Purified water <u>8.00</u> Kg	18.27	18.28	Vishva	J

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

UNCONTROLLED CC7Y

UNCONTROLLED CC7Y



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF 20100H

Customer:

Generic Health Care Pvt. Ltd.

7.2 DRYING:

7.3 FBD Finger bag Integrity checks:

7.4 SET PARAMETERS:

7.5 SIFTING AND MILLING:

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>YOF</i>	<i>anyin</i>	<i>8-10/10/2020</i>
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED CCZY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09
	Product		Batch Size: 6,00,000 Tablets
RAMITHIAZIDE 5/12.5		BMR. No.: BMR/T/134-00	Batch No.: C F 201004
		Customer:	Generic Health Care Pvt. Ltd.

7.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 20/10/2020		Integrity checked After use	Done by	Checked by
			Time				
			Started	Completed			
20 #	0130SE-20/02	OK/ Not OK	19.52	20.05	OK/ Not OK	Karthik	2
1.5 mm	0130mm SE 1.5/02	OK/ Not OK	20.06	20.16	OK/ Not OK	Karthik	2

7.7 WEIGHING OF DRIED GRANULES:

S. No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighed By	Checked By
1	2.900	41.470	38.570	Karthik	2
2	2.300	36.890	34.590	Karthik	2
3	2.300	39.530	37.230	Karthik	2
4					
5					
6					
Total			110.390	na	na

Theoretical Weight: 114.210 Kg

Theoretical Yield (Weight): Actually yield will be calculated after 3 validation batches.

Actual Yield (Weight): 110.390 Kg % Yield: 96.65 %

Date: 26/10/2020

Production Executive Sign. /Date: 26/10/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	POB		
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED CC2Y

UNCONTROLLED CC2Y



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 13 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: CIP 201004

Customer:

Generic Health Care Pvt. Ltd.

8.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 27/10/2020 1 GT 1 NA

Sr. No.	Checks	Time	*Observations					
			13.00					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.		✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓				
10	Check and ensure that environment condition and record on BMR		✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		NA	NA				
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Blender	Area
EQP. ID No.	PD/OCB/001	Accumulation P.
Previous Product	Ingla m.o.s	
Batch No.	602000 UT	
Cleaned by	Prabhu	
Checked by	Prabhu	
Verified by	AT	

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 27/10/2020 Time: 17.05			Date:			Date:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	AT	AT						
RH % (NMT 60%)	52%	AT	AT						
DP (NLT 10 Pascal)	10 pascal	AT	AT						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	27/10/2020		
IPQA Sign/Date:	27/10/2020		
Start and End Time:	17.10	14.00	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	AT	AT	AT
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 14 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMRT/134-00

Batch No.: 7 F 70 1004

Customer:

Generic Health Care Pvt. Ltd.

8.1 BLENDING AND LUBRICATION PROCESS:

Date: 27/10/2020 Shift: 7.....

Step No.	Process Instructions	Time		Done by	Checked by Prod.
		Started	Completed		
1	Use hand gloves and goggles while handling the materials.				
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.				
Lubrication:					
1	Load the dried and sifted granules from step 7.7, sifted Sodium Starch Glycollate and Colloidal Silicon Dioxide from step 7.0 (10,11) in to the blender and mix at 10 rpm for 5 minutes (To be established). 15 min	17.10	18.25	prabu	f
2	Load sifted Magnesium Stearate into the above Pre-lubricated blend and mix for further 3 minutes at 10 RPM (To be established). 2 min	18.26	18.46	prabu	f
3	Unload the lubricated blend in HDPE container having double lined polybag.	18.50	19.00	prabu	f

8.2 WEIGHING OF FINAL BLEND:

Balance LD. No.: PD/DAL/005

Date: 27/10/2020 Shift: 7..... Time: 14.10

Sr. No.	Gross Weight(Kg)	Tare Weight(Kg)	Net weight(Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	36.460	2.300	34.160	prabu	f	Δ
2	40.160	2.300	37.860	prabu	f	Δ
3	46.740	2.500	44.240	prabu	f	Δ
4						
5						
6						
Total:			115.860			

8.3 RECONCILIATION:

1.0	Theoretical weight of blend	:	120.210 Kg
2.0	Actual Weight of blend	:	115.860 / 115.860 Kg
3.0	Manufacturing Loss (Blending stage) @	:	4.350 Kg
4.0	In-process samples		
	A IPQC Samples	:	0.050 Kg.
	B QC Samples	:	0.100 Kg.
	C Validation Samples	:	0.020 Kg.
5.0	Total samples: (A + B + C)	:	0.170 Kg
6.0	Total: (2.0 + 5.0)	:	116.030 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	96.53 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 4.350 Kg. (Rejected materials shall be destroyed as per SOP: QAGN/048).

Recovery Addition Quantity in Kg: 4.350 (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: 27/10/2020 Checked By IPQA sign/Date: 27/10/2020

Test request form raised by Prod Sign/Date: 27/10/2020

Test request form received by IPQA Sign/Date: 27/10/2020

8.4 RELEASED FOR COMPRESSION:

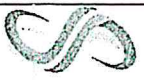
Reconciliation checked and blend is released for compression

IPQA Sign: 27/10/2020

Date: 27/10/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POA	27/10/2020	J. Anand
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMRT/134-00 Customer:	Batch No.: C7 F 201004 Generic Health Care Pvt. Ltd.

9.6 COMPRESSION LINE CLEARANCE CHECKS:

Date: 27/10/2020 / 31/10/2020 /

Sr. No.	Checks	Time:	*Observations					
			15:30		09:45			
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		✓	✓	✓	✓		
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		✓	✓	✓	✓		
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		✓	✓	✓	✓		
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		✓	✓	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.		✓	✓	✓	✓		
6	Check and ensure that Deduster and hosepipe are clean.		✓	✓	✓	✓		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		✓	✓	✓	✓		
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		✓	✓	✓	✓		
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		✓	✓	✓	✓		
10	Check and ensure that environmental conditions are recorded in the BMR.		✓	✓	✓	✓		
11	Area, equipment and preventive maintenance status board is updated.		✓	✓	✓	✓		
12	Check and ensure that rinse water /Surface swab is released from QC and attached the test request from (TRF) in BMR		✓	✓	✓	✓		
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		✓	✓	✓	✓		

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD/COM/001	PD/DED/001, PD/DED/002	Compression-001
Previous Product	Xaldin		
Batch No.	X0100083		
Cleaned by	Bala		
Checked by	J. 27/10/2020		
Verified by	A. 27/10/2020		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 27/10/2020 Time: 15:31			Date: 31/10/2020 Time: 09:58			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	J	A	24°C	J	A			
RH % (NMT 60%)	62%	J	A	53%	J	A			
DP (NLT 10 Pascal)	12 Pascal	J	A	10 Pascal	J	A			

APPROVAL FOR COMPRESSION:

Production Sign/Date:	J. 27/10/2020	A. 31/10/2020		
IPQA Sign/Date:	A. 27/10/2020	A. 31/10/2020		
Start and End Time:	NA	10:10	18:45	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	DR		
Date	26/10/2020	26/10/2020		

MAINTENANCE

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 16 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: CF 201004

Customer:

Generic Health Care Pvt. Ltd.

10.0 COMPRESSION

10.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 8.00 mm Circular shaped flat faced beveled edge punches. b. Lower punches: 8.00 mm Circular shaped flat faced plain punches. c. Dies: 8.00 mm suitable for above punches. d. Type of tooling - D. Punch Issued by: sign./Date: <i>N Bal 27/10/2020</i> Checked and Received by Sign./Date: <i>J 27/10/2020</i> Verified by Sign./Date: <i>AT 27/10/2020</i>
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

10.2 GRANULES RECEIPT RECORD:

Balance ID. No.: *PD/BA/011* Date: *27/10/2020* Shift: *B* Time: *15:36*

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	<i>36.150</i>	<i>2</i>	<i>2</i>
2	<i>10.160</i>	<i>2</i>	<i>2</i>
3	<i>16.340</i>	<i>2</i>	<i>2</i>
4			
5			
6			

10.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	20	Every 30 min.	Every 2 Hr.
2.	Average weight(mg)	200.000 mg $\pm$ 3.0 % (194.000 mg – 206.000 mg)	20		
3.	Group Weight	4.000 g $\pm$ 3.0 % (3.880 g to 4.120g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)	20	Every 2 Hr.	Every 4 Hr.
6	Hardness	NLT 3.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Thickness (mm)	3.20 mm $\pm$ 0.3 mm (2.90 mm – 3.50 mm) (To be established)	4	Every 30 min.	Every 2 Hr.
9.	Diameter (mm)	7.94 mm $\pm$ 0.1 mm (7.84 mm – 8.04 mm) (To be established)	30	Initial	
8.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
9.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>POD</i>	<i>26/10/2020</i>	<i>26/10/2020</i>
Date	<i>26/10/2020</i>	<i>26/10/2020</i>	<i>26/10/2020</i>	<i>26/10/2020</i>

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 17 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C/F 201004

Customer:

Generic Health Care Pvt. Ltd.

10.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	M/C Speed	Tablets Output	Done By	Checked By
31/10/2020	A	10:10	18:45	25	5752577700	Sathy	J

10.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness & Diameter):

Balance I.D. No.: PD/BAL/004

Date: 31/10/2020 Shift: C Time: 10:00

LHS					RHS				
Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)	Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)
1	OK	199	3.07	8.01	1	OK	197	3.08	8.01
2	OK	198	3.08	8.02	2	OK	200	3.08	8.00
3	OK	200	3.09	8.04	3	OK	199	3.10	8.00
4	OK	200	3.10	8.00	4	OK	199	3.07	8.00
5	OK	200	3.08	8.01	5	OK	200	3.08	8.01
6	OK	200	3.08	8.00	6	OK	201	3.08	8.00
7	OK	201	3.09	8.01	7	OK	200	3.07	8.00
8	OK	200	3.08	7.98	8	OK	200	3.08	8.01
9	OK	200	3.07	8.00	9	OK	199	3.08	8.00
10	OK	199	3.08	8.01	10	OK	200	3.07	8.01
11	OK	198	3.09	8.01	11	OK	199	3.08	8.02
12	OK	198	3.10	8.01	12	OK	200	3.07	8.01
13	OK	199	3.10	8.00	13	OK	199	3.08	8.02
14	OK	198	3.08	8.01	14	OK	199	3.07	8.02
15	OK	199	3.09	8.00	15	OK	200	3.08	8.02
16	OK	198	3.08	8.00	16	OK	200	3.07	8.02
17	OK	199	3.08	8.00	17	OK	199	3.08	8.02
18	OK	199	3.09	8.00	18	OK	200	3.09	8.02
19	OK	198	3.09	8.01	19	OK	200	3.08	8.01
20	OK	200	3.10	8.00	20	OK	200	3.07	8.00
21	OK	200	3.08	8.00	21	OK	200	3.08	8.00
22	OK	199	3.09	8.01	22	OK	200	3.09	8.00
23	OK	199	3.08	8.00	23	OK	199	3.08	8.02
24	OK	199	3.09	8.00	24	OK	200	3.08	8.02
25	OK	200	3.10	8.00	25	OK	200	3.09	8.02
26	OK	200	3.09	8.01	26	OK	200	3.09	8.02
27	OK	200	3.09	8.02	27	OK	199	3.08	8.01
28	OK	199	3.10	8.02	28	OK	200	3.07	8.02
29	OK	199	3.10	8.01	29	OK	200	3.08	8.01
30	OK	198	3.09	8.00	30	OK	200	3.09	8.02

Note: * Write OK if complies and (X) if does not comply.

Done by Production Sign/Date: *[Signature]* 31/10/2020

Checked by IPQA Sign/Date: *[Signature]* 31/10/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

MASTER COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BMR. No.: BMR/T/134-00 Batch No.: C1F201004 Customer: Generic Health Care Pvt. Ltd.

10.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 21/10/2020 Shift: G Time: 10:10

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits
			Min	Max	Min	Max	
Appearance	Visual	NA	OK		OK		Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side
Group Weight	Electronic Balance	PD/BAL/1007	3.998 g		3.999 g		4.000 g $\pm$ 3.0 % (3.880 g to 4.120g)
Average weight	Electronic Balance		199.92 mg		199.98 mg		200.000 mg $\pm$ 3.0 % (194.000 mg – 206.000 mg)
Individual weight	Electronic Balance		198 mg	200 mg	199 mg	200 mg	200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)
Uniformity of weight	Electronic Balance		-0.96 %	0.04 %	-0.49 %	0.01 %	
Thickness	Vernier Caliper	DA/VER/1001	3.01 mm	3.10 mm	3.02 mm	3.09 mm	3.20 mm $\pm$ 0.3 mm (2.90 mm – 3.50 mm) (To be established)
Hardness	Hardness Tester	DA/HST/1001	3	3.5	3	3.5	NLT 3.0 Kg (To be established)
Friability	Friabilator	DA/FRI/1001	0.02 %		0.01 %		NMT 1.0% w/w
DT	DT Apparatus	DA/DTA/1001	1 min 58 sec		02 min 02 sec		NMT 15 minutes

M/C set done by Operator Name: Sathya M/C set up Checked by (Prod. Sign/Date): 21/10/2020
 M/C Speed: 25 RPM (To be Established)

Initial Setting Tablets Destroyed by: Sign: [Signature] Date: 21/10/2020 Quantity in Kg: 0.020 Quantity in No: 100

Approval for Batch Compression by IPQA: Sign: [Signature] Date: 21/10/2020 Time: 10:15

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

MASTER COPY

UNCONTROLLED CC7Y



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 19 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C/F-201004

Customer:

Generic Health Care Pvt. Ltd.

10.7 IN-PROCESS CHECKS: (For Production)

Date: 31/10/2020

31/12/20

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

MASTER COPY

UNCONTROLLED COPY



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Generic Health Care Pvt. Ltd.

Done by
Production

MASTER COPY

UNCONTROLLED COPY



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 21 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: CF 201004

Customer:

Generic Health Care Pvt. Ltd.

10.9 IN-PROCESS CHECKS: (For Production)

Date:.....

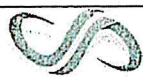
[illegible]

31/10/2020

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

MASTER COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 22 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C F 201004

Customer:

Generic Health Care Pvt. Ltd.

10.10 IN-PROCESS CHECKS: (For IPQA)

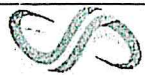
Date: 27/10/2020

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by IPQA
	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side		4.000 g $\pm$ 3.0 % (3.880 g to 4.120g)		NLT 3.0 Kg (To be established)				3.20 mm $\pm$ 0.3 mm (2.90 mm – 3.50 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
11:10	OK	OK	4.020	4.034	3.0	3.0	3.0	3.0	3.12	3.15	3.14	3.19	24/10/2020
11:20	OK	OK	3.919	3.924	3.5	3.0	2.5	3.0	3.09	3.03	3.11	3.19	24/10/2020
12:05	OK	OK	4.010	3.997	2.5	3.5	3.0	3.5	3.07	3.10	3.12	3.10	24/10/2020
14:20	OK	OK	3.994	4.033	3.0	3.0	3.0	2.5	3.13	3.15	3.09	3.09	24/10/2020
16:20	OK	OK	3.997	3.991	3.0	3.5	3.0	2.5	3.11	3.11	3.06	3.12	24/10/2020
18:05	OK	OK	4.011	4.021	3.5	3.0	3.0	3.5	3.01	3.12	3.08	3.06	24/10/2020
18:15	OK	OK	4.006	3.984	3.0	3.5	3.0	3.5	3.06	3.08	3.09	3.12	24/10/2020
18:25	OK	OK	3.994	3.989	3.5	3.0	3.5	3.0	3.12	3.04	3.12	3.15	24/10/2020
18:35	OK	OK	3.992	4.020	5.0	4.5	5.0	5.0	3.96	3.01	2.97	2.97	24/10/2020
18:45	OK	OK	3.991	4.021	3.5	4.0	3.0	4.0	3.26	3.11	3.17	3.26	24/10/2020
18:55	OK	OK	4.041	4.017	3.5	3.0	3.5	3.5	3.01	3.07	3.09	3.07	24/10/2020
1													

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

MASTER COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 23 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C/F 201004

Customer:

Generic Health Care Pvt. Ltd.

10.11 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 21/10/2020		Time: 10:20		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	199	8	199	15	200
2	198	9	199	16	201
3	200	10	198	17	200
4	201	11	199	18	199
5	200	12	200	19	198
6	201	13	201	20	199
7	201	14	202		
Balance ID No.: PD/BAL/007			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 3977.5 g. Avg. wt: 198.875 mg			Group weight of 20 Tablets: 3985 g. Avg. wt: 199.25 mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: 198 mg Max. weight: 201 mg			Min weight: 192 mg Max. weight: 200 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.01%	0.01%	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		1 min 58 sec	02 min 06 sec	Equipment ID No.: QA/DTA/ 001	
Done by: (Production)					
Date: 21/10/2020		Time: 12:25		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	199	8	199	15	200
2	200	9	198	16	201
3	201	10	199	17	200
4	200	11	198	18	200
5	199	12	199	19	199
6	198	13	200	20	198
7	199	14	200		
Balance ID No.: PD/BAL/007			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 3988 g. Avg. wt: 199.4 mg			Group weight of 20 Tablets: 3999 g. Avg. wt: 199.95 mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: 198 mg Max. weight: 201 mg			Min weight: 198 mg Max. weight: 200 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.01%	0.02%	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		02 min 06 sec	02 min 02 sec	Equipment ID No.: QA/DTA/ 001	
Done by: (Production)					

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

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 24 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C1F201004

Customer:

Generic Health Care Pvt. Ltd.

10.12 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 31/10/2020		Time: 14:30		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	199	8	199	15	199
2	200	9	198	16	199
3	201	10	201	17	199
4	200	11	202	18	200
5	199	12	199	19	196
6	198	13	198	20	200
7	199	14	199		
Balance ID No.: PD/BAL/009			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 3.985 g. Avg. wt.: 199.25 mg			Group weight of 20 Tablets: 3.991 g. Avg. wt.: 199.55 mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: 196 mg Max. weight: 201 mg			Min weight: 198 mg Max. weight: 201 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 53 sec	01 min	Equipment ID No.: QA/DTA/001	
Done by: JS (Production)					
Date: 31/10/2020		Time: 14:25		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	197	8	197	15	199
2	198	9	198	16	198
3	199	10	199	17	201
4	198	11	198	18	197
5	199	12	199	19	200
6	199	13	200	20	198
7	200	14	198		
Balance ID No.: PD/BAL/000			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 3.974 g. Avg. wt.: 198.70 mg			Group weight of 20 Tablets: 3.980 g. Avg. wt.: 199 mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: 197 mg Max. weight: 201 mg			Min weight: 197 mg Max. weight: 201 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 59 sec	01 min 09 sec	Equipment ID No.: QA/DTA/ 001	
Done by: JS (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	JS	JS	JS
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

MASS VESICULOPHARMACEUTICALS

UNCONTROLLED CC7Y

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 26 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
	Product	RAMITHIAZIDE 5/12.5	Batch No.: CF201004 Generic Health Care Pvt. Ltd.

10.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:				Time :				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15				1		8		15			
2		9		16				2		9		16			
3		10		17				3		10		17			
4		11		18				4		11		18			
5		12		19				5		12		19			
6		13		20				6		13		20			
7		14						7		14					
Balance ID No.:								M/C Speed: RPM							
Group weight of 20 Tablets:.....g. Avg. wt:.....mg								Group weight of 20 Tablets:.....g. Avg. wt:.....mg							
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)								Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)							
Min weight. :..... mg Max. weight.: mg								Min weight. :..... mg Max. weight.: mg							
								LHS		RHS					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)												Equipment ID No.: QA/DTA/			
Done by:(Production)															
Date:				Time :				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15				1		8		15			
2		9		16				2		9		16			
3		10		17				3		10		17			
4		11		18				4		11		18			
5		12		19				5		12		19			
6		13		20				6		13		20			
7		14						7		14					
Balance ID No.:								M/C Speed: RPM							
Group weight of 20 Tablets:.....g. Avg. wt:.....mg								Group weight of 20 Tablets:.....g. Avg. wt:.....mg							
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)								Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)							
Min weight. :..... mg Max. weight.: mg								Min weight. :..... mg Max. weight.: mg							
								LHS		RHS					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)												Equipment ID No.: QA/DTA/			
Done by:(Production)															

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	P. K.	[Signature]	[Signature]	
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020	

UNCONTROLLED CC7Y

UNCONTROLLED CC7Y

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: <u>CF 201074</u> Generic Health Care Pvt. Ltd.

10.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:				Time :				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15		1		8		15					
2		9		16		2		9		16					
3		10		17		3		10		17					
4		11		18		4		11		18					
5		12		19		5		12		19					
6		13		20		6		13		20					
7		14				7		14							
Balance ID No.:						M/C Speed: RPM									
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight:..... mg						Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight:..... mg									
						LHS		RHS							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):										Equipment ID No.: QA/FRT/					
Disintegration Time (Limit - NMT 15 minutes)										Equipment ID No.: QA/DTA/					
Done by:(Production)															
Date:				Time :				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15		1		8		15					
2		9		16		2		9		16					
3		10		17		3		10		17					
4		11		18		4		11		18					
5		12		19		5		12		19					
6		13		20		6		13		20					
7		14				7		14							
Balance ID No.:						M/C Speed: RPM									
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight:..... mg						Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight:..... mg									
						LHS		RHS							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):										Equipment ID No.: QA/FRT/					
Disintegration Time (Limit - NMT 15 minutes)										Equipment ID No.: QA/DTA/					
Done by:(Production)															

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>

MAS 1530 0121 01400011

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 28 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C/F 201004

Customer:

Generic Health Care Pvt. Ltd.

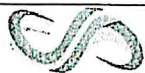
10.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)				Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			
Min weight. :..... mg Max. weight.: mg				Min weight. :..... mg Max. weight.: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)				Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			
Min weight. :..... mg Max. weight.: mg				Min weight. :..... mg Max. weight.: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

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

MASTER COPY
150001108100011

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 29 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C1 F 201004

Customer:

Generic Health Care Pvt. Ltd.

10.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): P₂ - Compression

Date: 27/10/2020		Time: 11:15		Shift: B1	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	194	8	201	15	197
2	201	9	202	16	197
3	200	10	201	17	199
4	190	11	200	18	201
5	197	12	197	19	200
6	199	13	198	20	201
7	202	14	199		
Balance ID No.: QA/B02/1002			M/C Speed: 1.5 RPM		
Group weight of 20 Tablets: 3998.8g. Avg. wt: 199.94mg			Group weight of 20 Tablets: 3999.9g. Avg. wt: 199.99mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: 197.1mg Max. weight: 202.1mg			Min weight: 197.1mg Max. weight: 202.1mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.02%	0.04%	Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)		56 second	51 second	Equipment ID No.: QA/DTA/001	
Done by: 27/10/2020 (IPQA)					
Date: 27/10/2020		Time: 14:30		Shift: B1	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	199	8	198	15	200
2	196	9	199	16	201
3	197	10	196	17	197
4	199	11	199	18	199
5	200	12	199	19	197
6	199	13	201	20	198
7	197	14	200		
Balance ID No.: QA/B02/1002			M/C Speed: 20 RPM		
Group weight of 20 Tablets: 3991.1g. Avg. wt: 199.55mg			Group weight of 20 Tablets: 3991.1g. Avg. wt: 199.55mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: 196.1mg Max. weight: 201.1mg			Min weight: 196.1mg Max. weight: 201.1mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.02%	0.04%	Equipment ID No.: QA/FRT/001	
Disintegration Time (Limit - NMT 15 minutes)		01 min 50 sec	02 min 10 sec	Equipment ID No.: QA/DTA/001	
Done by: 27/10/2020 (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	FOR	26/10/2020	26/10/2020
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

MASTER COPY

UNCONTROLLED COPY

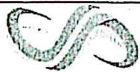
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 30 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: C/F 20 1004 Generic Health Care Pvt. Ltd.

10.18 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 31/10/2020		Time: 14:30		Shift: G1											
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).											
1	198	8	197	15	196	1	199	8	200	15	200				
2	195	9	197	16	197	2	200	9	200	16	200				
3	196	10	198	17	197	3	200	10	200	17	200				
4	200	11	198	18	200	4	200	11	198	18	202				
5	195	12	197	19	199	5	200	12	203	19	198				
6	202	13	197	20	195	6	200	13	200	20	197				
7	198	14	197			7	198	14	199						
Balance ID No.: QA/BAL/002						M/C Speed: 25 RPM									
Group weight of 20 Tablets: 3.949 g. Avg. wt: 197.45 mg						Group weight of 20 Tablets: 4.009 g. Avg. wt: 200.45 mg									
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)						Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)									
Min weight: 195 mg Max. weight: 200 mg						Min weight: 197 mg Max. weight: 202 mg									
						<table border="1"> <tr> <td>LHS</td> <td>RHS</td> </tr> <tr> <td>0.02%</td> <td>0.01%</td> </tr> </table>						LHS	RHS	0.02%	0.01%
LHS	RHS														
0.02%	0.01%														
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						Equipment ID No.: QA/FRT/004									
Disintegration Time (Limit - NMT 15 minutes)						Equipment ID No.: QA/DTA/004									
Done by: [Signature] (IPQA)															
Date: 31/10/2020		Time: 18:15		Shift: G1											
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).											
1	199	8	197	15	200	1	199	8	199	15	200				
2	197	9	199	16	199	2	198	9	197	16	201				
3	199	10	197	17	197	3	197	10	199	17	199				
4	197	11	196	18	190	4	197	11	198	18	197				
5	190	12	196	19	199	5	199	12	198	19	197				
6	199	13	197	20	200	6	200	13	199	20	199				
7	197	14	197			7	201	14	197						
Balance ID No.: QA/BAL/002						M/C Speed: 25 RPM									
Group weight of 20 Tablets: 3.962 g. Avg. wt: 198.1 mg						Group weight of 20 Tablets: 3.971 g. Avg. wt: 198.55 mg									
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)						Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)									
Min weight: 196 mg Max. weight: 201 mg						Min weight: 197 mg Max. weight: 200 mg									
						<table border="1"> <tr> <td>LHS</td> <td>RHS</td> </tr> <tr> <td>0.00%</td> <td>0.02%</td> </tr> </table>						LHS	RHS	0.00%	0.02%
LHS	RHS														
0.00%	0.02%														
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						Equipment ID No.: QA/FRT/004									
Disintegration Time (Limit - NMT 15 minutes)						Equipment ID No.: QA/DTA/004									
Done by: [Signature] (IPQA)															

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	[Signature]	[Signature]	[Signature]
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 31 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: CAF 201004

Customer:

Generic Health Care Pvt. Ltd.

10.19 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): 'High RPM' 30'

Date: 21/10/2020 Time: 12:20 Shift:

LHS: Individual weight of 20 tablets (in mg). RHS: Individual weight of 20 tablets (in mg).

1	197	8	197	15	197	1	196	8	197	15	197
2	197	9	197	16	197	2	197	9	197	16	197
3	197	10	197	17	197	3	197	10	197	17	197
4	197	11	197	18	200	4	197	11	197	18	197
5	197	12	197	19	197	5	197	12	197	19	197
6	197	13	201	20	197	6	200	13	197	20	197
7	197	14	200			7	200	14	197		

Balance ID No.: QA/BDL/002

M/C Speed: 30 RPM

Group weight of 20 Tablets: 3.960 g. Avg.
wt: 198.0 mg

Group weight of 20 Tablets: 3.954 g. Avg.
wt: 197.7 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 196 mg Max. weight: 201 mg

Min weight: 197 mg Max. weight: 200 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.02%	0.02%	Equipment ID No.: QA/FRT/004
Disintegration Time (Limit - NMT 15 minutes)	01 min 31 sec	01 min 20 sec	Equipment ID No.: QA/DTA/004

Done by: A. S. S. (IPQA) Low RPM: 10'

Date: 21/10/2020 Time: 12:30 Shift:

LHS: Individual weight of 20 tablets (in mg). RHS: Individual weight of 20 tablets (in mg).

1	197	8	197	15	197	1	197	8	197	15	197
2	197	9	197	16	197	2	197	9	197	16	197
3	197	10	197	17	197	3	197	10	197	17	197
4	197	11	197	18	197	4	197	11	197	18	197
5	197	12	200	19	197	5	197	12	197	19	197
6	197	13	197	20	197	6	197	13	197	20	200
7	200	14	197			7	197	14	200		

Balance ID No.: QA/BDL/002

M/C Speed: 10 RPM

Group weight of 20 Tablets: 3.945 g. Avg.
wt: 197.25 mg

Group weight of 20 Tablets: 3.934 g. Avg.
wt: 196.7 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 197 mg Max. weight: 200 mg

Min weight: 196 mg Max. weight: 200 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.02%	0.02%	Equipment ID No.: QA/FRT/004
Disintegration Time (Limit - NMT 15 minutes)	01 min 21 sec	01 min 14 sec	Equipment ID No.: QA/DTA/004

Done by: A. S. S. (IPQA)

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

MASTERY COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 32 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHLAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C1F 201004

Customer:

Generic Health Care Pvt. Ltd.

10.20 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): High Hardness, 5 kg

Date: 31/10/2020 Time: 12:40 Shift: G

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	199	8	199	15	199	1	199	8	199	15	199
2	199	9	200	16	199	2	199	9	199	16	199
3	199	10	199	17	199	3	199	10	199	17	199
4	199	11	199	18	199	4	199	11	199	18	200
5	199	12	199	19	199	5	200	12	199	19	199
6	199	13	199	20	199	6	200	13	199	20	199
7	199	14	199			7	199	14	199		

Balance ID No.: QA/BAL/1002

M/C Speed: 25 RPM

Group weight of 20 Tablets: 3.960 g. Avg. wt: 198.0 mg

Group weight of 20 Tablets: 3.962 g. Avg. wt: 198.1 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 196.0 mg Max. weight: 200.0 mg

Min weight: 196.0 mg Max. weight: 201.0 mg

LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.04%	0.00%
Disintegration Time (Limit - NMT 15 minutes)	02 min 34 sec	02 min 00 sec
		Equipment ID No.: QA/FRT/004
		Equipment ID No.: QA/DTA/004

Done by: 31/10/2020 (IPQA)

Date: 31/10/2020 Time: 12:50 Shift: G

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	199	8	199	15	199	1	199	8	199	15	199
2	199	9	199	16	199	2	199	9	199	16	199
3	199	10	199	17	200	3	199	10	199	17	199
4	199	11	199	18	200	4	200	11	199	18	199
5	199	12	199	19	200	5	200	12	199	19	200
6	200	13	200	20	199	6	200	13	200	20	199
7	200	14	200			7	199	14	200		

Balance ID No.: QA/BAL/1002

M/C Speed: 25 RPM

Group weight of 20 Tablets: 3.973 g. Avg. wt: 198.6 mg

Group weight of 20 Tablets: 3.977 g. Avg. wt: 198.8 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 196.0 mg Max. weight: 201.0 mg

Min weight: 197.0 mg Max. weight: 201.0 mg

LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.06%	0.04%
Disintegration Time (Limit - NMT 15 minutes)	01 min 05 sec	01 min 01 sec
		Equipment ID No.: QA/FRT/004
		Equipment ID No.: QA/DTA/004

Done by: 31/10/2020 (IPQA)

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

MASTER COPY
1530011001000011

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 32 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMRT/134-00

Batch No.: 61F201004

Customer:

Generic Health Care Pvt. Ltd.

10.20 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 31/10/2020		Time: 19:00		Shift: G1	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	197	8	197	15	196
2	197	9	197	16	197
3	197	10	197	17	197
4	197	11	197	18	196
5	197	12	196	19	197
6	195	13	197	20	199
7	199	14	196		
Balance ID No.: QA/B02/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 3.951 g. Avg. wt: 197.5 mg			Group weight of 20 Tablets: 3.967 g. Avg. wt: 198.4 mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: 196 mg Max. weight: 199 mg			Min weight: 196 mg Max. weight: 201 mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.02%	0.02%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			01 Min 42 Sec	01 Min 37 Sec	Equipment ID No.: QA/DTA/001
Done by: 31/10/2020 (IPQA)					
Date:		Time:		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1		8		15	
2		9		16	
3		10		17	
4		11		18	
5		12		19	
6		13		20	
7		14			
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets: g. Avg. wt: mg			Group weight of 20 Tablets: g. Avg. wt: mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: mg Max. weight: mg			Min weight: mg Max. weight: mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):					Equipment ID No.: QA/FRT/
Disintegration Time (Limit - NMT 15 minutes)					Equipment ID No.: QA/DTA/
Done by: (IPQA)					

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

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 33 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: CF 201004

Customer:

Generic Health Care Pvt. Ltd.

10.21 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPOA
1	26.900	2.200	24.700	Sathya	S	SH
2	27.180	2.200	24.980	Sathya	S	SH
3	23.200	2.200	21.000	Sathya	S	SH
4	23.510	2.200	21.310	Sathya	S	SH
5	26.410	2.200	23.210	Sathya	S	SH
6						
7						
8						
9						
10						

10.22 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: ..2.00..mg

1.0	Standard Batch size	:	120.210 Kg.	6,00,000 No.
2.0	Actual weight of Lubricated granules	:	115.860..Kg	579300 Nos.
3.0	Weight of compressed tablets	:	115.280..Kg	576250 Nos.
4.0	Rejection during Compression @	:	0.060..Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	: 0.200..Kg.	
	B	QC Samples	: 0.070..Kg.	
	C	Validation Samples	: 0.020Kg.	
6.0	Total in process samples: (A + B + C)	:	0.290..Kg.	
7.0	Total: (3.0 + 6.0)	:	115.540..Kg.	577900 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		96.28 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed:0.060..Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date:Sathya/26/10/2020..... Checked by IPQA Sign/Date:Sathya/26/10/2020.....

Test request form raised by Prod Sign/Date:Sathya/26/10/2020.....

Test request form received by IPQA Sign/Date:Sathya/26/10/2020.....

10.23 RELEASE FOR INSPECTION:

Reconciliation checked and Uncoated tablets released for inspection

IPQA Sign:Sathya/26/10/2020..... Date:26/10/2020.....

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	POB	Sathya	Sathya
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

MASTRO COPY

UNCONTROLLED COPY

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: CF 201004

Customer:

Generic Health Care Pvt. Ltd.

11.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 11/11/2020

Sr. No.	Checks	*Observation			
		Prod	IPQA	Prod	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	NA	NA		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PD/Env/1009	PD/MO/E/002	Inspection Belt-15
Previous product	Pregnacone breast feeding		
Batch No.	PD 2016 S		
Cleaned by	noh		
Checked by Production Sign/Date:	11/11/2020		
Verified by IPQA Sign/Date:	11/11/2020		

ENVIRONMENTAL CONDITIONS:

		Date: 11/11/2020 Time: 13:32			Date: Time:		
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	23°C	✓	✓			
	Relative Humidity % Limit: NMT 60%	52%	✓	✓			

APPROVAL FOR INSPECTION:

Production Sign/Date: 11/11/2020

Line Clearance IPQA Sign. / Date: 11/11/2020

Start Time/Date: 13:35/11/11/2020

End Time/Date: 14:25/11/11/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	✓	✓	✓
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

MASTER COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 35 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C/F 201004

Customer:

Generic Health Care Pvt. Ltd.

12.0 INSPECTION PROCESS

12.1 INSTRUCTIONS

S. No.	Process Instructions
1	Carry out visual inspection of tablets on inspection belt area as per the SOP No. PDOP/019.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

12.1 PERFORMANCE CHECKS RECORD FOR METAL DETECTOR:

Sr. No.	Process instructions
1.	At the start of the activity, after each break and at the end of operation/shift) as per SOP No. PDGN/022.
2.	Testing frequency: Startup, End of the activity and after every break time.
3.	Acceptance Criteria: 1. Ferrous, Stainless steel & Non-Ferrous shall be detected & rejected. 2. Nonmetallic shall not be detected.

Date & Time	Trial No.	Metal Detector ID No.: PD/MED/002 & PD/MED/004...					Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.3 mm)	Non-metallic	Result		
13:36 4/11/2020	1	✓	✓	✓	X	Pass	✓	✓
	2	✓	✓	✓	X	Pass	✓	✓
	3	✓	✓	✓	X	Pass	✓	✓
14:20 11/11/2020	1	✓	✓	✓	X	Pass	✓	✓
	2	✓	✓	✓	X	Pass	✓	✓
	3	✓	✓	✓	X	Pass	✓	✓
	1							
	2							
	3							
	1							
	2							
	3							
	1							
	2							
	3							

Note: Put ✓ mark for detection and x mark for non-detection

If during the test Metal Detector fails to reject any of the Standard chips then mention the corrective action taken.

..... (To be filled by Production)

Note: Take QA Approval before proceeding to next stage

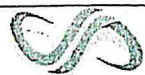
12.2 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
4/11/2020	01	05	13:38	14:25	0-050	Done 4/11/2020	4/11/2020

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

MASTER COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 36 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMRT/134-00

Batch No.: C1F201004

Customer:

Generic Health Care Pvt. Ltd.

12.3 WEIGHING RECORD OF INSPECTED TABLETS:

Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	26.890	2.200	23.990	6			
2	27.120	2.200	24.920	7			
3	23.190	2.200	20.990	8			
4	23.500	2.200	21.300	9			
5	25.500	2.200	23.300	10			
Total			115.200 Kg	Total			Kg
				Grand Total			115.200 Kg

Weighing Done By: Checked By Prod./ Date: Verified by IPQA Sign./Date:

12.4 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	120.210 kg	600000 No's
2.0	Tablets transferred for Inspection	:	115.250 kg	576250 No's
3.0	Total weight of good Tablets	:	115.200 kg	576000 No's
4.0	Rejected Tablets	:	0.050 kg	250 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:		96% %

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed: 0.050Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign/Date:

Checked by IPQA sign/Date:

12.5 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date :

BMR Released for packing by QA Head Sign/Date:

13.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	Jandhi Ramani	27/11/2020
QA Executive	Prabakaran	27/11/2020
Production Assistant Manager/ HOD	B. S. S. Ramani	27/11/2020
QA Manager/ HOD	Stephen R	27/11/2020

14.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMRT/134-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. S.	Sanjay	S. J.
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

MASTHEAD COPY

UNCONTROLLED COPY



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF 201207

Customer:

Generic Health Care Pvt. Ltd.

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
	: 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	: AF201004 / 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)	:  24/12/2020
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:  24/12/2020
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets (120.210 Kg)
MFG. DATE: 12/2020	: EXP. DATE: 11/2023

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
		12		

ALLOTTED BY:
QA SIGN/DATE: 24/12/2020

COUNTER CHECKED BY: *J. [Signature]*
QA SIGN/DATE: *2/1/12*

DATE OF COMMENCEMENT: 25/12/2020

: DATE OF COMPLETION: 26/12/2020..

RELEASED QUANTITY OF TABLETS FOR PACKING : 597050 tablets

RELEASE FOR PACKING STAGE
HEAD OF QA SIGN/DATE:

This BMR contains 36 Pages + 3 Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

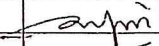
UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 36
	BATCH MANUFACTURING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
	Product	RAMITHIAZIDE 5/12.5	Batch No.: G F201207
		Customer:	Generic Health Care Pvt. Ltd.

1.0 INDEX

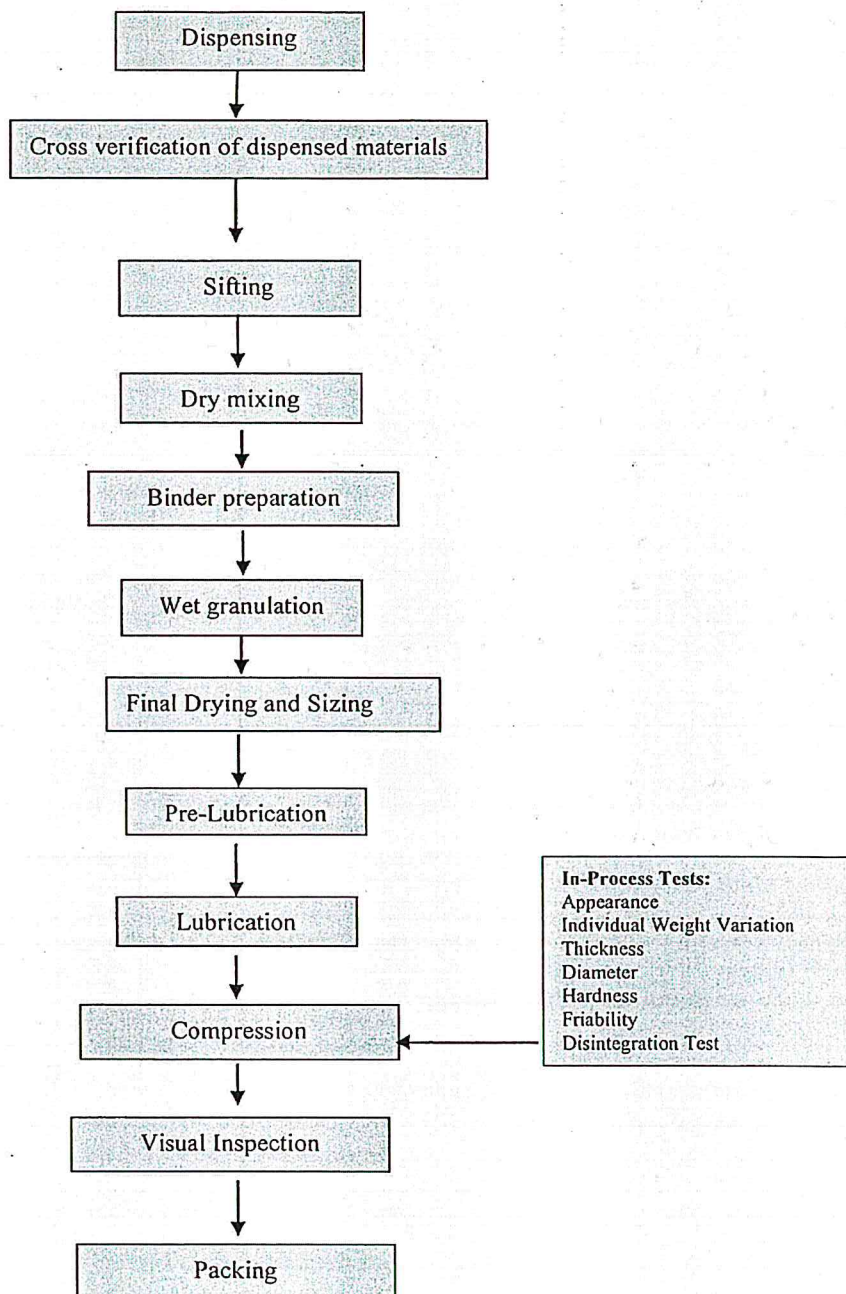
Sr. No.	Content	Page No.
	Batch manufacturing cover sheet	1
1.0	Index	2
2.0	Flow Chart	3
3.0	Indent of active pharmaceutical ingredients & excipients	4
4.0	Calculation	5-6
5.0	Dispensing line clearance checks, Dispensing weighing sheet	7-8
6.0	Line clearance for Sifting and granulation.	9
7.0	Granulation instruction, sieve integrity checks, sifting instruction, wet granulation, drying record, sifting and milling record	10-12
8.0	Blending Line clearance, Blending and Lubrication process, Lubrication material sifting record, Blending and Lubrication records, Weight record, Reconciliation, Release for Compression	13-14
9.0	Compression Line Clearance	15
10.0	Compression instruction, Granules receipt record, compression specification, compression machine running status, initial In-process checks, Compression specification/ Parameters, In-process checks (Production and IPQA), uniformity of weight checks (Production and IPQA), weight record of compressed tablets, Reconciliation	16-33
11.0	Release for Inspection	33
12.0	Inspection Line clearance	34
13.0	Inspection Process instruction, performance checks record for metal detector, tablets visual inspection record, weight record, Reconciliation of inspected tablets	35-36
14.0	Release for Packing	36
15.0	BMR Review details	36
16.0	Revision History	36

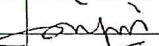
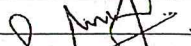
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020



 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 36
	BATCH MANUFACTURING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00	Batch No.: Gf201207
		Customer:	Generic Health Care Pvt. Ltd.

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

UNCONTROLLED CC7Y

UNCONTROLLED CC7Y

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: G-201207 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)
Dry mixing material:							
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
Binder Material:							
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
Theoretical Weight of Dried Granules				190.000	114.000	-	114.210
Lubrication Material:							
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
Theoretical Weight of the Lubricated granules				200.000	120.000	-	120.210
Theoretical weight of Compressed tablet				200.000	120.000	-	120.210

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

OA: Overages, PL: Process loss

Potency calculation:

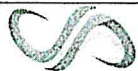
Theoretical Quantity of Ramipril and Hydrochlorothiazide required in Kg for a batch size of 6,00,000 Tablets are calculated.

* 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. Ke	P. P.	[Signature]	[Signature]
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 5 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 24F201207

Customer:

Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR RAMIPRIL:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Ramipril: 3.060 Kg (A)

Calculation for Ramipril:

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} + \text{Overages} = \frac{5 \times 6,00,000}{1000 \times 1000} + 2\% = 3.060 \text{ kg}$$

1) Calculation for Single A. R. No. Rmcl 00009, Assay on dried basis: 99.16 w/w, LOD: 0.1 w/w
Exp. Date: 12/2024

$$\text{Actual Quantity (Kg) (B)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{3.060 \times 100 \times 100}{99.16 \times (100 - 0.1)} = 3.089 \text{ Kg}$$

2) Calculation for Ramipril Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (C)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
Total Actual Quantity (D)					

Calculation for Remaining Quantity Required (E):

$$\text{Theoretical Qty.} - \text{Actual Quantity (D)} = 1.60 \text{ Kg}$$

AR. No.: _____, Assay on dried basis: _____ w/w, LOD: _____ %w/w, Exp. Date: _____

$$\text{Actual Remaining Quantity (Kg) (F)} = \frac{\text{Remaining qty. required (E)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{1.60 \times 100 \times 100}{99.16 \times (100 - 0.1)} = 1.61 \text{ Kg}$$

$$\text{Total Qty. of Ramipril to be dispensed (G)} = (C) + (F) = 4.699 \text{ Kg}$$

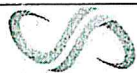
Done By/On (QA): 26/10/2020

Checked By/On (Production): 24/11/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 6 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

BMR. No.: BMR/T/134-00

Batch No.: 4F201207

Customer:

Generic Health Care Pvt. Ltd.

Product

RAMITHIAZIDE 5/12.5

4.1 ASSAY AND LOD CALCULATIONS FOR HYDROCHLOROTHIAZIDE:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Hydrochlorothiazide: 7.650 Kg (A)

Standard quantity of Dried Maize Starch (B): 36.840 Kg

Calculation for Hydrochlorothiazide:

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} + \text{Overages} = \frac{12.5 \times 6,00,000}{1000 \times 1000} + 2\% = 7.650 \text{ kg}$$

1) Calculation for Single A. R. No. R09/00097, Assay on dried basis: 99.91 w/w, LOD: 0.15 w/w
Exp. Date: 05/12/20

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{7.65 \times 100 \times 100}{99.91 \times (100 - 0.15)} = 7.669 \text{ Kg}$$

2) Calculation for Dried Maize Starch (B):

Actual Quantity (Kg) (D) = Standard quantity of Maize Starch - (Excess Calculated quantity of Ramipril + Excess Calculated quantity of Hydrochlorothiazide)

$$= 36.840 \text{ Kg} - (0.029 \text{ Kg} + 0.019 \text{ Kg})$$

$$= 36.793 \text{ Kg.}$$

3) Calculation for Hydrochlorothiazide Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (E)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
Total Actual Quantity (F)					

Calculation for Remaining Quantity Required (G):

$$\text{Theoretical Qty.} - \text{Actual Quantity (F)} = \text{Kg}$$

AR. No.: _____, Assay on dried basis: _____ w/w, LOD: _____ %w/w, Exp. Date: _____

$$\text{Actual Quantity (Kg) (H)} = \frac{\text{Remaining qty. required (G)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{X \times 100 \times 100}{X(100 -)} = \text{Kg.}$$

$$\text{Total Qty. of Hydrochlorothiazide to be dispensed (I)} = (E) + (H) = \text{Kg}$$

4) Calculation for Dried Maize Starch (B):

Actual Quantity (Kg) (J) = Standard quantity of Dried Maize Starch - (Excess Calculated quantity of Ramipril + Excess Calculated quantity of Hydrochlorothiazide)

$$= 36.840 \text{ Kg} - (\text{Kg} + \text{Kg})$$

$$= \text{Kg.}$$

Done By/On (QA):

Checked By/On (Production):

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

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 7 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF 201207

Customer:

Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 25/12/2020 Time: 3:35

Sr. No.	Checks	Observation*	
		Store	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags, documents and scrap from waste bin of previous batch/product are removed from the area.	/	/
2	Check and ensure that display stand and weighing balance are clean.	/	/
3	Check and ensure that SS scoop, SS spatula and SS trolley are clean.	/	/
4	Check and ensure that area (floor, walls, ceiling, doors and windows) are clean.	/	/
5	Check and ensure that Magnehelic gauges, tube light fixtures, supply grills, return riser grills and filters, electrical fixture are clean.	/	/
6	Check and ensure that all the sides of dispensing booth is clean	/	/
7	Check all the gauges of dispensing booth before switching ON.	/	/
8	Check and ensure that weighing balances and pressure gauges to be used are within calibration due date.	/	/
9	Check that the daily records (Balance Logbook, RH & Temp. record) are updated and signed.	/	/
10	Equipment status is updated for Cleaned and Preventive maintenance.	/	/

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Dispensing Booth	Weighing Balance	Area
ID No.	85/DPB/001	85/Bal/004	85/Bal/005
Previous Product	Ascorbic acid chewable 500mg		
B. No.	GF 013120		
Cleaned by Sign/Date	Vignesh 25/12/2020		
Checked by Store Sign/Date	85/ 25/12/2020		
Verified by IPQA Sign/Date	R. Karthi 25/12/2020		

ENVIRONMENTAL CONDITIONS: Date: 25/12/2020 Time: 3:35			
(For Reference SOP No.: QAGN/011)	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
Temperature (Limit: NMT 25°C)	23°C	85/ 25/12/2020	R.K. 25/12/2020
Relative Humidity % (Limit: NMT 60%)	55%	85/ 25/12/2020	R.K. 25/12/2020
Differential Pressure (NLT 10 Pascal)	11Pa	85/ 25/12/2020	R.K. 25/12/2020
Differential Pressure across the booth Limit: 5 to 20 mm Water	13mm	85/ 25/12/2020	R.K. 25/12/2020

APPROVAL FOR DISPENSING BY IPQA: Sign: R. Karthi Date: 25/12/2020

Dispensing start Time 12:00 End Time 12:00

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	P. Q.	Sanjay	S. Jeyaraj
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune,
Puducherry-605009.

Page 8 of 36

Product

RAMITHIAZIDE 5/12.5

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C-1F-201207

Product

RAMITHIAZIDE 5/12.5

Customer:

Generic Health Care Pvt. Ltd.

Dispensing Weighing Sheet:

Balance ID: 51321606, 51321605, 51321604 Date: 25/12/2020 Shift: Night Time: 11:45 AM

Balance ID: 21/12/2024 10:05:55 Batch: 20240101 Date: 21/12/2024 Time: 10:05:55													
Sl. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R. No.	Issued Qty.		Weighed By (Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Tare Wt.			Net Wt.	Checked Production (Sign & Date)
Dry mixing material:													
1	Ramipril*	BP	RAI/GH/R001	Kg	3.060	3.089	RAI/00009	3.177	0.090	3.089	25/12/2020	P.V.J	25/12/2020
2	Hydrochlorothiazide^	BP	RAI/GH/H002	Kg	7.650	7.668	RAI/00037	7.898	0.230	7.668	25/12/2020	P.V.J	25/12/2020
3	Dried Maize Starch***	BP	IRM/SP/M001	Kg	36.840	24.793	RAI/00154	36.983	0.190	36.793	25/12/2020	P.V.J	25/12/2020
4	Lactose Monohydrate	BP	REX/SP/L003	Kg	44.400	44.400	RAI/00094	44.400	0.000	44.400	25/12/2020	P.V.J	25/12/2020
5	Microcrystalline Cellulose PH 102	BP	REX/SP/M010	Kg	18.000	18.000	RAI/00145	18.000	0.000	18.000	25/12/2020	P.V.J	25/12/2020
Binder Material:													
6	Gelatin	BP	REX/SP/G001	Kg	1.200	1.200	RAI/00043	1.200	0.000	1.200	25/12/2020	P.V.J	25/12/2020
7	Dried Maize Starch	BP	IRM/SP/M001	Kg	3.000	3.000	RAI/00154	3.000	0.000	3.000	25/12/2020	P.V.J	25/12/2020
8	Erythrosine Supra	IHS	REX/SP/E005	Kg	0.060	0.060	RAI/00000	0.060	0.000	0.060	25/12/2020	P.V.J	25/12/2020
9	Purified Water	BP	NA	Kg	30.000	30.000	RAI/00145	30.000	0.000	30.000	25/12/2020	P.V.J	25/12/2020
Lubrication Material:													
10	Sodium Starch Glycollate	BP	REX/SP/S004	Kg	3.000	3.000	RAI/00053	3.000	0.000	3.000	25/12/2020	P.V.J	25/12/2020
11	Colloidal Silicon Dioxide	BP	REX/SP/C001	Kg	0.600	0.600	RAI/00053	0.600	0.000	0.600	25/12/2020	P.V.J	25/12/2020
12	Magnesium Stearate	BP	REX/SP/M011	Kg	2.400	2.400	RAI/00053	2.400	0.000	2.400	25/12/2020	P.V.J	25/12/2020

Prepared by:			Checked by:			Approved By:		
Production			Quality Assurance			Head Quality Assurance		
L.K.			26/10/2020			26/10/2020		
Date			26/10/2020			26/10/2020		

MASTER COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 9 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G7F201307

Customer:

Generic Health Care Pvt. Ltd.

6.0 GRANULATION LINE CLEARANCE CHECKS: Date/Time: 25/12/2020 / 18.00 / NA

Sr. No.	Checks	*Observations					
		Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.	✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.	✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.	✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine	✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean	✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean	✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.	✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.	✓	✓				
10	Check and ensure that environment condition and record on BMR	✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)	✓	✓				
12	Equipment status is updated for Cleaned and Preventive maintenance.	✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Sifter	Multimill	Mass Mixer/RMG	FBD/ Tray Drier	Area
EQP. ID No.	P9/vbs101	P91 m/m/101	PD/mam/001	PD/TRD/001	G-I
Previous Product	Ultra D3				
Batch No.	4320920				
Cleaned by	Wingayaga				
Checked by					
Verified by					

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 25/12/2020 Time: 18-01			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	24.8	✓	✓						
RH % (NMT 60%)	55%	✓	✓						
DP (NLT 10 Pascal)	0.95	✓	✓						

APPROVAL FOR SIFTING AND GRANULATION:

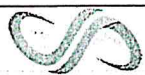
Production Sign/Date:			
IPQA Sign/Date:			
Start and End Time:	18.02	19.38	

25/12/2020

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

UNCONTROLLED CC7Y

UNCONTROLLED CC7Y



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 10 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF 201207

Customer:

Generic Health Care Pvt. Ltd.

7.0 GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: Date 25/12/2020 Shift: II

S. No.	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by
						From	To			
Dry mixing:										
1	Ramipril*	3.089	40#	PD/30-SE-40/02	L OK/ Not OK	18.02	18.04	OK/ Not OK	muthu	P.vij
2	Hydrochlorothiazide^	7.668	40#			18.05	18.08		muthu	P.vij
3	Dried Maize Starch**^^	36.793	40#			18.09	18.13		muthu	P.vij
4	Lactose Monohydrate	44.400	40#			18.14	18.18		muthu	P.vij
5	Microcrystalline Cellulose PH 102	18.00	40#			18.19	18.21		muthu	P.vij

Binder Material:

6	Gelatin	1.200	NA	NA	NA	-	-	NA	-	-
7	Maize Starch	3.00				-	-		-	-
8	Erythrosine Supra	0.060				-	-		-	-
9	Purified Water	30.00				-	-		-	-

Lubrication:

10	Sodium Starch Glycollate	3.00	60#	PD/30-SE-60/02	OK/Not OK	18.22	18.24	OK/Not OK	muthu	P.vij
11	Colloidal Silicon Dioxide	0.600	30#	PD/30-SE-30/02	OK/Not OK	18.25	18.26	OK/Not OK	muthu	P.vij
12	Magnesium Stearate	2.400	60#	PD/30-SE-60/02	OK/Not OK	18.27	18.29	OK/Not OK	muthu	P.vij

7.1 MANUFACTURING PROCESS:

Step No	Process Instructions	Date: 25/12/2020		Done by	Checked by
		Time			
		Started	Completed		
1	Dry mixing: Transfer the sifted Dried maize starch followed by Ramipril, Hydrochlorothiazide, Microcrystalline Cellulose PH 102 and finally lactose into the RMG/Mass mixer. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: <u>55 NA</u> RPM	18.30	18.40	muthu	P.vij
2	Binder Preparation: Take 3.000 Kg of Purified Water and mix Maize Starch to form a slurry.	18.20	18.24	muthu	P.vij
3	Take 18.000 Kg Purified Water in Paste Kettle and heat till reaches 95°C and dissolve Erythrosine Supra and Gelatin in it to form a solution. Then Immediately add the starch slurry prepared in the above step.	18.25	18.40	muthu	P.vij
4	Wet Granulation: Binder Addition: Add binder solution into RMG/Mass mixer take 2 min for binder addition with impeller slow speed and Chopper OFF. Take 1.000 Kg of purified water to rinse the paste vessel then transfer into RMG. Impeller Speed: <u>55 NA</u> RPM,	18.41	18.43	muthu	P.vij
5	After binder addition allow mixing for 3-4 minutes with Impeller slow and Chopper slow. If required add 6.000 Kg of Purified water then allow mixing for 5 min or till required consistency of granules obtained with impeller at fast speed and chopper at fast speed. Impeller Speed: <u>55 NA</u> RPM, <u>NA</u> RPM Chopper Speed: <u>NA</u> RPM, <u>NA</u> RPM Additional quantity of Purified water <u>NA</u> Kg	18.44	18.48	muthu	P.vij

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. Ka</u>	<u>P. Vij</u>	<u>P. Vij</u>	<u>P. Vij</u>	
Date	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>	

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
	Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMRT/134-00 Customer:

6	Note the Ampere at granulation end point AMP. (Limit: 21-22 Ampere)				R.vij
7	Discharge the wet mass to FBD bowl by operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: NA RPM Chopper Speed: NA RPM	18.49	18.53	mith	R.vij

7.2 DRYING:

Step No	Process Instructions	Date : 25/12/2020		Done by	Checked by
		Time			
		Started	Completed		
1	Load the wet mass into the FBD bowl and air dry the wet mass for 10 min.				
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 50-55°C till the LOD reached up to 2.2% w/w.	18.55	19.26	mithu	P.vijay
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5 – 2.2 % w/w.	Observed LOD in %		mithu	P.vijay
		2.11			
4	Same procedure should be followed for all the lots.	_____		_____	_____

7.3 FBD Finger bag Integrity checks:

S. No.	Items	Integrity before use	Integrity after use	Checked by (Production)	Verified by QA
1.	FBD finger bag				
2.	FBD bowl mesh		NA		

7.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (50-55°C)	Outlet Temp.	Product Temp. (To be Established)	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	18.55	NA	NA	NA	19.05	10 min	-	mith	R.vij
2.	Raking-I	19.06	NA	NA	NA	19.10	4 min	NA	mith	R.vij
3.	Drying-I	19.11	55°C	45°C	40°C	20.46	16 min	2.11	mith	R.vij
4.	Raking-II		NA	NA	NA			NA		
5.	Drying-II									
6.	Raking-III		NA	NA	NA			NA		
7.	Drying-III									
Total Drying Time (Exclude Raking & Air-Drying time): 16 min 14 min							LOD Verified By IPQA: [Signature]			
Total Drying time: 36 min 109 min										

7.5 SIFTING AND MILLING:

S. No	Process Instructions	Date : 25/12/2020		Done by	Checked by
		Time			
		Started	Completed		
1.	Sift the dried granules through 20 # sieve. Record the observation.	19-47	19-59	mithu	P.vij
2.	Mill the oversized granules through 1.5 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 20# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	21-00 19-33	21-10 19-37	mithu	P.vij
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	21-11 19-38	21-20 19-42	mithu	P.vij

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

UNCONTROLLED CC7Y

UNCONTROLLED CC7Y



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 12 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G F 201207

Customer:

Generic Health Care Pvt. Ltd.

7.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 25/12/2020		Integrity checked After use	Done by	Checked by
			Time				
			Started	Completed			
20 #	PD/30-SE-20/01	OK/ Not OK	20.47 20.47	20.59 20.59	OK/ Not OK	murthe	P.vij
1.5 mm	PD/1mm-SE-1.5/01	OK/ Not OK	19.33 ^{21.00}	19.38 ^{21.10}	OK/ Not OK	murthe	P.vij

7.7 WEIGHING OF DRIED GRANULES:

S. No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighed By	Checked By
1	<u>2.200</u>	<u>42.050</u>	<u>39.850</u>	<u>Ragupathi</u>	<u>P.vij</u>
2	<u>2.300</u>	<u>43.800</u>	<u>41.500</u>	<u>Ragupathi</u>	<u>P.vij</u>
3	<u>2.300</u>	<u>34.950</u>	<u>32.650</u>	<u>Ragupathi</u>	<u>P.vij</u>
4					
5					
6					
Total			<u>114.00</u>		

Theoretical Weight: 114.210 Kg

Theoretical Yield (Weight): Actually yield will be calculated after 3 validation batches.

Actual Yield (Weight): 114.00 Kg % Yield: 99.81 %

Date: 25/12/2020

P.vij 25/12/2020
Production Executive Sign./Date:

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.Ka</u>	<u>P.O</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>

UNCONTROLLED CC2Y

UNCONTROLLED CC2Y



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 13 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMRT/134-00

Batch No.: GFB01807

Customer:

Generic Health Care Pvt. Ltd.

8.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 26/11/2020 1 G 1 A/A

Sr. No.	Checks	Time	*Observations					
			9.00					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.		✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓				
10	Check and ensure that environment condition and record on BMR		✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		NA	NA				
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Blender	Area
E.Q. ID No.	P01/002/001	Granulation T
Previous Product	Sanfelix	
Batch No.	F50/00031	
Cleaned by	hmtly	
Checked by	hmtly	
Verified by	hmtly	

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 26/11/2020 Time: 9.05			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	hmtly	hmtly						
RH % (NMT 60%)	52%	hmtly	hmtly						
DP (NLT 10 Pascal)	10 pascals	hmtly	hmtly						

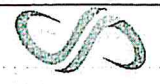
APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	hmtly 26/11/2020		
IPQA Sign/Date:	hmtly 26/11/2020		
Start and End Time:	09:10	09:40	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	hmtly	hmtly	hmtly
Date	26/11/2020	26/11/2020	26/11/2020	26/11/2020

UNCONTROLLED CC7Y

UNCONTROLLED CC7Y

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 36
	BATCH MANUFACTURING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00	Batch No.: GF 201207
		Customer:	Generic Health Care Pvt. Ltd.

8.1 BLENDING AND LUBRICATION PROCESS:

Date: 26/11/2020 Shift: G.....

Step No.	Process Instructions	Time		Done by	Checked by Prod.
		Started	Completed		
1	Use hand gloves and goggles while handling the materials.				
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.				
Lubrication:					
1	Load the dried and sifted granules from step 7.7, sifted Sodium Starch Glycollate and Colloidal Silicon Dioxide from step 7.0 (10,11) in to the blender and mix at 8 rpm for 15 minutes (To be established).	9.10	9.25	mutlu	h
2	Take 5.000 Kg of Pre-Lubricated blend and mix sifted Magnesium Stearate into it then Load into above Pre-lubricated blend and mix for further 2 minutes at 8 RPM (To be established).	9.26	9.28	mutlu	h
3	Unload the lubricated blend in HDPE container having double lined polybag.	9.30	9.40	mutlu	h

8.2 WEIGHING OF FINAL BLEND:

Balance I.D. No.: PD/PA/1005

Date: 26/11/2020 Shift: G..... Time: 9.45

Sr. No.	Gross Weight(Kg)	Tare Weight(Kg)	Net weight(Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	33.860	2.500	31.360	mutlu	h	h
2	34.800	2.000	32.800	mutlu	h	h
3	33.300	2.500	30.800	mutlu	h	h
4	30.800	4.600	26.200	mutlu	h	h
5						
Total:						

8.3 RECONCILIATION:

1.0	Theoretical weight of blend	:	120.210 Kg
2.0	Actual Weight of blend	:	120.160 Kg
3.0	Manufacturing Loss (Blending stage) @	:	0.050 Kg
4.0	In-process samples		
	A IPQC Samples	:	0.010 Kg.
	B QC Samples	:	0.010 Kg.
	C Validation Samples	:	0.010 Kg.
5.0	Total samples: (A + B + C)	:	0.030 Kg
6.0	Total: (2.0 + 5.0)	:	120.170 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.96 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 0.050 Kg. (Rejected materials shall be destroyed as per SOP: QAGN/048).

Recovery Addition Quantity in Kg: 0.050 (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: 26/11/2020 Checked By IPQA sign/Date: 26/11/2020

Test request form raised by Prod Sign/Date: 26/11/2020

Test request form received by IPQA Sign/Date: 26/11/2020

8.4 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: 26/11/2020 Date: 26/11/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	26/11/2020	26/11/2020	26/11/2020
Date	26/11/2020			





SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 15 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 57F00207

Customer:

Generic Health Care Pvt. Ltd.

9.0 COMPRESSION LINE CLEARANCE CHECKS:

Date: 26/12/2020

Sr. No.	Checks	Time:	Observations					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.	10:15	✓	✓				
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		✓	✓				
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		✓	✓				
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		✓	✓				
5	Check and ensure that working desk, analytical balance and other accessories are clean.		✓	✓				
6	Check and ensure that Deduster and hosepipe are clean.							
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		✓	✓				
10	Check and ensure that environmental conditions are recorded in the BMR.		✓	✓				
11	Area, equipment and preventive maintenance status board is updated.		✓	✓				
12	Check and ensure that rinse water /Surface swab is released from QC and attached the test request from (TRF)in BMR		✓	✓				
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD/COM/001	PD/DED/001 & PD/DED/002	Compression-01
Previous Product	Pregnacare breastfeeding		
Batch No.	PRB20315		
Cleaned by	Bala		
Checked by	26/12/2020		
Verified by	26/12/2020		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 26/12/2020	Time: 10:20	Date:	Time:	Date:	Time:
	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	24°C	AS	AS			
RH % (NMT 60%)	53 %	AS	AS			
DP (NLT 10 Pascal)	11 pascal	AS	AS			

APPROVAL FOR COMPRESSION:

Production Sign/Date:	26/12/2020		
IPQA Sign/Date:	26/12/2020		
Start and End Time:	10:25	18:30	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	26/12/2020	26/12/2020	
Date	26/12/2020			

UNCONTROLLED COPY

UNCONTROLLED COPY

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 71201207

Customer:

Generic Health Care Pvt. Ltd.

10.0 COMPRESSION

10.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 7.93 mm Circular shaped flat faced beveled edge punches. b. Lower punches: 7.93 mm Circular shaped flat faced plain punches. c. Dies: 7.93 mm suitable for above punches. d. Type of tooling - D.
	Punch Issued by: sign./Date: 26/10/2020 Checked and Received by Sign./Date: 26/10/2020 Verified by Sign./Date: 26/10/2020
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

10.2 GRANULES RECEIPT RECORD:

Balance ID. No.: PD/BAL/014 Date: 26/10/2020 Shift: G Time: 10:25

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	33.860	JS	JS
2	34.800	JS	JS
3	33.300	JS	JS
4	30.800	JS	JS
5			
6			NA

10.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	20	Every 30 min.	Every 2 Hr.
2.	Average weight(mg)	200.000 mg $\pm$ 3.0 % (194.000 mg – 206.000 mg)	20		
3.	Group Weight	4.000 g $\pm$ 3.0 % (3.880 g to 4.120g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)	20	Every 2 Hr.	Every 4 Hr.
6	Hardness	NLT 3.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Thickness (mm)	3.20 mm $\pm$ 0.3 mm (2.90 mm – 3.50 mm) (To be established)	4	Every 30 min.	Every 2 Hr.
9.	Diameter (mm)	(7.93 mm – 8.10 mm) (To be established)	30	Initial	
8.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
9.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	JS	JS	JS
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 17 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G F201207

Customer:

Generic Health Care Pvt. Ltd.

10.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	M/C Speed	Tablets Output	Done By	Checked By
26/12/2020	G	10:50	18:30	25	598400	Bala	[Signature]

10.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness & Diameter):

Balance I.D. No.: PD1BAL1007

Date: 26/12/2020 Shift: G Time:

LHS					RHS				
Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)	Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)
1	OK	199	3.06	8.01	1	OK	199	3.06	8.01
2	OK	198	3.08	8.04	2	OK	200	3.06	8.04
3	OK	200	3.09	8.02	3	OK	201	3.04	8.03
4	OK	201	3.08	8.06	4	OK	199	3.04	8.04
5	OK	200	3.09	8.01	5	OK	198	3.02	8.04
6	OK	198	3.06	8.04	6	OK	199	3.02	8.03
7	OK	199	3.09	8.06	7	OK	198	3.04	8.04
8	OK	199	3.08	8.04	8	OK	199	3.06	8.06
9	OK	200	3.09	8.06	9	OK	200	3.06	8.07
10	OK	201	3.08	8.04	10	OK	201	3.04	8.04
11	OK	201	3.09	8.06	11	OK	201	3.06	8.09
12	OK	200	3.08	8.06	12	OK	200	3.08	8.09
13	OK	199	3.06	8.04	13	OK	196	3.09	8.09
14	OK	196	3.06	8.06	14	OK	196	3.08	8.09
15	OK	196	3.06	8.04	15	OK	199	3.06	8.09
16	OK	196	3.06	8.06	16	OK	198	3.07	8.09
17	OK	196	3.08	8.04	17	OK	198	3.08	8.02
18	OK	194	3.04	8.04	18	OK	199	3.08	8.02
19	OK	196	3.06	8.04	19	OK	198	3.06	8.02
20	OK	196	3.06	8.06	20	OK	199	3.08	8.08
21	OK	199	3.08	8.04	21	OK	198	3.09	8.03
22	OK	200	3.09	8.06	22	OK	200	3.08	8.08
23	OK	201	3.08	8.04	23	OK	201	3.09	8.03
24	OK	200	3.08	8.02	24	OK	200	3.04	8.04
25	OK	196	3.09	8.04	25	OK	199	3.06	8.06
26	OK	199	3.09	8.04	26	OK	198	3.06	8.04
27	OK	196	3.08	8.06	27	OK	198	3.07	8.08
28	OK	196	3.09	8.06	28	OK	199	3.08	8.09
29	OK	194	3.08	8.04	29	OK	198	3.08	8.09
30	OK	199	3.09	8.06	30	OK	199	3.09	8.09

Note: * Write OK if complies and (X) if does not comply.

Done by Production Sign/Date: [Signature] 26/12/2020

Checked by IPQA Sign/Date: [Signature] 26/12/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: G F 8.01807 Generic Health Care Pvt. Ltd.

10.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 26/12/2020 Shift: G Time: 10:39

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits
			Min	Max	Min	Max	
Appearance	Visual	NA	OK		OK		Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side
Group Weight	Electronic Balance	PD/BA/6007	3986 g		3.989 g		4.000 g $\pm$ 3.0 % (3.880 g to 4.120g)
Average weight	Electronic Balance		199.30 mg		199.45 mg		200.000 mg $\pm$ 3.0 % (194.000 mg – 206.000 mg)
Individual weight	Electronic Balance		194 mg	201 mg	196 mg	201 mg	200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)
Uniformity of weight	Electronic Balance		%	%	%	%	
Thickness	Vernier Caliper	QAL/Vec/001	3.01 mm	3.09 mm	3.02 mm	3.09 mm	3.20 mm $\pm$ 0.3 mm (2.90 mm – 3.50 mm) (To be established)
Hardness	Hardness Tester	QAL/Vec/001	3.0	3.0	3.0	3.5	NLT 3.0 Kg (To be established)
Friability	Friabilator	QAL/Fri/001	0.02 %		0.0		NMT 1.0% w/w
DT	DT Apparatus	QAL/DTA/001	01 min 28 sec		01 min 32 sec		NMT 15 minutes
M/C set done by Operator Name: <u>Bala</u> M/C set up Checked by (Prod. Sign/Date): <u>JS/26/12/2020</u> M/C Speed: <u>25</u> RPM (To be Established)							
Initial Setting Tablets Destroyed by: Sign: <u>JS/26/12/2020</u> Date: <u>26/12/2020</u> Quantity in Kg: <u>0.030</u> Quantity in No: <u>150</u> tablets							
Approval for Batch Compression by IPQA: Sign: <u>[Signature]</u> Date: <u>26/12/2020</u> Time: <u>10:45</u>							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>26/12/2020</u>	<u>26/12/2020</u>	<u>26/12/2020</u>	<u>26/12/2020</u>

UNCONTROLLED COPY

UNCONTROLLED COPY



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 19 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G F2 01207

Customer:

Generic Health Care Pvt. Ltd.

10.7 IN-PROCESS CHECKS: (For Production)

Date: 26/12/2020

[illegible]

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

UNCONTROLLED COPY

UNCONTROLLED CCFY



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 20 of 36

Product Code: R09

Batch Size: 6,00,000 Tablets

Product**RAMITHIAZIDE 5/12.5**

BMR. No.: BMR/T/134-00

Batch No.: 67 F201207

Customer:

Generic Health Care Pvt. Ltd.

10.8 IN-PROCESS CHECKS: (For Production)

Date:

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	26/10/2020	26/10/2020		



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Batch Size: 6,00,000 Tablets

RAMITHIAZIDE 5/12.5

Batch No.: GF2012,07

Generic Health Care Pvt. Ltd.

Date:.....

[illegible]

12/26/2020

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

УКЗ дел. 108740001:

UNCONTROLLED COPY



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 22 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G F 2.012.04

Customer:

Generic Health Care Pvt. Ltd.

Date: 26/12/20

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POH	aym	8.1.2020
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED CCZY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BMR. No.: BMRT/134-00 Batch No.: GF201807 Customer: Generic Health Care Pvt. Ltd.

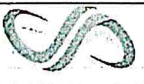
10.11 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 26/12/2020		Time: 10:55		Shift: G							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	200	8	198	15	195	1	199	8	196	15	199
2	199	9	199	16	194	2	198	9	199	16	198
3	198	10	198	17	193	3	199	10	194	17	199
4	199	11	199	18	192	4	198	11	196	18	202
5	200	12	200	19	199	5	199	12	199	19	200
6	201	13	201	20	194	6	194	13	194	20	201
7	199	14	196			7	194	14	199		
Balance ID No.: PD/BAL/007				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 3.955.....g. Avg. wt.: 197.75.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 192.....mg Max. weight: 201.....mg				Group weight of 20 Tablets: 3.957.....g. Avg. wt.: 197.85.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 194.....mg Max. weight: 202.....mg							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				LHS		RHS		Equipment ID No.: QA/FRT/002			
Disintegration Time (Limit - NMT 15 minutes)				0.01%		0.01%		Equipment ID No.: QA/DTA/001			
Done by: J (Production)				Done by: J (Production)							
Date: 26/12/2020		Time: 12:55		Shift: G							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	199	8	195	15	193	1	198	8	200	15	201
2	198	9	197	16	197	2	195	9	197	16	200
3	199	10	199	17	195	3	197	10	199	17	196
4	198	11	201	18	199	4	192	11	195	18	198
5	200	12	196	19	196	5	194	12	198	19	194
6	201	13	198	20	202	6	199	13	198	20	199
7	199	14	195			7	198	14	199		
Balance ID No.: PD/BAL/007				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 3.957.....g. Avg. wt.: 197.85.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 193.....mg Max. weight: 202.....mg				Group weight of 20 Tablets: 3.947.....g. Avg. wt.: 197.35.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 192.....mg Max. weight: 201.....mg							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				LHS		RHS		Equipment ID No.: QA/FRT/002			
Disintegration Time (Limit - NMT 15 minutes)				0.01%		0.01%		Equipment ID No.: QA/DTA/001			
Done by: J (Production)				Done by: J (Production)							

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	J	J	J	
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020	

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 24 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
	Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:

10.12 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 26/12/2020		Time: 15:00		Shift: G							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	198	8	200	15	199	1	199	8	198	15	199
2	195	9	199	16	196	2	195	9	200	16	195
3	201	10	197	17	198	3	200	10	197	17	198
4	199	11	202	18	199	4	202	11	199	18	199
5	197	12	200	19	201	5	200	12	195	19	197
6	195	13	195	20	199	6	198	13	194	20	199
7	196	14	193			7	195	14	203		
Balance ID No.: PD/BAL/007				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 3.959 g. Avg. wt: 197.95 mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 193 mg Max. weight: 202 mg				Group weight of 20 Tablets: 3.962 g. Avg. wt: 198.10 mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 194 mg Max. weight: 203 mg							
				LHS	RHS						
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.01%	0.01%	Equipment ID No.: QA/FRT/002					
Disintegration Time (Limit - NMT 15 minutes)				03 min 05 sec	02 min 53 sec	Equipment ID No.: QA/DTA/001					
Done by: (Production)											
Date: 26/12/2020		Time: 17:00		Shift: G							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	201	8	192	15	199	1	198	8	199	15	197
2	200	9	195	16	197	2	200	9	194	16	195
3	197	10	198	17	196	3	200	10	199	17	199
4	199	11	199	18	195	4	199	11	202	18	200
5	195	12	197	19	199	5	196	12	198	19	198
6	193	13	202	20	198	6	199	13	199	20	204
7	199	14	200			7	195	14	199		
Balance ID No.: PD/BAL/007				M/C Speed: 25 RPM							
Group weight of 20 Tablets: 3.951 g. Avg. wt: 197.55 mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 192 mg Max. weight: 202 mg				Group weight of 20 Tablets: 3.970 g. Avg. wt: 198.50 mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 194 mg Max. weight: 204 mg							
				LHS	RHS						
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.01%	0.01%	Equipment ID No.: QA/FRT/002					
Disintegration Time (Limit - NMT 15 minutes)				02 min 45 sec	03 min 05 sec	Equipment ID No.: QA/DTA/001					
Done by: (Production)											

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

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 25 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: G1 F2018107 Generic Health Care Pvt. Ltd.

10.13 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)				Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			
Min weight. :..... mg Max. weight:..... mg				Min weight. :..... mg Max. weight:..... mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)				Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			
Min weight. :..... mg Max. weight:..... mg				Min weight. :..... mg Max. weight:..... mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

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

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD
Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 26 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G F 201207

Customer:

Generic Health Care Pvt. Ltd.

10.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time :		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	8	15	1	8	15
2	9	16	2	9	16
3	10	17	3	10	17
4	11	18	4	11	18
5	12	19	5	12	19
6	13	20	6	13	20
7	14		7	14	
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets:.....g. Avg. wt:.....mg			Group weight of 20 Tablets:.....g. Avg. wt:.....mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight. :..... mg Max. weight:..... mg			Min weight. :..... mg Max. weight:..... mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			Equipment ID No.: QA/FRT/		
Disintegration Time (Limit - NMT 15 minutes)			Equipment ID No.: QA/DTA/		
Done by:(Production)					
Date:		Time :		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	8	15	1	8	15
2	9	16	2	9	16
3	10	17	3	10	17
4	11	18	4	11	18
5	12	19	5	12	19
6	13	20	6	13	20
7	14		7	14	
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets:.....g. Avg. wt:.....mg			Group weight of 20 Tablets:.....g. Avg. wt:.....mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight. :..... mg Max. weight:..... mg			Min weight. :..... mg Max. weight:..... mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			Equipment ID No.: QA/FRT/		
Disintegration Time (Limit - NMT 15 minutes)			Equipment ID No.: QA/DTA/		
Done by:(Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.		
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 27 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF301207

Customer:

Generic Health Care Pvt. Ltd.

10.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time :		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	8	15	1	8	15
2	9	16	2	9	16
3	10	17	3	10	17
4	11	18	4	11	18
5	12	19	5	12	19
6	13	20	6	13	20
7	14		7	14	
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets:.....g. Avg. wt:.....mg			Group weight of 20 Tablets:.....g. Avg. wt:.....mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight. :..... mg Max. weight:..... mg			Min weight. :..... mg Max. weight:..... mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			Equipment ID No.: QA/FRT/		
Disintegration Time (Limit - NMT 15 minutes)			Equipment ID No.: QA/DTA/		
Done by:(Production)					
Date:		Time :		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	8	15	1	8	15
2	9	16	2	9	16
3	10	17	3	10	17
4	11	18	4	11	18
5	12	19	5	12	19
6	13	20	6	13	20
7	14		7	14	
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets:.....g. Avg. wt:.....mg			Group weight of 20 Tablets:.....g. Avg. wt:.....mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight. :..... mg Max. weight:..... mg			Min weight. :..... mg Max. weight:..... mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			Equipment ID No.: QA/FRT/		
Disintegration Time (Limit - NMT 15 minutes)			Equipment ID No.: QA/DTA/		
Done by:(Production)					

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

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 28 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G F 01 207

Customer:

Generic Health Care Pvt. Ltd.

10.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time :		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	8	15	1	8	15
2	9	16	2	9	16
3	10	17	3	10	17
4	11	18	4	11	18
5	12	19	5	12	19
6	13	20	6	13	20
7	14		7	14	
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets:.....g. Avg. wt:.....mg			Group weight of 20 Tablets:.....g. Avg. wt:.....mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight. :..... mg Max. weight: mg			Min weight. :..... mg Max. weight: mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			Equipment ID No.: QA/FRT/		
Disintegration Time (Limit - NMT 15 minutes)			Equipment ID No.: QA/DTA/		
Done by:(Production)					
Date:		Time :		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	8	15	1	8	15
2	9	16	2	9	16
3	10	17	3	10	17
4	11	18	4	11	18
5	12	19	5	12	19
6	13	20	6	13	20
7	14		7	14	
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets:.....g. Avg. wt:.....mg			Group weight of 20 Tablets:.....g. Avg. wt:.....mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight. :..... mg Max. weight: mg			Min weight. :..... mg Max. weight: mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			Equipment ID No.: QA/FRT/		
Disintegration Time (Limit - NMT 15 minutes)			Equipment ID No.: QA/DTA/		
Done by:(Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.		
Date	26/10/2020	26/10/2020	26/10/2020	

UNCONTROLLED CC7Y

UNCONTROLLED CC7Y

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G F 2.01207

Customer:

Generic Health Care Pvt. Ltd.

10.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 26/12/2020		Time: 11:05		Shift: G (P-4)	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	198	8	199	15	200
2	201	9	200	16	201
3	198	10	200	17	204
4	206	11	204	18	202
5	199	12	202	19	203
6	202	13	201	20	204
7	205	14	199		
Balance ID No.: QA/BA/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 4.022 g. Avg. wt: 201.1 mg			Group weight of 20 Tablets: 4.032 g. Avg. wt: 201.6 mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: 198 mg Max. weight: 206 mg			Min weight: 199 mg Max. weight: 205 mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.28%	0.27%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			1min 54sec	1min 06sec	Equipment ID No.: QA/DTA/001
Done by: S. S. S. (IPQA)					
Date: 26/12/2020		Time: 14:10		Shift: G (M-4)	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	199	8	200	15	199
2	200	9	201	16	200
3	201	10	202	17	201
4	200	11	199	18	204
5	199	12	199	19	203
6	192	13	201	20	202
7	199	14	202		
Balance ID No.: QA/BA/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 4.007 g. Avg. wt: 200.35 mg			Group weight of 20 Tablets: 4.000 g. Avg. wt: 200 mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: 192 mg Max. weight: 204 mg			Min weight: 199 mg Max. weight: 202 mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.27%	0.29%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			1min 29sec	1min 30sec	Equipment ID No.: QA/DTA/001
Done by: S. S. S. (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.	S. S. S.	S. S. S.
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020





SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD
Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 30 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF 201207

Customer:

Generic Health Care Pvt. Ltd.

10.18 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 26/12/2020		Time: 12:10		Shift: G (E-4)	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	199	8	201	15	203
2	201	9	193	16	201
3	204	10	197	17	202
4	202	11	192	18	199
5	201	12	200	19	201
6	202	13	201	20	202
7	203	14	199		
Balance ID No.: CH/RAL/002			M/C Speed: 25 RPM		
Group weight of 20 Tablets: 4.013 g. Avg. wt: 200.6 mg			Group weight of 20 Tablets: 4.009 g. Avg. wt: 200.45 mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: 197 mg Max. weight: 204 mg			Min weight: 197 mg Max. weight: 204 mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.30%	0.25%	Equipment ID No.: QA/FRT/ 002
Disintegration Time (Limit - NMT 15 minutes)			1 min	1 min	Equipment ID No.: QA/DTA/ 001
Done by: 26/12/2020 (IPQA)					
Date:		Time:		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1		8		15	
2		9		16	
3		10		17	
4		11		18	
5		12		19	
6		13		20	
7		14			
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets: g. Avg. wt: mg			Group weight of 20 Tablets: g. Avg. wt: mg		
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)		
Min weight: mg Max. weight: mg			Min weight: mg Max. weight: mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):					Equipment ID No.: QA/FRT/
Disintegration Time (Limit - NMT 15 minutes)					Equipment ID No.: QA/DTA/
Done by: (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	26/12/2020	26/12/2020	26/12/2020	26/12/2020

UNCONTROLLED CC7Y

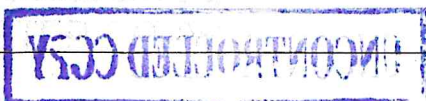
UNCONTROLLED CC7Y

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 31 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: G1 F2012.07 Generic Health Care Pvt. Ltd.

10.19 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date:				Time:				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15				1		8		15			
2		9		16				2		9		16			
3		10		17				3		10		17			
4		11		18				4		11		18			
5		12		19				5		12		19			
6		13		20				6		13		20			
7		14						7		14					
Balance ID No.: _____								M/C Speed: _____ RPM							
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight: mg								Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight: mg							
								LHS		RHS					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)												Equipment ID No.: QA/DTA/			
Done by:(IPQA)															
Date:				Time:				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15				1		8		15			
2		9		16				2		9		16			
3		10		17				3		10		17			
4		11		18				4		11		18			
5		12		19				5		12		19			
6		13		20				6		13		20			
7		14						7		14					
Balance ID No.: _____								M/C Speed: _____ RPM							
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight: mg								Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight: mg							
								LHS		RHS					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)												Equipment ID No.: QA/DTA/			
Done by:(IPQA)															

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	P. K.	M. K.		
Date	26/10/2020	26/10/2020	28/10/2020	26/10/2020	



 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 32 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: 51F201207 Generic Health Care Pvt. Ltd.

10.20 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date:				Time:				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15		1		8		15					
2		9		16		2		9		16					
3		10		17		3		10		17					
4		11		18		4		11		18					
5		12		19		5		12		19					
6		13		20		6		13		20					
7		14				7		14							
Balance ID No.:						M/C Speed: _____ RPM									
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight:..... mg						Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight:..... mg									
						LHS		RHS							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):										Equipment ID No.: QA/FRT/					
Disintegration Time (Limit - NMT 15 minutes)										Equipment ID No.: QA/DTA/					
Done by:(IPQA)															
Date:				Time:				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15		1		8		15					
2		9		16		2		9		16					
3		10		17		3		10		17					
4		11		18		4		11		18					
5		12		19		5		12		19					
6		13		20		6		13		20					
7		14				7		14							
Balance ID No.:						M/C Speed: _____ RPM									
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight:..... mg						Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight:..... mg									
						LHS		RHS							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):										Equipment ID No.: QA/FRT/					
Disintegration Time (Limit - NMT 15 minutes)										Equipment ID No.: QA/DTA/					
Done by:(IPQA)															

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<i>L. Ka</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020	

UNCONTROLLED CC7Y

UNCONTROLLED CC7Y



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 33 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF2012.07

Customer:

Generic Health Care Pvt. Ltd.

10.21 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPOA
1	32.530	2.200	30.330	Bala	JS	(S)
2	32.620	2.200	30.420	Bala	JS	(S)
3	33.030	2.200	31.030	Prem	JS	(S)
4	27.890	2.200	25.690	Prem	JS	(S)
5						
6						
7						
8						
9						
10						

10.22 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: 200.....mg

1.0	Standard Batch size	:	120.210 Kg.	6,00,000 No.
2.0	Actual weight of Lubricated granules	:	119.47 120.160 Kg	600800 Nos.
3.0	Weight of compressed tablets	:	119.47 119.920 Kg	599750 599600 Nos.
4.0	Rejection during Compression @	:	0.480..Kg.	
5.0	In-process samples of all stages			
	A IPQC Samples	:	0.180..Kg.	
	B QC Samples	:	0.030Kg.	
	C Validation Samples	:	NA..Kg.	
6.0	Total in process samples: (A + B + C)	:	0.210 0.140...Kg.	
7.0	Total: (3.0 + 6.0)	:	119.680 120.660..Kg.	598400 600300 Nos.
8.0	Yield {7.0 / 1.0 x 100} *	:		99.73 100.05 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.480.....Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: JS 26/12/2020 Checked by IPQA Sign/Date: JS 26/12/2020

Test request form raised by Prod Sign/Date: JS 26/12/2020

Test request form received by IPQA Sign/Date: JS 26/12/2020

10.23 RELEASE FOR INSPECTION:

Reconciliation checked and Uncoated tablets released for inspection

IPQA Sign: JS Date: 26/12/2020

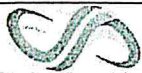
* W.E

JS 26/12/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	POK	JS	JS
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 34 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 01 F 201207

Customer:

Generic Health Care Pvt. Ltd.

11.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 26/12/2020 / G / 1

Sr. No.	Checks	*Observation			
		Prod	IPQA	Prod	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	NA	NA		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PD/INB/002	PD/MED/002	Inspection belt - 02
Previous product	Metabellix		
Batch No.	592 SPL 2007F		
Cleaned by	kamali		
Checked by Production Sign/Date:	26/12/2020		
Verified by IPQA Sign/Date:	26/12/2020		

ENVIRONMENTAL CONDITIONS:

ENVIRONMENTAL CONDITIONS:		Date: 26/12/2020 Time: 18:45			Date: Time:		
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	22°C	PS	PS			
	Relative Humidity % Limit: NMT 60%	50%	PS	PS			

APPROVAL FOR INSPECTION:

Production Sign/Date: 26/12/2020

Line Clearance IPQA Sign. / Date: 26/12/2020

Start Time/Date: 18:45 / 26/12/2020

End Time/Date: 20:35 / 26/12/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	1. K	✓	✓	✓
Date	26/12/2020	26/12/2020	26/12/2020	26/12/2020

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 35 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF2012.07

Customer:

Generic Health Care Pvt. Ltd.

12.0 INSPECTION PROCESS

12.1 INSTRUCTIONS

S. No.	Process Instructions
1	Carry out visual inspection of tablets on inspection belt area as per the SOP No. PDOP/019.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

12.1 PERFORMANCE CHECKS RECORD FOR METAL DETECTOR:

Sr. No.	Process instructions
1.	At the start of the activity, after each break and at the end of operation/shift) as per SOP No. PDGN/022.
2.	Testing frequency: Startup, End of the activity and after every break time.
3.	Acceptance Criteria: 1. Ferrous, Stainless steel & Non-Ferrous shall be detected & rejected.
	2. Nonmetallic shall not be detected.

Date & Time	Trial No.	Metal Detector ID No.: PD/MED/008 & PD/MED/...NA					Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.3 mm)	Non-metallic	Result		
26/12/2020 18:55	1	✓	✓	✓	X	PASS	GS	NA
	2	✓	✓	✓	X	PASS	GS	NA
	3	✓	✓	✓	X	PASS	GS	NA
26/12/2020 20:15	1	✓	✓	✓	X	PASS	GS	NA
	2	✓	✓	✓	X	PASS	GS	NA
	3	✓	✓	✓	X	PASS	GS	NA
	1							
	2							
	3							
	1							
	2							
	3							
	1							
	2							
	3							

Note: Put ✓ mark for detection and x mark for non-detection

If during the test Metal Detector fails to reject any of the Standard chips then mention the corrective action taken.

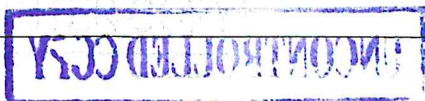
..... (To be filled by Production)

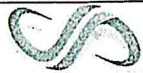
Note: Take QA Approval before proceeding to next stage

12.2 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
26/12/2020	18:45	20:25	18:45	20:35	0.060	GS	GS 26/12/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	PO	Signature	Signature
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020





SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 36 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G F 201207

Customer:

Generic Health Care Pvt. Ltd.

12.3 WEIGHING RECORD OF INSPECTED TABLETS:

Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	32.500	2.200	30.300	6			
2	32.610	2.200	30.410	7			
3	33.220	2.200	31.020	8			
4	27.880	2.200	25.680	9			
5		NA		10			
Total			119.410 Kg	Total			NA Kg
				Grand Total			119.410 Kg

Weighing Done By: Tegan Checked By Prod./ Date: 25/12/2020 Verified by IPQA Sign./Date: 26/12/2020

12.4 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	120.210 kg	600000 No's
2.0	Tablets transferred for Inspection	:	119.410 kg	597350 No's
3.0	Total weight of good Tablets	:	119.410 kg	597050 No's
4.0	Rejected Tablets	:	0.060 kg	300 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:	99.51%	%

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed: 0.060 Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign/Date: 26/12/2020

Checked by IPQA sign/Date: 26/12/2020

12.5 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date: 26/12/2020

BMR Released for packing by QA Head Sign/Date: 26/12/2020

13.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	<u>Lathech Kumar</u>	<u>26/12/2020</u>
QA Executive	<u>C. Sudha</u>	<u>26/12/2020</u>
Production Assistant Manager/ HOD	<u>BOJASUBRAMAN, DN.A</u>	<u>26/12/2020</u>
QA Manager/ HOD	<u>Stephen R</u>	<u>26/12/2020</u>

14.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMR/T/134-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K</u>	<u>DP</u>	<u>Farmer</u>	<u>26/12/2020</u>
Date	<u>26/12/2020</u>	<u>26/12/2020</u>	<u>26/12/2020</u>	

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 1 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: <u>GF210317</u> Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

PRODUCT NAME : RAMITHIAZIDE 5/12.5
GENERIC NAME : Ramipril and Hydrochlorothiazide Tablets
LABEL CLAIM : Each Uncoated tablet contains:
 Ramipril BP.....5 mg
 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) : 27/03/2021
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : L. Ke 22/03/2021
SHELF LIFE : 36 Months
BATCH SIZE : 6,00,000 Tablets (120.210 Kg)
MFG. DATE: 03/2021 **EXP. DATE:** 02/2024

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
1		N/A		1

ALLOTTED BY: 27/03/2021
QA SIGN/DATE:
DATE OF COMMENCEMENT: 21/03/2021
RELEASED QUANTITY OF TABLETS FOR PACKING : 589300 NOS
RELEASE FOR PACKING STAGE
HEAD OF QA SIGN/DATE: 26/04/21
COUNTER CHECKED BY: 27/03/21
QA SIGN/DATE:
DATE OF COMPLETION: 26/04/21

This BMR contains 36 Pages + 01 Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ke</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 36
	BATCH MANUFACTURING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMRT/134-00	Batch No.: GTF210317
		Customer:	Generic Health Care Pvt. Ltd.

1.0 INDEX

Sr. No.	Content	Page No.
	Batch manufacturing cover sheet	1
1.0	Index	2
2.0	Flow Chart	3
3.0	Indent of active pharmaceutical ingredients & excipients	4
4.0	Calculation	5-6
5.0	Dispensing line clearance checks, Dispensing weighing sheet	7-8
6.0	Line clearance for Sifting and granulation.	9
7.0	Granulation instruction, sieve integrity checks, sifting instruction, wet granulation, drying record, sifting and milling record	10-12
8.0	Blending Line clearance, Blending and Lubrication process, Lubrication material sifting record, Blending and Lubrication records, Weight record, Reconciliation, Release for Compression	13-14
9.0	Compression Line Clearance	15
10.0	Compression instruction, Granules receipt record, compression specification, compression machine running status, initial In-process checks, Compression specification/ Parameters, In-process checks (Production and IPQA), uniformity of weight checks (Production and IPQA), weight record of compressed tablets, Reconciliation	16-33
11.0	Release for Inspection	33
12.0	Inspection Line clearance	34
13.0	Inspection Process instruction, performance checks record for metal detector, tablets visual inspection record, weight record, Reconciliation of inspected tablets	35-36
14.0	Release for Packing	36
15.0	BMR Review details	36
16.0	Revision History	36

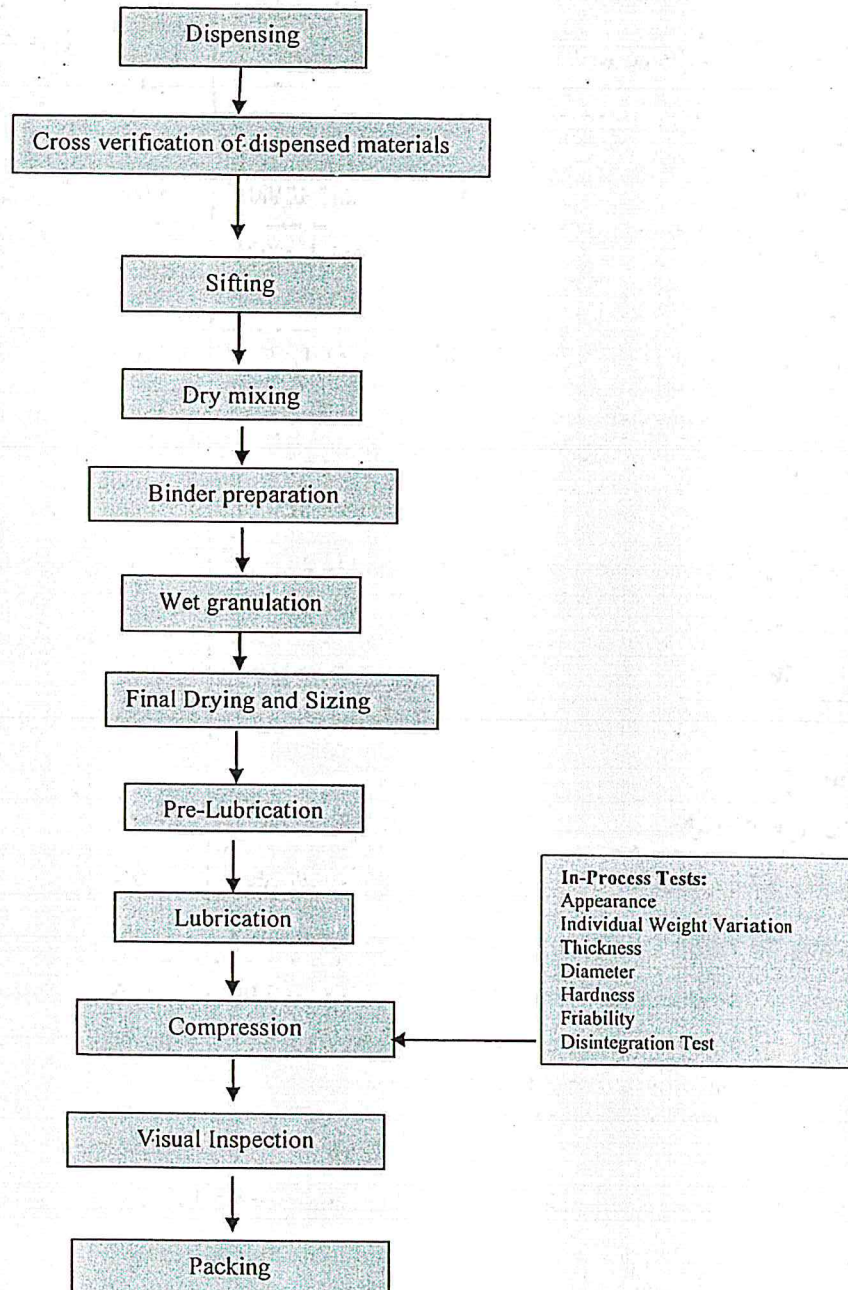
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	26/10/2020	26/10/2020	26/10/2020	

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: GF2103M Generic Health Care Pvt. Ltd.

2.0 PROCESS FLOW CHART



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

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: GTF210317 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)
Dry mixing material:							
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
Binder Material:							
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
Theoretical Weight of Dried Granules				190.000	114.000	-	114.210
Lubrication Material:							
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
Theoretical Weight of the Lubricated granules				200.000	120.000	-	120.210
Theoretical weight of Compressed tablet				200.000	120.000	-	120.210

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.	<i>L. Ke</i>	<i>P. P.</i>	<i>anym</i>	<i>S. M.</i>
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 5 of 36

Product	BATCH MANUFACTURING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
	RAMITHLAZIDE 5/12.5	BMR. No.: BMRT/134-00	Batch No.: <u>31 F210317</u>
		Customer:	Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR RAMIPRIL:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Ramipril: 3.060 Kg (A)

Calculation for Ramipril:

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} + \text{Overages} = \frac{5 \times 6,00,000}{1000 \times 1000} + 2\% = 3.060 \text{ kg}$$

RM/100977

1) Calculation for Single A. R. No. RM/100977, Assay on dried basis: 99.43 w/w, LOD: 0.1 w/w
Exp. Date: 01/02/2021

$$\text{Actual Quantity (Kg) (B)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{3.060 \times 100 \times 100}{99.43 \times (100 - 0.1)} = 3.081 \text{ Kg}$$

2) Calculation for Ramipril Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (C)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
Total Actual Quantity (D)					

Calculation for Remaining Quantity Required (E):

Theoretical Qty. – Actual Quantity (D) = _____ Kg

AR. No.: _____, Assay on dried basis: _____ w/w, LOD: _____ %w/w, Exp. Date: _____

$$\text{Actual Remaining Quantity (Kg) (F)} = \frac{\text{Remaining qty. required (E)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{\text{X} \times 100 \times 100}{\text{X}(100 - \text{LOD})} = \text{_____ Kg.}$$

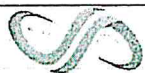
Total Qty. of Ramipril to be dispensed (G) = (C) + (F) = _____ Kg

Done By/On (QA): [Signature]

Checked By/On (Production): L. K. 27/03/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>

UNCONTROLLED COPY

SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 6 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 618210317

Customer:

Generic Health Care Pvt. Ltd.

4.1 ASSAY AND LOD CALCULATIONS FOR HYDROCHLOROTHIAZIDE:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Hydrochlorothiazide: 7.650 Kg (A)

Standard quantity of Dried Maize Starch (B): 36.840 Kg

Calculation for Hydrochlorothiazide:

$$\text{Theoretical Qty} = \frac{\text{Label Claim} \times \text{Std. Batch Size (in no's)}}{1000 \times 1000} + \text{Overages} = \frac{12.5 \times 6,00,000}{1000 \times 1000} + 2\% = 7.650 \text{ kg}$$

1) Calculation for Single A. R. No. _____, Assay on dried basis: _____ w/w, LOD: _____ w/w
Exp. Date: _____

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{\text{_____} \times 100 \times 100}{\text{_____} \times (100 - \text{_____})} = \text{_____ Kg}$$

2) Calculation for Dried Maize Starch (B):

Actual Quantity (Kg) (D) = Standard quantity of Maize Starch - (Excess Calculated quantity of Ramipril + Excess Calculated quantity of Hydrochlorothiazide)

$$= 36.840 \text{ Kg} - (\text{_____ Kg} + \text{_____ Kg})$$

$$= \text{_____ Kg.}$$

3) Calculation for Hydrochlorothiazide Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (E)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
1.	Ram/000057	4.052	99.19	0.2	4.011
Total Actual Quantity (F)					4.011

Calculation for Remaining Quantity Required (G):

$$\text{Theoretical Qty.} - \text{Actual Quantity (F)} = 3.639 \text{ Kg}$$

AR. No.: Ram/000057, Assay on dried basis: 99.52 w/w, LOD: 0.22 %w/w, Exp. Date: 11/25

$$\text{Actual Quantity (Kg) (H)} = \frac{\text{Remaining qty. required (G)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{3.639 \times 100 \times 100}{99.52 \times (100 - 0.22)} = 3.665 \text{ Kg.}$$

$$\text{Total Qty. of Hydrochlorothiazide to be dispensed (I)} = (E) + (H) = 7.717 \text{ Kg}$$

4) Calculation for Dried Maize Starch (B):

Actual Quantity (Kg) (J) = Standard quantity of Dried Maize Starch - (Excess Calculated quantity of Ramipril + Excess Calculated quantity of Hydrochlorothiazide)

$$= 36.840 \text{ Kg} - (0.021 \text{ Kg} + 0.067 \text{ Kg})$$

$$= 36.752 \text{ Kg.}$$

Done By/On (QA):

Checked By/On (Production):

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

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD
Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 7 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF210317

Customer:

Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 29/03/2021 Time: 11:20

Sr. No.	Checks	Observation*	
		Store	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags, documents and scrap from waste bin of previous batch/product are removed from the area.	/	/
2	Check and ensure that display stand and weighing balance are clean.	/	/
3	Check and ensure that SS scoop, SS spatula and SS trolley are clean.	/	/
4	Check and ensure that area (floor, walls, ceiling, doors and windows) are clean.	/	/
5	Check and ensure that Magnehelic gauges, tube light fixtures, supply grills, return riser grills and filters, electrical fixture are clean.	/	/
6	Check and ensure that all the sides of dispensing booth is clean	/	/
7	Check all the gauges of dispensing booth before switching ON.	/	/
8	Check and ensure that weighing balances and pressure gauges to be used are within calibration due date.	/	/
9	Check that the daily records (Balance Logbook, RH & Temp. record) are updated and signed.	/	/
10	Equipment status is updated for Cleaned and Preventive maintenance.	/	/

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Dispensing Booth	Weighing Balance			Area
ID No.	ST/PPS1001	ST/BAL004	ST/BAL005	ST/BAL006	Dispensing Booth-I
Previous Product	Ramithiazide 10/25				
B. No.	GF210316				
Cleaned by Sign/Date	Permal 29/03/2021				
Checked by Store Sign/Date	J. Anand 29/03/2021				
Verified by IPQA Sign/Date	Jesj 29/03/2021				

ENVIRONMENTAL CONDITIONS: Date: 29/03/2021 Time: 11:25

(For Reference SOP No.: QAGN/011)

Temperature (Limit: NMT 25°C)

Relative Humidity % (Limit: NMT 60%)

Differential Pressure (NLT 10 Pascal)

Differential Pressure across the booth Limit: 5 to 20 mm Water

Observation

Checked by
Store
Sign/Date

Verified by
IPQA
Sign/Date

24°C

60%

10

11mm

J. Anand 29/03/2021

J. Anand 29/03/2021

J. Anand 29/03/2021

J. Anand 29/03/2021

Jesj 29/03/2021

Jesj 29/03/2021

Jesj 29/03/2021

Jesj 29/03/2021

APPROVAL FOR DISPENSING BY IPQA: Sign: Jesj Date: 29/03/2021

Dispensing start Time: 11:45 End Time: 12:00

Prepared by:

Checked by:

Approved By:

Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	PQP	Jesj	J. Anand
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune,
Puducherry-605009.

Page 8 of 36

Product

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMTHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 618210314

Customer:

Generic Health Care Pvt. Ltd.

Dispensing Weighing Sheet:

Balance ID: S11000004 S11000004 S11000004 Date: 22/03/2021 Shift: 1 Time: 11:15

Balance ID: ST 1701004, ST 1701007, ST 1701008, ST 1701009, ST 1701010, ST 1701011, ST 1701012, ST 1701013, ST 1701014, ST 1701015, ST 1701016, ST 1701017, ST 1701018, ST 1701019, ST 1701020, ST 1701021, ST 1701022, ST 1701023, ST 1701024, ST 1701025, ST 1701026, ST 1701027, ST 1701028, ST 1701029, ST 1701030, ST 1701031, ST 1701032, ST 1701033, ST 1701034, ST 1701035, ST 1701036, ST 1701037, ST 1701038, ST 1701039, ST 1701040, ST 1701041, ST 1701042, ST 1701043, ST 1701044, ST 1701045, ST 1701046, ST 1701047, ST 1701048, ST 1701049, ST 1701050, ST 1701051, ST 1701052, ST 1701053, ST 1701054, ST 1701055, ST 1701056, ST 1701057, ST 1701058, ST 1701059, ST 1701060, ST 1701061, ST 1701062, ST 1701063, ST 1701064, ST 1701065, ST 1701066, ST 1701067, ST 1701068, ST 1701069, ST 1701070, ST 1701071, ST 1701072, ST 1701073, ST 1701074, ST 1701075, ST 1701076, ST 1701077, ST 1701078, ST 1701079, ST 1701080, ST 1701081, ST 1701082, ST 1701083, ST 1701084, ST 1701085, ST 1701086, ST 1701087, ST 1701088, ST 1701089, ST 1701090, ST 1701091, ST 1701092, ST 1701093, ST 1701094, ST 1701095, ST 1701096, ST 1701097, ST 1701098, ST 1701099, ST 1701100, ST 1701101, ST 1701102, ST 1701103, ST 1701104, ST 1701105, ST 1701106, ST 1701107, ST 1701108, ST 1701109, ST 1701110, ST 1701111, ST 1701112, ST 1701113, ST 1701114, ST 1701115, ST 1701116, ST 1701117, ST 1701118, ST 1701119, ST 1701120, ST 1701121, ST 1701122, ST 1701123, ST 1701124, ST 1701125, ST 1701126, ST 1701127, ST 1701128, ST 1701129, ST 1701130, ST 1701131, ST 1701132, ST 1701133, ST 1701134, ST 1701135, ST 1701136, ST 1701137, ST 1701138, ST 1701139, ST 1701140, ST 1701141, ST 1701142, ST 1701143, ST 1701144, ST 1701145, ST 1701146, ST 1701147, ST 1701148, ST 1701149, ST 1701150, ST 1701151, ST 1701152, ST 1701153, ST 1701154, ST 1701155, ST 1701156, ST 1701157, ST 1701158, ST 1701159, ST 1701160, ST 1701161, ST 1701162, ST 1701163, ST 1701164, ST 1701165, ST 1701166, ST 1701167, ST 1701168, ST 1701169, ST 1701170, ST 1701171, ST 1701172, ST 1701173, ST 1701174, ST 1701175, ST 1701176, ST 1701177, ST 1701178, ST 1701179, ST 1701180, ST 1701181, ST 1701182, ST 1701183, ST 1701184, ST 1701185, ST 1701186, ST 1701187, ST 1701188, ST 1701189, ST 1701190, ST 1701191, ST 1701192, ST 1701193, ST 1701194, ST 1701195, ST 1701196, ST 1701197, ST 1701198, ST 1701199, ST 1701200, ST 1701201, ST 1701202, ST 1701203, ST 1701204, ST 1701205, ST 1701206, ST 1701207, ST 1701208, ST 1701209, ST 1701210, ST 1701211, ST 1701212, ST 1701213, ST 1701214, ST 1701215, ST 1701216, ST 1701217, ST 1701218, ST 1701219, ST 1701220, ST 1701221, ST 1701222, ST 1701223, ST 1701224, ST 1701225, ST 1701226, ST 1701227, ST 1701228, ST 1701229, ST 1701230, ST 1701231, ST 1701232, ST 1701233, ST 1701234, ST 1701235, ST 1701236, ST 1701237, ST 1701238, ST 1701239, ST 1701240, ST 1701241, ST 1701242, ST 1701243, ST 1701244, ST 1701245, ST 1701246, ST 1701247, ST 1701248, ST 1701249, ST 1701250, ST 1701251, ST 1701252, ST 1701253, ST 1701254, ST 1701255, ST 1701256, ST 1701257, ST 1701258, ST 1701259, ST 1701260, ST 1701261, ST 1701262, ST 1701263, ST 1701264, ST 1701265, ST 1701266, ST 1701267, ST 1701268, ST 1701269, ST 1701270, ST 1701271, ST 1701272, ST 1701273, ST 1701274, ST 1701275, ST 1701276, ST 1701277, ST 1701278, ST 1701279, ST 1701280, ST 1701281, ST 1701282, ST 1701283, ST 1701284, ST 1701285, ST 1701286, ST 1701287, ST 1701288, ST 1701289, ST 1701290, ST 1701291, ST 1701292, ST 1701293, ST 1701294, ST 1701295, ST 1701296, ST 1701297, ST 1701298, ST 1701299, ST 1701300, ST 1701301, ST 1701302, ST 1701303, ST 1701304, ST 1701305, ST 1701306, ST 1701307, ST 1701308, ST 1701309, ST 1701310, ST 1701311, ST 1701312, ST 1701313, ST 1701314, ST 1701315, ST 1701316, ST 1701317, ST 1701318, ST 1701319, ST 1701320, ST 1701321, ST 1701322, ST 1701323, ST 1701324, ST 1701325, ST 1701326, ST 1701327, ST 1701328, ST 1701329, ST 1701330, ST 1701331, ST 1701332, ST 1701333, ST 1701334, ST 1701335, ST 1701336, ST 1701337, ST 1701338, ST 1701339, ST 1701340, ST 1701341, ST 1701342, ST 1701343, ST 1701344, ST 1701345, ST 1701346, ST 1701347, ST 1701348, ST 1701349, ST 1701350, ST 1701351, ST 1701352, ST 1701353, ST 1701354, ST 1701355, ST 1701356, ST 1701357, ST 1701358, ST 1701359, ST 1701360, ST 1701361, ST 1701362, ST 1701363, ST 1701364, ST 1701365, ST 1701366, ST 1701367, ST 1701368, ST 1701369, ST 1701370, ST 1701371, ST 1701372, ST 1701373, ST 1701374, ST 1701375, ST 1701376, ST 1701377, ST 1701378, ST 1701379, ST 1701380, ST 1701381, ST 1701382, ST 1701383, ST 1701384, ST 1701385, ST 1701386, ST 1701387, ST 1701388, ST 1701389, ST 1701390, ST 1701391, ST 1701392, ST 1701393, ST 1701394, ST 1701395, ST 1701396, ST 1701397, ST 1701398, ST 1701399, ST 1701400, ST 1701401, ST 1701402, ST 1701403, ST 1701404, ST 1701405, ST 1701406, ST 1701407, ST 1701408, ST 1701409, ST 1701410, ST 1701411, ST 1701412, ST 1701413, ST 1701414, ST 1701415, ST 1701416, ST 1701417, ST 1701418, ST 1701419, ST 1701420, ST 1701421, ST 1701422, ST 1701423, ST 1701424, ST 1701425, ST 1701426, ST 1701427, ST 1701428, ST 1701429, ST 1701430, ST 1701431, ST 1701432, ST 1701433, ST 1701434, ST 1701435, ST 1701436, ST 1701437, ST 1701438, ST 1701439, ST 1701440, ST 1701441, ST 1701442, ST 1701443, ST 1701444, ST 1701445, ST 1701446, ST 1701447, ST 1701448, ST 1701449, ST 1701450, ST 1701451, ST 1701452, ST 1701453, ST 1701454, ST 1701455, ST 1701456, ST 1701457, ST 1701458, ST 1701459, ST 1701460, ST 1701461, ST 1701462, ST 1701463, ST 1701464, ST 1701465, ST 1701466, ST 1701467, ST 1701468, ST 1701469, ST 1701470, ST 1701471, ST 1701472, ST 1701473, ST 1701474, ST 1701475, ST 1701476, ST 1701477, ST 1701478, ST 1701479, ST 1701480, ST 1701481, ST 1701482, ST 1701483, ST 1701484, ST 1701485, ST 1701486, ST 1701487, ST 1701488, ST 1701489, ST 1701490, ST 1701491, ST 1701492, ST 1701493, ST 1701494, ST 1701495, ST 1701496, ST 1701497, ST 1701498, ST 1701499, ST 1701500, ST 1701501, ST 1701502, ST 1701503, ST 1701504, ST 1701505, ST 1701506, ST 1701507, ST 1701508, ST 1701509, ST 1701510, ST 1701511, ST 1701512, ST 1701513, ST 1701514, ST 1701515, ST 1701516, ST 1701517, ST 1701518, ST 1701519, ST 1701520, ST 1701521, ST 1701522, ST 1701523, ST 1701524, ST 1701525, ST 1701526, ST 1701527, ST 1701528, ST 1701529, ST 1701530, ST 1701531, ST 1701532, ST 1701533, ST 1701534, ST 1701535, ST 1701536, ST 1701537, ST 1701538, ST 1701539, ST 1701540, ST 1701541, ST 1701542, ST 1701543, ST 1701544, ST 1701545, ST 1701546, ST 1701547, ST 1701548, ST 1701549, ST 1701550, ST 1701551, ST 1701552, ST 1701553, ST 1701554, ST 1701555, ST 1701556, ST 1701557, ST 1701558, ST 1701559, ST 1701560, ST 1701561, ST 1701562, ST 1701563, ST 1701564, ST 1701565, ST 1701566, ST 1701567, ST 1701568, ST 1701569, ST 1701570, ST 1701571, ST 1701572, ST 1701573, ST 1701574, ST 1701575, ST 1701576, ST 1701577, ST 1701578, ST 1701579, ST 1701580, ST 1701581, ST 1701582, ST 1701583, ST 1701584, ST 1701585, ST 1701586, ST 1701587, ST 1701588, ST 1701589, ST 1701590, ST 1701591, ST 1701592, ST 1701593, ST 1701594, ST 1701595, ST 1701596, ST 1701597, ST 1701598, ST 1701599, ST 1701600, ST 1701601, ST 1701602, ST 1701603, ST 1701604, ST 1701605, ST 1701606, ST 1701607, ST 1701608, ST 1701609, ST 1701610, ST 1701611, ST 1701612, ST 1701613, ST 1701614, ST 1701615, ST 1701616, ST 1701617, ST 1701618, ST 1701619, ST 1701620, ST 1701621, ST 1701622, ST 1701623, ST 1701624, ST 1701625, ST 1701626, ST 1701627, ST 1701628, ST 1701629, ST 1701630, ST 1701631, ST 1701632, ST 1701633, ST 1701634, ST 1701635, ST 1701636, ST 1701637, ST 1701638, ST 1701639, ST 1701640, ST 1701641, ST 1701642, ST 1701643, ST 1701644, ST 1701645, ST 1701646, ST 1701647, ST 1701648, ST 1701649, ST 1701650, ST 1701651, ST 1701652, ST 1701653, ST 1701654, ST 1701655, ST 1701656, ST 1701657, ST 1701658, ST 1701659, ST 1701660, ST 1701661, ST 1701662, ST 1701663, ST 1701664, ST 1701665, ST 1701666, ST 1701667, ST 1701668, ST 1701669, ST 1701670, ST 1701671, ST 1701672, ST 1701673, ST 1701674, ST 1701675, ST 1701676, ST 1701677, ST 1701678, ST 1701679, ST 1701680, ST 1701681, ST 1701682, ST 1701683, ST 1701684, ST 1701685, ST 1701686, ST 1701687, ST 1701688, ST 1701689, ST 1701690, ST 1701691, ST 1701692, ST 1701693, ST 1701694, ST 1701695, ST 1701696, ST 1701697, ST 1701698, ST 1701699, ST 1701700, ST 1701701, ST 1701702, ST 1701703, ST 1701704, ST 1701705, ST 1701706, ST 1701707, ST 1701708, ST 1701709, ST 1701710, ST 1701711, ST 1701712, ST 1701713, ST 1701714, ST 1701715, ST 1701716, ST 1701717, ST 1701718, ST 1701719, ST 1701720, ST 1701721, ST 1701722, ST 1701723, ST 1701724, ST 1701725, ST 1701726, ST 1701727, ST 1701728, ST 1701729, ST 1701730, ST 1701731, ST 1701732, ST 1701733, ST 1701734, ST 1701735, ST 1701736, ST 1701737, ST 1701738, ST 1701739, ST 1701740, ST 1701741, ST 1701742, ST 1701743, ST 1701744, ST 1701745, ST 1701746, ST 1701747, ST 1701748, ST 1701749, ST 1701750, ST 1701751, ST 1701752, ST 1701753, ST 1701754, ST 1701755, ST 1701756, ST 1701757, ST 1701758, ST 1701759, ST 1701760, ST 1701761, ST 1701762, ST 1701763, ST 1701764, ST 1701765, ST 1701766, ST 1701767, ST 1701768, ST 1701769, ST 1701770, ST 1701771, ST 1701772, ST 1701773, ST 1701774, ST 1701775, ST 1701776, ST 1701777, ST 1701778, ST 1701779, ST 1701780, ST 1701781, ST 1701782, ST 1701783, ST 1701784, ST 1701785, ST 1701786, ST 1701787, ST 1701788, ST 1701789, ST 1701790, ST 1701791, ST 1701792, ST 1701793, ST 1701794, ST 1701795, ST 1701796, ST 1701797, ST 1701798, ST 1701799, ST 1701800, ST 1701801, ST 1701802, ST 1701803, ST 1701804, ST 1701805, ST 1701806, ST 1701807, ST 1701808, ST 1701809, ST 1701810, ST 1701811, ST 1701812, ST 1701813, ST 1701814, ST 1701815, ST 1701816, ST 1701817, ST 1701818, ST 1701819, ST 1701820, ST 1701821, ST 1701822, ST 1701823, ST 1701824, ST 1701825, ST 1701826, ST 1701827, ST 1701828, ST 1701829, ST 1701830, ST 1701831, ST 1701832, ST 1701833, ST 1701834, ST 1701835, ST 1701836, ST 1701837, ST 1701838, ST 1701839, ST 1701840, ST 1701841, ST 1701842, ST 1701843, ST 1701844, ST 1701845, ST 1701846, ST 1701847, ST 1701848, ST 1701849, ST 1701850, ST 1701851, ST 1701852, ST 1701853, ST 1701854, ST 1701855, ST 1701856, ST 1701857, ST 1701858, ST 1701859, ST 1701860, ST 1701861, ST 1701862, ST 1701863, ST 1701864, ST 1701865, ST 1701866, ST 1701867, ST 1701868, ST 1701869, ST 1701870, ST 1701871, ST 1701872, ST 1701873, ST 1701874, ST 1701875, ST 1701876, ST 1701877, ST 1701878, ST 1701879, ST 1701880, ST 1701881, ST 1701882, ST 1701883, ST 1701884, ST 1701885, ST 1701886, ST 1701887, ST 1701888, ST 1701889, ST 1701890, ST 1701891, ST 1701892, ST 1701893, ST 1701894, ST 1701895, ST 1701896, ST 1701897, ST 1701898, ST 1701899, ST 1701900, ST 1701901, ST 1701902, ST 1701903, ST 1701904, ST 1701905, ST 1701906, ST 1701907, ST 1701908, ST 1701909, ST 1701910, ST 1701911, ST 1701912, ST 1701913, ST 1701914, ST 1701915, ST 1701916, ST 1701917, ST 1701918, ST 1701919, ST 1701920, ST 1701921, ST 1701922, ST 1701923, ST 1701924, ST 1701925, ST 1701926, ST 1701927, ST 1701928, ST 1701929, ST 1701930, ST 1701931, ST 1701932, ST 1701933, ST 1701934, ST 1701935, ST 1701936, ST 1701937, ST 1701938, ST 1701939, ST 1701940, ST 1701941, ST 1701942, ST 1701943, ST 1701944, ST 1701945, ST 1701946, ST 1701947, ST 1701948, ST 1701949, ST 1701950, ST 1701951, ST 1701952, ST 1701953, ST 1701954, ST 1701955, ST 1701956, ST 1701957, ST 1701958, ST 1701959, ST 1701960, ST 1701961, ST 1701962, ST 1701963, ST 1701964, ST 1701965, ST 1701966, ST 1701967, ST 1701968, ST 1701969, ST 1701970, ST 1701971, ST 1701972, ST 1701973, ST 1701974, ST 1701975, ST 1701976, ST 1701977, ST 1701978, ST 1701979, ST 1701980, ST 1701981, ST 1701982, ST 1701983, ST 1701984, ST 1701985, ST 1701986, ST 1701987, ST 1701988, ST 1701989, ST 1701990, ST 1701991, ST 1701992, ST 1701993, ST 1701994, ST 1701995, ST 1701996, ST 1701997, ST 1701998, ST 1701999, ST 1702000, ST 1702001, ST 1702002, ST 1702003, ST 1702004, ST 1702005, ST 1702006, ST 1702007, ST 1702008, ST 1702009, ST 1702010, ST 1702011, ST 1702012, ST 1702013, ST 1702014, ST 1702015, ST 1702016, ST 1702017, ST 1702018, ST 1702019, ST 1702020, ST 1702021, ST 1702022, ST 1702023, ST 1702024, ST 1702025, ST 1702026, ST 1702027, ST 1702028, ST 1702029, ST 1702030, ST 1702031, ST 1702032, ST 1702033, ST 1702034, ST 1702035, ST 1702036, ST 1702037, ST 1702038, ST 1702039, ST 1702040, ST 1702041, ST 1702042, ST 1702043, ST 1702044, ST 1702045, ST 1702046, ST 1702047, ST 1702048, ST 1702049, ST 1702050, ST 1702051, ST 1702052, ST 1702053, ST 1702054, ST 1702055, ST 1702056, ST 1702057, ST 1702058, ST 1702059, ST 1702060, ST 1702061, ST 1702062, ST 1702063, ST 1702064, ST 1702065, ST 1702066, ST 1702067, ST 1702068, ST 1702069, ST 1702070, ST 1702071, ST 1702072, ST 1702073, ST 1702074, ST 1702075, ST 1702076, ST 1702077, ST 1702078, ST 1702079, ST 1702080, ST 1702081, ST 1702082, ST 1702083, ST 1702084, ST 1702085, ST 1702086, ST 1702087, ST 1702088, ST 1702089, ST 1702090, ST 1702091, ST 1702092, ST 1702093, ST 1702094, ST 1702095, ST 1702096, ST 1702097, ST 1702098, ST 1702099, ST 1702100, ST 1702101, ST 1702102, ST 1702103, ST 1702104, ST 1702105, ST 1702106, ST 1702107, ST 1702108, ST 1702109, ST 1702110, ST 1702111, ST 1702112, ST 1702113, ST 1702114, ST 1702115, ST 1702116, ST 1702117, ST 1702118, ST 1702119, ST 1702120, ST 1702121, ST 1702122, ST 1702123, ST 1702124, ST 1702125, ST 1702126, ST 1702127, ST 1702128, ST 1702129, ST 1702130, ST 1702131, ST 1702132, ST 1702133, ST 1702134, ST 1702135, ST 1702136, ST 1702137, ST 1702138, ST 1702139, ST 1702140, ST 1702141, ST 1702142, ST 1702143, ST 1702144, ST 1702145, ST 1702146, ST 1702147, ST 1702148, ST 1702149, ST 1702150, ST 1702151, ST 1702152, ST 1702153, ST 1702154, ST 1702155, ST 1702156, ST 1702157, ST 1702158, ST 1702159, ST 1702160, ST 1702161, ST 1702162, ST 1702163, ST 1702164, ST 1702165, ST 1702166, ST 1702167, ST 1702168, ST 1702169, ST 1702170, ST 1702171, ST 1702172, ST 1702173, ST 1702174, ST 1702175, ST 1702176, ST 1702177, ST 1702178, ST 1702179, ST 1702180, ST 1702181, ST 1702182, ST 1702183, ST 1702184, ST 1702185, ST 1702186, ST 1702187, ST 1702188, ST 1702189, ST 1702190, ST 1702191, ST 1702192, ST 1702193, ST 1702194, ST 1702195, ST 1702196, ST 1702197, ST 1702198, ST 1702199, ST 1702200, ST 1702201, ST 1702202, ST 1702203, ST 1702204, ST 1702205, ST 1702206, ST 1702207, ST 1702208, ST 1702209, ST 1702210, ST 1702211, ST 1702212, ST 1702213, ST 1702214, ST 1702215, ST 1702216, ST 1702217, ST 1702218, ST 1702219, ST 1702220, ST 1702221, ST 1702222, ST 1702223, ST 1702224, ST 1702225, ST 1702226, ST 1702227, ST 1702228, ST 1702229, ST 1702230, ST 1702231, ST 1702232, ST 1702233, ST 1702234, ST 1702235, ST 1702236, ST 1702237, ST 1702238, ST 1702239, ST 1702240, ST 1702241, ST 1702242, ST													
--	--	--	--	--	--	--	--	--	--	--	--	--	--

Binder Material:

6	Gelatin	BP	REX/SP/G001	Kg	1.200	1.200	Rm-100-497	12.400	12.000	J. Chinn 29/03/2021	J. Chinn 29/03/2021	31/03/2021	J. Chinn 31/03/2021
7	Dried Maize Starch	BP	IRM/SP/M001	Kg	3.000	3.000	Rm-100-1388	3.070	0.070	J. Chinn 29/03/2021	J. Chinn 29/03/2021	31/03/2021	J. Chinn 31/03/2021
8	Erythrosine Supra	IHS	REX/SP/E005	Kg	0.060	0.060	Rm-110-2068	6.000	6.000	J. Chinn 29/03/2021	J. Chinn 29/03/2021	31/03/2021	J. Chinn 31/03/2021
9	Purified Water	BP	NA	Kg	30.000	30.000	Rm-210-112	24.000	4.000	J. Chinn 29/03/2021	J. Chinn 29/03/2021	31/03/2021	J. Chinn 31/03/2021

Lubrication Material:

10	Sodium Starch Glycollate	BP	REX/SP/S004	Kg	3.000	3.000	Rm-100-923	3.070	0.070	J. Chinn 29/03/2021	J. Chinn 29/03/2021	31/03/2021	J. Chinn 31/03/2021
11	Colloidal Silicon Dioxide	BP	REX/SP/C001	Kg	0.600	0.600	Rm-100-921	0.690	0.090	J. Chinn 29/03/2021	J. Chinn 29/03/2021	31/03/2021	J. Chinn 31/03/2021
12	Magnesium Stearate	BP	REX/SP/M011	Kg	2.400	2.400	Rm-100-898	2.460	0.060	J. Chinn 29/03/2021	J. Chinn 29/03/2021	31/03/2021	J. Chinn 31/03/2021

Prepared by:

Production

L.K

26/10/2020

Checked by:

Production

J. Chinn

26/10/2020

Approved By:

Quality Assurance

J. Chinn

26/10/2020

Head Quality Assurance

J. Chinn

26/10/2020

MASTER COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: <u>GF210317</u> Generic Health Care Pvt. Ltd.

6.0 GRANULATION LINE CLEARANCE CHECKS: Date/Time: 21/03/2021 05:55 /

Sr. No.	Checks	*Observations					
		Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.	✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.	✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.	✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine	✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean	✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean	✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.	✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.	✓	✓				
10	Check and ensure that environment condition and record on BMR	✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)	NA	NA				
12	Equipment status is updated for Cleaned and Preventive maintenance.	✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Sifter	Multimill	Mass Mixer/RMG	FBD/ Tray Drier	Area
EQP. ID No.	Pd/VBS/002	Pd/MLM/002	Pd/RMG/001	Pd/FBD/001	G-02
Previous Product	Gemset				
Batch No.	GF210301				
Cleaned by	Rajiv				
Checked by	Rajiv				
Verified by	Bala Subar				

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 21/03/2021 Time: 05:55			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	22	✓	✓						
RH % (NMT 60%)	52	✓	✓						
DP (NLT 10 Pascal)	10	✓	✓						

APPROVAL FOR SIFTING AND GRANULATION:

Production Sign/Date:	<u>Rajiv</u> 21/03/2021		
IPQA Sign/Date:	<u>Bala Subar</u>		
Start and End Time:	6:00	9:07	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>IPQA</u>	<u>Signature</u>	<u>Signature</u>
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

Y500 (01/10/2020)

UNCONTROLLED CC7Y

SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 10 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 615-210319

Customer:

Generic Health Care Pvt. Ltd.

7.0 GRANULATION SIFTING INSTRUCTIONS AND SIFTING RECORD: Date: 31/03/2021 Shift: III

S. No.	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by		
						From	To					
Dry mixing:												
1	Ramipril*	3.081	40#	PD/20SE-40/02	OK/Not OK	06.00	6.02	OK/Not OK	Raju	R		
2	Hydrochlorothiazide^	7.717	40#			6.03	6.06		Raju	R		
3	Dried Maize Starch***	36.752	40#			06.07	6.12		Raju	R		
4	Lactose Monohydrate	44.400	40#			6.12	6.17		Raju	R		
5	Microcrystalline Cellulose PH 102	18.000	40#			6.17	6.19		Raju	R		
Binder Material:												
6	Gelatin	1.200	NA	NA	NA			NA				
7	Maize Starch	2.000										
8	Erythrosine Supra	0.060										
9	Purified Water											
Lubrication:												
10	Sodium Starch Glycollate	2.000	60#	PD/20SE-60/02	OK/Not OK	9.40	9.42	OK/Not OK	Praman	R		
11	Colloidal Silicon Dioxide	0.600	30#	PD/20SE-30/03	OK/Not OK	9.43	9.44	OK/Not OK	Praman	R		
12	Magnesium Stearate	2.400	60#	PD/20SE-60/02	OK/Not OK	9.46	9.47	OK/Not OK	Praman	R		

7.1 MANUFACTURING PROCESS:

Step No	Process Instructions	Date: 31/03/2021		Done by	Checked by
		Time			
		Started	Completed		
1	Dry mixing: Transfer the sifted Dried maize starch followed by Ramipril, Hydrochlorothiazide, Microcrystalline Cellulose PH 102 and finally lactose into the RMG/Mass mixer. Mix for 10 minute with impeller at slow speed and chopper 'off'. Impeller Speed: 55 RPM	6.20	6.30	Raju	R
2	Binder Preparation: Take 3.000 Kg of Purified Water and mix Maize Starch to form a slurry.	6.15	6.20	Seethy	R
3	Take 18.000 Kg Purified Water in Paste Kettle and heat till reaches 95°C and dissolve Erythrosine Supra and Gelatin in it to form a solution. Then Immediately add the starch slurry prepared in the above step.	6.20	6.30	Seethy	R
4	Wet Granulation: Binder Addition: Add binder solution into RMG/Mass mixer take 2 min for binder addition with impeller slow speed and Chopper OFF. Take 1.000 Kg of purified water to rinse the paste vessel then transfer into RMG. Impeller Speed: 55 RPM,	6.32	6.34	Seethy	R
5	After binder addition allow mixing for 3-4 minutes with Impeller slow and Chopper slow. If required add 6.000 Kg of Purified water then allow mixing for 5 min or till required consistency of granules obtained with impeller at fast speed and chopper at fast speed. Impeller Speed: 110 RPM, - RPM Chopper Speed: 2800 RPM, - RPM Additional quantity of Purified water Kg	6.35	6.39	Seethy	R

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	PD	Seethy	Seethy	
Date	26/01/2020	26/01/2020	26/01/2020	26/01/2020	

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 36
	BATCH MANUFACTURING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00	Batch No.: 61F2103M
		Customer:	Generic Health Care Pvt. Ltd.

6	Note the Ampere at granulation end point .22... AMP. (Limit: 21-22 Ampere)				
7	Discharge the wet mass to FBD bowl by operating slow speed of Impeller and slow speed of Chopper. Impeller Speed: ...55.....RPM Chopper Speed..... RPM	6.30	6.32	Seethy	2

7.2 DRYING:

Step No	Process Instructions	Date : 21/03/2021		Done by	Checked by
		Time			
		Started	Completed		
1	Load the wet mass into the FBD bowl and air dry the wet mass for 10 min.				
2	Load the wet mass into the cleaned FBD bowl Dry at inlet temperature 50-55°C till the LOD reached up to 2.2% w/w.	6.53	8.40	Seethy	2
3	LOD checking temperature at 105°C (Auto mode). LOD should be 1.5 – 2.2 % w/w.	Observed LOD in %			
		2.1 %			
4	Same procedure should be followed for all the lots.				

7.3 FBD Finger bag Integrity checks:

S. No.	Items	Integrity before use	Integrity after use	Checked by (Production)	Verified by QA
1.	FBD finger bag	OK	OK	2	2
2.	FBD bowl mesh	OK	OK	2	2

7.4 SET PARAMETERS:

Sr. No.	Operation	Started at	Inlet Temp. (50-55°C)	Outlet Temp.	Product Temp. (To be Established)	Completed at	Total Time (mins)	LOD Observed	Done by	Checked By
1.	Air-Drying-I	6.35		NA		6.45	10 min	NA	Seethy	2
2.	Raking-I	6.46	NA	NA	NA	6.57	5 min	NA	Seethy	2
3.	Drying-I	6.53	55	45	40	8.40	107 min	2.1	Seethy	2
4.	Raking-II		NA	NA	NA			NA		
5.	Drying-II				NA					
6.	Raking-III		NA	NA	NA			NA		
7.	Drying-III									
Total Drying Time (Exclude Raking & Air-Drying time): 107 min							LOD Verified By IPQA: 2			
Total Drying time: 122 min										

7.5 SIFTING AND MILLING:

S. No	Process Instructions	Date : 21/03/2021		Done by	Checked by
		Time			
		Started	Completed		
1.	Sift the dried granules through 20 # sieve. Record the observation.	8.42	8.55	Rajiv	2
2.	Mill the oversized granules through 1.5 mm multi mill screen fitted with (knives forward medium speed) followed by sifting through 20# sieve on vibrating sifter and collect the sifted granules in double polythene lined cleaned HDPE containers, record the weights.	8.56	9.07	Jayanth	2
3.	Unload the granules in to cleaned HDPE containers in double polythene bag.	9.08	9.10	Jayanth	2

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	208	208	208	
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020	

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
	Product RAMITHIAZIDE 5/12.5	BMR. No.: BMRT/134-00 Customer:	Batch No.: 31F210377 Generic Health Care Pvt. Ltd.

7.6 SIZING RECORD:

Mesh and screen size	Sieve ID No	Integrity checked before use	Date : 31/03/2021		Integrity checked After use	Done by	Checked by
			Time				
			Started	Completed			
20 #	PBPOSF20/02	OK/Not OK	8.41	9.08	OK/Not OK	Raju	
1.5 mm	PBIMSL1.5/02	OK/Not OK	8.55	9.00	OK/Not OK	Jayakar	

7.7 WEIGHING OF DRIED GRANULES:

S. No.	Tare Weight (Kg)	Gross Weight (Kg)	Net Weight (Kg)	Weighed By	Checked By
1	3.060	49.460	46.400	praveen	
2	2.700	32.660	30.260	praveen	
3	2.300	38.760	36.600	praveen	
4					
5					
6					
Total					

Theoretical Weight: 114.210 Kg

Theoretical Yield (Weight): Actually yield will be calculated after 3 validation batches.

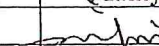
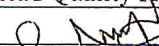
Actual Yield (Weight): 113.100 Kg % Yield: 99.02 %

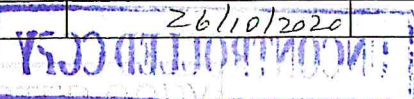
Date: 31/03/2021

Production Executive Sign./Date:



 31/03/2021

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





 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
	Product RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: GF210317 Generic Health Care Pvt. Ltd.

8.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 21/03/2021 / I.

Sr. No.	Checks	Time	*Observations					
			9.30					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.		✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓				
10	Check and ensure that environment condition and record on BMR		✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		NA	NA				
12	Equipment status is updated for Cleaned and Preventive maintenance.		✓	✓				

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Blender	Area
EQP. ID No.	9D/002/002	Blender
Previous Product	Genset	
Batch No.	GF210301	
Cleaned by	Pranav	
Checked by		
Verified by		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 21/03/2021 Time: 9.35			Date: Time:			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	22	✓	✓						
RH % (NMT 60%)	52	✓	✓			NA			
DP (NLT 10 Pascal)	10	✓	✓						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	21/03/2021		
IPQA Sign/Date:	21/03/2021		
Start and End Time:	9.50	10.20	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	POA	Signature	Signature
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 14 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 71F210317

Customer:

Generic Health Care Pvt. Ltd.

8.1 BLENDING AND LUBRICATION PROCESS:

Date: 31/10/2020 Shift: I

Step No.	Process Instructions	Time		Done by	Checked by Prod.
		Started	Completed		
1	Use hand gloves and goggles while handling the materials.				
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.				
Lubrication:					
1	Load the dried and sifted granules from step 7.7, sifted Sodium Starch Glycollate and Colloidal Silicon Dioxide from step 7.0 (10,11) in to the blender and mix at 8 rpm for 15 minutes (To be established).	9.50	10.05	Pommm	g
2	Take 5.000 Kg of Pre-Lubricated blend and mix sifted Magnesium Stearate into it then Load into above Pre-lubricated blend and mix for further 2 minutes at 8 RPM (To be established).	10.08 10.15	10.09 10.12	Pommm	g
3	Unload the lubricated blend in HDPE container having double lined polybag.	10.25 10.45	10.35 10.20	Pommm	g

8.2 WEIGHING OF FINAL BLEND:

Balance I.D. No.: PD/BAL/005

Date: 31/10/2020 Shift: I Time: 10:25

Sr. No.	Gross Weight(Kg)	Tare Weight(Kg)	Net weight(Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	35.710	2.300	33.310	Anbu	L	P
2	46.430	3.100	43.330	Anbu	L	P
3	16.190	2.300	13.890	Anbu	L	P
4	31.260	2.300	28.960	Anbu	L	P
5						
Total:			119.490			

8.3 RECONCILIATION:

1.0	Theoretical weight of blend	:	120.210 Kg
2.0	Actual Weight of blend	:	119.490 Kg
3.0	Manufacturing Loss (Blending stage) @	:	0.720 Kg
4.0	In-process samples		
	A IPQC Samples	:	0.110 Kg
	B QC Samples	:	0.100 Kg
	C Validation Samples	:	0.030 Kg
5.0	Total samples: (A + B + C)	:	0.140 Kg
6.0	Total: (2.0 + 5.0)	:	119.630 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.51 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 0.720 Kg. (Rejected materials shall be destroyed as per SOP: QAGN/048).

Recovery Addition Quantity in Kg: NA (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: 31/10/2020 Checked By IPQA sign/Date: 31/10/2020

Test request form raised by Prod Sign/Date: 31/10/2020

Test request form received by IPQA Sign/Date: 31/10/2020

8.4 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: 31/10/2020 Date: 31/10/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	PQP	Amma	J. Jeyaraj
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: CHF210317 Generic Health Care Pvt. Ltd.

9.0 COMPRESSION LINE CLEARANCE CHECKS:

Date: 01/04/2021 / 02/04/2021 /

Sr. No.	Checks	Time:	*Observations					
			16:00		09:00			
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		✓	✓	✓	✓		
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		✓	✓	✓	✓		
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		✓	✓	✓	✓		
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		✓	✓	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.		✓	✓	✓	✓		
6	Check and ensure that Deduster and hosepipe are clean.		✓	✓	✓	✓		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		✓	✓	✓	✓		
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		✓	✓	✓	✓		
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		✓	✓	✓	✓		
10	Check and ensure that environmental conditions are recorded in the BMR.		✓	✓	✓	✓		
11	Area, equipment and preventive maintenance status board is updated.		✓	✓	✓	✓		
12	Check and ensure that rinse water /Surface swab is released from QC and attached the test request from (TRF)in BMR		NA	✓	✓	✓		
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		✓	✓	✓	✓		

Note: *Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD/COM/003	-NA-	Compression - III
Previous Product	Dolex 50		
Batch No.	CHF210327		
Cleaned by	Vetri		
Checked by	AK/01/04/2021		
Verified by	S 01/04/2021		

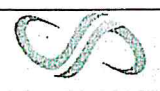
ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 01/04/2021 Time: 16:03			Date: 02/04/2021 Time: 09:15			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	AK	S	22°C	S	S			
RH % (NMT 60%)	52%	AK	S	50%	S	S			
DP (NLT 10 Pascal)	11 Pascal	AK	S	12 Pascal	S	S			

APPROVAL FOR COMPRESSION:

Production Sign/Date:	AK/01/04/2021	S 02/04/2021	
IPQA Sign/Date:	S 01/04/2021	S 02/04/2021	
Start and End Time:	16:08	22:05	09:23 13:05

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	AK	S	S
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 16 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: <u>G1F210317</u> Generic Health Care Pvt. Ltd.

10.0 COMPRESSION

10.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 7.93 mm Circular shaped flat faced beveled edge punches. upper breakline b. Lower punches: 7.93 mm Circular shaped flat faced plain punches. 01/04/2021 c. Dies: 7.93 mm suitable for above punches. 01/04/2021 d. Type of tooling - D. 01/04/2021 Punch Issued by: sign./Date: 01/04/2021 Checked and Received by Sign./Date: 01/04/2021 Verified by Sign./Date: 01/04/2021
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

10.2 GRANULES RECEIPT RECORD:

Balance ID. No.: PD04/014 Date: 01/04/2021 Shift: B Time: 16:10

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	35.810	<u>L</u>	<u>J</u>
2	46.480	<u>L</u>	<u>J</u>
3	16.190	<u>L</u>	<u>J</u>
4	31.260	<u>L</u>	<u>J</u>
5			
6			

10.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	20	Every 30 min.	Every 2 Hr.
2.	Average weight(mg)	200.000 mg $\pm$ 3.0 % (194.000 mg – 206.000 mg)	20		
3.	Group Weight	4.000 g $\pm$ 3.0 % (3.880 g to 4.120g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)	20	Every 2 Hr.	Every 4 Hr.
6	Hardness	NLT 3.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Thickness (mm)	3.20 mm $\pm$ 0.3 mm (2.90 mm – 3.50 mm) (To be established)	4	Every 30 min.	Every 2 Hr.
9.	Diameter (mm)	(7.93 mm – 8.10 mm) (To be established)	30	Initial	
8.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
9.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K</u>	<u>P</u>	<u>M</u>	<u>P</u>
Date	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 17 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G1F210317

Customer:

Generic Health Care Pvt. Ltd.

10.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	M/C Speed	Tablets Output	Done By	Checked By
01/04/2021	B	16:08	22:05	15	3,24,000	vetri	Am
02/04/2021	A	09:23	13:05	20	2,67,850	vetri	Am

10.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness & Diameter):

Balance I.D. No.: PD/BAL/009

Date: 01/04/2021. Shift: B. Time: 16:13...

LHS					RHS				
Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)	Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)
1	OK	201	3.08	8.03	1	OK	202	3.08	8.03
2	OK	202	3.10	8.03	2	OK	203	3.10	8.05
3	OK	199	3.10	8.03	3	OK	201	3.10	8.04
4	OK	198	3.09	8.05	4	OK	202	3.09	8.05
5	OK	202	3.11	8.05	5	OK	201	3.11	8.03
6	OK	201	3.12	8.05	6	OK	199	3.09	8.05
7	OK	202	3.09	8.04	7	OK	198	3.12	8.03
8	OK	203	3.11	8.04	8	OK	199	3.08	8.05
9	OK	199	3.10	8.04	9	OK	203	3.10	8.04
10	OK	201	3.12	8.05	10	OK	201	3.12	8.05
11	OK	202	3.09	8.03	11	OK	202	3.10	8.04
12	OK	203	3.08	8.05	12	OK	199	3.12	8.05
13	OK	199	3.10	8.03	13	OK	201	3.09	8.04
14	OK	198	3.09	8.05	14	OK	203	3.09	8.05
15	OK	199	3.12	8.03	15	OK	198	3.08	8.04
16	OK	198	3.10	8.05	16	OK	199	3.10	8.05
17	OK	201	3.09	8.04	17	OK	201	3.12	8.04
18	OK	202	3.08	8.05	18	OK	202	3.09	8.05
19	OK	201	3.09	8.03	19	OK	203	3.08	8.03
20	OK	201	3.10	8.05	20	OK	201	3.09	8.05
21	OK	203	3.12	8.05	21	OK	199	3.12	8.03
22	OK	201	3.09	8.03	22	OK	201	3.10	8.05
23	OK	202	3.09	8.05	23	OK	198	3.11	8.04
24	OK	203	3.10	8.04	24	OK	203	3.11	8.05
25	OK	201	3.10	8.05	25	OK	202	3.10	8.03
26	OK	202	3.09	8.03	26	OK	199	3.12	8.05
27	OK	203	3.10	8.05	27	OK	201	3.09	8.04
28	OK	199	3.12	8.05	28	OK	202	3.10	8.05
29	OK	198	3.09	8.05	29	OK	199	3.09	8.04
30	OK	199	3.08	8.05	30	OK	202	3.12	8.05

Note: * Write OK if complies and (X) if does not comply.

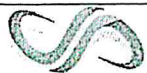
Done by Production Sign/Date: A/c 01/04/2021

Checked by IPQA Sign/Date: 01/04/2021

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

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 18 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G1F210317

Customer:

Generic Health Care Pvt. Ltd.

10.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 01/04/2021 Shift: B Time: 16:30

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits
			Min	Max	Min	Max	
Appearance	Visual	NA	OK		OK		Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side
Group Weight	Electronic Balance	pp/BAL/009	4.010 g		4.019 g		4.000 g $\pm$ 3.0 % (3.880 g to 4.120g)
Average weight	Electronic Balance		200.50 mg		200.95 mg		200.000 mg $\pm$ 3.0 % (194.000 mg – 206.000 mg)
Individual weight	Electronic Balance		198 mg	203 mg	198 mg	203 mg	200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)
Uniformity of weight	Electronic Balance		(-) 1.24 %	(+) 1.23 %	(-) 1.46 %	(+) 1.02 %	
Thickness	Vernier Caliper	QA/VEL/001	3.08 mm	3.12 mm	3.08 mm	3.12 mm	3.20 mm $\pm$ 0.3 mm (2.90 mm – 3.50 mm) (To be established)
Hardness	Hardness Tester	QA/HRD/001	4.0	4.5	4.0	4.5	NLT 3.0 Kg (To be established)
Friability	Friabilator	QA/FRI/002	0.05 %		0.03 %		NMT 1.0% w/w
DT	DT Apparatus	QA/DTA/002	68 minutes 30 Sec		68 minutes 45 Sec		NMT 15 minutes

M/C set done by Operator Name: M/C set up Checked by (Prod. Sign/Date): Ak/01/04/2021

M/C Speed: 15 RPM (To be Established)

Initial Setting Tablets Destroyed by: Sign: Date: 01/04/2021 Quantity in Kg: 0.060 Quantity in No: 300,000

Approval for Batch Compression by IPQA: Sign: Date: 01/04/2021 Time: 16:35

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	POK	Sign	Sign
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Batch Size: 6,00,000 Tablets

RAMITHIAZIDE 5/12.5

Batch No.: G1F210317

Generic Health Care Pvt. Ltd.

Date: 01/04/2021..

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	26/10/2020	26/10/2020	28/10/2020	28/10/2020

MONTROSE COUNTY

UNCONTROLLED CCZY



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.

Page 20 of 36

SAI PRIMUS
LIFE BIOTECH PVT LTD

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHLAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 61F210317

Customer:

Generic Health Care Pvt. Ltd.

10.8 IN-PROCESS CHECKS: (For Production)

Date:.....

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	26/10/2020	26/10/2020	<i>[Signature]</i>	<i>[Signature]</i>

UNCONTROLLED COPY

UNCONTROLLED COPY



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: G1F210314

Customer:

Generic Health Care Pvt. Ltd.

Date:.....

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

УБ.О. ДОКУМЕНТИ:

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 22 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 015210317

Customer:

Generic Health Care Pvt. Ltd.

10.10 IN-PROCESS CHECKS: (For IPQA)

Date: 01/04/2024

Time	Appearance		Weight of 20 Tablets		Hardness				Thickness				Done by IPQA
	Pink coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side		4.000 g $\pm$ 3.0 % (3.880 g to 4.120g)		NLT 3.0 Kg (To be established)				3.20 mm $\pm$ 0.3 mm (2.90 mm – 3.50 mm) (To be established)				
	LHS	RHS	LHS	RHS	LHS	LHS	RHS	RHS	LHS	LHS	RHS	RHS	
16:50	Ok	Full Hopper Ok	4.024	4.019	4.0	4.0	4.5	4.0	3.08	3.11	3.09	3.12	R
18:45	Ok	Ok	4.058	4.027	4.0	4.5	4.0	4.0	3.12	3.09	3.13	3.08	R
20:40	Ok	Ok	3.983	3.979	4.0	4.0	4.5	4.0	3.06	3.08	3.11	3.08	As
22:15	Ok	Mid Hopper Ok	3.992	3.981	4.0	4.5	4.0	4.5	3.08	3.09	3.10	3.11	As
24/04/2024 09:40	Ok	Ok	3.987	3.994	4.0	4.5	4.0	4.5	3.09	3.11	3.13	3.08	R
11:45	Ok	Ok	3.998	4.012	4.0	4.5	4.0	4.0	3.09	3.12	3.11	3.08	R
13:00	Ok	End Hopper Ok	3.977	3.984	4.0	4.5	4.5	4.0	3.09	3.11	3.08	3.06	R
13:04	Ok	L RPM Ok	4.013	4.007	4.0	4.0	4.5	4.0	3.11	3.10	3.08	3.13	R
13:08	Ok	H RPM Ok	4.021	4.003	4.0	4.5	4.5	4.0	3.10	3.08	3.12	3.09	R
13:15	Ok	L Hardness Ok	3.984	3.991	3.0	3.5	3.0	3.0	3.14	3.16	3.18	3.15	R
13:20	Ok	H Hardness Ok	3.994	4.007	4.5	4.5	4.5	4.5	3.04	3.03	3.05	3.06	R
13:25	Ok	Composite Ok	3.984	3.977	4.0	4.0	4.0	4.0	3.09	3.08	3.09	3.08	R

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

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: GF210317 Generic Health Care Pvt. Ltd.

10.11 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 01/04/2021		Time: 17:02		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	199	8	199	15	200
2	200	9	198	16	201
3	198	10	200	17	200
4	201	11	201	18	200
5	197	12	200	19	199
6	199	13	199	20	200
7	200	14	198		
Balance ID No.: PD/BA/1009			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 3991.g. Avg. wt: 199.55.mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 197 mg Max. weight: 202 mg			Group weight of 20 Tablets: 4021.g. Avg. wt: 201.05.mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 198 mg Max. weight: 202 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS: 0.04% RHS: 0.04% Equipment ID No.: QA/FRT/1002		
Disintegration Time (Limit - NMT 15 minutes)			02 min 35 sec 02 min 48 sec Equipment ID No.: QA/DTA/002		
Done by: (Production)					
Date: 01/04/2021		Time: 19:10		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	200	8	200	15	199
2	201	9	200	16	200
3	199	10	198	17	201
4	202	11	199	18	201
5	201	12	201	19	200
6	200	13	202	20	200
7	198	14	201		
Balance ID No.: PD/BA/1009			M/C Speed: 22 RPM		
Group weight of 20 Tablets: 4003.g. Avg. wt: 200.15.mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 198 mg Max. weight: 202 mg			Group weight of 20 Tablets: 3997.g. Avg. wt: 199.85.mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 198 mg Max. weight: 202 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS: 0.03% RHS: 0.04% Equipment ID No.: QA/FRT/002		
Disintegration Time (Limit - NMT 15 minutes)			02 min 41 sec 02 min 46 sec Equipment ID No.: QA/DTA/002		
Done by: (Production)					

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

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 24 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 61F210317

Customer:

Generic Health Care Pvt. Ltd.

10.12 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 02/04/2024			Time: 21:18			Shift: B					
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	200	8	198	15	200	1	199	8	200	15	200
2	199	9	199	16	199	2	200	9	201	16	199
3	201	10	201	17	200	3	201	10	200	17	201
4	200	11	200	18	199	4	200	11	201	18	200
5	200	12	199	19	201	5	198	12	203	19	200
6	198	13	201	20	198	6	199	13	200	20	198
7	200	14	200			7	201	14	201		

Balance ID No.: PD/BAL/009

M/C Speed: 20 RPM

Group weight of 20 Tablets: 399.7 g. Avg.
wt.: 199.85 mg

Group weight of 20 Tablets: 400.4 g. Avg.
wt.: 200.2 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 198 mg Max. weight: 202 mg

Min weight: 198 mg Max. weight: 202 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.06%	0.04%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	02 min 46 sec	02 min 51 sec	Equipment ID No.: QA/DTA/002

Done by: AK/02/04/2021 (Production)

Date: 02/04/2021	Time: 09:45	Shift: A									
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	198	8	201	15	202	1	199	8	202	15	198
2	199	9	202	16	200	2	200	9	199	16	199
3	199	10	200	17	200	3	198	10	201	17	200
4	200	11	199	18	201	4	201	11	200	18	201
5	201	12	197	19	200	5	200	12	199	19	201
6	200	13	201	20	199	6	199	13	200	20	200
7	196	14	203			7	198	14	200		

Balance ID No.: PD/BAL/009

M/C Speed: 20 RPM

Group weight of 20 Tablets: 399.78 g. Avg.
wt.: 199.89 mg

Group weight of 20 Tablets: 399.5 g. Avg.
wt.: 199.75 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 198 mg Max. weight: 203 mg

Min weight: 198 mg Max. weight: 202 mg

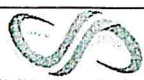
	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.06%	0.05%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	02 min 49 sec	02 min 50 sec	Equipment ID No.: QA/DTA/002

Done by: AK/02/04/2021 (Production)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	AK	AK	AK
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 25 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BMR. No.: BMR/T/134-00 Batch No.: G1 F210317 Customer: Generic Health Care Pvt. Ltd.

10.13 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 02/04/2021		Time: 11:56		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	196	8	204	15	197
2	201	9	200	16	201
3	200	10	201	17	197
4	202	11	203	18	200
5	198	12	197	19	203
6	201	13	203	20	197
7	199	14	200		
Balance ID No.: DD/BA/009			M/C Speed: 22 RPM		
Group weight of 20 Tablets:.....g. Avg. wt: 200.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. : 196..... mg Max. weight: 203..... mg			Group weight of 20 Tablets:.....g. Avg. wt: 200.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. : 197..... mg Max. weight: 203..... mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/ 002
Disintegration Time (Limit - NMT 15 minutes)			02 min 21 sec	02 min 36 sec	Equipment ID No.: QA/DTA/ 002
Done by: A. V. 02/04/2021 (Production)					
Date:		Time:		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1		8		15	
2		9		16	
3		10		17	
4		11		18	
5		12		19	
6		13		20	
7		14			
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight:..... mg			Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight. :..... mg Max. weight:..... mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/
Disintegration Time (Limit - NMT 15 minutes)					Equipment ID No.: QA/DTA/
Done by:(Production)					

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

UNCONTROLLED CC2Y

UNCONTROLLED CC2Y



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 26 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 4F210317

Customer:

Generic Health Care Pvt. Ltd.

10.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)				Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			
Min weight. :..... mg Max. weight.: mg				Min weight. :..... mg Max. weight.: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)				Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			
Min weight. :..... mg Max. weight.: mg				Min weight. :..... mg Max. weight.: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY

SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 27 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 51210317

Customer:

Generic Health Care Pvt. Ltd.

10.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time:		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)				Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			
Min weight: mg Max. weight: mg				Min weight: mg Max. weight: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time:		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)				Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			
Min weight: mg Max. weight: mg				Min weight: mg Max. weight: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

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	

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 28 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: 416210317

Customer:

Generic Health Care Pvt. Ltd.

10.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)				Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			
Min weight. :..... mg Max. weight:..... mg				Min weight. :..... mg Max. weight:..... mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)				Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)			
Min weight. :..... mg Max. weight:..... mg				Min weight. :..... mg Max. weight:..... mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

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

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 29 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BMR. No.: BMR/T/134-00 Batch No.: 71F210317 Customer: Generic Health Care Pvt. Ltd.

10.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 01/04/2024		Time: 17:00		Shift: G1	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	200	8	200	15	199
2	201	9	201	16	202
3	202	10	199	17	200
4	200	11	198	18	199
5	199	12	201	19	198
6	199	13	200	20	200
7	201	14	200		
Balance ID No.: QA/BAL/002			M/C Speed: 20 RPM		
Group weight of 20 Tablets: 4.012 g. Avg. wt: 200.6 mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 198 mg Max. weight: 202 mg			Group weight of 20 Tablets: 4.012 g. Avg. wt: 200.6 mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 198 mg Max. weight: 202 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS: 0.06%	RHS: 0.03%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			LHS: 2 min 32 sec	RHS: 2 min 41 sec	Equipment ID No.: QA/DTA/002
Done by: [Signature] (IPQA)					
Date: 01/04/2024		Time: 21:05		Shift: B	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	204	8	205	15	201
2	204	9	203	16	202
3	202	10	200	17	201
4	201	11	201	18	201
5	202	12	202	19	202
6	200	13	200	20	200
7	202	14	202		
Balance ID No.: QA/BAL/002			M/C Speed: 20 RPM		
Group weight of 20 Tablets: 4.034 g. Avg. wt: 201.7 mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 200 mg Max. weight: 205 mg			Group weight of 20 Tablets: 4.017 g. Avg. wt: 200.85 mg Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg) Min weight: 200 mg Max. weight: 205 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS: 0.03%	RHS: 0.05%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			LHS: 2 min 14 sec	RHS: 2 min 21 sec	Equipment ID No.: QA/DTA/002
Done by: [Signature] (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	[Signature]	[Signature]	[Signature]
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: HF210317

Customer:

Generic Health Care Pvt. Ltd.

10.18 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): Mid Hoppe v

Date: 01/04/2021 Time: 22:30 Shift: B

LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	200	8	199	15	199	1	200	8	202	15	199
2	192	9	199	16	198	2	199	9	201	16	198
3	199	10	200	17	199	3	198	10	200	17	199
4	198	11	201	18	198	4	199	11	199	18	201
5	199	12	202	19	199	5	199	12	200	19	202
6	199	13	201	20	200	6	200	13	200	20	201
7	200	14	200			7	201	14	198		

Balance ID No.: QA/BAL/002

M/C Speed: 20 RPM

Group weight of 20 Tablets: 3.986 g. Avg. wt: 199.30 mg

Group weight of 20 Tablets: 3.994 g. Avg. wt: 199.70 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 197 mg Max. weight: 201 mg

Min weight: 197 mg Max. weight: 202 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.08%	0.04%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	2 min 14 sec	2 min 10 sec	Equipment ID No.: QA/DTA/002

Done by: As 01/04/2021 (IPQA)

Date: 02/04/2021 Time: 10:00 Shift: G

LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	199	8	201	15	198	1	200	8	201	15	203
2	201	9	202	16	200	2	201	9	202	16	204
3	202	10	200	17	201	3	198	10	198	17	201
4	201	11	199	18	200	4	199	11	199	18	200
5	198	12	198	19	198	5	200	12	200	19	199
6	199	13	199	20	199	6	198	13	201	20	200
7	200	14	199			7	199	14	201		

Balance ID No.: QA/BAL/002

M/C Speed: 20 RPM

Group weight of 20 Tablets: 3.990 g. Avg. wt: 199.50 mg

Group weight of 20 Tablets: 4.005 g. Avg. wt: 200.25 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 197 mg Max. weight: 202 mg

Min weight: 198 mg Max. weight: 204 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.09%	0.06%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	2 min 14 sec	2 min 27 sec	Equipment ID No.: QA/DTA/002

Done by: As 02/04/2021 (IPQA)

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

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 32 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: C1F210317

Customer:

Generic Health Care Pvt. Ltd.

10.20 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): H.RPM

Date: 02/04/2021						Time: 13:18			Shift: G1		
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	198	8	202	15	198	1	200	8	200	15	202
2	199	9	200	16	200	2	201	9	201	16	201
3	200	10	201	17	201	3	202	10	202	17	204
4	198	11	202	18	202	4	201	11	200	18	201
5	199	12	199	19	201	5	199	12	199	19	203
6	200	13	202	20	199	6	200	13	198	20	200
7	201	14	198			7	201	14	199		

Balance ID No.: QA/BAL/002

M/C Speed: 30 RPM

Group weight of 20 Tablets: 1.000 g. Avg.
wt: 200.0 mg

Group weight of 20 Tablets: 1.014 g. Avg.
wt: 202.7 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 198 mg Max. weight: 202 mg

Min weight: 198 mg Max. weight: 204 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.04%	0.06%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	2 min 45 sec	2 min 39 sec	Equipment ID No.: QA/DTA/002

Done by: S. S. S. (IPQA)

Date: 02/04/2021

Time: 13:22

Shift: G1

LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	199	8	200	15	200	1	200	8	198	15	200
2	200	9	199	16	201	2	200	9	199	16	202
3	201	10	200	17	201	3	201	10	200	17	203
4	202	11	201	18	202	4	201	11	200	18	200
5	198	12	197	19	200	5	201	12	198	19	198
6	199	13	198	20	201	6	200	13	199	20	199
7	200	14	199			7	197	14	200		

Balance ID No.: QA/BAL/002

M/C Speed: 20 RPM

Group weight of 20 Tablets: 3.998 g. Avg.
wt: 199.9 mg

Group weight of 20 Tablets: 3.995 g. Avg.
wt: 199.75 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 198 mg Max. weight: 202 mg

Min weight: 197 mg Max. weight: 203 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.07%	0.08%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	2 min 51 sec	2 min 56 sec	Equipment ID No.: QA/DTA/002

Done by: S. S. S. (IPQA)

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

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 32 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMR/T/134-00

Batch No.: GF 210317(A)

Customer:

Generic Health Care Pvt. Ltd.

10.20 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

H. Handover

Date: 02/04/2021

Time: 13:30

Shift: G

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	200	8	201	15	199	1	198	8	199	15	198
2	197	9	202	16	201	2	199	9	198	16	200
3	199	10	201	17	202	3	200	10	200	17	200
4	200	11	201	18	204	4	201	11	201	18	197
5	201	12	200	19	201	5	202	12	200	19	199
6	198	13	200	20	202	6	201	13	199	20	198
7	199	14	200			7	202	14	200		

Balance ID No.: QA/BAL/002

M/C Speed: 20 RPM

Group weight of 20 Tablets: 4.002 g. Avg.
wt: 200.1 mg

Group weight of 20 Tablets: 3.992 g. Avg.
wt: 199.6 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 197 mg Max. weight: 204 mg

Min weight: 197 mg Max. weight: 202 mg

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.11%

0.14%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

3 min 19 sec

3 min 14 sec

Equipment ID No.: QA/DTA/002

Done by: S. Jeyaraj (IPQA)

Date: 02/04/2021

Time:

Shift: G

Composite

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	199	8	198	15	199	1	198	8	201	15	198
2	201	9	199	16	200	2	200	9	202	16	199
3	202	10	201	17	201	3	197	10	204	17	201
4	200	11	202	18	202	4	199	11	200	18	202
5	199	12	200	19	200	5	200	12	198	19	203
6	200	13	201	20	201	6	199	13	199	20	202
7	201	14	197			7	200	14	200		

Balance ID No.: QA/BAL/002

M/C Speed: 20 RPM

Group weight of 20 Tablets: 4.003 g. Avg.
wt: 200.15 mg

Group weight of 20 Tablets: 4.002 g. Avg.
wt: 200.1 mg

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Limit: 200.000 mg $\pm$ 5.0 % (190.000 mg – 210.000 mg)

Min weight: 198 mg Max. weight: 202 mg

Min weight: 197 mg Max. weight: 204 mg

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.17%

0.14%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

2 min 40 sec

2 min 27 sec

Equipment ID No.: QA/DTA/002

Done by: S. Jeyaraj (IPQA)

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

MASTER COPY

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 33 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: <u>G1F210317</u> Generic Health Care Pvt. Ltd.

10.21 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by-IPQA
1	30.440	2.200	28.240	vehi	ff	ls
2	40.260	2.200	38.060	vehi	ff	ls
3	25.670	2.200	23.470	vehi	ff	ls
4	30.490	2.200	28.290	vehi	ff	ls
5						
6						
7						
8						
9						
10						

10.22 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: 200...mg

1.0	Standard Batch size	:	120.210 Kg.	6,00,000 No.
2.0	Actual weight of Lubricated granules	:	119.490...Kg	594450 Nos.
3.0	Weight of compressed tablets	:	118.060...Kg	590800 Nos.
4.0	Rejection during Compression @	:	0.260...Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	: 0.210...Kg.	
	B	QC Samples	: 0.030...Kg.	
	C	Validation Samples	: 0.070...Kg.	
6.0	Total in process samples: (A + B + C)	:	0.310...Kg.	
7.0	Total: (3.0 + 6.0)	:	118.370...Kg.	591850 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		98.64 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.260...Kg. (Rejected materials shall be destroyed as per SOP No. QAGN/048)

Done by Production Sign/Date: ff 02/04/2021 Checked by IPQA Sign/Date: ls 02/04/2021

Test request form raised by Prod Sign/Date: ff 02/04/2021

Test request form received by IPQA Sign/Date: ls 02/04/2021

10.23 RELEASE FOR INSPECTION:

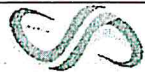
Reconciliation checked and Uncoated tablets released for inspection

IPQA Sign: ls Date: 26/04/21

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L.K</u>	<u>ff</u>	<u>ls</u>	<u>ls</u>
Date	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>	<u>26/10/2020</u>

UNCONTROLLED COPY

UNCONTROLLED COPY



SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Page 34 of 36

BATCH MANUFACTURING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BMR. No.: BMRT/134-00

Batch No.: G1F210317

Customer:

Generic Health Care Pvt. Ltd.

11.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 26/04/2021 / 03:00:21 /

NA

Sr. No.	Checks	*Observation			
		Prod	IPQA	Prod	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR.	NR	NR		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

Note: *Tick mark (✓) if Complies and (X) if does not comply.

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PD1INB/602	PD1MED/602	Inspection-02
Previous product	pregnarene tablets		
Batch No.	113SPL2106F		
Cleaned by	Sety8		
Checked by Production Sign/Date:	N-Bal 26/04/2021		
Verified by IPQA Sign/Date:	S 26/04/2021		

ENVIRONMENTAL CONDITIONS:		Date: 26/04/2021 Time: 06:20			Date: Time:		
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
(Refer to SOP No.: OAGN/011)	Temperature °C Limit: NMT 25 °C	23°C	N.Bal	S			
	Relative Humidity % Limit: NMT 60%	52%	N.Bal	S			

APPROVAL FOR INSPECTION:

Production Sign/Date: N-Bal 26/04/2021
Line Clearance IPQA Sign. / Date: S 26/04/2021
Start Time/Date: 8:00 26/04/2021
End Time/Date: 12:00 26/04/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	POB	Signature	Signature
Date	26/04/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 35 of 36
	BATCH MANUFACTURING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
	Product RAMITHIAZIDE 5/12.5	BMR. No.: BMR/T/134-00 Customer:	Batch No.: GF210317 Generic Health Care Pvt. Ltd.

12.0 INSPECTION PROCESS

12.1 INSTRUCTIONS

S. No.	Process Instructions
1	Carry out visual inspection of tablets on inspection belt area as per the SOP No. PDOP/019.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

12.1 PERFORMANCE CHECKS RECORD FOR METAL DETECTOR:

Sr. No	Process instructions
1.	At the start of the activity, after each break and at the end of operation/shift) as per SOP No. PDGN/022.
2.	Testing frequency: Startup, End of the activity and after every break time.
3.	Acceptance Criteria: 1. Ferrous, Stainless steel & Non-Ferrous shall be detected & rejected. 2. Nonmetallic shall not be detected.

Date & Time	Trial No.	Metal Detector ID No.: PD/MED/.....&PD/MED/..Nf.....				Result	Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.3 mm)	Non-metallic			
21/04/20 8:00 9:00 10:00	1	✓	✓	✓	✓	pass		
	2	✓	✓	✓	✓	pass		
	3	✓	✓	✓	✓	pass		
	1							
	2							
	3							
	1							
	2							
	3							
	1							
	2							
	3							
	1							
	2							
	3							

Note: Put ✓ mark for detection and x mark for non-detection
 If during the test Metal Detector fails to reject any of the Standard chips then mention the corrective action taken.
 (To be filled by Production)
 Note: Take QA Approval before proceeding to next stage

12.2 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
26/10/20	01	04	8:00	10:00	0 - 200	Janaka	26/10/20

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

UNCONTROLLED COPY

UNCONTROLLED COPY



Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
Commune, Puducherry-605009.

Generic Health Care Pvt. Ltd.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	D. D.	[Signature]	[Signature]
Date	26/10/2020	26/10/2020	26/10/2020	26/10/2020

UNCONTROLLED COPY