 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: <u>GF201004</u>
		Customer:	Generic Health Care Pvt. Ltd.


BATCH PACKAGING 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
CODE NO.	: PON/DRUGS/19 13 4323
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/134-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: <u>GF201004 / 31/10/2020</u>
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets
PACKING CONFIGURATION	: 3 x 10 Tablets Sales Pack (Alu Álu Packing)
BPR ISSUED BY/DATE (QA)	: <u>[Signature] 31/10/2020</u>
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <u>L.K. 31/10/2020</u>
MFG. DATE: <u>10/2020</u>	EXP. DATE: <u>09/2023</u>
ALLOTTED BY: QA SIGN/DATE: <u>[Signature] 31/10/2020</u>	COUNTER CHECKED BY: QA SIGN/DATE: <u>[Signature] 31/10/2020</u>
QUANTITY RECEIVED FROM PRODUCTION	: <u>576000</u>
DATE OF COMMENCEMENT: <u>13/11/2020</u>	DATE OF COMPLETION: <u>20/11/2020</u>
QUANTITY	: 6,00,000
RELEASED QUANTITY OF PACKED TABLETS	: <u>5440</u>
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	: <u>[Signature] 21/11/2020</u>
This BPR contains 29 Pages + Additional Pages	

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>31/10/2020</u>	<u>31/10/2020</u>	<u>21/10/2020</u>	<u>21/10/2020</u>

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: GFR201001
		Customer:	Generic Health Care Pvt. Ltd.

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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	APR	in pin	g. Jungs
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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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.

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BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: GTF 2010011

Customer:

Generic Health Care Pvt. Ltd.

2. CHECKLIST FOR BATCH PACKING RECORD REVIEW:

Instruction:

Check the following points before submitting the documents for final Review

Sr. No.	Checklist	Observation (Yes/No/NA/No.)*
1.	No. of pages of BPR+ Additional pages (If any) *	Yes
2.	Line clearance and environmental record	Yes
3.	Processing activity done by and checked by is signed	Yes
4.	Dispensing	
a)	Equipment clean tag and dispensing tag attached with batch record	Yes
b)	Packaging material is checked	Yes
5.	Packing	
a)	Rinse water analysis report attached with BPR	NA
b)	Approved specimen of printed foil, show box and shipper label are attached	Yes
c)	Control / Stability / Finished product analysis samples are withdrawn	Yes
d)	Reconciliation of packing materials is done	Yes
e)	Tablet reconciliation is done	Yes
f)	In process checks parameters done at regular interval and recorded into BPR	Yes
6.	Attachment	
a)	Finished Goods Transfer Note	Yes
b)	Certificate of analysis of finished product is submitted	Yes
c)	Stereo Impression Form and Destruction Record	Yes
7.	Complete set of BPR Submitted	Yes

Checked By QA/Date:

[Signature]

*Mention total number of pages.


Remarks (If any)

NA

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POB	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/10/2020	31/10/2020	21/10/2020	<i>[Signature]</i>

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: <u>GF201001</u>
		Customer:	Generic Health Care Pvt. Ltd.

3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Printed item material code	Specification	UOM	Standard Qty. for Batch Size 6.0 Lac.	% Overages	Qty. Required 6.0 Lac with overages
1	252mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Width – 252 ± 1 mm Thickness – 0.025 mm Language – French Color – 2 Colors GHPL ITEM CODE – 13/0232	Kg	45.000 (To be established)	2	45.900 (To be established)
2	252 mm Alu Alu Base foil	PPF/SP/A019	Width – 252 ± 1 mm Plain non-printed (text matter) aluminum foil.	Kg	150.000 (To be established)	2	153.000 (To be established)
3	3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	Size – 130 x 60 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 3 colour Language – English/French GHPL ITEM CODE – 15/0362	No	20000	2	20400
4	Ramithiazide Printed Leaflet	PPL/SP/R002	Size – 280 x 150 mm (L x H) Specification – NLT 60 gsm Maplitho Paper. Colour – 2 colours Language – French/ English	No	20000	2	20400
5	Shrink Sleeves (PVC)	PPS/SP/P001	Plain PVC Shrink Sleeves	No	2000	2	2040
6	5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 430 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	75	-	75
7	3' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	10	-	10
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	3	-	3
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width – 12 mm Thickness – 0.6 mm	Mtrs	300	-	300
10	Shipper Label	NA	Half A4 size Computer printed label	No	76	-	76

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>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF201004 Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS

Date: 11/11/2020 Time: 14:05

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 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 Mobile Laminar Air Flow is clean	✓	✓
7	Check all the gauges of Mobile Laminar Air flow 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	Mobile Laminar Air Flow	Weighing Balance			Area
ID No.	STLAF1001	STIBAL011	NA	NA	Foil Store
Previous Product	Pregnacare Breastfeeding T34m				
B. No.	PRB 20235				
Cleaned by Sign/Date	Ellapan (11/11/2020)				
Checked by Store Sign/Date	Vijy 11/11/2020				
Verified by IPQA Sign/Date	[Signature] 11/11/2020				

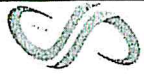
ENVIRONMENTAL CONDITIONS: Date: 11/11/2020 Time: 14:15		Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)				
Temperature (Limit: NMT 25°C)		22°C	by 11/11/2020	11/11/2020
Differential Pressure across the booth Limit: 5 to 20 mm Water		12mm	by 11/11/2020	11/11/2020

APPROVAL FOR DISPENSING BY IPQA: Sign [Signature] Date: 11/11/2020
Dispensing start Time 14:20 End Time 14:45

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	[Signature]	[Signature]	[Signature]
Date	31/10/2020	31/10/2020	21/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G1F201004 Generic Health Care Pvt. Ltd.

5. DISPENSING RECORD OF PACKING MATERIALS: Date: 11/11/2020 Shift: 1 Time: 14:20

Material Name	Item code	UOM	Req. Qty. for 6.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
252mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Kg	45.900 (To be established)	52.20	PMY/00531	03	ky 11/11/2020	11/11/2020
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	153.000 (To be established)	157.00	PMY/00641	07	ky 11/11/2020	11/11/2020
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	20400	20400	PMY/00518	10	ky 11/11/2020	11/11/2020
Ramithiazide Printed Leaflet	PPL/SP/R002	No	20400	20400	PMY/00521	03	ky 11/11/2020	11/11/2020
Shrink Sleeves (PVC)	PPS/SP/P001	No	2040					11/11/2020
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	75	75	PMY/00639	08	ky 11/11/2020	11/11/2020
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	10	10	PMY/00134	03	ky 11/11/2020	11/11/2020
3' Plain BOPP Tape	PUB/SP/B001	No	3	3	PMY/241019/02	01	ky 11/11/2020	11/11/2020
Strapping role.	PPR/SP/S001	Mtrs	300	300	PMY/00001	01	ky 11/11/2020	11/11/2020
Shipper Label	NA	No	76					11/11/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	100	12/11/2020	12/11/2020
Date	3-11-2020	3/11/2020	12/11/2020	12/11/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GR201004</u> Generic Health Care Pvt. Ltd.

6. LINE CLEARANCE CHECKS:

6.1 PRIMARY PACKING:

Date/ Shift 13/11/2020 / 12:00 / PM

Previous Product: <u>Ultravision D2</u>		Batch No.: <u>UD 20245</u>				
Sr. No.	Checks	Time	Observation			
			Packing	IPQA	Packing	IPQA
1.	Area status board is updated for "CLEANED" status.		✓	✓	✓	✓
2.	Check and ensure that the area is visually clean and free from previous product		✓	✓	✓	✓
3.	Check and ensure the differential pressure of the area is within specified limit		✓	✓	✓	✓
4.	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
5.	Check the temperature and relative humidity of the area within specified limit		✓	✓	✓	✓
6.	Check the tablets of the previous product/ batch removed.		✓	✓	✓	✓
7.	Check the loose Alu Alu strip cutting, rejected rolls, empty cores of foil of previous product /batch are removed.		✓	✓	✓	✓
8.	Check the surroundings of the machine and free from the previous products and batch		✓	✓	✓	✓
9.	Check the foil printing stereos, Labels of previous product/batch are removed.		✓	✓	✓	✓
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.		✓	✓	✓	✓
11.	Check and ensure the Cleanliness following change part of Alu Alu strip packing machine		✓	✓	✓	✓
12.	Check for the absence of previous batch/ product at machine conveyor belt.					
a)	Check Hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit.		✓	✓	✓	✓
b)	Check for cleaning of hopper, feeding channel, vibrator plate, in feed roller and sweep brush.		✓	✓	✓	✓
c)	Check tool box, thinner and ink box		✓	✓	✓	✓

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

Cleaning satisfactory/Not-satisfactory
 Checked by Packing (Sign. /Date): Amal 13/11/2020 Cleaning satisfactory/Not-satisfactory
 Verified by IPQA (Sign. /Date): 13/11/2020

#In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, recheck the area / line and record.

6.2 AREA AND EQUIPMENT CLEARANCE OF PRIMARY PACKING

Date/Time: 13/11/2020 / 2:00

Previous Product: <u>Ultravision D2</u>		Batch No.: <u>UD 20245</u>					
S. No.	Equipment / Area Name	Eq.ID. /Area. No.	Cleaning Type A/B	Operation and cleaning as per SOP number	Cleaned by Sign/Date	Checked by (Packing) Sign/Date	Verified by (IPQA) Sign/Date
1.	Alu Alu Packing Area	<u>3211 PAFI 001</u>	<u>B</u>	<u>PDGN/006</u>	<u>Amal</u>	<u>Amal</u>	<u>13/11/2020</u>
2.	Alu Alu Packing Machine	<u>PDOP/020</u>	<u>B</u>	<u>PDOP/020, PDCL/020</u>	<u>Amal</u>	<u>Amal</u>	<u>13/11/2020</u>

6.3 ENVIRONMENTAL CONDITIONS:


(Check the environmental conditions of primary packing area at the start of process and Record in the below in table)

Refer to SOP No.: SOP: QAGN/011	Date: <u>13/11/2020</u> Time: <u>2:00</u>	Date: <u>13/11/2020</u> Time: <u>2:00</u>
Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	<u>23°C</u>	<u>13/11/2020</u>
RH % Limit: NMT 60%	<u>52%</u>	<u>13/11/2020</u>
DP Limit: NLT 10 Pascal	<u>11 Pascal</u>	<u>13/11/2020</u>
Primary Packing Started Date/Time: <u>13/11/2020</u> Completed Date/Time: <u>21:00</u>		

APPROVAL FOR PRIMARY PACKING: IPQA Sign. /Date: 13/11/2020

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L.K.</u>	<u>Amal</u>	<u>Amal</u>	<u>Amal</u>	
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>21/10/2020</u>	<u>21/10/2020</u>	

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF201001 Generic Health Care Pvt. Ltd.

7. VERIFICATION OF DISPENSED PACKING MATERIALS: Date: 13/11/2020 Shift: G1 Time: 8:40...

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
252mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Kg	pmu/00531	03	AS	SP
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	pmu/00641	07	AS	SP
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	pmu/00518	10	AS	SP
Ramithiazide Printed Leaflet	PPL/SP/R002	No	pmu/00521	03	AS	SP
Shrink Sleeves (PVC)	PPS/SP/P001	No				
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	pmu/00639	08	AS	SP
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	pmu/00134	03	AS	SP
3' Plain BOPP Tape	PUB/SP/B001	No	pmu/0016162	01	AS	SP
Strapping role.	PPR/SP/S001	Mtrs	pmu/00001	01	AS	SP
Shipper Label	NA	No				

8. STEREO ISSUANCE AND SETTING RECORD

S. No.	Type of Stereos	No. of Stereos Issued	Issued By (packing) Sign. & Date	Received By (Packing) Sign. & Date	Stereos Setting Done By	Checked By (Packing) Sign. & Date	Verified By QA Sign. & Date
1.	Stereos	6	Mahim 12/11/2020	S. P. 12/11/2020	giva	S. P. 12/11/2020	12/11/2020

9. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift: 13/11/2020 Time: 8:11...
(Check the following before start of packing activity and record the observation.)


S. No.	Check Points	Observation	Done by (Packing)	Verified By (IPQA)
1.	Temperature observed on display (Limit: NMT 25°C)	25°C	AS	SP
2.	Relative Humidity observed on display (Limit: NMT 60%)	52%	AS	SP
3.	Bulk product containers are of the required product/Batch number and is approved by QC	no	no	SP
4.	Status label of machine/ line is for same product	yes	AS	SP
5.	Printed foil/Base rolls are of the required product.	yes	AS	SP
6.	All secondary packing materials are of the required product	yes	AS	SP

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	20mg	AS	SP
2.	Colour of Tablet	Pink color	AS	SP
3.	Quantity (Net Qty.in Kg)	115.200	AS	SP
4.	Number of Containers	05	AS	SP

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	SP	AS	SP
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GF201004</u> Generic Health Care Pvt. Ltd.

11. WEIGHT VERIFICATION RECORD OF RECEIVED SEMI-FINISHED PRODUCT:

Balance I.D. No.: 81/BAL/015

1. Verify the semi-finished Tablets before starting the packing operation.
2. Verify the batch details on the labels affixed over the Containers against the respective BMR and record the details in below table.

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Ramithiazide 5/12.5	GF201004	10/2020	09/2023	11200 Kg Equivalent to 576000 Nos.	From Container No. <u>01</u> To Container No. <u>05</u> Total No. of Containers taken <u>05</u>
Checked by Packing (Sign. /Date): <u>[Signature]</u> 31/11/2020				Verified By IPQA (Sign. /Date): <u>[Signature]</u>	

12. CONTAINER WEIGHT DETAILS:

Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA	Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA
1	26.290	vepal	[Signature]	11			
2	27.120	vepal	[Signature]	12			
3	23.190	vepal	[Signature]	13			
4	23.500	vepal	[Signature]	14			
5	25.500	vepal	[Signature]	15			
6				16			
7				17			
8				18			
9				19			
10				20			

13. CONTAINER CONSUMPTION DETAILS:

S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	8:30	9:30	01	man	11				
2	9:31	10:30	02	man	12				
3	10:31	11:00	03	man	13				
4	13:01	16:50	04	man	14				
5	16:55	20:00	05	man	15				
6					16				
7					17				
8					18				
9					19				
10					20				


Checked By Packing (Sign. /Date): [Signature] 31/11/2020

Verified by IPQA (Sign. /Date): [Signature]

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>31/10/2020</u>	<u>31/10/2020</u>	<u>21/10/2020</u>	<u>[Signature]</u>

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: G1F201004
		Customer:	Generic Health Care Pvt. Ltd.

14. OVERPRINTING OF PRIMARY PACKAGING MATERIALS:

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/19 13 4323	G1F201004 NA	OK
Batch No.:	G1F201004	OK
Mfg. Date:	10/2020	OK
Exp. Date:	09/2023	OK
Item Code: 13/0232	OK	OK
Pack size (3 x 10's)- Carton	NA	NA
Other instructions if any	NA	NA
Initiated by	Agul	NA
Checked by Packing (Sign. & Date)	Agul 12/11/2020	Agul 12/11/2020
Verified by IPQA (Sign. & Date)	P. Subhakar 12/11/2020	P. Subhakar 12/11/2020

15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	12/11/2020	01	Agul	Agul 12/11/2020	P. Subhakar 12/11/2020

16. PACKING INSTRUCTIONS:

- Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
- Issue the stereotypes to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.
- Set and operate Alu Alu Packing Machine as per SOP No. PDOP/020.
- Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.
- Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.
- Perform Leak Test as per Table or during change of Printed foil rolls & plain film rolls and after every start of operation or when machine is stopped due to some break down.
- Attach proof of printed foil from each roll dispensed as and when used on machine.
- Overprinting Details on printed foil shall be checked by Packing and cross-checked by IPQA before starting the operation as per given in the respective Table.
- Affix first overprinted AL. foil, Carton, Shipper and shipper label duly checked by Packing and verified by IPQA.
- Pack 10 tablets per Alu Alu strip.

Time record for packing detail

Sr. No.	Date/Shift	Primary packing		Secondary packing		Checked by (Packing) Sign. & Date
		Started at	Completed at	Started at	Completed at	
01	12/11/2020	8:20	9:00	8:25 NA	21:00 NA	Agul
02	12/11/2020	NA	NA	8:25	19:00	Agul
03	14/11/2020	9:22 NA	NA	9:30	11:00	Agul
04	14/11/2020	NA	NA	12:00	19:00	Agul
05	20/11/2020	NA	NA	9:00	11:00	Agul

17. PACKING/IPQA IN-PROCESS CHECKS FOR PRIMARY PACKING:

In process checks frequency for packing and IPQA. (As per SOP No.: QAGN/024)

Stage	Packing	IPQA
Primary packing/Secondary Packing	At start of the batch, every one hour	At batch start, followed by every two-hour (random time) Minimum two In process checks by IPQA per batch.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Agul	Agul	Agul
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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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.

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BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BPR. No.: BPRT/134-00

Batch No.: GF201004

Customer:

Generic Health Care Pvt. Ltd.

18. ALU ALU PACKING MACHINE PARAMETERS:

Date/Shift: 13/11/2020 Time: 8:30..

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	BM 4510	OK	13/11/2020	13/11/2020
Sealing Temperature	(160 °C - 200°C) To be established	190°C	13/11/2020	13/11/2020
Leak test to be performed on 04 Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	OK	13/11/2020	13/11/2020
Machine Speed	To be established	30	13/11/2020	13/11/2020

19. CHALLENGE TEST FOR NON FILLING DETECTION SYSTEM :

Sr. No	Process instructions										
1.	Testing frequency: Startup, End of the activity and after every break										
2.	Acceptance Criteria: Broken Tablet, Empty Packet, Black Particle, Colour variation, Foreign Matter, Dual Tablets / Capsules and all defects should be detected & rejected.										
Date & Time	S. No.	Broken Tablet	Empty Packet	Black Particle	Colour variation	Foreign Matter	Dual Tablets / Capsules	Result	Done By	Checked by Packing	Verified By IPQA
13/11/2020 16:00	1	x	x	x	x	x	x	OK	Lokesh	Am	B
	2	x	x	x	x	x	x	OK	Lokesh	Am	B
	3	x	x	x	x	x	x	OK	Lokesh	Am	B
	4	x	x	x	x	x	x	OK	Lokesh	Am	B
	5										
	6										
	7										
	8										
	9										
	10										
	11										
	12										
	13										
	14										
	15										
	16										
	17										
	18										
	19										
	20										

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


7 A

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Am	Am	Am
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GTF201004</u> Generic Health Care Pvt. Ltd.

20. MACHINE IN-PROCESS CONTROL:

Date/ Shift	13/11/2020 / U1																
Machine Operator Name	Anand																
Time of inspection	8:35	8:50	9:10	9:30	9:50	10:10	10:30	10:50	11:10	11:30	11:50	12:10	12:30	12:50	13:10	13:30	13:50
Sealing Temperature (To be established)	185°C	184°C	185°C	185°C	185°C	185°C	185°C	185°C	185°C	185°C	185°C	185°C	185°C	185°C	185°C	185°C	185°C
Leak test on Alu Alu Strips* (Qty.: 04)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Knurling /Sealing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Code No.:	PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.:	GTF201004	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	10/2020	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	09/2023	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed (To be established)	29	28	27	29	29	29	29	28	28	27	27	25	27	27	27	26	26
Checked by (Packing)	AK	AK	AK	AK	AK	AK	AK	AK	AK	AK	AK	AK	AK	AK	AK	AK	AK
Checked by (IPQA)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	[Signature]	[Signature]	[Signature]
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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Product Code: R09

Batch Size: 6,00,000 Tablets

RAMITHIAZIDE 5/12.5

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

Batch No.: GTF201004




Customer:

Generic Health Care Pvt. Ltd.


20.1 MACHINE IN-PROCESS CONTROL:

[illegible]

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF201004 Generic Health Care Pvt. Ltd.


20.2 MACHINE IN-PROCESS CONTROL:

Date/ Shift																			
Machine Operator Name																			
Time of inspection																			
Sealing Temperature (To be established)																			
Leak test on Alu Alu Strips* (Qty.: _____)																			
Knurling /Sealing																			
Pocket Formation																			
Horizontal cutting																			
Vertical cutting																			
Quality of Over printing																			
Code No.:	PON/DRUGS/ 19 13 4323																		
B. No.:																			
Mfg. Date																			
Exp. Date																			
Machine Speed (To be established)																			
Checked by (Packing)																			
Checked by (IPQA)																			

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	POB	21/10/2020	21/10/2020
Date	31/10/2020	31/10/2020	21/10/2020	21/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G1F 201001 Generic Health Care Pvt. Ltd.

21. DEFOILING OF ALU ALU STRIPS:


Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	De-foiling Done by	Checked by/ Date (Packing)	Verified by Date (QA)
13/11/20	19:20	19:30	0.350	neel. Jeeva	Am 13/11/20	P 13/11/20
Total Weight of De-foiled Tablets			0.350	Checked By / Date (Packing): Am 23/11/20	Verified By / Date (IPQA): P 13/11/20	

21.1 INSPECTION OF DE-FOILED TABLETS:

Date	Inspection started at	Inspection completed at	Inspection Done by	Quantity of Good tablets		Qty. of Rejected Tablets		Checked by/ Date (Packing)	Verified by Date (QA)
				Kgs	Nos	Kgs	Nos		
13/11/2020	19:35	19:50	neel	0.300	1500	0.050	250	Am 13/11/20	P 13/11/20
Total									
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing): Am 23/11/20			Verified By / Date (IPQA): P 13/11/20		
0.050 Kgs ... 250 Nos.									

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	Am	Am	Am
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GR201004 Generic Health Care Pvt. Ltd.

22. LINE CLEARANCE CHECKS – BATCH CODING:

Date/ Shift 16/11/2020 / N / M

Previous Product: <i>pragmate B/F</i>		Batch No.: <i>PRB 2021</i>				
Sr. No.	Checks	Time	Observation			
			<i>1) Line</i> Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		<i>✓</i>	<i>✓</i>		
2	Check and ensure that waste bin is emptied out and cleaned		<i>✓</i>	<i>✓</i>		
3	Check the Pallets and crates area clean and free from any leftovers of previous product /Batch.		<i>✓</i>	<i>✓</i>		
4	Check and ensure the Correct status board is written.		<i>✓</i>	<i>✓</i>		
5	Check and ensure the previous batch details are deleted from the inkjet machine.		<i>✓</i>	<i>✓</i>		
6	Check and ensure the rejected Cartons of previous product/batch are removed.		<i>✓</i>	<i>✓</i>		
7	Check and ensure the cleanliness of hatch for conveyor belt.		<i>✓</i>	<i>✓</i>		
8	Check and ensure the cleanliness of conveyer belt with collateral block.		<i>✓</i>	<i>✓</i>		
9	Check and ensure the dispensed secondary packing material.		<i>✓</i>	<i>✓</i>		
10	Check and ensure the Preventive maintenance records and log book.		<i>✓</i>	<i>✓</i>		

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

Cleaning Satisfactory / Not-satisfactory#
(Packing) Sign. /Date: *[Signature]* 16/11/2020

Cleaning Satisfactory / Not-satisfactory#
(IPQA) Sign. /Date: *[Signature]* 16/11/2020

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.


22.1 AREA AND EQUIPMENT CLEARANCE FOR CODING:

1. Check and ensure that the over printing area and machine is cleared from previous products.
2. Transfer uncoded printed Carton to Overprinting area.
3. Set and operate Overprinting Machine.
4. Overprinting shall be in indelible ink.
5. Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Equipment	Inkjet Machine	Conveyor	Area
ID. No.:	<i>PD/INF/202</i>	<i>PD/INF/002</i>	Batch Coding
Previous Product:	<i>pragame core B/F</i>		
Batch No.:	<i>PRB 2021S</i>		
Cleaned by:	<i>[Signature]</i>		
Checked by Packing:	<i>[Signature]</i> 16/11/2020		
Verified by IPQA:	<i>[Signature]</i> 16/11/2020		

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	<i>31/10/2020</i>	<i>31/10/2020</i>	<i>31/10/2020</i>	<i>31/10/2020</i>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GF 201004</u> Generic Health Care Pvt. Ltd.

22.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.:	<u>GF 201004</u>	<u>OK</u>
Mfg. Date:	<u>10/2020</u>	<u>OK</u>
Exp. Date:	<u>09/2023</u>	<u>OK</u>
Item Code: 15/0362	<u>15/0362</u>	<u>OK</u>
Code No.: PON/DRUGS/19 13 4323	<u>PON/DRUGS/19 13 4323</u>	<u>OK</u>
Other instructions if any	<u>NA</u>	<u>NA</u>
Initiated by Sign. & Date	<u>Itanasi 16/11/2020</u>	<u>OK</u>
Checked by Packing Sign. & Date	<u>S.B. 16/11/2020</u>	<u>S.B. 16/11/2020</u>
Verified by IPQA Sign. & Date	<u>[Signature] 16/11/2020</u>	<u>[Signature] 16/11/2020</u>

22.3 TIME RECORD FOR BATCH CODING:

Sr. No.	Date/Shift	Batch Coding Done By	Batch Coding		Checked by (Packing) Sign. & Date	Verified by (IPQA) Sign. & Date
			Started at	Completed at		
1	<u>16/11/2020</u>	<u>Ponni</u>	<u>11:30</u>	<u>14:40</u>	<u>[Signature]</u>	<u>[Signature] 16/11/2020</u>


22.4 CARTON OVERPRINTING SPECIMEN:

S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
<u>01</u>	<u>16/11/2020</u>	<u>01</u>	<u>[Signature]</u>	<u>[Signature] 16/11/2020</u>

Note – Attach specimen copy of over printed carton

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>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GF201004</u> Generic Health Care Pvt. Ltd.

23. **LINE CLEARANCE CHECKS - SECONDARY PACKING:** *13/11/2020*
 Date/ Shift 13/11/2020 / 13/11/2020

Previous Product: Ultra vitamin?		Batch No.: VD20848				
Sr. No.	Checks	Time	Observation			
			08:40	NA	09:29	NA
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	
4	Check and ensure the Correct status board is written.		✓	✓	✓	
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓	✓	
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	✓	
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓	✓	
9	Check and ensure the dispensed secondary packing material.		✓	✓	✓	
10	Check and ensure the cleanliness of documentation table.		✓	✓	✓	
11	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	

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

Cleaning Satisfactory / Not satisfactory#
 (Packing) Sign. /Date:

Cleaning Satisfactory / Not satisfactory#
 (IPQA) Sign. /Date:

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.


Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	<u>PD/0031</u>	<u>PD/0041</u>	<u>NA</u>	<u>PD/STP/001</u>	<u>PD/BDL/029</u>	Secondary Packing Hall
Previous Product:	<u>Ultra vitamin D3</u>					
Batch No.:	<u>VD 20848</u>					
Cleaned by:	<u>Sothyen</u>					
Checked by Packing:	<u>13/11/2020</u>					
Verified by IPQA:	<u>13/11/2020</u>					

for
Amey
13/11/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>POB</u>	<u>Amey</u>	<u>S. Jeyaraj</u>
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 19 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G1F201004 Generic Health Care Pvt. Ltd.

23.1 ENVIRONMENTAL CONDITIONS:

(Check the environmental conditions of Secondary packing area at the start of process and Record in the below in table)

Shift:.....	Date/Time: 16/11/2020 / 8:40			Date/Time: 17/11/2020 / 09:29		
	Observation	Checked by Packing	Verified by IPQA	Observation	Checked by Packing	Verified by IPQA
Refer to SOP No.: SOP: QAGN/011	Temperature °C Limit: NMT 25°C	23°C	Amg	23°C	Amg	Amg
Secondary Packing Started Date/Time: 16/11/2020 / 8:35 Completed Date/Time: 17/11/2020 / 09:29						
APPROVAL FOR SECONDARY PACKING: Approved by IPQA Sing/Date: 16/11/2020 / 11:00						

23.2 PACKING DETAILS:

10 Tablets in each Alu Alu strip, over code the Alu Alu strip with the batch details given below,

Place 3 x 10's Alu Alu strip and one leaflet in each carton.

Place 10 filled carton in a Shrink Sleeve.

Place 27 Shrink sleeves in each 5 ply shipper.

Seal the shipper with BOPP tape with "H" type.

24. OVER PRINTING DETAILS:

Overprinting Details (Secondary & Tertiary PM)

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)	5 Ply Shipper Label (OK/ Not OK)
Batch No.:	G1F201004	OK	OK
Mfg. Date:	10/2020	OK	OK
Exp. Date:	09/2023	OK	OK
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19/13 4323	OK	NA
Pack size:	NA	3 x 10's	27 x 10 x 3 x 10's
Other instructions if any	NA	NA	NA
Initiated by Sign. & Date	Mani/Amg	Amg	Amg
Checked by Packing Sign. & Date	Amg 16/11/2020	Amg 16/11/2020	Amg 16/11/2020
Verified by IPQA Sign. & Date	Amg 16/11/2020	Amg 16/11/2020	Amg 16/11/2020

24.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	16/11/2020	01	Amg 16/11/2020	Amg 16/11/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Amg	Amg	Amg
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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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.

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BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: GF201004

Customer:

Generic Health Care Pvt. Ltd.

25. INDIVIDUAL STRIP WEIGHING LIMIT:

Weight of ten individual Empty Alu Alu strips are given below:

1. 1.7	3. 1.6	5. 1.7	7. 1.7	9. 1.7
2. 1.7	4. 1.7	6. 1.6	8. 1.7	10. 1.7

Total weight of ten Empty Alu Alu strips = 16.8

Avg. Weight of a Empty Alu Alu strip (A): total weight of ten Empty Alu Alu strip/10 = 1.68

Weight of ten individual Filled Alu Alu strips are given below:

1. 7.4	3. 7.4	5. 7.52	7. 7.40	9. 7.47
2. 7.4	4. 7.4	6. 7.41	8. 7.46	10. 7.40

Total weight of ten Filled Alu Alu strips = 74.23

Avg. Weight of a Filled Alu Alu strip (B): total weight of ten Filled Alu Alu strip/10 = 7.42

Limit (C) =

(Each missing tablet should be identified)

Strip weighing Done By: <i>hamalun</i>	Checked By: <i>hamalun</i>	Verified By: <i>hamalun</i>
--	----------------------------	-----------------------------

25.1 CARTON WEIGHT LIMIT SETTING: Date/Shift: 11/11/2020 Time: 8:32...

Weight of ten individual empty cartons are given below:

1. 8.9	3. 8.8	5. 8.7	7. 8.9	9. 8.8
2. 8.9	4. 8.8	6. 8.9	8. 8.8	10. 8.9

Total weight of ten empty cartons = 88.4

Average weight of an empty carton (D) = Total weight of ten empty carton /10 = 8.84

Weight of ten individual Leaflets are given below:

1. 2.4	3. 2.3	5. 2.4	7. 2.4	9. 2.5
2. 2.3	4. 2.4	6. 2.4	8. 2.3	10. 2.4

Total weight of ten Leaflets = 23.8

Avg. Weight of a Leaflet (E): total weight of ten Leaflets/10 = 2.38

25.2 WEIGHT CHECKS ON CARTON:


Weight of ten empty Carton: 88.4	Average weight of one empty Carton (D): 8.84
Weight of ten filled Alu Alu strip: 74.23	Average weight of one filled Alu Alu strip (B): 7.42
Weight of ten Leaflets: 23.8	Average weight of one Leaflet (E): 2.38
Weight of one filled Carton F = (D+3B+E) 21.48	Limit: G = F ± 1 % = (To be established) 21.26 — 21.69
Checked by Packing/Date: <i>hamalun</i>	Verified by IPQA/Date: <i>hamalun</i>

25.3 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7 x 10 ⁵	<i>hamalun</i>
2	Control Sample (Middle)	6 x 10 ⁵	<i>hamalun</i>
3	Control Sample (Final)	4 x 10 ⁵	<i>hamalun</i>
4	Stability Sample	3 x 10 ⁵	<i>hamalun</i>
5	Other Sample	— NA —	— NA —
6	Analytical sample	12 x 10 ⁵	<i>hamalun</i>
Total Qty.		62 x 10 ⁵	<i>hamalun</i>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>hamalun</i>	<i>hamalun</i>	<i>hamalun</i>
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00 Batch No.: G F 201004 Customer: Generic Health Care Pvt. Ltd.

26. SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift		16/11/2020														17/11/2020
Parameters	Specification	observation														
		Packing							IPQA							
Time		8.35	9.30	10.30	11.30	12.30	13.30	14.30	15.35	16.10	17.35	18.40	19.50			20.30
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			OK
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			OK
No. of cartons in a shrink sleeves	10 packed cartons	OK	OK	OK	OK	OK	OK	OK								OK
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA								NA
No. of shrink sleeves in a 5 ply shipper	27 shrinks	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			OK
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			OK
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			OK
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			OK
Checked by																

*Temperature to be mentioned.


26.1 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift		17/11/2020														
Parameters	Specification	observation														
		Packing							IPQA							
Time		15.30	16.30	17.30	18.30	19.05	20.00	21.00	22.00	23.00	24.00	25.00	26.00	27.00	28.00	
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
No. of cartons in a shrink sleeves	10 packed cartons	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
No. of shrink sleeves in a 5 ply shipper	27 shrinks	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Checked by																

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/10/2020	31/10/2020	31/10/2020	

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GF201004</u> Generic Health Care Pvt. Ltd.

26.2 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	Specification	observation											
Parameters	Specification	Packing						IPQA					
		19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020
Time		12:30	13:30	14:30	15:30	16:30	17:30	18:30	19:30	20:30	21:30	22:30	23:30
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
No. of cartons in a shrink sleeves	10 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
No. of shrink sleeves in a 5 ply shipper	27 shrinks	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Checked by		J	J	J	J	J	J	J	J	J	J	J	J

*Temperature to be mentioned.

26.3 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")


Date/ Shift	Specification	observation											
Parameters	Specification	Packing						IPQA					
		19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020	19/11/2020
Time		9:30	10:30	11:30	12:30	13:30	14:30	15:30	16:30	17:30	18:30	19:30	20:30
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
No. of cartons in a shrink sleeves	10 packed cartons	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
No. of shrink sleeves in a 5 ply shipper	27 shrinks	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Checked by		J	J	J	J	J	J	J	J	J	J	J	J

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	J	J	J
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00 Batch No.: G1F201004 Customer: Generic Health Care Pvt. Ltd.

27. SHIPPERS WEIGHING: Date/Shift: 15/11/2020 / 1 Time: 9.30 AM Balance I.D. No.: 101/1000

Weight of ten Shrinks: 22.9			Average weight of one filled Shrink (H): 22.9		
Weight of ten empty shippers: 11.95			Average weight of one empty shipper (I): 1.195		
Weight of one filled shipper (J) = (27H+I): 8.030			Limit: K = J ± 1% = 7.950 - 8.150 (to be established)		
Checked by Packing/Date: [Signature] 10/11/2020			Verified by IPQA/Date: [Signature] 10/11/2020		
Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By
1	8.100	Priya	20	8.125	Priya
2	8.115	Priya	21	8.120	Priya
3	8.105	Priya	22	8.130	Priya
4	8.105	Priya	23	8.130	Priya
5	8.100	Priya	24	8.175	Priya
6	8.090	Priya	25	8.140	Priya
7	8.090	Priya	26	8.140	Priya
8	8.085	Priya	27	8.150	Priya
9	8.100	Priya	28	8.150	Priya
10	8.100	Priya	29	8.135	Priya
11	8.105	Priya	30	8.140	Priya
12	8.100	Priya	31	8.160	Priya
13	8.085	Priya	32	8.160	Priya
14	8.065	Priya	33	8.130	Priya
15	8.065	Priya	34	8.150	Priya
16	8.080	Priya	35	8.140	Priya
17	8.135	Priya	36	8.145	Priya
18	8.125	Priya	37	8.135	Priya
19	8.145	Priya	38	8.140	Priya
Total No. of shippers weighed: 59		De-foiled tablets packed in Shipper No: 89		Checked by Sign / Date: [Signature] 10/11/2020	
				Verified by Sign / Date: [Signature] 10/11/2020	
Loose pack details: Shipper No: 59 Quantity: 200 x 3 x 10's Weight: 7.895					

Note - If any shipper weight found out of limit, the same shall be checked physically by opening the shipper.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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

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BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: GTF201001

Customer:

Generic Health Care Pvt. Ltd.

28. MAN POWER ALLOCATION:

DATE: 16/11/2020	
SHIFT: 5	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Lakshmi
Printing Checking in Alu Alu strip	mahashwari
Alu Alu strip weighing	Lakshmi
Insertion of Alu Alu strip and leaflet into carton	Bhanu
Cartons weighing	Varsha
Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Natya
Shipper Weighing	Mishra
Shipper Strapping	Dhanalakshmi
Shipper packed	From 01 to 50/19
Signature of Packing	Arj

DATE: 17/11/2020	
SHIFT: 5	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Bhanu, Geetha
Printing Checking in Alu Alu strip	Lakshmi
Alu Alu strip weighing	malagushwari
Insertion of Alu Alu strip into carton	Bhanu
Cartons weighing	Varsha
Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Balraj
Shipper Weighing	Lakshmi
Shipper Strapping	
Shipper packed	From 24 to 39
Signature of Packing	Arj


DATE: 29/11/2020	
SHIFT: 5	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Sunaga, Saranya
Printing Checking in Alu Alu strip	Saranya
Insertion of Alu Alu strip and leaflet into carton	P. Sathya, Kalpana
Alu Alu strip weighing	Lakshmi, magushwari
Cartons weighing	Natya
Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	NA
Shipper Weighing	Natya, Varsha
Shipper Strapping	NA
Shipper packed	From 40 to 50
Signature of Packing	Arj

DATE: 20/11/2020	
SHIFT: 5	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Bhanu
Printing Checking in Alu Alu strip	Lakshmi
Insertion of Alu Alu strip into carton	magushwari
Alu Alu strip weighing	magushwari
Cartons weighing	Varsha
Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Natya
Shipper Weighing	Dhanalakshmi
Shipper Strapping	Dhanalakshmi
Shipper packed	From 51 to 59
Signature of Packing	Arj

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	Arj	Arj	Arj
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF201009 Generic Health Care Pvt. Ltd.

29. **PRODUCT COUNTER CHECK LINE CLEARANCE:**
 Date/ Shift: 21/10/2020 / m

Previous Product:		Batch No.:				
Ramithiazide 10/12.5		GF201009				
Sr. No.	Checks	Time	Observation			
			09:10			
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓		
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓		
4	Check and ensure the Correct status board is written.		✓	✓		
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓		
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓		
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	✓	
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓		
9	Check and ensure the dispensed secondary packing material.		✓	✓		
10	Check and ensure the cleanliness of documentation table.		✓	✓		
11	Check and ensure the Preventive maintenance records and log book.		✓	✓		

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

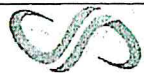
Cleaning Satisfactory / Not satisfactory#
 (Packing) Sign./Date: [Signature] 21/10/2020
 Cleaning Satisfactory / Not satisfactory#
 (IPQA) Sign./Date: [Signature] 21/10/2020

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	PD/COB/1002	PD/BAL/013	MA	PD/STA/001	PD/BAL/029	Packing
Previous Product:	Ramithiazide 10/12.5					
Batch No.:	GF201009					
Cleaned by:	Sivamani					
Checked by Packing:	[Signature] 21/10/2020					
Verified by IPQA:	[Signature] 21/10/2020					
Rechecking Started Date/Time:	09:15					
Completed Date/Time:	18:30					
APPROVAL FOR COUNTER CHECK:			Approved by IPQA Sing/Date: [Signature] 21/10/2020			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	31/10/2020	31/10/2020	21/10/2020	21/10/2020

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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.

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BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: GR201004

Customer:

Generic Health Care Pvt. Ltd.

27.1 COUNTER CHECK OF PACKED SHIPPERS :

DATE: 21/11/2020	
SHIFT: N	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Bhama Jayalalini
Printing Checking in Alu Alu strip	Indira
Alu Alu strip weighing	Lakshmi. magudum
Checking of Alu Alu strip and leaflet in carton	Surya. va
Cartons weighing	Vargha,
Printing Checking in Shipper Label	neetha
Shipper Weighing	Ureema
Shipper Strapping	Dhanalakshmi
Shipper Checked	From 01 to 59
Checked By Packing	21/11/2020
Verified By IPQA	

DATE:	
SHIFT:	
ACTIVITIES	DONE BY
Alu Alu strip Checking	
Printing Checking in Alu Alu strip	
Alu Alu strip weighing	
Checking of Alu Alu strip and leaflet in carton	
Cartons weighing	ma
Printing Checking in Shipper Label	
Shipper Weighing	
Shipper Strapping	
Shipper Checked	From..... to.....
Checked By Packing	
Verified By IPQA	

DATE:	
SHIFT:	
ACTIVITIES	DONE BY
Alu Alu strip Checking	
Printing Checking in Alu Alu strip	
Alu Alu strip weighing	
Checking of Alu Alu strip and leaflet in carton	
Cartons weighing	ma
Printing Checking in Shipper Label	
Shipper Weighing	
Shipper Strapping	
Shipper Checked	From..... to.....
Checked By Packing	
Verified By IPQA	

DATE:	
SHIFT:	
ACTIVITIES	DONE BY
Alu Alu strip Checking	
Printing Checking in Alu Alu strip	
Alu Alu strip weighing	
Checking of Alu Alu strip and leaflet in carton	
Cartons weighing	ma
Printing Checking in Shipper Label	
Shipper Weighing	
Shipper Strapping	
Shipper Checked	From..... to.....
Checked By Packing	
Verified By IPQA	

No. of Defects Identified:


1. Minor: NIL
2. Major: NA
3. Critical: NA

Batch Allowed for Despatch: Checked By: NIL

Verified By: NA

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	JCP	JCP	JCP
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GIF 201003</u> Generic Health Care Pvt. Ltd.

30. PACKING MATERIAL RECONCILIATION:

Sr. No.	Material	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
A	Quantity received for the batch	52.200	157.00	20400	20400		75	300 (mtr)	03
B	Additional material received for the batch	NA	NA	NA	NA		NA	NA	NA
C	Total material received (A+B)	52.200	157.000	20400	20400		75	300 (mtr)	03
D	Quantity packed	21.240	98.450	17948	17948		59	150 (mtr)	03
E	Quantity rejected (Online) & Destroyed	8.520	7.215	340	NA		NA	NA	NA
F	Quantity Returned	22.040	51.050	2100	2440		16	150 (mtr)	NA
G	Sample affixed on BPR	0.0002	NA	01	01		NA	NA	NA
H	QC samples	0.003	0.030	NA	NA		NA	NA	NA
I	Other samples (If any)	0.009	0.091	11	11		NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	51.912	56.866	20400	20400		75	300 (mtr)	03
K	Variation (C - J)	0.287	0.134	-0-	-0-		-0-	NA -0-	-0-
L	%Variation (K x 100)/C	0.55%	0.08%	-0-	-0-		-0-	-0-	-0-
M	Acceptable limit	± 2%	± 2%	± 2%	± 2%	± 2%			

If % Variation is out of the acceptable limit, investigate & specify the reason:

31. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. NA

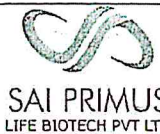
Material	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
Quantity Returned	22.040	51.050	2100	2440	NA	16	150	NA
Material returned by packing Sign./Date	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Verified By IPQA Sign./Date	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Material received by Store Sign./Date	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>

32. DESTRUCTION OF REJECTED/UNUSED PRINTED PACKING MATERIALS AND STEREOS:

Date	Stereos	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
21/11/2020	06	8.520	7.215	340	NA	NA	NA	NA	NA
Total Qty. Destroyed	06	8.520	7.215	340	NA	NA	NA	NA	NA
Destroyed by (Packing)	<u>[Signature]</u>								
Verified by (IPQA)	<u>[Signature]</u>								

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	31/10/2020	31/10/2020	31/10/2020	<u>[Signature]</u>	

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF201004 Generic Health Care Pvt. Ltd.

33. BATCH RECONCILIATION:

A	Batch Size	6,00,000 Nos.
B	Quantity received for packing	576000
C	Total quantity packed	538440
D	Control samples	200
E	Analytical Samples	120
F	In process samples	760
G	Others samples if any (Stability, Regulatory Samples, etc.)	NA
H	Packing Loss = B - (C + D + E + F + G)	3680
I	Total Loss = A - (C + D + E + F + G)	60480
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit %.....)*	93.66%
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %.....)*	89.72%

*To be established

Checked by Packing /Date:

[Signature]
21/11/2020

Verified by IPQA/Date:

[Signature]
21/11/2020

34. TRANSFER OF FINISHED GOODS:

Date	FGTN No.	Sales	Pack Size	No. of Units in a shipper	No. of Shippers	Transferred Quantity	FGTN Raised by Packing	FGTN Checked by IPQA	FGTN Received by Stores
21/11/2020	0989	sale.	3x105	306x3x105	59	53244	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
				200x3x105	01	600	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Total Qty. Transferred						53844	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>

35. DEVIATION/ EXCEPTION DETAILS:

During process if there is any Deviation / Exception are observed then record in below table

Deviation / Exception details

Sr. No.	Stage	Deviation / Exception details	Action taken	Observed By
1				

Checked by
Packing:

Verified by
Packing manager:

Approved by
Head QA:


36. BPR REVIEW DETAILS:

Reviewed by	Name	Sign. /Date
Packing Executive	Senthil Kumar P	<i>[Signature]</i> 21/11/2020
QA Executive	Ram Kumar	<i>[Signature]</i> 21/11/2020
Production Assistant Manager/ HOD	BALASUBRAMANIAN.B	<i>[Signature]</i> 21/11/2020
QA Manager/ HOD	BALAMURUGAN.R.S.	<i>[Signature]</i> 21/11/2020

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	21/10/2020	21/10/2020	21/10/2020	21/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GF 201004</u> Generic Health Care Pvt. Ltd.

37. BATCH RELEASED FOR DESPATCH:

Total quantity released: 528440 No's

Head QA sign/ Date: J. Anand 21/11/2020


38. REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/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>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>21/11/2020</u>	<u>21/11/2020</u>

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 1 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GF 201207</u> Generic Health Care Pvt. Ltd.

BATCH PACKAGING 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
CODE NO.	: PON/DRUGS/19 13 4323
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/134-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: <u>GF 201004 / 31/10/2020</u>
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets
PACKING CONFIGURATION	: 3 x 10 Tablets Sales Pack (Alu Alu Packing)
BPR ISSUED BY/DATE (QA)	: <u>[Signature] 24/12/2020</u>
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <u>[Signature] 24/12/2020</u>
MFG. DATE: <u>12/12/2020</u>	EXP. DATE: <u>11/2023</u>
ALLOTTED BY: QA SIGN/DATE: <u>[Signature] 24/12/2020</u>	COUNTER CHECKED BY: QA SIGN/DATE: <u>[Signature] 24/12/2020</u>
QUANTITY RECEIVED FROM PRODUCTION	: 597050 Tablets
DATE OF COMMENCEMENT: <u>24/12/2020</u>	DATE OF COMPLETION: <u>25/12/2020</u>
QUANTITY	: 6,00,000 tablets
RELEASED QUANTITY OF PACKED TABLETS	: 596700 tablets
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	<u>[Signature] 24/12/2020</u>
This BPR contains 29 Pages + Additional Pages	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>21/10/2020</u>	<u>24/12/2020</u>

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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 29

BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: 57F201867

Customer:


Generic Health Care Pvt. Ltd.

I. INDEX

Sr. No.	Content	Page No.
	Batch Packaging cover sheet	1
1	Index	2
2	Check list for batch packing record review	3
3	Packing Material Specification and Indent	4
4	Dispensing line clearance	5
5	Dispensing record of packing materials	6
6	Line clearance for primary packing	7
7	Verification of dispensed packing material	8
8	Stereo Issuance and setting Record, Receipt of product and materials, Detail of the product as per BMR	8
9	Weight verification record of received semi-finished product	9
10	Container weight details, Container consumption details	9
11	Over printing of primary packing, Specimen of printed foil	10
12	Packing instruction, specimen of printed foil, time record for packing detail, Packing In-process checks for primary packing	10
13	Alu Alu packing machine parameters	11
14	Challenge test for Non Filling Detection System	11
15	Machine In-Process control	12-14
16	Defoiling of Alu Alu strips, Inspection of defoiled Tablets	15
17	Line Clearance for Batch Coding, Area and equipment clearance for coding, Overprinting Details, Time record for batch coding, Carton overprinting specimen	16-17
18	Line clearance for secondary packing, Environmental condition, Packing Details	18-19
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22	Shipper Weighing	23
23	Man power allocation	24
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29	Transfer of finished goods	28
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31	BPR review details	28
32	Batch released for Despatch	29
33	Revision History	29

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: G F 201207
		Customer:	Generic Health Care Pvt. Ltd.

2. CHECKLIST FOR BATCH PACKING RECORD REVIEW:

Instruction:

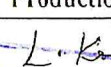

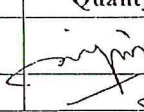
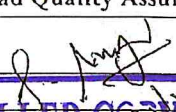
Check the following points before submitting the documents for final Review

Sr. No.	Checklist	Observation (Yes/No/NA/No.*)
1.	No. of pages of BPR+ Additional pages (If any) *	no
2.	Line clearance and environmental record	yes
3.	Processing activity done by and checked by is signed	yes
4.	Dispensing	
a)	Equipment clean tag and dispensing tag attached with batch record	yes
b)	Packaging material is checked	yes
5.	Packing	
a)	Rinse water analysis report attached with BPR	-
b)	Approved specimen of printed foil, show box and shipper label are attached	yes
c)	Control / Stability / Finished product analysis samples are withdrawn	yes
d)	Reconciliation of packing materials is done	yes
e)	Tablet reconciliation is done	yes
f)	In process checks parameters done at regular interval and recorded into BPR	yes
6.	Attachment	
a)	Finished Goods Transfer Note	yes
b)	Certificate of analysis of finished product is submitted	-
c)	Stereo Impression Form and Destruction Record	yes
7.	Complete set of BPR Submitted	yes

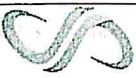
Checked By QA/Date: 

*Mention total number of pages.

Remarks (If any)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign				
Date	31/10/2020	29/10/2020	29/10/2020	

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
	Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Batch No.: G1 F801207 Customer: Generic Health Care Pvt. Ltd.

3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Printed item material code	Specification	UOM	Standard Qty. for Batch Size 6.0 Lac.	% Overages	Qty. Required 6.0 Lac with overages
1	252mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Width – 252 ± 1 mm Thickness – 0.025 mm Language – French Color – 2 Colors GHPL ITEM CODE – 13/0232	Kg	45.000 (To be established)	2	45.900 (To be established)
2	252 mm Alu Alu Base foil	PPF/SP/A019	Width – 252 ± 1 mm Plain non-printed (text matter) aluminum foil.	Kg	150.000 (To be established)	2	153.000 (To be established)
3	3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	Size – 130 x 60 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 3 colour Language – English/French GHPL ITEM CODE – 15/0362	No	20000	2	20400
4	Ramithiazide Printed Leaflet	PPL/SP/R002	Size – 280 x 150 mm (L x H) Specification – NLT 60 gsm Maplitho Paper. Colour – 2 colours Language – French/ English	No	20000	2	20400
5	Shrink Sleeves (PVC)	PPS/SP/P001	Plain PVC Shrink Sleeves	No	2000	2	2040
6	5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 430 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	75	-	75
7	3' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	10	-	10
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	3	-	3
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width – 12 mm Thickness – 0.6 mm	Mtrs	300	-	300
10	Shipper Label	NA	Half A4 size Computer printed label	No	76	-	76

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke			
Date	31/10/2020	31/10/2020	31/10/2020	

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>G7F201207</u> Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS

Date: 25/10/2020 Time: 15:35

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 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 Mobile Laminar Air Flow is clean	/	/
7	Check all the gauges of Mobile Laminar Air flow 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	Mobile Laminar Air Flow	Weighing Balance			Area
ID No.	<u>ST/LAF/001</u>	<u>ST/001/011</u>	<u>NA</u>	<u>NA</u>	<u>Fall Store</u>
Previous Product	<u>79/028-12</u>				
B. No.	<u>7110002 L</u>				
Cleaned by Sign/Date	<u>Elilalam / 25/10/2020</u>				
Checked by Store Sign/Date	<u>000 / 25/10/2020</u>				
Verified by IPQA Sign/Date	<u>25/10/2020</u>				

ENVIRONMENTAL CONDITIONS: Date: <u>25/10/2020</u> Time: <u>15:48</u>	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	<u>23°C</u>	<u>25/10/2020</u>	<u>25/10/2020</u>
Differential Pressure across the booth Limit: 5 to 20 mm Water	<u>12mm</u>	<u>25/10/2020</u>	<u>25/10/2020</u>

APPROVAL FOR DISPENSING BY IPQA: Sign: <u>[Signature]</u> Date: <u>25/10/2020</u>
Dispensing start Time <u>15:30</u> End Time <u>16:35</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>31/10/2020</u>	<u>31/10/2020</u>	<u>21/10/2020</u>	<u>21/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00 Batch No.: G F20 / 207 Customer: Generic Health Care Pvt. Ltd.


5. DISPENSING RECORD OF PACKING MATERIALS: Date: 25/12/2020 Shift: C Time: 15:50

Material Name	Item code	UOM	Req. Qty. for 6.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
252mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Kg	45.900 (To be established)	19.400 28.800	Pm9/00531 Pm9/00731	02 02	by 25/12/2020	25/12/2020
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	153.000 (To be established)	166.70	Pm9/00766	07	by 25/12/2020	25/12/2020
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	20400	6600 13800	Pm9/00518 Pm9/00728	02 07	by 25/12/2020	25/12/2020
Ramithiazide Printed Leaflet	PPL/SP/R002	No	20400	20400	Pm9/00521	03	by 25/12/2020	25/12/2020
Shrink Sleeves (PVC)	PPS/SP/P001	No	2040			NA		18
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	75	75	Pm9/00639	08	by 25/12/2020	25/12/2020
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	10	10	Pm9/00036	02	by 25/12/2020	25/12/2020
3' Plain BOPP Tape	PUB/SP/B001	No	3	03	Pm9/00109/02	01	by 25/12/2020	25/12/2020
Strapping role.	PPR/SP/S001	Mtrs	300	300	Pm9/00032	01	by 25/12/2020	25/12/2020
Shipper Label	NA	No	76			NA		18

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	200	200	
Date	31/10/2020	31/10/2020	31/10/2020	

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>G F 201207</u> Generic Health Care Pvt. Ltd.

6. LINE CLEARANCE CHECKS:

6.1 PRIMARY PACKING:

Date/ Shift 24/12/2020 G / 24/12/2020 G

Previous Product: <u>Calumax P</u>		Batch No.: <u>743CP 2023P</u>				
Sr. No.	Checks	Time	Observation			
			09:00 Packing	IPQA	09:10 Packing	IPQA
1.	Area status board is updated for "CLEANED" status.		✓	✓	✓	✓
2.	Check and ensure that the area is visually clean and free from previous product		✓	✓	✓	✓
3.	Check and ensure the differential pressure of the area is within specified limit		✓	✓	✓	✓
4.	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
5.	Check the temperature and relative humidity of the area within specified limit		✓	✓	✓	✓
6.	Check the tablets of the previous product/ batch removed.		✓	✓	✓	✓
7.	Check the loose Alu Alu strip cutting, rejected rolls, empty cores of foil of previous product /batch are removed.		✓	✓	✓	✓
8.	Check the surroundings of the machine and free from the previous products and batch		✓	✓	✓	✓
9.	Check the foil printing stereotypes, Labels of previous product/batch are removed.		✓	✓	✓	✓
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.		✓	✓	✓	✓
11.	Check and ensure the Cleanliness following change part of Alu Alu strip packing machine		✓	✓	✓	✓
12.	Check for the absence of previous batch/ product at machine conveyor belt.					
a)	Check Hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit.		✓	✓	✓	✓
b)	Check for cleaning of hopper, feeding channel, vibrator plate, in feed roller and sweep brush.		✓	✓	✓	✓
c)	Check tool box, thinner and ink box		✓	✓	✓	✓

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

Cleaning satisfactory/Not-satisfactory 8/24/12/2020 Cleaning satisfactory/Not-satisfactory 8/24/12/2020
 Checked by Packing (Sign./Date): 8/24/12/2020 Verified by IPQA (Sign./Date): 8/24/12/2020

#In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, recheck the area / line and record.

6.2 AREA AND EQUIPMENT CLEARANCE OF PRIMARY PACKING

Date/Time: 24/12/2020 09:10

Previous Product: <u>Calumax P</u>		Batch No.: <u>743CP 2023P</u>					
S. No.	Equipment / Area Name	Eq.ID. /Area. No.	Cleaning Type A/B	Operation and cleaning as per SOP number	Cleaned by Sign/Date	Checked by (Packing) Sign/Date	Verified by (IPQA) Sign/Date
1.	Alu Alu Packing Area	<u>SPC/APP/Alu/01</u>	<u>B</u>	<u>PDGN/006</u>	<u>Mani</u>	<u>8/24/12/2020</u>	<u>8/24/12/2020</u>
2.	Alu Alu Packing Machine	<u>PD/Alu/01</u>	<u>B</u>	<u>PDOP/020, PDCL/020</u>	<u>Mani</u>	<u>8/24/12/2020</u>	<u>8/24/12/2020</u>

6.3 ENVIRONMENTAL CONDITIONS:


(Check the environmental conditions of primary packing area at the start of process and Record in the below in table)

Refer to SOP No.: SOP: QAGN/011	Date: <u>24/12/2020</u> Time: <u>09:10</u>			Date: <u>24/12/2020</u> Time: <u>09:10</u>		
	Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	<u>24°C</u>	<u>8/24/12/2020</u>	<u>8/24/12/2020</u>	<u>25°C</u>	<u>8/24/12/2020</u>	<u>8/24/12/2020</u>
RH % Limit: NMT 60%	<u>58%</u>	<u>8/24/12/2020</u>	<u>8/24/12/2020</u>	<u>58%</u>	<u>8/24/12/2020</u>	<u>8/24/12/2020</u>
DP Limit: NLT 10 Pascal	<u>10</u>	<u>8/24/12/2020</u>	<u>8/24/12/2020</u>	<u>12</u>	<u>8/24/12/2020</u>	<u>8/24/12/2020</u>
Primary Packing Started Date/Time: <u>24/12/2020</u> <u>09:10</u> Completed Date/Time: <u>24/12/2020</u> <u>15:30</u>						

APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: 8/24/12/2020

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L.K.</u>	<u>8/24/12/2020</u>	<u>8/24/12/2020</u>	<u>8/24/12/2020</u>	
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
	Product: RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: G1 F2 01207
		Customer:	Generic Health Care Pvt. Ltd.

7. VERIFICATION OF DISPENSED PACKING MATERIALS: Date 27/12/2020 Shift G Time: 09:10

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
252mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Kg	PMG/00531 PMG/00731	02 02	Sy	Q
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	PMG/00766	07	Sy	Q
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	PMG/00518 PMG/00708	02 07	Sy	Q
Ramithiazide Printed Leaflet	PPL/SP/R002	No	PMG/00521	03	Sy	Q
Shrink Sleeves (PVC)	PPS/SP/P001	No				
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	PMG/00639	08	Sy	Q
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	PMG/00036	02	Sy	Q
3' Plain BOPP Tape	PUB/SP/B001	No	PMG/241019/02	01	Sy	Q
Strapping role.	PPR/SP/S001	Mtrs	PMG/00632	01	Sy	Q
Shipper Label	NA	No				

8. STEREO ISSUANCE AND SETTING RECORD

S. No.	Type of Stereos	No. of Stereos Issued	Issued By (packing) Sign. & Date	Received By (Packing) Sign. & Date	Stereos Setting Done By	Checked By (Packing) Sign. & Date	Verified By QA Sign. & Date
1.	Stereos	06	Malim	Sy 27/12/2020	Mani	Sy 27/12/2020	Sy 27/12/2020

9. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift 27/12/2020 G Time: 09:15

(Check the following before start of packing activity and record the observation.)


S. No.	Check Points	Observation	Done by (Packing)	Verified By (IPQA)
1.	Temperature observed on display (Limit: NMT 25°C)	24°C	Sy	Q
2.	Relative Humidity observed on display (Limit: NMT 60%)	58%	Sy	Q
3.	Bulk product containers are of the required product/Batch number and is approved by QC	Yes	Sy	Q
4.	Status label of machine/ line is for same product	Yes	Sy	Q
5.	Printed foil/Base rolls are of the required product.	Yes	Sy	Q
6.	All secondary packing materials are of the required product	Yes	Sy	Q

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	200 mg	Sy	Q
2.	Colour of Tablet	Pink colour	Sy	Q
3.	Quantity (Net Qty.in Kg)	119.410	Sy	Q
4.	Number of Containers	04	Sy	Q

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K	[Signature]	[Signature]	[Signature]
Date	31/10/2020	31/10/2020	21/10/2020	

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>Gf201207</u> Generic Health Care Pvt. Ltd.

11. WEIGHT VERIFICATION RECORD OF RECEIVED SEMI-FINISHED PRODUCT:

Balance I.D. No.: PD/BAL/04

1. Verify the semi-finished Tablets before starting the packing operation.
2. Verify the batch details on the labels affixed over the Containers against the respective BMR and record the details in below table.

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Ramithiazide 5/12.5	Gf201207	12/2022	11/2023	119.410 Kg Equivalent to 597050 Nos.	From Container No. <u>01</u> To Container No. <u>04</u> Total No. of Containers taken <u>04</u>
Checked by Packing (Sign. /Date): <u>[Signature]</u> 25/12/2022				Verified By IPQA (Sign. /Date): <u>[Signature]</u> 25/12/2022	

12. CONTAINER WEIGHT DETAILS:


Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA	Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA
1	32.500	Jorish	[Signature]	11			
2	32.610	Jorish	[Signature]	12			
3	33.220	Jorish	[Signature]	13			
4	29.880	Jorish	[Signature]	14			
5				15			
6				16			
7				17			
8				18			
9				19			
10				20			

13. CONTAINER CONSUMPTION DETAILS:

S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	09:10	12:10	01	Mani	11				
2	12:15	15:00	02	Mani	12				
3	09:10	14:45	03	Mani	13				
4	14:50	18:30	04	Mani	14				
5					15				
6					16				
7					17				
8					18				
9					19				
10					20				
Checked By Packing (Sign. /Date): <u>[Signature]</u> 28/12/2022				Verified by IPQA (Sign. /Date): <u>[Signature]</u> 28/12/2022					

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. Ko</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>21/10/2020</u>	<u>[Signature]</u>	

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: G/F 201207
		Customer:	Generic Health Care Pvt. Ltd.

14. OVERPRINTING OF PRIMARY PACKAGING MATERIALS:

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/19 13 4323	OK	OK
Batch No.:	G/F 201207	OK
Mfg. Date:	12/2020	OK
Exp. Date:	11/2022	OK
Item Code: 13/0232	OK	OK
Pack size (3 x 10's)- Carton	OK	OK
Other instructions if any	NA	NA
Initiated by	Manjiv	Manjiv
Checked by Packing (Sign. & Date)	Sy 27/12/2020	Sy 27/12/2020
Verified by IPQA (Sign. & Date)	Sy 27/12/2020	Sy 27/12/2020

15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	27/12/2020	01	Manjiv	Sy 27/12/2020	Sy 27/12/2020
			NA		

16. PACKING INSTRUCTIONS:

1. Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
2. Issue the stereotypes to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.
3. Set and operate Alu Alu Packing Machine as per SOP No. PDOP/020.
4. Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.
5. Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.
6. Perform Leak Test as per Table or during change of Printed foil rolls & plain film rolls and after every start of operation or when machine is stopped due to some break down.
7. Attach proof of printed foil from each roll dispensed as and when used on machine.
8. Overprinting Details on printed foil shall be checked by Packing and cross-checked by IPQA before starting the operation as per given in the respective Table.
9. Affix first overprinted Al. foil, Carton, Shipper and shipper label duly checked by Packing and verified by IPQA.
10. Pack 10 tablets per Alu Alu strip.

Time record for packing detail

Sr. No.	Date/Shift	Primary packing		Secondary packing		Checked by (Packing) Sign. & Date
		Started at	Completed at	Started at	Completed at	
01	27/12/2020	09:10	15:00	09:20	15:10	Sy 27/12/2020
02	28/12/2020	09:20	18:30	09:30	18:45	Sy 28/12/2020
			NA			
						1 Sy

17. PACKING/IPQA IN-PROCESS CHECKS FOR PRIMARY PACKING:


In process checks frequency for packing and IPQA. (As per SOP No.: QAGN/024)

Stage	Packing	IPQA
Primary packing/Secondary Packing	At start of the batch, every one hour	At batch start, followed by every two-hour (random time) Minimum two In process checks by IPQA per batch.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	OK	Signature	Signature
Date	31/10/2020	31/10/2020	28/10/2020	

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF201207 Generic Health Care Pvt. Ltd.





18. **ALU ALU PACKING MACHINE PARAMETERS:** Date/Shift...27/12/2020...Time:....05:15


Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	BPE GE 10'	OK	Sy 27/12/2020	Sy 27/12/2020
Sealing Temperature	(160 °C - 200°C) To be established	190 °C	Sy 27/12/2020	Sy 27/12/2020
Leak test to be performed on Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	OK	Sy 27/12/2020	Sy 27/12/2020
Machine Speed	To be established	28"	Sy 27/12/2020	Sy 27/12/2020


19. **CHALLENGE TEST FOR NON FILLING DETECTION SYSTEM :**

Sr. No	Process instructions										
1.	Testing frequency: Startup, End of the activity and after every break										
2.	Acceptance Criteria: Broken Tablet, Empty Packet, Black Particle, Colour variation, Foreign Matter, Dual Tablets / Capsules and all defects should be detected & rejected.										
Date & Time	S. No.	Broken Tablet	Empty Packet	Black Particle	Colour variation	Foreign Matter	Dual Tablets / Capsules	Result	Done By	Checked by Packing	Verified By IPQA
27/12/2020 09:10 28/12/2020 09:25 18:30	1	✓	✓	✓	✓	✓	✓	Reg. test	Mani	Sy	Sy
	2	✓	✓	✓	✓	✓	✓	Reg. test	Mani	Sy	Sy
	3	✓	✓	✓	✓	✓	✓	Reg. test	Mani	Sy	Sy
	4	✓	✓	✓	✓	✓	✓	Reg. test	Mani	Sy	Sy
	5										
	6										
	7										
	8										
	9										
	10										
	11										
	12										
	13										
	14										
	15										
	16										
	17										
	18										
	19										
	20										

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020



 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 12 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00 Batch No.: G1F201207 Customer: Generic Health Care Pvt. Ltd.

20. MACHINE IN-PROCESS CONTROL:


Date/ Shift		27/12/2020 G.								28/12/2020							
Machine Operator Name		Manikandan															
Time of inspection		09:15	09:25	10:25	11:30	11:40	12:30	13:40	T	14:45	15:20	16:30	17:20	18:30	19:20	20:30	21:20
Sealing Temperature (To be established)		185°C	185°C	185°C	185°C	185°C	190°C	190°C		190°C	190°C	187°C	190°C	190°C	190°C	190°C	190°C
Leak test on Alu Alu Strips* (Qty.: 04)		OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Knurling /Sealing		OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Pocket Formation		OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Horizontal cutting		OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Vertical cutting		OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Quality of Over printing		OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Code No.:	PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
B. No.:	G1F201207	OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	12/2020	OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	11/2023	OK	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed (To be established)		29	29	29	28	28	28	28		28	28	27	28	28	30	30	28
Checked by (Packing)		84	NA	84	84	NA	84	84		84	84	NA	84	84	NA	84	84
Checked by (IPQA)		NA	NA	NA	NA	NA	NA	NA		NA	NA	NA	NA	NA	NA	NA	NA

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.			
Date	31/10/2020	31/10/2020	31/10/2020	

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G1 F2 01267 Generic Health Care Pvt. Ltd.


20.1 MACHINE IN-PROCESS CONTROL:

Date/ Shift	28/12/2020							
Machine Operator Name	Manikandan							
Time of inspection	13:40	14:30	15:10	15:40	16:30	17:20	18:00	
Sealing Temperature (To be established)	137°C	140	140°C	140°C	140°C	140°C	147°C	
Leak test on Alu Alu Strips* (Qty.: 04)	OK	OK	OK	OK	OK	OK	OK	
Knurling /Sealing	OK	OK	OK	OK	OK	OK	OK	
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	
B. No.: GF 20/207	OK	OK	OK	OK	OK	OK	OK	
Mfg. Date: 12/2020	OK	OK	OK	OK	OK	OK	OK	
Exp. Date: 11/2023	OK	OK	OK	OK	OK	OK	OK	
Machine Speed (To be established)	30	30	30	30	30	30	30	
Checked by (Packing)	NA	84	84	NA	84	84	NA	
Checked by (IPQA)	84	84	84	84	84	84	84	

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	84	84	84
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G1 F001207 Generic Health Care Pvt. Ltd.

20.2 MACHINE IN-PROCESS CONTROL:


Date/ Shift																			
Machine Operator Name																			
Time of inspection																			
Sealing Temperature (To be established)																			
Leak test on Alu Alu Strips* (Qty.: _____)																			
Knurling /Sealing																			
Pocket Formation																			
Horizontal cutting																			
Vertical cutting																			
Quality of Over printing																			
Code No.:	PON/DRUGS/ 19 13 4323																		
B. No.:																			
Mfg. Date																			
Exp. Date																			
Machine Speed (To be established)																			
Checked by (Packing)																			
Checked by (IPQA)																			

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	PRP	21/10/2020	21/10/2020
Date	31/10/2020	31/10/2020	21/10/2020	21/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF2018.07 Generic Health Care Pvt. Ltd.

21. DEFOILING OF ALU ALU STRIPS:

Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	De-foiling Done by	Checked by/ Date (Packing)	Verified by Date (QA)
28/12/2020	17:35	17:50	4.156	Janki, Chitra	8/28/12/2020	8/28/12/2020
				NA		
Total Weight of De-foiled Tablets				Checked By / Date (Packing): 8/28/12/2020	Verified By / Date (IPQA): 8/28/12/2020	


21.1 INSPECTION OF DE-FOILED TABLETS:

Date	Inspection started at	Inspection completed at	Inspection Done by	Quantity of Good tablets		Qty. of Rejected Tablets		Checked by/ Date (Packing)	Verified by Date (QA)
				Kgs	Nos	Kgs	Nos		
28/12/2020	17:15	18:15	Srinivasan	4.100	2050	0.056	28	8/28/12/2020	8/28/12/2020
Total				4.100	2050	0.056	28		
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing):		Verified By / Date (IPQA):			
0.056 Kgs 28 Nos.				8/28/12/2020		8/28/12/2020			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	8/31/10/2020	8/31/10/2020	8/31/10/2020
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>G1 F201207</u> Generic Health Care Pvt. Ltd.

22. LINE CLEARANCE CHECKS – BATCH CODING:

Date/ Shift 26/12/2020 / N.A.....

Previous Product: <u>Ultra vitamin D</u>		Batch No.: <u>UD20948</u>				
Sr. No.	Checks	Time	Observation			
			7:00			
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	↓	
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓		
3	Check the Pallets and crates area clean and free from any leftovers of previous product /Batch.		✓	✓		
4	Check and ensure the Correct status board is written.		✓	✓		
5	Check and ensure the previous batch details are deleted from the inkjet machine.		✓	✓		
6	Check and ensure the rejected Cartons of previous product/batch are removed.		✓	✓		ND
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	↓	
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓		
9	Check and ensure the dispensed secondary packing material.		✓	✓		
10	Check and ensure the Preventive maintenance records and log book.		✓	✓		

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

Cleaning Satisfactory / Not satisfactory#
(Packing) Sign. /Date: 26/12/2020

Cleaning Satisfactory / Not satisfactory#
(IPQA) Sign. /Date: 26/12/2020

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.


22.1 AREA AND EQUIPMENT CLEARANCE FOR CODING:

1. Check and ensure that the over printing area and machine is cleared from previous products.
2. Transfer uncoded printed Carton to Overprinting area.
3. Set and operate Overprinting Machine.
4. Overprinting shall be in indelible ink.
5. Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Equipment	Inkjet Machine	Conveyor	Area
ID. No.:	<u>PD/IMP/002</u>	<u>PD/IMP/002</u>	Batch Coding
Previous Product:	<u>Ultra vitamin D</u>		
Batch No.:	<u>UD20948</u>		
Cleaned by:	<u>S. Manjula 26/12/2020</u>		
Checked by Packing:	<u>26/12/2020</u>		
Verified by IPQA:	<u>26/12/2020</u>		

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>26/12/2020</u>	<u>26/12/2020</u>	<u>26/12/2020</u>
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G F 201207 Generic Health Care Pvt. Ltd.

22.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.:	G F 201207	OK
Mfg. Date:	12/2020	OK
Exp. Date:	11/2023	OK
Item Code: 15/0362	15/0362	OK
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19 13 4323	OK
Other instructions if any	NA	NA
Initiated by Sign. & Date	S. Manju 26/12/2020	S. Manju 26/12/2020
Checked by Packing Sign. & Date	S. Manju 26/12/2020	S. Manju 26/12/2020
Verified by IPQA Sign. & Date	S. Manju 26/12/2020	S. Manju 26/12/2020

22.3 TIME RECORD FOR BATCH CODING:

Sr. No.	Date/Shift	Batch Coding Done By	Batch Coding		Checked by (Packing) Sign. & Date	Verified by (IPQA) Sign. & Date
			Started at	Completed at		
01	26/12/2020	S. Manju	07:40	13:30	S. Manju 26/12/2020	S. Manju 26/12/2020


22.4 CARTON OVERPRINTING SPECIMEN:

S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	26/12/2020	01	S. Manju 26/12/2020	S. Manju 26/12/2020

Note – Attach specimen copy of over printed carton

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	S. Manju	S. Manju	S. Manju
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>51F201207</u> Generic Health Care Pvt. Ltd.

23. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift .. 27/12/2020 .. 9 / .. 28/12/2020 ..

Previous Product: Metabotropic Calcium Batch No.: 5925PC 2004F 743SPC 2023P

Sr. No.	Checks	Time	Observation			
			09:00 Packing	IPQA	05:00 Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	✓
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	✓
4	Check and ensure the Correct status board is written.		✓	✓	✓	✓
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	✓
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓	✓	✓
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	✓	✓
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓	✓	✓
9	Check and ensure the dispensed secondary packing material.		✓	✓	✓	✓
10	Check and ensure the cleanliness of documentation table.		✓	✓	✓	✓
11	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	✓

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

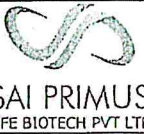
Cleaning Satisfactory / Not satisfactory# 84 Cleaning Satisfactory / Not satisfactory# 82
 (Packing) Sign. /Date: (IPQA) Sign. /Date:

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	<u>PD/COB/004</u>	<u>PD/BAL/015</u>	<u>m</u>	<u>PD/STP/002</u>	<u>PD/BAL/015</u>	Secondary Packing Hall
Previous Product:	<u>Calcium x P</u>					
Batch No.:	<u>743SPC 2023P.</u>					
Cleaned by:	<u>Sivaramkari</u>					
Checked by Packing:	<u>84</u> → <u>27/12/2020</u>					
Verified by IPQA:	<u>82</u> → <u>27/12/2020</u>					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>84</u>	<u>82</u>	<u>82</u>
Date	<u>31/12/2020</u>	<u>31/12/2020</u>	<u>27/12/2020</u>	<u>27/12/2020</u>

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 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 19 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF201207 Generic Health Care Pvt. Ltd.

23.1 ENVIRONMENTAL CONDITIONS:

(Check the environmental conditions of Secondary packing area at the start of process and Record in the below in table)

Shift:.....G.....		Date/Time: 27/12/2020			Date/Time: 28/12/2020		
		Observation	Checked by Packing	Verified by IPQA	Observation	Checked by Packing	Verified by IPQA
Refer to SOP No.: SOP: QAGN/011	Temperature °C Limit: NMT 25°C	24.6°C	By	27/12/2020	25°C	By	28/12/2020
Secondary Packing Started Date/Time: 27/12/2020		Completed Date/Time: 28/12/2020 18:45					
APPROVAL FOR SECONDARY PACKING:		Approved by IPQA Sing/Date: 28/12/2020					

23.2 PACKING DETAILS:

10 Tablets in each Alu Alu strip, over code the Alu Alu strip with the batch details given below,
Place 3 x 10's Alu Alu strip and one leaflet in each carton.
Place 10 filled carton in a Shrink Sleeve.
Place 27 Shrink sleeves in each 5 ply shipper.
Seal the shipper with BOPP tape with "H" type.

24. OVER PRINTING DETAILS:

Overprinting Details (Secondary & Tertiary PM)


Overprinting Details	Overprinted Text	Carton (OK/ Not OK)	5 Ply Shipper Label (OK/ Not OK)
Batch No.:	GF201207	OK	OK
Mfg. Date:	12/2020	OK	OK
Exp. Date:	11/2023	OK	OK
Code No.: PON/DRUGS/19 13 4323	OK	OK	NA
Pack size:	NA	3 x 10's	27 x 10 x 3 x 10's
Other instructions if any	ND	m	m
Initiated by Sign. & Date	Mary's	Mary's	Mary's
Checked by Packing Sign. & Date	By 27/12/2020	By 27/12/2020	By 27/12/2020
Verified by IPQA Sign. & Date	27/12/2020	27/12/2020	27/12/2020

24.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	27/12/2020	01	By 27/12/2020	27/12/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	By	By	By
Date	31/10/2020	31/10/2020	21/10/2020	31/10/2020

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 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 20 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G F 201207 Generic Health Care Pvt. Ltd.

25. INDIVIDUAL STRIP WEIGHING LIMIT:

Weight of ten individual Empty Alu Alu strips are given below:

1. 1.9	3. 1.8	5. 1.9	7. 1.8	9. 1.9
2. 1.8	4. 1.9	6. 1.8	8. 1.9	10. 1.8

Total weight of ten Empty Alu Alu strips = 18.5

Avg. Weight of a Empty Alu Alu strip (A): total weight of ten Empty Alu Alu strip/10= 1.85

Weight of ten individual Filled Alu Alu strips are given below:

1. 3.8	3. 3.7	5. 3.8	7. 3.7	9. 3.8
2. 3.8	4. 3.8	6. 3.7	8. 3.8	10. 3.9

Total weight of ten Filled Alu Alu strips = 38.0

Avg. Weight of a Filled Alu Alu strip (B): total weight of ten Filled Alu Alu strip/10= 3.80

Limit (C) =

(Each missing tablet should be identified)

Strip weighing Done By: Janaki	Checked By: [Signature]	Verified By: [Signature]
--------------------------------	-------------------------	--------------------------

25.1 CARTON WEIGHT LIMIT SETTING: Date/Shift: 27/12/2020 Time: 9:11:30.

Weight of ten individual empty cartons are given below:

1. 8.9	3. 8.9	5. 8.8	7. 8.7	9. 8.9
2. 8.8	4. 8.6	6. 8.8	8. 8.9	10. 8.8

Total weight of ten empty cartons = 88.1

Average weight of an empty carton (D) = Total weight of ten empty carton /10= 8.81

Weight of ten individual Leaflets are given below:

1. 2.5	3. 2.4	5. 2.4	7. 2.5	9. 2.4
2. 2.5	4. 2.4	6. 2.5	8. 2.4	10. 2.5

Total weight of ten Leaflets = 24.5

Avg. Weight of a Leaflet (E): total weight of ten Leaflets/10= 2.45

25.2 WEIGHT CHECKS ON CARTON:


Weight of ten empty Carton: 88.1	Average weight of one empty Carton (D): 8.81
Weight of ten filled Alu Alu strip: 38.0	Average weight of one filled Alu Alu strip (B): 3.80
Weight of ten Leaflets: 24.5	Average weight of one Leaflet (E): 2.45
Weight of one filled Carton F = (D+3B+E) 22.46	Limit: G = F ± 1 % = (To be established)
Checked by Packing/Date: [Signature]	Verified by IPQA/Date: [Signature]

25.3 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7 x 10 ⁵	[Signature] 27/12/2020
2	Control Sample (Middle)	6 x 10 ⁵	[Signature] 27/12/2020
3	Control Sample (Final)	6 x 10 ⁵	[Signature] 28/12/2020
4	Stability Sample	—	—
5	Other Sample	—	—
6	Analytical sample	12 x 10 ⁵	[Signature] 28/12/2020
Total Qty.		22 x 10 ⁵	[Signature]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	31/10/2020	31/10/2020	31/10/2020	

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 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 21 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00 Batch No.: G F 261207
		Customer:	Generic Health Care Pvt. Ltd.

26. SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	27/12/2020							27/12/2020							
Parameters	Specification	Packing							observation						
									IPQA						
Time		09:40	10:40	11:45	12:30	13:45	14:45	T	10:30						
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK		OK						
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK		OK						
No. of cartons in a shrink sleeves	10 packed cartons	NA	NA	NA	NA	NA	NA		NA						
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA		NA						
No. of shrink sleeves in a 5 ply shipper	27 shrinks 306 cartons	OK	OK	OK	OK	OK	OK		OK						
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK		OK						
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK		OK						
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK		OK						
Checked by		SY	SY	SY	SY	SY	SY		SY						

*Temperature to be mentioned.


26.1 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	28/12/2020	G													
Parameters	Specification	observation													
		Packing								IPQA					
Time		09:40	10:30	11:40	12:30	13:30	14:50	15:30	16:00	12:30	14:50	17:00			
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
No. of cartons in a shrink sleeves	10 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
No. of shrink sleeves in a 5 ply shipper	27 shrinks 306 carton.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
Checked by		SY	SY	SY	SY	SY	SY	SY	SY	SY	SY	SY			

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/10/2020	31/10/2020	31/10/2020	

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G 6201207 Generic Health Care Pvt. Ltd.

26.2 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	25/12/2020												
Parameters	Specification	observation											
		Packing						IPQA					
Time		18:30	19:30	20:30	21:30	22:30	23:30						
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	ok	ok	ok									
Carton Overprinting	Legible and readable	ok	ok	ok									
No. of cartons in a shrink sleeves	10 packed cartons	ok	ok	ok									
Shrink wrapping temperature*		ok	ok	ok									
No. of shrink sleeves in a 5 ply shipper	27 shrinks 306 carton	ok	ok	ok									
Shipper strapping	Proper strapping	ok	ok	ok									
Label appearance and Shipper appearance	Legible and readable	ok	ok	ok									
Sealing of the shipper with BOPP Tape	H type	ok	ok	ok									
Checked by		SH	SH	SH									

*Temperature to be mentioned.

26.3 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")


Date/ Shift													
Parameters	Specification	observation											
		Packing						IPQA					
Time													
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.												
Carton Overprinting	Legible and readable												
No. of cartons in a shrink sleeves	10 packed cartons												
Shrink wrapping temperature*													
No. of shrink sleeves in a 5 ply shipper	27 shrinks												
Shipper strapping	Proper strapping												
Label appearance and Shipper appearance	Legible and readable												
Sealing of the shipper with BOPP Tape	H type												
Checked by													SH

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	SH	SH	SH
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>Gf201207</u> Generic Health Care Pvt. Ltd.

27. SHIPPERS WEIGHING: Date/Shift: 27/12/2020 Time: 09:30 Balance I.D. No.: PD/BA/C/019

Weight of ten Shrinks:	<u>2280</u>	Average weight of one filled Shrink (H):	<u>22.8</u>
Weight of ten empty shippers:	<u>13.260</u>	Average weight of one empty shipper (I):	<u>1.326</u>
Weight of one filled shipper (J) = $\frac{30L}{27H+I}$:	<u>8.302</u>	Limit: $K = J \pm 1\%$ = (to be established)	<u>8.218 - 8.385</u>
Checked by Packing/Date:	<u>8/27/12/2020</u>	Verified by IPQA/Date:	<u>8/27/12/2020</u>

Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By
1	8.319	Nareny	20	8.342	Nareny	39	8.363	Wji	58	8.320	Wji
2	8.357	Nareny	21	8.351	Nareny	40	8.362	Wji	59	8.320	Wji
3	8.339	Nareny	22	8.344	Nareny	41	8.345	Wji	60	8.320	Wji
4	8.345	Nareny	23	8.344	Wji	42	8.330	Wji	61	8.330	Wji
5	8.315	Nareny	24	8.354	Wji	43	8.345	Wji	62	8.300	Wji
6	8.337	Nareny	25	8.326	Wji	44	8.365	Wji	63	8.310	Wji
7	8.339	Nareny	26	8.342	Wji	45	8.330	Wji	64	8.300	Wji
8	8.360	Nareny	27	8.341	Wji	46	8.356	Wji	65	8.340	Wji
9	8.372	Nareny	28	8.353	Wji	47	8.329	Wji	66	4.771	Wji
10	8.366	Nareny	29	8.360	Wji	48	8.324	Wji	67		
11	8.361	Nareny	30	8.370	Wji	49	8.342	Wji	68		
12	8.367	Nareny	31	8.339	Wji	50	8.345	Wji	69		
13	8.357	Nareny	32	8.380	Wji	51	8.329	Wji	70		
14	8.329	Nareny	33	8.364	Wji	52	8.325	Wji	71		
15	8.346	Nareny	34	8.375	Wji	53	8.335	Wji	72		
16	8.336	Nareny	35	8.391	Wji	54	8.330	Wji	73		
17	8.361	Nareny	36	8.350	Wji	55	8.290	Wji	74		
18	8.351	Nareny	37	8.366	Wji	56	8.320	Wji	75		
19	8.351	Nareny	38	8.361	Wji	57	8.330	Wji	76		


Total No. of shippers weighed: <u>66</u>	De-foiled tablets packed in Shipper No: <u>66</u>	Checked by Sign / Date: <u>L. Ke</u> <u>04/01/2021</u>	Verified by Sign / Date: <u>[Signature]</u> <u>04/01/2021</u>	Loose pack details: Shipper No: <u>..66.....</u> Quantity: <u>80X3X10'S</u> Weight: <u>4.771 Kg</u>
---	--	--	---	--

Note - If any shipper weight found out of limit, the same shall be checked physically by opening the shipper.

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>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: 51 F 2001007 Generic Health Care Pvt. Ltd.

28. MAN POWER ALLOCATION:


DATE: 27/12/2020	DATE: 28/12/2020																																																				
SHIFT: 9	SHIFT: 9																																																				
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>G1 F2.01307</u> Generic Health Care Pvt. Ltd.

29. **PRODUCT COUNTER CHECK LINE CLEARANCE:**


Date/ Shift/...../.....

Previous Product:		Batch No.:				
Sr. No.	Checks	Time	Observation			
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.					
2	Check and ensure that waste bin is emptied out and cleaned					
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.					
4	Check and ensure the Correct status board is written.					
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.					
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.					
7	Check and ensure the cleanliness of hatch for conveyor belt.					
8	Check and ensure the cleanliness of conveyor belt with collateral block.					
9	Check and ensure the dispensed secondary packing material.					
10	Check and ensure the cleanliness of documentation table.					
11	Check and ensure the Preventive maintenance records and log book.					
Note: Tick mark (✓) if Complies, (X) if does not comply and (NA) if not applicable.						
Cleaning Satisfactory / Not satisfactory# (Packing) Sign. /Date:			Cleaning Satisfactory / Not satisfactory# (IPQA) Sign. /Date:			
Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.						
Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:						
Previous Product:						
Batch No.:						
Cleaned by:						
Checked by Packing:						
Verified by IPQA:						
Rechecking Started Date/Time:.....			Completed Date/Time:.....			
APPROVAL FOR COUNTER CHECK:			Approved by IPQA Sing/Date:.....			

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>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G F 201207 Generic Health Care Pvt. Ltd.

27.1 COUNTER CHECK OF PACKED SHIPPERS :

DATE:		DATE:	
SHIFT:		SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking		Alu Alu strip Checking	
Printing Checking in Alu Alu strip		Printing Checking in Alu Alu strip	
Alu Alu strip weighing		Alu Alu strip weighing	
Checking of Alu Alu strip and leaflet in carton		Checking of Alu Alu strip and leaflet in carton	
Cartons weighing		Cartons weighing	
Printing Checking in Shipper Label		Printing Checking in Shipper Label	
Shipper Weighing		Shipper Weighing	
Shipper Strapping		Shipper Strapping	
Shipper Checked	From.....to.....	Shipper Checked	From.....to.....
Checked By Packing		Checked By Packing	
Verified By IPQA		Verified By IPQA	

DATE:		DATE:	
SHIFT:		SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking		Alu Alu strip Checking	
Printing Checking in Alu Alu strip		Printing Checking in Alu Alu strip	
Alu Alu strip weighing		Alu Alu strip weighing	
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Cartons weighing		Cartons weighing	
Printing Checking in Shipper Label		Printing Checking in Shipper Label	
Shipper Weighing		Shipper Weighing	
Shipper Strapping		Shipper Strapping	
Shipper Checked	From.....to.....	Shipper Checked	From.....to.....
Checked By Packing		Checked By Packing	
Verified By IPQA		Verified By IPQA	

No. of Defects Identified:

1. Minor:
2. Major:
3. Critical:


Batch Allowed for Despatch: Checked By:

Verified By:

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	[Signature]	[Signature]	[Signature]
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

UNCONTROLLED COPY

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G F 201207 Generic Health Care Pvt. Ltd.

30. PACKING MATERIAL RECONCILIATION:

Sr. No.	Material	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
A	Quantity received for the batch	48.200	166.700	20400	20400	NA	75	300 (mtr)	03
B	Additional material received for the batch	NA	NA	NA	NA		NA	NA	NA
C	Total material received (A+B)	48.200	166.700	20400	20400		75	300 (mtr)	03
D	Quantity packed	21.700	98.100	19890	19890		65	150 (mtr)	03
E	Quantity rejected (Online) & Destroyed	8.998	11.989	497	497		NA	NA	NA
F	Quantity Returned	17.500	56.510	NA	NA		10	150 (mtr)	NA
G	Sample affixed on BPR	0.006	NA	02	02	NA	NA	NA	NA
H	QC samples	0.002	0.006	NA	NA		NA	NA	NA
I	Other samples (If any)	0.002	0.030	11	11		NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	48.199	166.635	20400	20400		75	300 (mtr)	03
K	Variation (C - J)	0.001	0.065	-0-	-0-		-0-	-0-	-0-
L	%Variation (K x 100)/C	0.002%	0.03%	-0-	-0-		-0-	-0-	-0-
M	Acceptable limit	± 2 %	± 2 %	± 2 %	± 2 %	± 2 %			

If % Variation is out of the acceptable limit, investigate & specify the reason:

NA

31. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. NA

Material	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
Quantity Returned	17.500	56.510	NA	NA	NA	10	30 (50 Mtr)	NA
Material returned by packing Sign./Date	<i>[Signature]</i> 21/12/2020	<i>[Signature]</i> 21/12/2020	<i>[Signature]</i> 21/12/2020		NA	<i>[Signature]</i>	<i>[Signature]</i>	NA
Verified By IPQA Sign./Date	<i>[Signature]</i> 21/12/2020	<i>[Signature]</i> 21/12/2020	<i>[Signature]</i> 21/12/2020					
Material received by Store Sign./Date	<i>[Signature]</i> 21/12/2020	<i>[Signature]</i> 21/12/2020	<i>[Signature]</i> 21/12/2020					

32. DESTRUCTION OF REJECTED/UNUSED PRINTED PACKING MATERIALS AND STEREOS:

Date	Stereos	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
28/12/2020	06	8.998	11.989	497	497	NA	NA	NA	NA
				NA					1
Total Qty. Destroyed	06	8.998	11.989	497	497	NA	NA	NA	NA
Destroyed by (Packing)	<i>[Signature]</i> 28/12/2020								
Verified by (IPQA)	<i>[Signature]</i> 21/12/2020								

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>[Signature]</i> L.K.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	31/10/2020	21/10/2020	21/10/2020	21/10/2020

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




Generic Health Care Pvt. Ltd.

A	Batch Size	6,00,000 Nos.
B	Quantity received for packing	597050
C	Total quantity packed	596700
D	Control samples	200
E	Analytical Samples	120
F	In process samples	880
G	Others samples if any (Stability, Regulatory Samples, etc.)	NA
H	Packing Loss = B – (C + D + E + F+G)	850
I	Total Loss = A – (C + D + E + F+G)	2100
J	Packing yield % (C + D + E + F+G) / B X 100 (Yield Limit %.....)*	100.14%
K	Batch Yield % (C + D + E + F +G) / A X 100 (Yield Limit %.....)*	99.65%


Date	FGTN No.	Sales	Pack Size	No. of Units in a shipper	No. of Shippers	Transferred Quantity	FGTN Raised by Packing	FGTN Checked by IPQA	FGTN Received by Stores
	1014	8913	3x16's	306x2x16's	65	306x3x16's	84	8	108
Total Qty. Transferred						59670	84	8	108

Sr. No.	Stage	Deviation / Exception details	Action taken	Observed By
			Nil	

Reviewed by	Name	Sign. /Date
Packing Executive	Lathichuman	[Signature] 28/12/2020
QA Executive	S. Sudha	[Signature] 28/12/2020
Production Assistant Manager/ HOD	BDA & BRANDS MGR. B	[Signature] 28/12/2020
QA Manager/ HOD	Stephen R	[Signature]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/10/2022	31/10/2022	31/10/2022	31/10/2022

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: 07 F2 01207
		Customer:	Generic Health Care Pvt. Ltd.

37. BATCH RELEASED FOR DESPATCH:

Total quantity released: 596700 No's


Head QA sign/ Date: [Signature]
08/12/2020

38. REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/134-00	New Document	Nil

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>31/10/2020</u>	<u>31/10/2020</u>	<u>21/10/2020</u>	<u>[Signature]</u>

UNCONTROLLED CC:


 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GF210317</u> Generic Health Care Pvt. Ltd.

BATCH PACKAGING 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
CODE NO.	: PON/DRUGS/19 13 4323
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/134-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: <u>GF201004/ 31/10/2020</u>
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets
PACKING CONFIGURATION	: 3 x 10 Tablets Sales Pack (Alu Alu Packing)
BPR ISSUED BY/DATE (QA)	: <u>[Signature]</u> <u>27/03/2021</u>
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <u>L. Ka</u> <u>27/03/2021</u>
MFG. DATE: <u>03/2021</u>	EXP. DATE: <u>02/2024</u>
ALLOTTED BY: QA SIGN/DATE: <u>[Signature]</u> <u>27/03/2021</u>	COUNTER CHECKED BY: QA SIGN/DATE: <u>[Signature]</u> <u>20/04/21</u>
QUANTITY RECEIVED FROM PRODUCTION	: <u>589300</u>
DATE OF COMMENCEMENT: <u>26/04/2021</u>	DATE OF COMPLETION: <u>27/04/2021</u>
QUANTITY	: <u>600000</u>
RELEASED QUANTITY OF PACKED TABLETS	: <u>583320</u>
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	: <u>[Signature]</u> <u>29/04/21</u>
This BPR contains 29 Pages + ... Additional Pages	


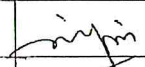
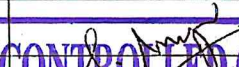
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>21/10/2020</u>	<u>21/10/2020</u>

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: G1F210319
		Customer:	Generic Health Care Pvt. Ltd.

1. INDEX

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3	Packing Material Specification and Indent	4
4	Dispensing line clearance	5
5	Dispensing record of packing materials	6
6	Line clearance for primary packing	7
7	Verification of dispensed packing material	8
8	Stereo Issuance and setting Record, Receipt of product and materials, Detail of the product as per BMR	8
9	Weight verification record of received semi-finished product	9
10	Container weight details, Container consumption details	9
11	Over printing of primary packing, Specimen of printed foil	10
12	Packing instruction, specimen of printed foil, time record for packing detail, Packing In-process checks for primary packing	10
13	Alu Alu packing machine parameters	11
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28	Batch reconciliation	28
29	Transfer of finished goods	28
30	Deviation Detail	28
31	BPR review details	28
32	Batch released for Despatch	29
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: GF210317
		Customer:	Generic Health Care Pvt. Ltd.

2. **CHECKLIST FOR BATCH PACKING RECORD REVIEW:**

Instruction:

Check the following points before submitting the documents for final Review

Sr. No.	Checklist	Observation (Yes/No/NA/No.)*
1.	No. of pages of BPR+ Additional pages (If any) *	25+05
2.	Line clearance and environmental record	Yes
3.	Processing activity done by and checked by is signed	Yes
4.	Dispensing	
a)	Equipment clean tag and dispensing tag attached with batch record	Yes
b)	Packaging material is checked	Yes
5.	Packing	
a)	Rinse water analysis report attached with BPR	NA
b)	Approved specimen of printed foil, show box and shipper label are attached	Yes
c)	Control / Stability / Finished product analysis samples are withdrawn	Yes
d)	Reconciliation of packing materials is done	Yes
e)	Tablet reconciliation is done	Yes
f)	In process checks parameters done at regular interval and recorded into BPR	Yes
6.	Attachment	
a)	Finished Goods Transfer Note	Yes
b)	Certificate of analysis of finished product is submitted	Yes
c)	Stereo Impression Form and Destruction Record	Yes
7.	Complete set of BPR Submitted	Yes


Checked By QA/Date: 25/10/21

*Mention total number of pages.

Remarks (If any) Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign	L. K.	POB		
Date	31/10/2020	31/10/2020		

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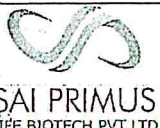
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: G1F21037
		Customer:	Generic Health Care Pvt. Ltd.

3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Printed item material code	Specification	UOM	Standard Qty. for Batch Size 6.0 Lac.	% Overages	Qty. Required 6.0 Lac with overages
1	252mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Width – 252 ± 1 mm Thickness – 0.025 mm Language – French Color – 2 Colors GHPL ITEM CODE – 13/0232	Kg	45.000 (To be established)	2	45.900 (To be established)
2	252 mm Alu Alu Base foil	PPF/SP/A019	Width – 252 ± 1 mm Plain non-printed (text matter) aluminum foil.	Kg	150.000 (To be established)	2	153.000 (To be established)
3	3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	Size – 130 x 60 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 3 colour Language – English/French GHPL ITEM CODE – 15/0362	No	20000	2	20400
4	Ramithiazide Printed Leaflet	PPL/SP/R002	Size – 280 x 150 mm (L x H) Specification – NLT 60 gsm Maplitho Paper. Colour – 2 colours Language – French/ English	No	20000	2	20400
5	Shrink Sleeves (PVC)	PPS/SP/P001	Plain PVC Shrink Sleeves	No	2000	2	2040
6	5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 430 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	75	-	75
7	3' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	10	-	10
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	3	-	3
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width – 12 mm Thickness – 0.6 mm	Mtrs	300	-	300
10	Shipper Label	NA	Half A4 size Computer printed label	No	76	-	76

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>APB</i>	<i>argim</i>	<i>argim</i>
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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	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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: G1F210317
		Customer:	Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS

Date: 24/04/2021 Time: 15:30

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 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 Mobile Laminar Air Flow is clean	✓	✓
7	Check all the gauges of Mobile Laminar Air flow 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.

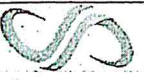
Equipment	Mobile Laminar Air Flow	Weighing Balance		Area
ID No.	ST/LAF/001	ST/BAL/011	NA	FOR STORE
Previous Product	Intoto Zinc			
B. No.	FI 022101D			
Cleaned by Sign/Date	Elappan 24/04/2021			
Checked by Store Sign/Date	[Signature] 24/04/2021			
Verified by IPQA Sign/Date	[Signature] 24/04/2021			

ENVIRONMENTAL CONDITIONS: Date: 24/04/2021 Time: 15:35	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	24.5°C	[Signature] 24/04/2021	[Signature] 24/04/2021
Differential Pressure across the booth Limit: 5 to 20 mm Water	15 mm	[Signature] 24/04/2021	[Signature] 24/04/2021



















APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature] Date: 24/04/2021
Dispensing start Time: 15:40 End Time: 16:00



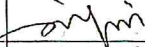

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign: [Signature]	[Signature]	[Signature]	[Signature]	[Signature]
Date: 31/10/2020	31/10/2020	31/10/2020	21/10/2020	21/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>61F210311</u> Generic Health Care Pvt. Ltd.

5. DISPENSING RECORD OF PACKING MATERIALS: Date: 24/04/2021 Shift: G Time: 15:40

Material Name	Item code	UOM	Req. Qty. for 6.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
252mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Kg	45.900 (To be established)	51.240	Pm6/01158	04		 24/04/2021
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	153.000 (To be established)	172.460	Pm6/00926	07		 24/04/2021
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	20400	20400	Pm6/01135	15		 24/04/2021
Ramithiazide Printed Leaflet	PPL/SP/R002	No	20400	20400	Pm6/00884	02		 24/04/2021
Shrink Sleeves (PVC)	PPS/SP/P001	No	2040	NA	Pm6/01000	NA		
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	75	75	Pm6/00905	08		 24/04/2021
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	10	10	Pm6/00936	03		 24/04/2021
3' Plain BOPP Tape	PUB/SP/B001	No	3	03	Pm6/00935	01		 24/04/2021
Strapping role.	PPR/SP/S001	Mtrs	300	300	Pm6/00032	01		 24/04/2021
Shipper Label	NA	No	76	NA	NA	NA		

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	<u>31/09/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>G1F210314</u> Generic Health Care Pvt. Ltd.

6. LINE CLEARANCE CHECKS:

6.1 PRIMARY PACKING:

Date/ Shift 26/10/2021 / G / 27/10/2021 / G

Previous Product: <u>Pantoprazole</u> -D		Batch No.: <u>G1F210323</u>				
Sr. No.	Checks	Time	Observation			
			10.00 Packing	IPQA	09.11 Packing	IPQA
1.	Area status board is updated for "CLEANED" status.		✓	✓	✓	✓
2.	Check and ensure that the area is visually clean and free from previous product		✓	✓	✓	✓
3.	Check and ensure the differential pressure of the area is within specified limit		✓	✓	✓	✓
4.	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
5.	Check the temperature and relative humidity of the area within specified limit		✓	✓	✓	✓
6.	Check the tablets of the previous product/ batch removed.		✓	✓	✓	✓
7.	Check the loose Alu Alu strip cutting, rejected rolls, empty cores of foil of previous product /batch are removed.		✓	✓	✓	✓
8.	Check the surroundings of the machine and free from the previous products and batch		✓	✓	✓	✓
9.	Check the foil printing stereotypes, Labels of previous product/batch are removed.		✓	✓	✓	✓
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.		✓	✓	✓	✓
11.	Check and ensure the Cleanliness following change part of Alu Alu strip packing machine		✓	✓	✓	✓
12.	Check for the absence of previous batch/ product at machine conveyor belt.					
a)	Check Hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit.		✓	✓	✓	✓
b)	Check for cleaning of hopper, feeding channel, vibrator plate, in feed roller and sweep brush.		✓	✓	✓	✓
c)	Check tool box, thinner and ink box		✓	✓	✓	✓

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

Cleaning satisfactory/Not-satisfactory ✓ Checked by Packing (Sign./Date): [Signature] / 26/10/2021

Cleaning satisfactory/Not-satisfactory ✓ Verified by IPQA (Sign./Date): [Signature] / 26/10/2021

#In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, recheck the area / line and record.

6.2 AREA AND EQUIPMENT CLEARANCE OF PRIMARY PACKING

Date/Time: 26/10/2021 / 12.00

Previous Product: <u>Pantoprazole</u> -D		Batch No.: <u>G1F210323</u>					
S. No.	Equipment / Area Name	Eq.ID. /Area. No.	Cleaning Type A/B	Operation and cleaning as per SOP number	Cleaned by Sign/Date	Checked by (Packing) Sign/Date	Verified by (IPQA) Sign/Date
1.	Alu Alu Packing Area	<u>26/10/2021</u>	<u>B</u>	PDGN/006	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u> / <u>26/10/2021</u>
2.	Alu Alu Packing Machine	<u>26/10/2021</u>	<u>B</u>	PDOP/020, PDCL/020	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u> / <u>26/10/2021</u>

6.3 ENVIRONMENTAL CONDITIONS:

(Check the environmental conditions of primary packing area at the start of process and Record in the below in table)


Refer to SOP No.: SOP: QAGN/011	Date: <u>26/10/2021</u> Time: <u>12.00</u>			Date: <u>27/10/2021</u> Time: <u>13.00</u>		
	Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	<u>23°C</u>	<u>[Signature]</u>	<u>[Signature]</u> / <u>26/10/2021</u>	<u>23°C</u>	<u>[Signature]</u>	<u>[Signature]</u> / <u>26/10/2021</u>
RH % Limit: NMT 60%	<u>52%</u>	<u>[Signature]</u>	<u>[Signature]</u> / <u>26/10/2021</u>	<u>52%</u>	<u>[Signature]</u>	<u>[Signature]</u> / <u>26/10/2021</u>
DP Limit: NLT 10 Pascal	<u>11</u>	<u>[Signature]</u>	<u>[Signature]</u> / <u>26/10/2021</u>	<u>11</u>	<u>[Signature]</u>	<u>[Signature]</u> / <u>26/10/2021</u>

Primary Packing Started Date/Time: 26/10/2021 Completed Date/Time: 27/10/2021 / 13.00

APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: [Signature] / 26/10/2021 [Signature] / 26/10/2021

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
	Product: RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GTF210317 Generic Health Care Pvt. Ltd.

7. VERIFICATION OF DISPENSED PACKING MATERIALS: Date: 26/04/2021 Shift: N Time: 1:30 PM

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
252mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Kg	pmh/01158	04	<i>[Signature]</i>	<i>[Signature]</i>
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	pmh/00926	07	<i>[Signature]</i>	<i>[Signature]</i>
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	pmh/01135	15	<i>[Signature]</i>	<i>[Signature]</i>
Ramithiazide Printed Leaflet	PPL/SP/R002	No	pmh/00834	02	<i>[Signature]</i>	<i>[Signature]</i>
Shrink Sleeves (PVC)	PPS/SP/P001	No	—	—	—	—
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	pmh/00905	08	<i>[Signature]</i>	<i>[Signature]</i>
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	pmh/00036	03	<i>[Signature]</i>	<i>[Signature]</i>
3' Plain BOPP Tape	PUB/SP/B001	No	pmh/00935	01	<i>[Signature]</i>	<i>[Signature]</i>
Strapping role.	PPR/SP/S001	Mtrs	pmh/00032	01	<i>[Signature]</i>	<i>[Signature]</i>
Shipper Label	NA	No	—	—	—	—

8. STEREO ISSUANCE AND SETTING RECORD

S. No.	Type of Stereos	No. of Stereos Issued	Issued By (packing) Sign. & Date	Received By (Packing) Sign. & Date	Stereos Setting Done By	Checked By (Packing) Sign. & Date	Verified By QA Sign. & Date
1.	Stereos	06	<i>[Signature]</i> 26/04/21	<i>[Signature]</i> 26/04/21	man	<i>[Signature]</i>	<i>[Signature]</i> 26/04/2021

9. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift: 26/04/2021 Time: 1:30 PM
(Check the following before start of packing activity and record the observation.)


S. No.	Check Points	Observation	Done by (Packing)	Verified By (IPQA)
1.	Temperature observed on display (Limit: NMT 25°C)	23°C	<i>[Signature]</i>	<i>[Signature]</i>
2.	Relative Humidity observed on display (Limit: NMT 60%)	52%	<i>[Signature]</i>	<i>[Signature]</i>
3.	Bulk product containers are of the required product/Batch number and is approved by QC	yp	<i>[Signature]</i>	<i>[Signature]</i>
4.	Status label of machine/ line is for same product	yp	<i>[Signature]</i>	<i>[Signature]</i>
5.	Printed foil/Base rolls are of the required product.	yp	<i>[Signature]</i>	<i>[Signature]</i>
6.	All secondary packing materials are of the required product	yp	<i>[Signature]</i>	<i>[Signature]</i>

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	200	<i>[Signature]</i>	<i>[Signature]</i>
2.	Colour of Tablet	Pink	<i>[Signature]</i>	<i>[Signature]</i>
3.	Quantity (Net Qty.in Kg)	117.860	<i>[Signature]</i>	<i>[Signature]</i>
4.	Number of Containers	04	<i>[Signature]</i>	<i>[Signature]</i>

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	31/10/2020	31/10/2020	21/04/2021	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00 Batch No.: <u>GIF210317</u>
	Customer:		Generic Health Care Pvt. Ltd.

11. WEIGHT VERIFICATION RECORD OF RECEIVED SEMI-FINISHED PRODUCT:

Balance I.D. No.: PD/B01014

1. Verify the semi-finished Tablets before starting the packing operation.
2. Verify the batch details on the labels affixed over the Containers against the respective BMR and record the details in below table.

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Ramithiazide 5/12.5	GP210317	03/2024	02/2024	117.860 Kg Equivalent to 529300 Nos.	From Container No. <u>01</u> To Container No. <u>04</u> Total No. of Containers taken <u>04</u>
Checked by Packing (Sign. /Date): <u>[Signature]</u> <u>28/04/24</u>				Verified By IPQA (Sign. /Date): <u>[Signature]</u> <u>27/04/24</u>	

12. CONTAINER WEIGHT DETAILS:


Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA	Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA
1	30.400	man	[Signature]	11			
2	10.200	man	[Signature]	12			
3	25.610	man	[Signature]	13			
4	30.400	man	[Signature]	14			
5				15			
6				16			
7				17			
8				18			
9				19			
10				20			

13. CONTAINER CONSUMPTION DETAILS:

S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	12:00	14:30	01	man	11				
2	14:31	17:00	02	man	12				
3	17:30	10:30	03	man	13				
4	10:31	12:30	04	man	14				
5					15				
6					16				
7					17				
8					18				
9					19				
10					20				
Checked By Packing (Sign. /Date): <u>[Signature]</u> <u>27/04/24</u>				Verified by IPQA (Sign. /Date): <u>[Signature]</u> <u>27/04/24</u>					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>21/10/2020</u>	<u>[Signature]</u>

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: G1F210317
		Customer:	Generic Health Care Pvt. Ltd.

14. OVERPRINTING OF PRIMARY PACKAGING MATERIALS:

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19 13 4323	OK
Batch No.:	G1F210317	OK
Mfg. Date:	03/2021	OK
Exp. Date:	02/2024	OK
Item Code: 13/0232	13/0232	OK
Pack size (3 x 10's)- Carton	3x10's	OK
Other instructions if any	N/D	N/A
Initiated by	man	man
Checked by Packing (Sign. & Date)	26/04/2021	26/04/2021
Verified by IPQA (Sign. & Date)	26/04/2021	26/04/2021

15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	26/04/2021	01	man	26/04/2021	26/04/2021

16. PACKING INSTRUCTIONS:

- Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
- Issue the stereotypes to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.
- Set and operate Alu Alu Packing Machine as per SOP No. PDOP/020.
- Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.
- Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.
- Perform Leak Test as per Table or during change of Printed foil rolls & plain film rolls and after every start of operation or when machine is stopped due to some break down.
- Attach proof of printed foil from each roll dispensed as and when used on machine.
- Overprinting Details on printed foil shall be checked by Packing and cross-checked by IPQA before starting the operation as per given in the respective Table.
- Affix first overprinted AL. foil, Carton, Shipper and shipper label duly checked by Packing and verified by IPQA.
- Pack 10 tablets per Alu Alu strip.

Time record for packing detail

Sr. No.	Date/Shift	Primary packing		Secondary packing		Checked by (Packing) Sign. & Date
		Started at	Completed at	Started at	Completed at	
1.	26/04/2021/01	12.30	19.00	12.30	19.00	26/04/2021
2.	27/04/2021/1	09.00	13.00	09.00	14.00	27/04/2021


17. PACKING/IPQA IN-PROCESS CHECKS FOR PRIMARY PACKING:

In process checks frequency for packing and IPQA. (As per SOP No.: QAGN/024)

Stage	Packing	IPQA
Primary packing/Secondary Packing	At start of the batch, every one hour	At batch start, followed by every two-hour (random time) Minimum two In process checks by IPQA per batch.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	26/04/2021	26/04/2021	26/04/2021
Date	26/04/2021	26/04/2021	26/04/2021	26/04/2021

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GIF210317 Generic Health Care Pvt. Ltd.

18. ALU ALU PACKING MACHINE PARAMETERS:

Date/Shift: 26/04/2021 Time: 12:00:00

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details				
Sealing Temperature	(160 °C - 200°C) To be established	180°C	L	26/04/2021
Leak test to be performed on 4 Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	00	L	26/04/2021
Machine Speed	To be established	30	L	26/04/2021


19. CHALLENGE TEST FOR NON FILLING DETECTION SYSTEM :

Sr. No	Process instructions										
1.	Testing frequency: Startup, End of the activity and after every break										
2.	Acceptance Criteria: Broken Tablet, Empty Packet, Black Particle, Colour variation, Foreign Matter, Dual Tablets / Capsules and all defects should be detected & rejected.										
Date & Time	S. No.	Broken Tablet	Empty Packet	Black Particle	Colour variation	Foreign Matter	Dual Tablets / Capsules	Result	Done By	Checked by Packing	Verified By IPQA
26/04/2021 12:00 to 16:00	1	✓	✓	✓	✓	✓	✓	pass	mm	L	26/04/2021
	2	✓	✓	✓	✓	✓	✓	pass	mm	L	26/04/2021
	3	✓	✓	✓	✓	✓	✓	pass	mm	L	26/04/2021
	4										
	5										
27/04/2021 09:00 to 13:00	6	✓	✓	✓	✓	✓	✓	pass	mm	L	27/04/2021
	7	✓	✓	✓	✓	✓	✓	pass	mm	L	27/04/2021
	8										
	9										
	10										
	11										
	12										
	13										
	14										
	15										
	16										
	17										
	18										
	19										
	20										

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. K.	Sign.	Sign.
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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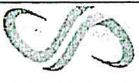
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GF 210317</u> Generic Health Care Pvt. Ltd.

20. MACHINE IN-PROCESS CONTROL:

Date/ Shift	26/04/2021								27/04/2021							
Machine Operator Name	Mani								Mani							
Time of inspection	12:05	12:15	13:15	14:35	14:50	15:30	16:45	16:50	9:30	09:50	10:30	11:35	11:50	12:30		
Sealing Temperature (To be established)	180°C	180°C	180°C	180°C	180°C	180°C	180°C	185°C	185°C	195°C	195°C	195°C	195°C	195°C		
Leak test on Alu Alu Strips* (Qty.: <u>4</u>)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Knurling /Sealing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Code No.:	PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
B. No.:	GF210317	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Mfg. Date	03/2021	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Exp. Date	02/2024	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Machine Speed (To be established)	30	30	30	30	30	30	30	30	30	30	30	30	30	30		
Checked by (Packing)		NA			NA			NA		NA		NA		NA		
Checked by (IPQA)	NA		NA	NA		NA	NA		NA							

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	31/10/2020	31/10/2020	31/10/2020	

 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G1F210317 Generic Health Care Pvt. Ltd.

20.1 MACHINE IN-PROCESS CONTROL:


Date/ Shift	27/04/21															
Machine Operator Name	M. M.															
Time of inspection	12.35	12.40	12.45	12.50												
Sealing Temperature (To be established)	200°C	180°C	200°C	180°C												
Leak test on Alu Alu Strips* (Qty.: <u>04</u>)	OK	OK	OK	OK												
Knurling /Sealing	OK	OK	OK	OK												
Pocket Formation	OK	OK	OK	OK												
Horizontal cutting	OK	OK	OK	OK												
Vertical cutting	OK	OK	OK	OK												
Quality of Over printing	OK	OK	OK	OK												
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK												
B. No.: G1F210317	OK	OK	OK	OK												
Mfg. Date: 07/2021	OK	OK	OK	OK												
Exp. Date: 02/2024	OK	OK	OK	OK												
Machine Speed (To be established)	10	10	10	10												
Checked by (Packing)	OK	OK	OK	OK												
Checked by (IPQA)	OK	OK	OK	OK												

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

27/04/21

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/10/2020	31/10/2020		



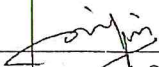
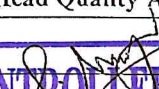
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF210317 Generic Health Care Pvt. Ltd.

20.2 MACHINE IN-PROCESS CONTROL:

Date/ Shift																			
Machine Operator Name																			
Time of inspection																			
Sealing Temperature (To be established)																			
Leak test on Alu Alu Strips* (Qty.: _____)																			
Knurling /Sealing																			
Pocket Formation																			
Horizontal cutting																			
Vertical cutting																			
Quality of Over printing																			
Code No.:	PON/DRUGS/ 19 13 4323																		
B. No.:																			
Mfg. Date																			
Exp. Date																			
Machine Speed (To be established)																			
Checked by (Packing)																			
Checked by (IPQA)																			

Note: * If leak test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by IPQA and to be released after approval from QA.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign				
Date	31/10/2020	31/10/2020	21/10/2020	21/10/2020

 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 15 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00 Batch No.: <u>GF 210317</u> Customer: Generic Health Care Pvt. Ltd.

21. DEFOILING OF ALU ALU STRIPS:

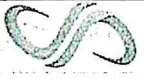
Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	De-foiling Done by	Checked by/ Date (Packing)	Verified by Date (QA)
27/04/21	11:30	11:50	0-280	<i>[Signature]</i>	<i>[Signature]</i> 27/04/21	<i>[Signature]</i> 27/04/21
Total Weight of De-foiled Tablets				Checked By / Date (Packing):	Verified By / Date (IPQA):	
				<i>[Signature]</i> 27/04/21	<i>[Signature]</i> 27/04/21	

21.1 INSPECTION OF DE-FOILED TABLETS:

Date	Inspection started at	Inspection completed at	Inspection Done by	Quantity of Good tablets		Qty. of Rejected Tablets		Checked by/ Date (Packing).	Verified by Date (QA)
				Kgs	Nos	Kgs	Nos		
27/04/21	11:55	12:10	mahe	0.200	1000	0.050	250	<i>[Signature]</i> 27/04/21	<i>[Signature]</i> 27/04/21
Total									
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing):		Verified By / Date (IPQA):			
...0.050 Kgs ...250 Nos.				<i>[Signature]</i> 27/04/21		<i>[Signature]</i> 27/04/21			

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	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G1F210317 Generic Health Care Pvt. Ltd.

22. LINE CLEARANCE CHECKS – BATCH CODING:

Date/ Shift 26/04/2021 / U

Previous Product: Pantopral		Batch No.: 07F210333				
Sr. No.	Checks	Time	Observation			
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓		
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓		
3	Check the Pallets and crates area clean and free from any leftovers of previous product /Batch.		✓	✓		
4	Check and ensure the Correct status board is written.		✓	✓		
5	Check and ensure the previous batch details are deleted from the inkjet machine.		✓	✓		
6	Check and ensure the rejected Cartons of previous product/batch are removed.		✓	✓		
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓		
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓		
9	Check and ensure the dispensed secondary packing material.		✓	✓		
10	Check and ensure the Preventive maintenance records and log book.		✓	✓		

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

Cleaning Satisfactory / Not satisfactory#
(Packing) Sign. /Date: D. Magavalli 26/4/2021

Cleaning Satisfactory / Not-satisfactory#
(IPQA) Sign. /Date:

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

22.1 AREA AND EQUIPMENT CLEARANCE FOR CODING:


- Check and ensure that the over printing area and machine is cleared from previous products.
- Transfer uncoded printed Carton to Overprinting area.
- Set and operate Overprinting Machine.
- Overprinting shall be in indelible ink.
- Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Equipment	Inkjet Machine	Conveyor	Area
ID. No.:	<u>PA/B-02/004</u>		Batch Coding
Previous Product:	<u>Pantopral</u>		
Batch No.:	<u>G1F210333</u>		
Cleaned by:	<u>Magavalli</u>		
Checked by Packing:	<u>D. Magavalli</u>		
Verified by IPQA:			

WIS PA
26/04/21

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign	<u>L. K.</u>	<u>D. Magavalli</u>	<u>D. Magavalli</u>	<u>D. Magavalli</u>
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>G1F210317</u> Generic Health Care Pvt. Ltd.

22.2 OVERRRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.: <u>G1F210317</u>		
Mfg. Date: <u>03/2021</u>		
Exp. Date: <u>02/2024</u>		
Item Code: 15/0362		
Code No.: PON/DRUGS/19 13 4323		
Other instructions if any		
Initiated by Sign. & Date		
Checked by Packing Sign. & Date		
Verified by IPQA Sign. & Date		

22.3 TIME RECORD FOR BATCH CODING:

Sr. No.	Date/Shift	Batch Coding Done By	Batch Coding		Checked by (Packing) Sign. & Date	Verified by (IPQA) Sign. & Date
			Started at	Completed at		


22.4 CARTON OVERRRINTING SPECIMEN:

S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)

Note – Attach specimen copy of over printed carton

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>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GIF210317 Generic Health Care Pvt. Ltd.

23. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift 26/10/2021 /

Previous Product: <u>paracetamol - D</u>		Batch No.: <u>GIF210333</u>				
Sr. No.	Checks	Time	Observation			
			<u>11:00</u>		<u>2:00</u>	
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	✓
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	✓
4	Check and ensure the Correct status board is written.		✓	✓	✓	✓
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	✓
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓	✓	✓
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	✓	✓
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓	✓	✓
9	Check and ensure the dispensed secondary packing material.		✓	✓	✓	✓
10	Check and ensure the cleanliness of documentation table.		✓	✓	✓	✓
11	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	✓

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

Cleaning Satisfactory / Not-satisfactory#
(Packing) Sign. /Date: 26/10/2021


Cleaning Satisfactory / Not-satisfactory#
(IPQA) Sign. /Date: 26/10/2021

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	<u>PD/COB/004</u>	<u>PD/BOL/017</u>	<u>NA</u>	<u>NA</u>	<u>PD/BOL/032</u>	Secondary Packing Hall
Previous Product:	<u>paracetamol - D</u>					
Batch No.:	<u>GIF210333</u>					
Cleaned by:	<u>Endra</u>					
Checked by Packing:	<u>26/10/2021</u>					
Verified by IPQA:	<u>26/10/2021</u>					






Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign:	<u>L. Ka</u>	<u>26/10/2021</u>	<u>26/10/2021</u>	<u>26/10/2021</u>
Date:	<u>31/10/2021</u>	<u>31/10/2021</u>	<u>31/10/2021</u>	<u>31/10/2021</u>

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 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 19 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G1F210317 Generic Health Care Pvt. Ltd.

23.1 ENVIRONMENTAL CONDITIONS:

(Check the environmental conditions of Secondary packing area at the start of process and Record in the below in table)




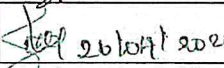
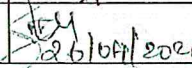
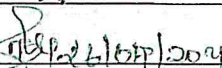
Shift:.....G.....		Date/Time: 26/04/2021 11:00			Date/Time: 27/04/2021 09:00		
		Observation	Checked by Packing	Verified by IPQA	Observation	Checked by Packing	Verified by IPQA
Refer to SOP No.: SOP: QAGN/011	Temperature °C Limit: NMT 25°C	23°C			23°C		
Secondary Packing Started Date/Time: 26/04/2021 12:35... Completed Date/Time: 27/04/2021 15:00							
APPROVAL FOR SECONDARY PACKING:				Approved by IPQA Sing/Date:  26/04/2021.....			

23.2 PACKING DETAILS:


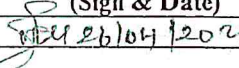
10 Tablets in each Alu Alu strip, over code the Alu Alu strip with the batch details given below,
Place 3 x 10's Alu Alu strip and one leaflet in each carton.
Place 10 filled carton in a Shrink Sleeve.
Place 27 Shrink sleeves in each 5 ply shipper.
Seal the shipper with BOPP tape with "H" type.




24. OVER PRINTING DETAILS:

Overprinting Details (Secondary & Tertiary PM)

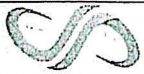
Overprinting Details	Overprinted Text	Carton (OK/ Not OK)	5 Ply Shipper Label (OK/ Not OK)
Batch No.: G1F210317	OK	OK	OK
Mfg. Date: 03/2021	OK	OK	OK
Exp. Date: 02/2024	OK	OK	OK
Code No.: PON/DRUGS/19 I3 4323	OK	OK	NA
Pack size: 10	NA	3 x 10's	27 x 10 x 3 x 10's
Other instructions if any	13/0232	15/0362	16/0255 NA
Initiated by Sign. & Date	NA	Manju	Malini
Checked by Packing Sign. & Date			
Verified by IPQA Sign. & Date	 26/04/2021	 26/04/2021	 26/04/2021

24.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
1	26/04/2021	01		 26/04/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka			
Date	31/10/2020	31/10/2020	31/10/2020	

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 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 20 of 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: 61F210317 Generic Health Care Pvt. Ltd.

25. INDIVIDUAL STRIP WEIGHING LIMIT:

Weight of ten individual Empty Alu Alu strips are given below:

1. 1.8	3. 1.7	5. 1.7	7. 1.7	9. 1.8
2. 1.7	4. 1.8	6. 1.7	8. 1.8	10. 1.7

Total weight of ten Empty Alu Alu strips = 17.4

Avg. Weight of a Empty Alu Alu strip (A): total weight of ten Empty Alu Alu strip/10 = 1.74

Weight of ten individual Filled Alu Alu strips are given below:

1. 3.8	3. 3.8	5. 3.8	7. 3.7	9. 3.8
2. 3.7	4. 3.8	6. 3.8	8. 3.7	10. 3.8

Total weight of ten Filled Alu Alu strips = 37.0

Avg. Weight of a Filled Alu Alu strip (B): total weight of ten Filled Alu Alu strip/10 = 3.7

Limit (C) = 3.73 to 3.80

(Each missing tablet should be identified)

Strip weighing Done By: <u>P. Arun</u>	Checked By: <u>A</u>	Verified By: <u>Jeeva</u>
--	----------------------	---------------------------

25.1 CARTON WEIGHT LIMIT SETTING: Date/Shift: 26/04/2021 Time:.....

Weight of ten individual empty cartons are given below:

1. 8.6	3. 8.6	5. 8.6	7. 8.6	9. 8.7
2. 8.7	4. 8.6	6. 8.7	8. 8.6	10. 8.6

Total weight of ten empty cartons = 86.3

Average weight of an empty carton (D) = Total weight of ten empty carton /10 = 8.63

Weight of ten individual Leaflets are given below:

1. 2.5	3. 2.4	5. 2.6	7. 2.6	9. 2.4
2. 2.5	4. 2.5	6. 2.4	8. 2.5	10. 2.6

Total weight of ten Leaflets = 25

Avg. Weight of a Leaflet (E): total weight of ten Leaflets/10 = 2.5

25.2 WEIGHT CHECKS ON CARTON:

Weight of ten empty Carton: 86.3	Average weight of one empty Carton (D): 8.63
Weight of ten filled Alu Alu strip: 37.7	Average weight of one filled Alu Alu strip (B): 3.77
Weight of ten Leaflets: 25	Average weight of one Leaflet (E): 2.5
Weight of one filled Carton F = (D+3B+E) = 22.44	Limit: G = F ± 1% = 22.21 to 22.66 (To be established)
Checked by Packing/Date: <u>A</u> 27/04/2021	Verified by IPQA/Date: <u>Jeeva</u> 27/04/2021

25.3 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7 x 10's	<u>Jeeva</u> 26/04/2021
2	Control Sample (Middle)	6 x 10's	<u>Jeeva</u> 27/04/2021
3	Control Sample (Final)	7 x 10's	<u>Jeeva</u> 27/04/2021
4	Stability Sample	N/A	N/A
5	Other Sample	N/A	N/A
6	Analytical sample	12 x 10's	<u>Jeeva</u> 26/04/2021
Total Qty.		32 x 10's	<u>Jeeva</u> 27/04/2021

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>P. Arun</u>	<u>Jeeva</u>	<u>Jeeva</u>
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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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.

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BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: G1F210317

Customer:

Generic Health Care Pvt. Ltd.

26. SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	Specification	observation									
Parameters	Specification	Packing					IPQA				
Time		12:25	14:25	16:45			12:25	14:25	16:00		
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK			OK	OK	OK		
Carton Overprinting	Legible and readable	OK	OK	OK			OK	OK	OK		
No. of cartons in a shrink sleeves	10 packed cartons	NA	NA	NA			NA	NA	NA		
Shrink wrapping temperature*	✓	NA	NA	NA			NA	NA	NA		
No. of shrink sleeves in a 5 ply shipper	27 shrinks 306 Cartons	OK	OK	OK			OK	OK	OK		
Shipper strapping	Proper strapping	OK	OK	OK			OK	OK	OK		
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK			OK	OK	OK		
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK			OK	OK	OK		
Checked by		OK	OK	OK			OK	OK	OK		

*Temperature to be mentioned.


26.1 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift	Specification	observation									
Parameters	Specification	Packing					IPQA				
Time		09:45	11:45	13:30	15:30	16:30	09:00	11:00	13:00		
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK		
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK		
No. of cartons in a shrink sleeves	10 packed cartons	NA	NA	NA	NA	NA	NA	OK	OK		
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	OK	OK		
No. of shrink sleeves in a 5 ply shipper	27 shrinks	OK	OK	OK	OK	OK	OK	OK	OK		
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK		
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK		
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK		
Checked by		OK	OK	OK	OK	OK	OK	OK	OK		

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign	L. K.	OK	OK	OK
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: G1F210317 Generic Health Care Pvt. Ltd.

26.2 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")





Date/ Shift													
Parameters	Specification	observation											
		Packing						IPQA					
Time													
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.												
Carton Overprinting	Legible and readable												
No. of cartons in a shrink sleeves	10 packed cartons												
Shrink wrapping temperature*													
No. of shrink sleeves in a 5 ply shipper	27 shrinks												
Shipper strapping	Proper strapping												
Label appearance and Shipper appearance	Legible and readable												
Sealing of the shipper with BOPP Tape	H type												
Checked by													

*Temperature to be mentioned.

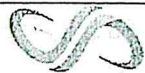
26.3 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep ✓ mark if found "Ok")

Date/ Shift													
Parameters	Specification	observation											
		Packing						IPQA					
Time													
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.												
Carton Overprinting	Legible and readable												
No. of cartons in a shrink sleeves	10 packed cartons												
Shrink wrapping temperature*													
No. of shrink sleeves in a 5 ply shipper	27 shrinks												
Shipper strapping	Proper strapping												
Label appearance and Shipper appearance	Legible and readable												
Sealing of the shipper with BOPP Tape	H type												
Checked by													

*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign				
Date	31/10/2020	31/10/2020		

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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.

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BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: G1F210311

Customer:

Generic Health Care Pvt. Ltd.

27. SHIPPERS WEIGHING:


Date/Shift: 26/04/2021 Time: 12:15 Balance I.D. No.: 10/Bac/091

Weight of ten Shrinks:						Average weight of one filled Shrink (H): 22.4					
Weight of ten empty shippers:						Average weight of one empty shipper (I): 1.250					
Weight of one filled shipper (J) = $\frac{26H+I}{27}$: 8.104						Limit: K = J ± 1% = 8.023 - 8.185 (to be established)					
Checked by Packing/Date: J. Madhu 26/04/21						Verified by IPQA/Date: J. Madhu 26/04/21					
Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By
1	8.170	R. Madhu	20	8.175	Pritya	39	8.140	Pritya	58	8.170	Pritya
2	8.165	R. Madhu	21	8.165	Pritya	40	8.150	Pritya	59	8.165	Pritya
3	8.180	R. Madhu	22	8.165	Pritya	41	8.135	Pritya	60	8.175	Pritya
4	8.075	R. Madhu	23	8.155	Pritya	42	8.150	Pritya	61	8.170	Pritya
5	8.085	R. Madhu	24	8.150	Pritya	43	8.160	Pritya	62	8.150	Pritya
6	8.075	R. Madhu	25	8.160	Pritya	44	8.160	Pritya	63	8.180	Pritya
7	8.175	R. Madhu	26	8.150	Pritya	45	8.180	Pritya	64	5.070	Pritya
8	8.190	R. Madhu	27	8.165	Pritya	46	8.170	Pritya	65		
9	8.135	R. Madhu	28	8.150	Pritya	47	8.155	Pritya	66		
10	8.075	R. Madhu	29	8.145	Pritya	48	8.160	Pritya	67		
11	8.190	R. Madhu	30	8.155	Pritya	49	8.160	Pritya	68		
12	8.170	R. Madhu	31	8.170	Pritya	50	8.155	Pritya	69		
13	8.180	R. Madhu	32	8.185	Pritya	51	8.170	Pritya	70		
14	8.165	R. Madhu	33	8.170	Pritya	52	8.165	Pritya	71		
15	8.160	R. Madhu	34	8.150	Pritya	53	8.190	Pritya	72		
16	8.165	R. Madhu	35	8.140	Pritya	54	8.170	Pritya	73		
17	8.145	R. Madhu	36	8.140	Pritya	55	8.175	Pritya	74		
18	8.160	R. Madhu	37	8.145	Pritya	56	8.180	Pritya	75		
19	8.170	R. Madhu	38	8.165	Pritya	57	8.175	Pritya	76		
Total No. of shippers weighed: 64		De-foiled tablets packed in Shipper No: 64		Checked by Sign / Date: J. Madhu 28/04/21		Verified by Sign / Date: J. Madhu 28/04/21		Loose pack details: Shipper No: 64.... Quantity: 1667.34.61 Weight: 5.070.....			

Note - If any shipper weight found out of limit, the same shall be checked physically by opening the shipper.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	J. Madhu	J. Madhu	J. Madhu
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00 Batch No.: G1F210317
Customer:			Generic Health Care Pvt. Ltd.


28.. MAN POWER ALLOCATION:

DATE: 26/10/2020 SHIFT: 1		DATE: SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking	Tanaka. Selvasankar	Alu Alu strip Checking	
Printing Checking in Alu Alu strip	Tanaka. Sankar	Printing Checking in Alu Alu strip	
Alu Alu strip weighing	maler	Alu Alu strip weighing	
Insertion of Alu Alu strip and leaflet into carton	Selvi. Katar	Insertion of Alu Alu strip into carton	
Cartons weighing	Dhanapras	Cartons weighing	
Insertion of carton into shrink sleeve	NA	Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper	NA	Insertion of shrink wrapped carton into shipper	
Shipper Label Pasting	Heetha	Shipper Label Pasting	
Shipper Weighing	Heetha	Shipper Weighing	
Shipper Strapping	Heetha	Shipper Strapping	
Shipper packed	From..21..to..22..	Shipper packed	From.....to.....
Signature of Packing		Signature of Packing	

DATE: 27/10/2020 SHIFT: 1		DATE: SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking	Tanaka. Selvasankar	Alu Alu strip Checking	
Printing Checking in Alu Alu strip	Dhanapras	Printing Checking in Alu Alu strip	
Insertion of Alu Alu strip and leaflet into carton	maler	Insertion of Alu Alu strip into carton	
Alu Alu strip weighing	Selvi. Kashinri	Alu Alu strip weighing	
Cartons weighing	Dhanapras	Cartons weighing	
Insertion of carton into shrink sleeve	NA	Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper	NA	Insertion of shrink wrapped carton into shipper	
Shipper Label Pasting	Heetha	Shipper Label Pasting	
Shipper Weighing	Heetha	Shipper Weighing	
Shipper Strapping	Heetha	Shipper Strapping	
Shipper packed	From..21..to..24	Shipper packed	From.....to.....
Signature of Packing		Signature of Packing	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	31/10/2020	31/10/2020	31/10/2020	

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: <u>GIF210317</u> Generic Health Care Pvt. Ltd.

29. **PRODUCT COUNTER CHECK LINE CLEARANCE:**

Date/ Shift 26/04/2021 / G / NA

Previous Product: Ramithiazide - pantoprazole Batch No.: GF210333

Sr. No.	Checks	Time	Observation			
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓		
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓		
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓		
4	Check and ensure the Correct status board is written.		✓	✓		
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓		
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓		
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓		
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓		
9	Check and ensure the dispensed secondary packing material.		✓	✓		
10	Check and ensure the cleanliness of documentation table.		✓	✓		
11	Check and ensure the Preventive maintenance records and log book.		✓	✓		

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


Cleaning Satisfactory / Not satisfactory# (Packing) Sign. /Date: 26/04/2021 Cleaning Satisfactory / Not satisfactory# (IPQA) Sign. /Date: 26/04/2021

Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	<u>NA</u>	<u>PD/BAL/17</u>	<u>NA</u>	<u>NA</u>	<u>PD/BAL/02</u>	
Previous Product:	<u>Pantoprazole</u>					
Batch No.:	<u>GF210333</u>					
Cleaned by:	<u>Vidya</u>					
Checked by Packing:	<u>26/04/2021</u>					
Verified by IPQA:	<u>26/04/2021</u>					
Rechecking Started Date/Time:	<u>26/04/2021</u>		<u>15:50</u>		Completed Date/Time:	<u>27/04/2021</u>
APPROVAL FOR COUNTER CHECK:			Approved by IPQA Sing/Date: <u>26/04/2021</u>			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>31/10/2020</u>

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF210317 Generic Health Care Pvt. Ltd.

27.1 COUNTER CHECK OF PACKED SHIPPERS :

DATE: 26/04/2021		DATE: 27/04/2021	
SHIFT: 07		SHIFT: 07	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking	Intilira, Parameshwary	Alu Alu strip Checking	Shobana, Dori praj
Printing Checking in Alu Alu strip	Parameshwary	Printing Checking in Alu Alu strip	Kamali, Paramesh
Alu Alu strip weighing	malan	Alu Alu strip weighing	malan
Checking of Alu Alu strip and leaflet in carton	malan	Checking of Alu Alu strip and leaflet in carton	malan
Cartons weighing	malan	Cartons weighing	Vidhya
Printing Checking in Shipper Label	Vidhya	Printing Checking in Shipper Label	Vidhya
Shipper Weighing	Vidhya	Shipper Weighing	Vidhya
Shipper Strapping	malan	Shipper Strapping	Vidhya
Shipper Checked	From...01...to...32...	Shipper Checked	From...31...to...64
Checked By Packing		Checked By Packing	
Verified By IPQA		Verified By IPQA	

DATE:		DATE:	
SHIFT:		SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking	/	Alu Alu strip Checking	/
Printing Checking in Alu Alu strip		Printing Checking in Alu Alu strip	
Alu Alu strip weighing		Alu Alu strip weighing	
Checking of Alu Alu strip and leaflet in carton		Checking of Alu Alu strip and leaflet in carton	
Cartons weighing		Cartons weighing	
Printing Checking in Shipper Label		Printing Checking in Shipper Label	
Shipper Weighing		Shipper Weighing	
Shipper Strapping		Shipper Strapping	
Shipper Checked		Shipper Checked	
Checked By Packing		From.....to.....	
Verified By IPQA		Verified By IPQA	

No. of Defects Identified:


1. Minor: NA
2. Major: NA
3. Critical: NA

Batch Allowed for Despatch: Checked By: [Signature] 28/04/21

Verified By: [Signature] 28/04/21

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign	L. Ka	[Signature]	[Signature]	[Signature]
Date	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00 Batch No.: <u>GIF210317</u>
Customer:			Generic Health Care Pvt. Ltd.

30. PACKING MATERIAL RECONCILIATION:

Sr. No.	Material	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
A	Quantity received for the batch	51.240	172.460	20400	20400	NA	75	300	10
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	51.240	172.460	20400	20400	NA	75	300	10
D	Quantity packed	23.330	87.490	19444	19444	NA	64	300	10
E	Quantity rejected (Online) & Destroyed	5.591	13.448	948	NA	NA	6	NA	NA
F	Quantity Returned	22.300	71.500	NA	948	NA	5	NA	NA
G	Sample affixed on BPR	0.002	NA	1	1	NA	NA	NA	NA
H	QC samples	0.001	0.005	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.010	0.020	1	1	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	51.220	172.460	20400	20400	NA	75	300	10
K	Variation (C - J)	NA	NA	NA	NA	NA	NA	NA	NA
L	%Variation (K x 100)/C	NA	NA	NA	NA	NA	NA	NA	NA
M	Acceptable limit	± 2 %	± 2 %	± 2 %	± 2 %	± 2 %	NA	NA	NA

If % Variation is out of the acceptable limit, investigate & specify the reason:

NA

31. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. NA


Material	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
Quantity Returned	22.300	71.500	NA	948	NA	NA	NA	NA
Material returned by packing Sign./Date	<u>[Signature]</u> 24/04/20	<u>[Signature]</u> 24/04/20	<u>[Signature]</u> 24/04/20	<u>[Signature]</u> 24/04/20				
Verified By IPQA Sign./Date	<u>[Signature]</u> 24/04/20	<u>[Signature]</u> 24/04/20	<u>[Signature]</u> 24/04/20	<u>[Signature]</u> 24/04/20				
Material received by Store Sign./Date	<u>[Signature]</u> 24/04/20	<u>[Signature]</u> 24/04/20	<u>[Signature]</u> 24/04/20	<u>[Signature]</u> 24/04/20				

32. DESTRUCTION OF REJECTED/UNUSED PRINTED PACKING MATERIALS AND STEREOS:

Date	Stereos	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
24/04/20	6	5.591	13.448	948	NA	NA	6	NA	NA
Total Qty. Destroyed	6	5.591	13.448	948					
Destroyed by (Packing)	<u>[Signature]</u> 24/04/20								
Verified by (IPQA)	<u>[Signature]</u> 24/04/20								

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	21/10/2020	21/10/2020	21/10/2020	21/10/2020

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 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 29
	BATCH PACKING RECORD		Product Code: R09 Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00 Customer:	Batch No.: GF210317 Generic Health Care Pvt. Ltd.

33. BATCH RECONCILIATION:

A	Batch Size	6,00,000 Nos.
B	Quantity received for packing	589300
C	Total quantity packed	583320
D	Control samples	200
E	Analytical Samples	120
F	In process samples	560
G	Others samples if any (Stability, Regulatory Samples, etc.)	NA
H	Packing Loss = B - (C + D + E + F+G)	5100
I	Total Loss = A - (C + D + E + F+G)	15800
J	Packing yield % (C + D + E + F+G) / B X 100 (Yield Limit %.....)*	99.18
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %.....)*	97.36

*To be established

Checked by Packing /Date: *[Signature]* 28/04/2021

Verified by IPQA/Date: *[Signature]* 28/04/2021

34. TRANSFER OF FINISHED GOODS:

Date	FGTN No.	Sales	Pack Size	No. of Units in a shipper	No. of Shippers	Transferred Quantity	FGTN Raised by Packing	FGTN Checked by IPQA	FGTN Received by Stores
28/04/2021	0567	Sale	3x100	366 x 3x100	63	57234	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i> 28/04/2021
				166 x 3x100	1	498	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i> 28/04/2021
Total Qty. Transferred						58332	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i> 28/04/2021

35. DEVIATION/ EXCEPTION DETAILS:

During process if there is any Deviation / Exception are observed then record in below table

Deviation / Exception details

Sr. No.	Stage	Deviation / Exception details	Action taken	Observed By
		<i>[Signature]</i>		

Checked by
Packing:

Verified by
Packing manager:


Approved by
Head QA:

36. BPR REVIEW DETAILS:

Reviewed by	Name	Sign. /Date
Packing Executive	<i>[Signature]</i>	<i>[Signature]</i> 28/04/2021
QA Executive	<i>[Signature]</i>	<i>[Signature]</i> 28/04/2021
Production Assistant Manager/ HOD	<i>[Signature]</i>	<i>[Signature]</i> 28/04/2021
QA Manager/ HOD	<i>[Signature]</i>	<i>[Signature]</i> 28/04/2021

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	31/10/2020	31/10/2020	31/10/2020	31/10/2020

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 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 29
	BATCH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR/T/134-00	Batch No.: <u>G1F210317</u>
		Customer:	Generic Health Care Pvt. Ltd.

37. BATCH RELEASED FOR DESPATCH:

Total quantity released: 583320 No's

Head QA sign/ Date: [Signature] 29/04/21

38. REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/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>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>31/10/2020</u>	<u>31/10/2020</u>	<u>29/10/2020</u>	<u>[Signature]</u>

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