SAI PRIMUS	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, K Villianur Commune, Pu	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.: GFQ01004
Troduct	TOWN THE PARTY OF	Customer:	Generic Health Care Pvt. Ltd.

		Customer: Generic Health Care Pvt. Ltd.
BATCH PACK	AGIN	IG RECORD COVER SHEET
PRODUCT NAME	•	RAMITHIAZIDE 5/12.5
GENERIC NAME	÷	Ramipril and Hydrochlorothiazide Tablets Each Uncoated tablet contains: Ramipril BP
LABEL CLAIM	:	Hydrochlorothiazide BP12.5 mg Excipientsq.s. Colour: Erythrosine Supra
CODE NO.	:	PON/DRUGS/19 13 4323
DOSAGE FORM	:	Tablet
BPR No.	:	BPR/T/134-00
REVISION No.	1	00
SUPERSEDE No		NIL
EFFECTIVE BATCH. No. /DATE	:	GF201004/ 31/10/2020
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)	:	a le la de
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:	L-K3111012020
MFG. DATE: 10 20.20		EXP. DATE: 09 2023
ALLOTTED BY: QA SIGN/DATE:		COUNTER CHECKED BY: QA SIGN/DATE:
QUANTITY RECEIVED FROM PRODUCTION	:	3/10/2020
DATE OF COMMENCEMENT: 13/11/2020		DATE OF COMPLETION: 20/11/2020.
QUANTITY	:	6.00,000
RELEASED QUANTITY OF PACKED TABLETS	1	\$6440
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	.:	P. My 111/2000

This BPR contains 29 Pages + ... Additional Pages

	Prepared by:	Che	ecked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko_	A OF	- July	I find lo
Date	31/10/2020	31/10/2020	21/0/220	7,10/10

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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 2 of 29

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

BATCH PACKING RECORD

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

Product Code: R09

Batch No.: 67 F2010013

Generic Health Care Pvt. Ltd. Customer:

INDEX

Sr. No.	Content	Page No.
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5	Dispensing record of packing materials	6
6	Line clearance for primary packing	7
7	Verification of dispensed packing material	8
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9	Weight verification record of received semi-finished product	9
10	Container weight details, Container consumption details	9
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12	Packing instruction, specimen of printed foil, time record for packing detail, Packing In-process checks for primary packing	10
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28	Batch reconciliation .	28
29	Transfer of finished goods	28
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	Prepared by:	Che	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko-	ACH	infin	1 Jung 10
Date	31/10/2020	31/10/2020	Mohro	1
in a Albert	MOUNT DESCRIPTION	1	> CINCON	CROLLED CC.2Y
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	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, I Villianur Commune, Pu	Page 3 of 29	
SAI PRIMUS	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.: CTF201004
roduct	KAMITITIAZIDE 3/12.3	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) *	7:5
2.	Line clearance and environmental record	Fel
3.	Processing activity done by and checked by is signed	Yes
4.	Dispensing	
a)	Equipment clean tag and dispensing tag attached with batch record	Feg
b)	Packaging material is checked	Yes
5.	Packing	
a)	Rinse water analysis report attached with BPR	Ni-
b)	Approved specimen of printed foil, show box and shipper label are attached	Ya
c)	Control / Stability / Finished product analysis samples are withdrawn	Tes .
d)	Reconciliation of packing materials is done	Yaq
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	Fox
7.	Complete set of BPR Submitted	Ya

Checked By QA/Date:		a regimentation of the state of
*Mention total number of pages.		
Remarks (If any)	MA	

	Prepared by:	Chec	eked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
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Date	31/10/2020	21/10/2020	21/10/1000	1 20,0
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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.

Product Code: R09

Batch Size: 6,00,000 Tablets

Page 4 of 29

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: GREO 1004
Generic Health Care Pvt. Ltd.

3. PACKING MATERIAL SPECIFICATION AND INDENT:

BATCH PACKING RECORD

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:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	ADP.	enfin	1 hours
Date	31/10/2020	31/10/2000	2 1 Valoria	mp of in active
PROPERTY AND PROPERTY AND PERSONS ASSESSMENTS	CARLEST CO. C.			

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, F Villianur Commune, Pu	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.: GF201004
	KANILI IIIAZIDE 3/12.3	Customers	Canaria Health Care Put I td

4. DISPENSING LINE CLEARANCE CHECKS

Date 11/11/2020 Time 14:05

Sr.	CHECKS	Observation ³		
No.	CHECKS	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.	1.	1	
3	Check and ensure that SS trolley are clean.	-	1	
4	Check and ensure that area (floor, walls, ceiling, doors and windows) are clean.	-	1	
5	Check and ensure that Magnehelic gauges, tube light fixtures, supply grills, return riser grills and filters, electrical fixture are clean.	/	1	
6	Check and ensure that all the sides of Mobile Laminar Air Flow is clean	-	V	
7	Check all the gauges of Mobile Laminar Air flow before switching ON.	. (1	
8	Check and ensure that weighing balances and pressure gauges to be used are within calibration due date.	1	1	
9	Check that the daily records (Balance Logbook, RH & Temp. record) are updated and signed.	1	1	
0	Equipment status is updated for Cleaned and Preventive maintenance.	~		

Note: *Tick mark $(\sqrt{})$ if Complies, (X) if does not comply and (NA) if not applicable. Mobile Laminar Equipment Weighing Balance Area Air Flow ID No. Foil Store NA STLAFIODI STIBBLION NB Previous Product Prejng care Breat feeding T34m B. No. PRB 20235 Ellapan (11/11/2020 Cleaned by Sign/Date Checked by Store 111/11/2020 Sign/Date Verified by IPQA Sign/Date

ENVIRONMENTAL CONDITIONS: Date: \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Observation	Checked by Store	Verified by
(For Reference SOP No.: QAGN/011)	Observation	Sign/Date	IPQA Sign/Date
Temperature (Limit: NMT 25°C)	22°€	121/11/200	malning-
Differential Pressure across the booth Limit: 5 to 20 mm Water	1200	ky,1/11/2020	70

APPROVAL FOR DISPENSING BY IPQA: Sign	gn.	Date: lt[[t[lono	- तिलामा
Dispensing start Time 141.20	End Time 14:4	·X	- or w

Prepared by:	Che	cked by:	Approved By:
Production	Production	Quality Assurance	Head Quality Assurance
L.Ka	701	min	O hope wi
31/10/2020	31/10/200	21/0/2020	1-10
	Production L. Ka	Production Production	Production Production Quality Assurance

SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009. 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.: 61 F2 0 1 CO21 Customer: Generic Health Care Pvt. Ltd.

DISPENSING RECORD OF PACKING MATERIALS: Date 11/11/2012 Shift 4. Time: 14, 20 Issued and Issued Req. Qty. for No. of Verified by UOM A.R No. Checked by Item code Material Name 6.0 Lac Roll/Box Qty. **IPQA** Store 45.900 252mm Ramithiazide 52.20 Pny 100531 03 PPF/SP/R009 Kg (To be 5/12.5 Printed foil established) 153.000 157,00 Pmy 00 b41 252 mm Alu Alu 50 PPF/SP/A019 (To be Kg 1111/2020 Base foil established) 3x10'S Ramithiazide to PPC/SP/R010 No 20400 20400 pmg/00518 5/12.5mg Carton Ramithiazide Printed 20400 Pmg 00521 03 PPL/SP/R002 20400 No Leaflet Shrink Sleeves ers. PPS/SP/P001 2040 No (PVC) 5 Ply 390x390x430 Pmylos 639 80 42 PPS/SP/G002 75 mm GHPL Printed No Shipper 3' GHPL Printed 03 PM4/00/34 PPB/SP/B002 No 10 10 Bopp Tape PMB/241019/02 3 PUB/SP/B001 3' Plain BOPP Tape No 3 300 8m4/00001 10 PPR/SP/S001 Mtrs 300 Strapping role. NB. 76 Shipper Label NA No

	Prepared by:	Check	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	401	infrio	a trust
Date	31/10/2020	32/10/2000	-taylopois	1 100
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(-	A .			IS LIFE BIC		- 100 mg			_	= 00		1	*
4		Fact	ory: R.		Plot No.33, Formune, Pu			al Est	ate,	Page 7 of 29				
	PRIMU		CH P	H PACKING RECORD Product Code: R09					Batch Size: 6,00,000 Tablets				blets	
			rrr A 771	DE 5/12 5		BPR.	No.: BPR	/T/13	4-00	Ba	tch No.:	SIFO	010	2021
	Product	RAMIT	HIAZI	IDE 5/12.5	÷ , r	Custo	mer:				neric He			
6.	6. LINE CLEARANCE CHECKS: 6.1 PRIMARY PACKING: Date/ Shift 1.3 / ly/1999.													
Previo		uct: Uthrow		Da	Date/		h No.: U			./		!?	•••••	•••
	Jus 1 100	uct. Ogravo	11000	1Dig		Date	11 140 ()	D.Y	13042		Obser	vation		
Sr. No.	- [-			Checks				Time	8100	3				- 4
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3.		nd ensure the dif							15	Y.	<u></u>	+		
4.		nd ensure that w							4		~			
5.		ne temperature a					ecified lim	ıit	₩ W					4 1
6.		ne tablets of the							~					
7.		he loose Alu A product/batch			rejected rolls	, empty of	cores of f	oil of	- C		~	-		
		ne surroundings			d free from t	he previo	us product	ts and						
8.	batch	6 17 1 11	-	·										
9.		ne foil printing s hat the daily rec							10		✓		+-	
10.	signed.	nat the daily rec	orus (log book, b	atance, temp.	. & K(1)	are upuate	u anu	<u> </u>	1	~			
11.		nd ensure the Cl	eanline	ess followin	g change part	t of Alu A	lu strip		-		1		V	1 .
12.	Packing Check for	machine or the absence of	Forevi	our batch/ n	roduct at mac	hine cons	vevor helt	•						\
		Topper from Top												_
a)	side of c	onveyor belt and	d collar	ting unit.	H 3 1 1 1		7 0 5		ب ا)				
b)	Check for sweep b	or cleaning of h	opper,	feeding cha	nnel, vibrato	r plate, in	feed rolle	er and	0		5			1
c)		ool box, thinner	and ink	cbox						-				201
		rk (√) if Compl			not comply			/					-	-84
		factory/Not sat		الريد الم	3)11/000		ning satis				ctory _	Patito	270	¥
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42.3.		EA AND EQUI		NT CLEAR	ANCE OF I			NG	Date/T	ime:	13711	1200	2 6	3,08
Pre	vious Pr	oduct: Ultra Ye	kmon	PZ	<u> </u>	Batch N		2084	5		_ ii _ i 355,i iii	0		1 12
S.	Equi	oment / Area N	ame	Eq.ID. /Area.	Cleaning Type		ation and ing as per		Cleaned		Check (Pack			fied by PQA)
No.		21-11-11-1	1 E 1	No.	A/B		number	*_	Sign/Da	te	Sign/			n/Date
1.		lu Packing Are		epulpapian			GN/006		. Wraf		ASI		800	טרשר לוול
2.		lu Packing Mad				PDOP/02	20, PDCL/	020	mil		Þ√,		1	े हिर्मानिक
Check		VIRONMENT ronmental condi				t the start	of process	and F	Record in	the b	elow in	table)		
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	to SOP 1				Packing		ified by				Packing		Verif	ied by
SOP:	QAGN/0	011	Obs	servation	Sign/Date		PQA	Obs	ervation		Sign/Dat			QA
Tem	°C I ::	t: NMT 25°C		00'		Sig	n/Date			+			Sign	/Date
		VMT 60%		23°C	Interface	174				+		9		
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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. 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.: (3/ = 2/20) (Customer: Generic Health Care Pvt. Ltd.

7	VERIFICATION OF DISPENSED	PACKING MATERIALS.	Date 13 11 bo Shift G Time: 8.219
1.	VERIFICATION OF DISFERSED	TACKING MATERIALS.	Date. A. M. M. Shift. M. L. Line O. C. Y. L.

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	צט	RA	4
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	pmonloob 41	70	M	
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	pmulous18	10	A/S	4
Ramithiazide Printed Leaflet	PPL/SP/R002	No	Par 100521	63	Art L	一堂
Shrink Sleeves (PVC)	PPS/SP/P001	No	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	N		
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	pmn 100 639	৩৴	X7	车
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	Pm4/00/34	03	342	4
3' Plain BOPP Tape	PUB/SP/B001	No	PmB / 2416 19/02	. 01	CA	1
Strapping role.	PPR/SP/S001	Mtrs	pmv/60001	(0)	1mg	P
Shipper Label	NA	No	Topi (Sec.)		·ix	

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	Malinia	& puties	3149	9. Velhilis	.00
			ishility	15/11			1/2/60

S. No.	Check Points	Observation	Done by (Packing)	Verified By (IPQA)
1.	Temperature observed on display (Limit: NMT 25°C)	23°C	And	10
2.	Relative Humidity observed on display (Limit: NMT 60%)	521	25	P
3.	Bulk product containers are of the required product/Batch number and is approved by QC	No	m	P
4.	Status label of machine/ line is for same product	des	Ph. 7	165
5.	Printed foil/Base rolls are of the required product.	43	Ard	185
6.	All secondary packing materials are of the required product	47	An	+0

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	Dong	And	\$
2.	Colour of Tablet	Pilale codor	41	- 40
3.	Quantity (Net Qty.in Kg)	115.200	As	b
4.	Number of Containers	75	Anny	一种

	Prepared by:	Che	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko.	100	Simi	0 May 1/2
Date	3,1,10/2020	31/10/2020	21/2020	4-10-10-10-10-10-10-10-10-10-10-10-10-10-
B. A. Trees	MH-LILLEN TO THE STATE OF THE S	1 1 1 2 2 2	INCOR	TOOF FINCES

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	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, K Villianur Commune, Puo	Kurumbapet Industrial Estate,	Page 9 of 29
SAI PRIMUS	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.: 678201004
Tioduct	KAWITHIADIDE 3/12.5	Customer:	Generic Health Care Pvt. Ltd.
Balance I 1. Verify the semi-f	TVERIFICATION RECORD OF RECE D. No.: 87 BAL 015 Thinished Tablets before starting the packing details on the labels affixed over the Conta	operation.	

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Ramioth and 5/12 x	HF201004		० १/१०२५	Equivalent to 57 6000 Nos.	From Container No. (a) To Container No. (b) Total No. of Containers taken (c)
Checked by Packing (Sign. /Date):				Verified By IPQA	(Sign. /Date):

12. CONTAINER WEIGHT DETAILS:

Container	Gross Weight	Weighed By	Checked	Container	Gross Weight in	Weighed By	Checked
No.	in Kg	Packing	By IPQA	No.	Kg	Packing	By IPQA
. 1	26.300	hand	10	11	7		
2	24.120	Jackel	-, b	12			124
3	23.190	voral	lo "	13			
4	23.500	monop	7 6	14			
5	25.500	himil	0	15			- 2 =
6	twings" a live		7	16			
7				17		ma	
8				. 18			
9		wa,		19		0	
10			181	20		18	4-

13. CONTAINER CONSUMPTION DETAILS:

C N.	Tin	Time		Container Consumed		Time		Container	Consumed
S. No	From	To	No.	by	S. No	From	To	No.	by
1	8:30	مرايم	ol	mm's	11	1		31 more 1 k 1	1
2	9:31	10:30	02	man;	12	at Pages 1			2. 2. 3.
3	10:31	18 100	63	promi	13				Tes I
4	13:01	16, 50	04	nan'	14			le didiciento de	2
5	16:55	24:00	06	man'	15	70			
6					16		`		
7	7.0				17		V -11 -12 X.1-11	M.	1 70/14
8			25		18				
9	1	ett a sammer			. 19	King -			10
10	7 a 1	- Shekii	AND THE RESERVE OF THE PARTY OF	To a	20	1 11			13.

Checked By Packing (Sign. /Date): Agailan Verified by IPQA (Sign. /Date):

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	404	infrie	O King W.
Date	31/10/2020	31/10/2020	21/0/200	1. 0/10

MANTOR (COPY

SAL PRIMITS LIFE BIOTECH PUT LTD SAI PRIMUS Product

SALL KINIOS LIFE BIOLECILL VI LID
Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,
Villianur Communa Puducherry 605000

Villianur Commune, Puducherry-605009.

Page 10 of 29

BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

RAMITHIAZIDE 5/12.5

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

Batch No.: GF201004 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	biffeotoot NA	010
Batch No.:	ME201004	ok
Mfg. Date:	10/2000	OK
Exp. Date:	09/2023	(7) Kg
Item Code: 13/0232	OK	જા(/
Pack size (3 x 10's)- Carton	d:M	ML
Other instructions if any	M	NO
Initiated by	Aral	WA
Checked by Packing (Sign. & Date)	ar and 11/2, Erya	Ard 10 11 120
Verified by IPQA (Sign. & Date)	Phalass	Palm

15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
UI	18/11/100	(2)	Armo	And 13/11/00	Politino
9	A STATE OF THE SECOND S		1 2 2		
			- NA		
		. 48590		1.63%	The state of the s

PACKING INSTRUCTIONS: 16.

- 1. Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
- Issue the stereos to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table. 2.
- Set and operate Alu Alu Packing Machine as per SOP No. PDOP/020. 3.
- 4. 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. 5.
- 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.
- 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

	K 20 F -0	Primary packing		Secondar	Checked by	
Sr. No.	Date/Shift	Started at	Completed at	Started at	Completed at	(Packing) Sign. & Date
101	18/11/00/14	8:20	81,00	8:25 NA	21.00 M	A-A
02	12/11/nonly	- nc	.PVQ	9:35	19702	Agrand
03	17/11/20 00/11/11/11	9132 M2	AB	9130	11 60	Lyn2
04	talutions	4	No	12200	19360	Cylin
05	20/11/1000	NS-	wi	9:00	11200	g-had

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

In process checks frequency for packing and IPOA. (As per SOP No.: OAGN/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:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	DOK.	infri	0 met
Date	31/10/2020	31/10/2010	20/10/200	V-1.
THANKS THE	NONVENDELEN		INCO	MALDAITEDACSA

C/D	,
SAI PRIMUS	

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,

Villianur Commune, Puducherry-605009. BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Page 11 of 29

Product

RAMITHIAZIDE 5/12.5

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

Batch No .: 61201004

Customer:

Generic Health Care Pvt. Ltd.

18. ALU ALU PACKII	NG MACHINE PARAMET	ERS:	Date/Shift.13.111.20 Time: 8.3.20				
Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date			
Change Parts Details	BAM GEIO	oh	300(11/81/1/81)	13/1/20			
Sealing Temperature	(160 °C - 200°C) To be established	· 190C	A 9 13/2/20	Pilliliono			
Leak test to be performed on <u>o 4</u> Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	06	Ard 17/1/22	Biolin trons			
Machine Speed	To be established	30	Arristulas	Palatoo			

19. CHALLENGE TEST FOR NON FILLING DETECTION SYSTEM:

Sr. No	Proc	ess instru	ctions		,	91	5 _ 0		* 1	11	
1.	Testi	ng freque	ncy: Startuj	p, End of the	activity and	after every	break		ш .		,
2.	Acce Caps	ptance Cr ules and al	iteria: Bro l defects sh	ken Tablet, ould be dete	Empty Packe cted & reject	et, Black Parted.	ticle, Colou	r variatior	, Foreign N	Matter, Dual	Tablets /
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
13/11/200	-1	*	~	A	У	X	义	Ue	Loderen.	"Arri	B
صمارد	2	义	*	1	*	×	×	تدر	Ldove	And	B
19,00	3	oc	j¢.	~	R	~	2	טע	Cier	do	Ø
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	6	1				2 Feb 1999 Com			, <u>5</u> , , , , ,		20.
	7										ALT THE
	8				16/1	1		,	electives to the	-i	
	9	- 77		10	1		- 9				
	10							- "	vy E as		
	11			11 401		2/ ja-	Eddigo:		- ryklfilai	- A = -	1 #35
	12					1 257	17.17				
	13	4				1 34					,
	14			8 -4 4	-						1
	15						na_		71 . 3		
1	16			1 20		. as show				6	14 (2)
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	18			e specie	,		f 1				
	19			de skurjets ou							
	20										1 A

	Prepared by:	Che	Approved By:		
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L.Ko	A&	ingin	0 put	
Date	31/10/2020	31/10/2000	2/2/20	X 15 1/20	
VECTOR SA		1.01.60		TITLE CONT.	

	Factory: R.S. No. 4/3, Plot No.33, F	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.					
SAI PRIMUS	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.: 677201004				
Product	RAIVILLE HIAZIDE 5/12.5	Customer:	Generic Health Care Pvt Ltd				

MACHINE IN-PROCESS CONTROL: 20. Date/Shift 18/11/0000 Dura Machine Operator Name 4,00 12,15 17-20 11-10 Time of inspection 8:35 11:30 17:30 18:30 9:30 10,00 12:20 13/10 14:30 15:30 16:30 Sealing Temperature 184 155 185 1850 1850 185°C 185= 1-27E C 139 185 1856 1850 1281 185°C 135C (To be established) Leak test on Alu Alu Strips* de et 0F 3/ DK 50 EF 510 QH DIC 20 oic OF OL 00 010 (Qty.: 04 el Knurling /Sealing 00 DE ejc ob de DIC OL 0 de de Dic OK CÓ 210 Ole 2/2 Pocket Formation cic 02 30 250 DE ON ex(de ec oc 33 1 ch UC 0 Horizontal cutting di Ole 50 dob 16 ot eh OK CLC de cic CIC OIC Vertical cutting 0= Ola ch ac vo DIC di Dia te 5× 00 OC Ob 00 OC c(-00 Quality of Over printing de di Ob de ot CZQ Oc DIC 水 DIC UK CIC ok 00 PON/DRUGS/ de de シル Code No .: OK 00 山 CIC CLC OK TK ch DIC 200 50 Or OC 19 13 4323 وأد B. No.: eli Ole de a ON 24 ck Clc 45201004 OC Cr bc CK CIC W. elc de Mfg. Date d ob 00 ER-UE 10/2000 on eli aic ck oc ce de UC 06 A 1 de Exp. Date 09/2023 Ob cit Ore olt OL. cic t oc tic CCO OC 0oxe Machine Speed 28 25 38 27 bic 27 20 28 27 27 21 2.7 (To be established) NE -الم NA Ky Checked by (Packing) Ni rit 1 NA 型 0 NO 3 Checked by (IPQA) gur ans-

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 IPOA and to be released after approval from QA.

	Prepared by:	Chec	eked by:	Approved By:		
Dept.	Production	Production	Quality Assurance	Head Quality Assurance		
Sign.	L·Ka) Gl	juri 12	O My hour		
Date	31/10/2020	31/10/2000	3/1/2/2	V.10/10,		
a a a a b	AMALIONI MINIMINI	1 8	TINC	ONTOOLIEDICCOV		
TOPHYLL	TICCOPYPIE		UNU	OMINOPPED COLL		

CIA	
SAI PRIMUS	

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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Product

RAMITHIAZIDE 5/12.5

BATCH PACKING RECORD

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

Product Code: R09

Batch Size: 6,00,000 Tablets Batch No .: 3 F 201004

Customer: Generic Health Care Pvt. Ltd.

20.1 MACHINE IN-PROCESS CONTROL:

Date/Shift		15)1	100														
Machine Op	erator Name	13-1	wp			1		162							W -		
Time of insp	pection	19.20	الاثكاء	24:30	1								,ie -		н		- x-0
Sealing Tem (To be estab			185%	1856	/												
	Alu Alu Strips*	亦	Ole	DIE									4				* b
Knurling/Se	ealing	ek-	ac	ાહ									×				
Pocket Form	nation	ch	ble	oc				1					, , , , , ,				
Horizontal c	utting	ek	OF	010							,						. 4.3
Vertical cutt	ing	ek	00	012				100								1	1
Quality of C	ver printing	4	00	uc				2 7									
Code No.:	PON/DRUGS/ 19 13 4323	0	DIC	٥١٤				i del	У		500			5	, ,		
B. No.:	HE50100H	et	Die	UK				26 A.			1	/	1	,			Will.
Mfg. Date	10/ 2010	et	ok	ØC.								/					
Exp. Date	09/2023	el	oic	σc												4	
Machine Sp (To be estab	eed lished)	27	21.	27								,				/	
Checked by	(Packing)	NE	May	Ar.			148								/		1
Checked by	(IPQA)	8	C _A	M						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					ii.	J. 6. 7	

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:		Chec	Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L, Ke	, 2 00	infrig.	O haret he
Date	31/10/2020	31/10/2020		X-1201.01

	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, k Villianur Commune, Puo	Page 14 of 29	
SAI PRIMUS	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.: 07F201004
Product	KANITIHAZIDE 3/12.3	Customer	Generic Health Care Pyt Ltd

MACHINE IN-PROCESS CONTROL: 20.2 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 PON/DRUGS/ Code No.: 19 13 4323 MA. 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:	Chec	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	DOX	sifico	O John Ture
Date	31/10/2020	31/10/2020	1 5/1/2 VE	COMMONETERSCO

C		Factory: R.S	I PRIMUS LIF . No. 4/3, Plot N Villianur Commu	Io.33, Ku	rumbapet Ind	ustrial Estate		Page	15 of 29	
	PRIMUS TECH PVT LTD	BATCH PA	RD	Product Co	ode: R09		Batch	Size: 6,00,0	00 Tablets	
D.	oduct	DAMITHIAZID	н	BPR. No.:	BPR/T/134-0	0	Batch	No.: G1F	20/001	
F1	oduci	RAMITHIAZID		Customer:			Gene	ric Health Ca	are Pvt. Ltd.	
21.	DEFOILIN	NG OF ALU ALU	J STRIPS:							a 7-\$_
Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets		De-foiling	Done by	1 1		ecked by/ e (Packing)	Verified by Date (QA)
13/11/10	19:00	19:30	0.320		wed. J	sch		A	and when En	Palutas
•									<	, 12.
* 3. z			v				2 6		-	A Supplied
				no	1					- 14
			- 18				- 1	1)		
		otal Weight of -foiled Tablets	0.350	Checke	ed By / Date	(Packing):	ଦ	Veri	fied By / Dat	e (IPQA):
21.1	INSPECT	ION OF DE-FOI	LED TABLETS	S:		-4 <i>9</i> (***			< 1 DI	- 2
Date	Inspect			ta	Quantity of Good Qty. of Reject tablets Tablets			314 × - 1	Checked by/ Date	Verified by Date (QA)
			20110 33	Kgs	Nos	Kgs	Nos	3	(Packing).	103
13) 11 (21	22 19735	19:50	Turch	0.300	1500	0.030	250	2	Anny	= 13/m/m
			30 L 37 X L							104-2-55-1
N-					Convert 100				y ·	* - \$65 A
- 2 E					NO				1	6-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1
	Addition of		Total				- 13/1		/	
	uantity of Ro	ejected Tablets D Nos.	estroyed	Checko	ed By / Date	(Packing): رحرمار)	Ve	rified	By / Date (II	PQA):

. 0	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko-	700	infin	O Josef In
Date	31/10/2020	31/10/2000	101/1900	Z. K. J.
MADY	MOUNT PARTER AND THE		, I I	CONTROLLED CC7Y

5

					-			
	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industria Villianur Commune, Puducherry-605009.				Page 10	Page 16 of 29		
	I PRIMUS BIOTECH PVT LTD	BATCH PACKING RECO	ORD	Product Code:	R09	Batch S	Size: 6,00,00	0 Tablets
	Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPI	R/T/134-00	Batch l	Vo.: 67 F2	4001004
	Troduct	KAMITHIABIDE 5/12.5	-	Customer:		Generi	c Health Ca	re Pvt. Ltd
22.	LINE CL	EARANCE CHECKS – BATCH	H CODIN ate/ Shift.	G: [] [] [] [] [V)/.	r		ane.
Prev	ious Product:	pragname BIF	Bat	tch No.: PEB	2021			
_	W	1,12,125	,	id"Age I	k+-	Obser	vation	
Sr. No.	10 L	Checks		Time	11 700		1 (1
1,0,) a 10 14	3.0		7 1 2 41 4	Packing	IPQA	Packing	IPQA
1	Check and en product.	sure that the area is visually clean	and free fi	rom previous	5	~	T	-
2	Check and en	sure that waste bin is emptied out	and cleane	ed	5		-\	
3	Check the Pal previous prod	llets and crates area clean and free luct /Batch.	from any	leftovers of	~	<i>></i>		
4	Check and en	sure the Correct status board is wr	ritten.		~	~		
5	machine.	sure the previous batch details are			S .	✓		8
6	Check and en removed.	sure the rejected Cartons of previo	ous produc	t/batch are	i	>		
7	Check and en	sure the cleanliness of hatch for co	onveyor be	elt.	<u>~</u>	~	1	
8	Check and en	sure the cleanliness of conveyer be	elt with co	ollateral block.	<u></u>	1	3	P
9	Check and en	sure the dispensed secondary pack	king mater	ial.		1		
10	Check and en	sure the Preventive maintenance r	ecords and	d log book.	c	/		
Note	: Tick mark (√)	if Complies, (X) if does not comp	ply and (N	A) if not applical	ole.			787
	ning Satisfacto king) Sign. /D	ate: 14/1/16490	Clo (IP	eaning Satisfacto QA)Sign. /Date:	ory / Not-sati	sfactory#	18/11/2	30
		the cleaning is not satisfactory / linarea / line and record.	ne is not co	ertified then inves	tigate the cau	se of the fa		

22.1AREA 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.
- Overprinting shall be in indelible ink.
- Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Inkjet Machine	Conveyor	Area	1
PD1=11 /002	PD/2NP/002	Batch Coding	100000
bardone care B)t			
Peb 20219			111 1111
Indu			1,1
: April 11 love	,		s = £1 _3
	PDIEN 1002 PRODUCTOR BIR Front	PDIIN 1002 PDIIN 1002 PEB 20213 Indu : Strip 1, 1000	PDIENT 1002 PDIENT 1002 Batch Coding PEB 20213 Tradu : April 11/1000

Verified by IPQA:

	Prepared by:	Ch	ecked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	A CO	min	O Marti wor
Date	31/10/2020	31/10/2020	2 Jahran	1.10/10
INAME OF	HHALIMANIANOM:		TINCON	TROTI ED CC 2V

SAL DRIMITS	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, F Villianur Commune, Pu	Page 17 of 29	
SAI PRIMUS	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.: 678 201004
Troduct	Iddinitition Strain	Customer:	Generic Health Care Pvt. Ltd.

22.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.:	61F201004	OK
Mfg. Date:	10/2020	OK
Exp. Date:	1912013	Ok
Item Code: 15/0362	15/0362	ok
Code No.: PON/DRUGS/19 13 4323	POH/08145/ 19 17 4723	OK
Other instructions if any	NA.	14
Initiated by Sign. & Date	Harassi 16/colors	olc
Checked by Packing Sign. & Date	8-16/11/22	8-8 16/Nors
Verified by IPQA Sign. & Date	2	Ar hor

22.3 TIME RECORD FOR BATCH CODING:

Sr. No. Date			Batch	Coding	Checked by	Verified by
	Date/Shift	Batch Coding Done By	Started at	Completed at	(Packing) Sign. & Date	(IPQA) Sign. & Date
1	ty 16/4/2020	poni	11:30	14:40	Ange	Daplerban
		war was a street of the	The scale of the s		Langer score	
r .					0-1-1-2	

22.4 CARTON OVERPRINTING SPECIMEN:

S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	46/11/2020	p)	LAmp	2 ibleibro
	ENDALL O	- ron	The state of the s	18

Note - Attach specimen copy of over printed carton

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	TOP	infri	O Met 100
Pate	31/10/2020	3110 2020	- tatrolos	12/1/2
THE YOU	GO X 22 Sasone Christian	2111	A FAITONI	TO OTTEN OF W

0		Factory: R.S.	I PRIMUS LIFE No. 4/3, Plot No.3 Villianur Commune	3, Kurumbapet	Industri	al Estate,	Page 18	3 of 29		
	I PRIMUS BIOTECH PVT LTD	BATCH PA	CKING RECORE	Product	Code:	R09				
	Product	RAMITHIAZID	NF 5/12 5	BPR. No	o.: BPR	/T/134-00 Batch No.: GT F201001				1004
				Custom			Generi	c Healtl	n Care	Pvt. Ltd.
23.	LINE CL	EARANCE CHE	CKS - SECONDA Date/	RY PACKING Shift . i会知	tiglerh		16].11.2	<u> </u>		
Previ	ous Product:	ulta vitame?	40	Batch No.: 1	1DD00	849				
		- 1 '	114		Charle	11	Obser	vation		
Sr. No.		Che	cks	Σ.	Time	68; ho	W	291.	207	NA
4			4. %	6 6	5.1	Packing	IPQA	Packi	ing	IPQA
1	product.		visually clean and	Ettel 1	ous	7	V	5		
2			is emptied out and		711	И	~	5		
3	Check the Pal product /Batcl		free from any lefto	vers of previous		\(\sigma_1\)	~	9	He de l	✓ <u> </u>
4	Check and en	sure the Correct sta	itus board is writter	1.		5	1		-	
5	Check and end cut into pieces	d ensure the stereo of the previous product/batch removed and pieces.					1	5		/
6		ck and ensure the Alu Alu strips, rejected Carton, Shipper and per label of previous product/batch are removed.					~	1		>
7	Check and en	sure the cleanlines		4	1			2.		
8	Check and en	sure the cleanlines:	ock.	4	~		211	/		
9	Check and en	sure the dispensed	secondary packing	material.		5		1		✓
10	Check and en	sure the cleanlines	s of documentation	table.		5	1	1		1
11	Check and en	sure the Preventive	maintenance reco	rds and log book		C	0	//		1
Note	Tick mark (√)	if Complies, (X) i	f does not comply a	and (NA) if not a	pplicab	le.				
	ning Satisfacto king) Sign. /Da	ry / Not satisfacto	ory#	Cleaning Sa (IPQA)Sign.		ry / Not sati	sfactory#	7	O del	22°
Rema	arks: # In case t	he cleaning is not:	satisfactory / line is			tigate the cau	ise of the fa	ilure an	d take	necessary
action	n, re check the	area / line and reco	rd. Weighing	The state of the s	T	244	Weigh	ing		Alter Market
I	Equipment	Packing Conveyor	Balance (Carton)	Shrink Sleeve	St	trapping	Balan (shipp	ce		Area
ID. N	lo.:	POLOSI	poloarl	20	Po	370 001	POBBO	-029	Secor Packi	ndary ng Hall
Previ	ious Product:	Vitra vitan	D3	· Jackson - 1						
Batcl	h No.:	VD 20848					0.1.			
Clea	ned by:	Sother								
Che	eked by Packin	18: AP 16/1	phos f.	_						
Veri	fied by IPQA:	(હું)	1 (2000	Prop						
- 13		,	Thurst 13/11/200	13/14		2-1	· .			

/	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	JOB	July	0 but ver
Date	31/10/2020	31/10/2020	21/10/10/	7.15/1/0,
Inanh-	CUNTRACTION OF THE PARTY OF THE	, //c INC	UNTROLLEDICCOV	
IN CALINI	THOO WATER		UIVO	OLI I WONTERD COLI

SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009. 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.: C1 C 20 100 14 Customer: Generic Health Care Pvt. Ltd.

23.1 ENVIRONMENTAL CONDITIONS:

Shift:		Date/Time: 13/11/20 / 8:40 Date				Date/Time: 17/11/20/291	
		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	A-D	D	234	Ard <	_0
Secondary Packing Star	ted Date/Time:	8:35/16	Comp	leted Date/	Time:?	1100	11200
APPROVAL FOR SECONDARY PACKING:			Approved by	IPQA Sing	Date:	30111	1 / 11

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.:	HF201604	08	DIC
Mfg. Date:	10/2000	ac	ac_
Exp. Date:	09/2023	010	oxie
Code No.: PON/DRUGS/19 13 4323	PON/ 10 RUUS / 1913 4323	UE	gotz NA
Pack size:	NA	3 x 10's	2012 1VA -27-x-10-x 3 x 10's
Other instructions if any	MA	nt	W
Initiated by Sign. & Date	man'/ soul	prul	M
Checked by Packing Sign. & Date	April 16/11/2000	Anderlater	And who
Verified by IPQA Sign. & Date	12/11/82w	Philoso	Piclochon

24.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
101	16)11/100	01	April policione	Prolection
			A	181

	Prepared by:	Check	Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	1. Ka-	POR	inju	O WAY wer
Date	31/10/2020	31/10/2020	21/10/200	7. 110

UNCONTROLLED CC21

	0	Factory: R.S. No.	4/3, Plo	LIFE BIO ot No.33, K nmune, Pud	urumbape	t Industrial	Estate,	Page	20 of 29		2
SAI PRI		BATCH PACKIN				ct Code: R	19	Batc	h Size: 6,00,0	000 Table	ets
		1 3 4 100 X 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		,	BPR. I	No.: BPR/T	/134-00	Batc	h No.:GF	20160	L
Prod	uct R	AMITHIAZIDE 5/1	2.5	10	Custor				eric Health C		
		L STRIP WEIGHIN dual Empty Alu Alu			below:						
1.).		3.)6			~7	7.	1.7			' 4	
2. j.		4. 기기 pty Alu Alu strips =	16,0	6.	b	8.	1,7		10. 1.	<u>. T</u>	-
Avg. Weig	ght of a Empt	y Alu Alu strip (A): dual Filled Alu Alu	total w			lu Alu strip	10= 1.68				
1. 勺,		3. 7. L	Jer rps	5. 7, A		7.	7.40		9. 4.	47	
2. Jr.	1,	4. %.4		6. h		8.	3.46		10. %.	40	
Total Weig	tht of ten Fill	ed Alu Alu strips = [5A. 2	3 7	D'II . J. A.I.	. i	۹ ۸_ پ		9		
Avg. Weig	ght of a Filled	l Alu Alu strip (B): t	otai we	eignt of ten	rillea Alt	i Aiu strip/i	0= 0.42	_			
		ould be identified)	* '								
Strip weig	ghing Done I	By: Aphamaloum	· CI	iecked By:	PA	-	Verified	By:	10	Alan Tara	
25.1		WEIGHT LIMIT SI				1 2020 7	Cime9.8.122	· <			
		lual empty cartons a							2 = 1 = 1 = 1 = 1 = 1 = 1 = 1 = 1 = 1 =		eser A
1.	6.9	3. & & &		5.	۲.9	7.	8.9	2 6	9. 8.8		· ·
2.	8.9	4 8.8			89	8.	8.8		10.		
		pty cartons = $8\mathcal{E}$		4,	1 -		1.20				
		empty carton (D) =To ual Leaflets are give			mpty cart	on /10= 8 ·	84				
		1	ii betov					a"	1		
1.	2.4	3. 2.3			2 1/4	7.	24			2.5	
2.	8.3	14 24		6.	2.4	8.	2.3		10.	24.	
	ght of ten Lea	aflets = 23 let (E): total weight of	often T	eaflets/10-	2.30	•					
Avg. Wei 25.2		CHECKS ON CAR		Leariets/10=	00						
	ten empty Ca		58 A		Avera	ge weight of	one empty	Carton	(D): 8·82	7	
Weight of	ten filled Alu		JA. 23		Avera	ge weight of	f one filled A	lu Alu	strip (B):	J.42.	
	ten Leaflets:		23.				f one Leaflet		2 . 38 ^	482300	9
		7.56				G = F + 1 %			- 30	Control of the contro	
Weight of	one filled Ca	rton F = (D+3B+E)	21/2	189	(To be	established	21.26	<u> </u>	1.69		
Checked I	by Packing/E	Date:	-,		Verifi	ed by IPQA	\/Date: <	Palu	120		
25.3	SAMPLE	DRAWN RECORD	:			- 2					-
Sr. No.		Sample collection	. 12		ty. of San	ple		10 0	ted by (Sign	. /Date)	19
1		nple (Initial)			Chols	* 1		112	्रत्या थी.		
2		nple (Middle)			2/01 %			母	while	- Greenwill	
3	Control San	nple (Final)		W	69			9 -	or will	Child Phone Stimes	
4	Stability Sa		. 13	300	1.61	10.1		9			
5	Other Samp	ole			JA-			-Mr			
6	Analytical s	sample		A GA	8-×101)	12×10/8		果	acatrifor		
× ×		Total Q	ty.	G	e xide		- 1	P	N. C.	F	
	Pr	repared by:			Check	ed by:	2011		Appro	oved By:	
Dept.	F	Production		Productio	n	Qualit	y Assurance		Head Qual	ity Assura	ınce
Sign.		L. Ka-		D00		inhi	4.		O Ka	of.	عمامها
Date		31/10/2020		31/10]	2020	To.	1 minor		X-122		
1	TYVALA		1	الاالات	/ / / /		TINCO	NTI	OLLED	CGSA	
INT	JUST HALL	TWATTANON!					UNICO	IIII	CHILID	0011	

	13)
	IMU H PVT I	

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.: GT F201004

Customer:

Generic Health Care Pvt. Ltd.

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

Date/ Shift	1	1		77				16	lesta	no				ורו	ilwo
Parameters	Specification	16	11/20	20	0		111	obser	vatior	ı				100	
Tarameters	Specification	Packing			IPQA										
Time		8:35	9 190	(4,30	0,00	12730	13/230	1450	65.55	1.10	13.36	15.40	17.50		10.00
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	40	er.	ois	olo	vla	षद	Q _O	elc	EK.	rok	既	ek.		ci
Carton Overprinting	Legible and readable	0b_	De	ok	অত	SIQ	aq	ಲ್ಟ	olc	je	et-	eic	ek	4	eil
No. of cartons in a shrink sleeves	10 packed cartons	TVC_	Qio	O) (Ole	Qa	oi_	a						ر	LX
Shrink wrapping temperature*		est.	<u>G;</u> ₩>	200	W.	ma isi	wa tit	no					<u>~</u>	-	- NA
No. of shrink sleeves in a 5 ply shipper	27 shrinks	CIKU	W.F	NE	24	m	wr	wn	ole	elc	ek	ek	0=	N.	36
Shipper strapping	Proper strapping	olo .	o)c	bh	ou	v.c	oi-	OL	de	ઝષ	elt	elv	ot		er!
Label appearance and Shipper appearance	Legible and readable	ØL.	ᇿ	છદ	3	رى	cis	oc	સ્	ok	e/c	6×	olc		74
Sealing of the shipper with BOPP Tape	H type	DIC	QIC	تارك	Oxo	OIC	062	do de	લો	ut	de	લંડ	터		d
Checked by		74	gr.	Jan	m	M	Ĭτ	λν	P	J.	\$	à	4		100

*Temperature to be mentioned.

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

Date/ Shift						-		1	oliile	oro	-		person and		
Parameters	Specification	171	11/20		Packin	g Lin		obser	vation			IPQA			
Time		パか	16,20			91.05		Second	1242	15:10Z					
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	da	વવ	٥١	de	иc		Ωc	relc tot	DK DK	此	0k		Street	= -
Carton Overprinting	Legible and readable	مد	ধ্ব	ole	er.	tx=	ue	OU	الالا	ыц	9k	Plc			
No. of cartons in a shrink sleeves	10 packed cartons	oi.	de	do	ol	Ole	DIT	de	Dic	Oli	DIC.	06			
Shrink wrapping temperature*		NA	NA	m	bis.	W	WC-	M	RiA	WIS	4	NA			i i
No. of shrink sleeves in a 5 ply shipper	27 shrinks	₽V#	wc	44	Ne	Ma	tus	Nr	NA-	Bo	NA	W-			
Shipper strapping	Proper strapping	DVE.	eve	OR	OF	ar	O-	œ	00	σk	€ċ_	06			
Label appearance and Shipper appearance	Legible and readable	OC.	ce	O.C	oi.	u	a	a	Die	0k	Ok.	ok	S CONTRACTOR OF THE STATE OF TH	المادم	1
Sealing of the shipper with BOPP Tape	H type	to	010	06	OZ	oc	or.	u	Ele	Ole	Ele	oŁ	201	-	
Checked by		747	K	34	1/2	N	2	m	10	à	0	(0)			Y

*Temperature to be mentioned.

	Prepared by:	Check	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	DOB	infra	O Mat us
Date	31/10/2020	31/10/2020	12/1/2020	CONTINUE DIVINO
	3111012020	31/10/2020	- 51/60/20	COMPROLLE

CD	SAI PRIMUS LIFE BIC Factory: R.S. No. 4/3, Plot No.33, R Villianur Commune, Pu	Curumbapet Industrial Estate,	Page 22 of 29
SAI PRIMUS	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.: 67 8 20 1004
Product	RAWIII MIAZIDE 3/12.3	Customer	Ceneric Health Care Put Ltd

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

Date/ Shift								19	111 mon	b		701	מכרון		
	C	19	11/12	020			- 3	obser	vation	ı		Lan Sept.			
Parameters	Specification	Packing					IPQA								
Time		1250	13.10	1410	1500	الله	17:62	18/10	12,70	15.00	1716	10:13		10	
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	00	vt_	Qc	ઇહ	Cyre	ae	oe	d.	6	4	cu.			ř
Carton Overprinting	Legible and readable	or	Ø.	عه	は、	٥١٦	α	œ	a	蚮	erc	ek	12 - 15-		
No. of cartons in a shrink sleeves	10 packed cartons	PAR	NO	100	the .	NA	Ne	No				~			_
Shrink wrapping temperature*	1	WE	WE	LAU	No	An	NB	Nt			7	_^	2 7077 HAD		
No. of shrink sleeves in a 5 ply shipper	27 shrinks	WE	NG	an	Ne	· Ne	Vo	w	_					-31	
Shipper strapping	Proper strapping	b/_	0i:	d-	رق	OF	ole	a	EF	ef.	6k	e/		1.7	
Label appearance and Shipper appearance	Legible and readable	ar .	ď٠	cia	Ol>	DOL.	00	02-	di	ER	ना	ল			
Sealing of the shipper with BOPP Tape	H type	Di	ರ್ಷ	Ofe	d-	Ø:-	oa	te	ac	4	ek	d.			
Checked by),,	1 9-	do	for	M	3000	- Jr	P	10	B	P	1. Section		

^{*}Temperature to be mentioned.

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

Date/ Shift		- we do	// int =		-	1					همند	- 500			
Parameters	Specification	Packing				obser	vation		IJ	IPQA					
Time	20/11/rona	atro	(g.m	นรอ	-1			- atylan -		11		36.51:			
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OC.	Ole	De	5					. I					
Carton Overprinting	Legible and readable	-35 <u>-</u>	ou	DE	ř z			Asid To	F E1'						
No. of cartons in a shrink sleeves	10 packed cartons	0p-	OI-	6L								18			
Shrink wrapping temperature*	1 52 1 52	itue	W.S	NO)		9 15 150 5 15	2			- Burn	27-3411 = 23 1X		
No. of shrink sleeves in a 5 ply shipper	27 shrinks	ale	ar	MA	gin L			1					20 10		
Shipper strapping	Proper strapping	yli	ÜL	200	5 4	r (1	(A)						OFFICE AND ADDRESS OF THE PARTY	
Label appearance and Shipper appearance	Legible and readable	d	dι	DIC			g -			-		.]			
Sealing of the shipper with BOPP Tape	H type	,pu	oi	ac											
Checked by		Just	Krr	des				1	4						

^{*}Temperature to be mentioned.

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka) (A)	infin.	O land was
Date	11/1/3/1/10/2020	31/10/2020	2000	V. 150110
ロソイドイナ	WWW.INVIEL		TIMONITO	I LED CO

Date/Shift. 15/11/1020 / Time: 9190 Balance I.D. No. P. D. B. D. SHIPPERS WEIGHING: Average weight of one filled Shrink (H): 222.9 Weight of ten Shrinks: 22.29 Average weight of one empty shipper (I): 1129. Weight of ten empty shippers: 11.295 Limit: $K = J \pm 1\% =$ Weight of one filled shipper (J) = (27H+I): 8.030 7.950 - 8.150 (to be established) pleilmon Checked by Packing/Date: Verified by IPQA/Date: Gross Gross Gross Gross Weighed Shipper Weighed Shipper Weighed Shipper Weighed Shipper weight weight weight weight By No. No. By No. By No. By (Kg) (Kg) (Kg) (Kg) Priys 39 58 20 1 2.125 Priles 8.130 8.100 8.135 40 59 2 21 Paive Pris 7.595 8.115 8.120 8-140 Prits Prive 3 22 41 60 Poly 8.105 8.130 8.115 Paire 61 4 23 42 8.130 Prive 1201,84 8.105 8.135 43 62 5 24 Prit Poly 8-100 8.175 2.140 25 63 6 44 Pris 8,090 8-140 45 64 7 26 8.140 Driy 2.150 8,090 Pary 65 27 46 8 8-145 8,085 Pric 8,150 POINS 66 47 9 28 Pry DE IN 8.100 8.150 8.155 Priys 67 10 29 48 8.135 poly 8-145 Poigs 2.100 Prik 30 49 68 11 Priys 8.11.0 Poly 2.149 Polys 8.105 Prix 69 31 50 12 Poly Driye 8.160 8-165 2.100 70 13 32 51 Pring Priys 8.085 8.160 Priv 8-110 71 14 33 52 Priye 8.115 8.065 Drive 8.130 Poik 53 72 15 34 8.150 Drige PHYS 8.065 8.130 35 54 73 16 8.080 8. ILD Polys 8.135 Prite Prly 17 36 55 74 2.135 8-145 8.135 Priga priya Drit 75 37 56 18 8,195 8.135 Drive 8,125 Prila Dric 19 57 76 2-140 Drise 8.145 8.125 priye Checked by Sign / Verified by Loose pack details: Total No. of De-foiled tablets Sign / Date: shippers weighed: Date: packed in Shipper No: ...5.9.. Shipper No: Quantity 200 x 3 x10 1 59 89

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

Prepared by:	Chec	Approved By:	
Production	Production	Quality Assurance	Head Quality Assurance
L.Ko.	ACP.	whi.	D hard los
31/10/2020	31/10/2020	13/12/2020	1. 1.
	Production L. Ka	Production Production L. Ka. 31/10/2020 31/10/2020	Production Production Quality Assurance L. Ka. 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.

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.: GF 201001
Customer: Generic Health Care Pvt. Ltd.

28. MAN POWER ALLOCATION:

DATE: 15111 /2	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Laleshu.
Printing Checking in Alu Alu strip	mahashuoro'
Alu Alu strip weighing	Laleshor
Insertion of Alu Alu strip and leaflet into carton	Bhann. Varsha
Cartons weighing	Varsha
Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	No -
Shipper Label Pasting	Mathyen
Shipper Weighing	Mishyon
Shipper Strapping	Dhanarboar
Shipper packed	From
Signature of Packing	574

DATE: 19.17.11/1922	
SHIFT: U	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Bhana, Greate
Printing Checking in Alu Alu strip	Lakehn
Alu Alu strip weighing	malogishow
Insertion of Alu Alu strip into carton	Bhan
Cartons weighing	Vargha
Insertion of carton into shrink sleeve	Na
Insertion of shrink wrapped carton into shipper	Na
Shipper Label Pasting	Baloraya
Shipper Weighing	120loby
Shipper Strapping	10
Shipper packed	From. 20 to. 327.
Signature of Packing	And

DATE: 20/11/100

ACTIVITIES	DONE BY
Alu Alu strip Checking	Sunoga, , Sarcinga
Printing Checking in Alu Alu strip	Barandar.
Insertion of Alu Alu strip and leaflet into carton	0
Alu Alu strip weighing	proha. , Golpana Laleshar, maguhan
Cartons weighing	Narlman.
Insertion of carton into shrink sleeve	N.A
Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	· NA
Shipper Weighing	Modhine - morastos
Shipper Strapping	N.J.
Shipper packed	From 40to 50.
Signature of Packing	Just

SHIFT:	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Bhany
Printing Checking in Alu Alu strip	Lakelmi
Insertion of Alu Alu strip into carton	magether anti
Alu Alu strip weighing	magishio an' Varshish
Cartons weighing	Varshish
Insertion of carton into shrink sleeve	No
Insertion of shrink wrapped carton into shipper	M
Shipper Label Pasting	Jakgen
Shipper Weighing	phanoldown
Shipper Strapping	Dhandeloun Dhonaleloun
Shipper packed	From 5.1to.59
Signature of Packing	CA.

	Prepared by:	Chec	ked by:	Approved By:		
Dept. Production		Production	Quality Assurance	Head Quality Assurance		
Sign.	L.Ko	ACO)	infri	O hard you		
Date	31/10/2020	31/10/2020	raplation	X 1/0		
" (V.)	VILL A SASSON AND COLOR	!	i i NCON	TRALKITURY		

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C/D	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Ku Villianur Commune, Pudu	Page 25 of 29	
SAI PRIMUS	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.: GF 201004
rioduct	KANITHAZIDE 3/12.5	Customer:	Generic Health Care Pvt. Ltd.

29.	PRODUC	T COUNTER CE	IECK LINE CLI Date	EARANCE: Shift 21 1129	n p		, M			
Previ	ous Product:	Dami thithia				ì				
Ċ.,			2				Obser	vation	4	
Sr. No.	3 3	Che	ecks	Ti	me og:	10				
	Cl. I. I.		. ,	16 6		king	IPQA	Packing	IPQA	
1	product.			d free from previous		7				
2		sure that waste bin				<u> </u>	/		**	
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.									
4	Check and ens	sure the Correct sta	itus board is writte	en.	. L	7	/	. \		
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 en	sure the cleanlines:	s of hatch for conv	eyor belt.	L		1	1)	
8	Check and en	sure the cleanlines	s of conveyer belt	with collateral bloc	k.	^				
9	Check and en	sure the dispensed	secondary packing	g material.	-		/	The beautiful and the second	1 12 13	
10	Check and en	sure the cleanlines	s of documentation	n table.	L	1	~			
11	Check and en	sure the Preventive	maintenance reco	ords and log book.					1-84	
Note	: Tick mark (√)	if Complies, (X) i	f does not comply	and (NA) if not app	licable.			~~	, i	
		ry / Not satisfacto		Cleaning Satis (IPQA)Sign. /I		ot - sati	sfactory#	20101	2500	
		he cleaning is not s area / line and reco		s not certified then	investigate 1	the cau	use of the fa	ilure and tal	ce necessary	
1	Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strappi	ng	Weighi Balan (shippo	ce	Area	
ID. N	lo.:	Polcos 1002.	PDBAL 013	Mã	POLSTAL	pol	po) Borl	1029 pa	idaing	
Previ	ous Product:	Rami'thay	ude lolio .x				X: E	D-1	9	
Batcl	n No.:	95201009					- Selection - 10	_11 =	× 11	
Clea	ned by:	Simeani							= = = = = = = = = = = = = = = = = = = =	
Chec	ked by Packin		محداً!		T aktion and a second				7: 1- a t	
Veri	fied by IPQA:	B	ound 11/1c	-			+			
Rech	ecking Started	Date/Time:	99:12	Completed Da	ite/Time:	18:	30			
AP	PROVAL FO	R COUNTER CH	ECK:	Approved by IPQA	Sing/Date:		Jahre			

	Prepared by:	Ch	ecked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	10k.	infin	O Mary
Date	31/10/2020	31/10/2020	2/1/10/2020	1-15/10/2

UNCONTROLLED CC7Y

CD	Factor	SAI PRIMUS LIFE BIO y: R.S. No. 4/3, Plot No.33, K Villianur Commune, Pud	urumbapet Industrial Estate,	Page 26 of 29
SAI PRIMUS	BATC	CH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
Product	DAMITHIAZIDE 5/12 5		BPR. No.: BPR/T/134-00	Batch No.: G F 201004
Product RAMITHIAZIDE 5/12.5		Customer:	Generic Health Care Pvt. Ltd.	
		OF PACKED SHIPPERS:		
DATE: .2.1.1.1/100	•		DATE:	
SHIFT:			SHIFT:	
ACTIVITI	ES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checki	. 17	Bhana Jayeldoshi	Alu Alu strip Checking	
Printing Checking in strip	Alu Alu	Indira Loleshy' maguhum'	Printing Checking in Alu Alu strip	
Alu Alu strip weighi	ng	Lakeling' magushung "	Alu Alu strip weighing	
Checking of Alu Alu leaflet in carton	strip and	Surayuz . Va	Checking of Alu Alu strip and leaflet in carton	
Cartons weighing		vargha,	Cartons weighing	va
Printing Checking in Label	Shipper	herha	Printing Checking in Shipper Label	9 - 8
Shipper Weighing		breena	Shipper Weighing	
Shipper Strapping		phonotoleshy,	Shipper Strapping	
Shipper Checked		From. 61to 5.9	Shipper Checked	Fromto
Checked By Packin	g	April 21/11/1000	Checked By Packing	
Verified By IPQA			Verified By IPQA	
DATE.			DATE:	
DATE:	sai	, Access to the v		
SHIFT:	NAME AND ADDRESS OF THE PARTY O	A CALL TO THE PARTY OF THE PART	SHIFT:	relations are an incident to the second
ACTIVITI		DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Check			Alu Alu strip Checking	
Printing Checking in strip	ı Alu Alu \	,	Printing Checking in Alu Alu strip	
Alu Alu strip weigh	ing		Alu Alu strip weighing	
Checking of Alu Alu leaflet in carton	u strip and		Checking of Alu Alu strip and leaflet in carton	
Cartons weighing	M	with the second	Cartons weighing	N_{c}
Printing Checking in Label			Printing Checking in Shipper Label	
Shipper Weighing			Shipper Weighing	
Shipper Strapping			Shipper Strapping	
Shipper Checked	4	Fromto	Shipper Checked	Fromto
Checked By Packin	ng	1,0	Checked By Packing	

No. of Defects Identified:

Verified By IPQA

1. Minor: -- WIL -2. Major: N4-3. Critical: NA

Batch Allowed for Despatch: Checked By: -- w-

Verified By: NA

Verified By IPQA

	Prepared by:	Che	ked by:	Approved By:	
Dept. Production		Production Quality Assurance		Head Quality Assuranc	
Sign.	L. Ke	AGP,	julyi,	O part 1100	
Date	31/10/2020	31/10/202	61/10/200	V. 150/1010	

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 .: GT & 20 1004 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	5 2.200	157.00	20400	00406	\neg	75	300 m/s/ks)	0월.
В	Additional material received for the batch	NA	H:0-1	I/A	PM		v a-	M	≅
C	Total material received (A+B)	\$2.200	157,000	20400	20/100		75	30 amz)	03
D	Quantity packed	21.340	98450	17948.	17948		59	150 分为)	03
Е	Quantity rejected (Online) & Destroyed		M. 215	340	MA		W.A	1/4	M
F	Quantity Returned	22.040	51.050	2100	24.40		16	150(mH)	ĮζΔ
G	Sample affixed on BPR	0.0002	B	01	01	נייט	NA	VA-	مكن
H	QC samples	0.003	0.030	. M	M	13	M	M	M
I	Other samples (If any)	0.009	0.091	11	11	2 44	an.	V~	ng.
J	Total accountable Quantity (D+ E+F+G+H+I)	51.912	154.864	20400	20400		45	300(m/s)	03
K	Variation (C – J)	0:251	134 ه	<i>-</i> 0-	-0-		-0-	10-0-	-0-
L	%Variation (K x 100)/C	0.55%	0 .08 ⋅v	_0 -	-0		-0	0-	-0 -
M	Acceptable limit	±2%	<u>+</u> 2 %	±2%	±2%	±2%	11/1-		

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

31. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. _____ NF

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	W-	16	150	8
Material returned by packing Sign./Date	Any July	exteritions	Anglina.	Angliano	N NS	And	Aprile	4
Verified By IPQA Sign./Date	D1020	Place	20	10	, 10	RP	36	8
Material received by Store Sign./Date	17. 12. 20 mg	~ Ash	N Ant	N My h				

32. DESTRUCTION OF REJECTED/INUSED PRINTED PACKING MATERIALS AND STEREOS.

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)
Db	8520	7.215	310	139-	NA-	M-	rys_	m
	- 4			1				184
06	8.520	7.215	340	150	ns-	Ma.	m	no,
A	19/11/20							
	06	Poil (Kg) Poil (Kg) Poil (Kg) Poil (Kg)	Stereos Foil (Kg) (Kg) Ob 8.520 7.215	Stereos Foil (Kg) (Kg) (Nos) Ob P. 520 7.215 340 Ob 8.520 7.215 340	Stereos Foil (Kg) (Kg) (Nos) (Nos) Ob 0520 7.215 340 90 Ob 8.520 7.215 340 100	Stereos Frinted Alu. Foil (Kg) Base Foil Cartons (Nos) Chos) Ob F520 7.215 340 PA Ob 8.520 7.215 340 PA	Stereos Frinted Alu. Base Foll (Kg) (Nos) Leatiets (Nos) Sleeves (Nos) (Nos) Ob 0520 7.215 340 M M M M M M M M M M M M M M M M M M M	Stereos Frinted Alu. Base Foil (Rg) (Nos) Cartons (Nos) Sleeves (Nos) Shipper (Nos) (Mtrs.) Ob 8.520 7.215 340 PA

Verified by (IPQA)

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	2 · Ko	496.	infro	0 loves were
Date	31/10/2020	31/10/2020	20/10/200	1.15/10

	0	Factory	: R.S. No. 4	MUS LIFE B 1/3, Plot No.33 1r Commune, F	, Kurumbap	et Industrial Esta	ite,	Page 28 of 29	3
SAI PR		BATC		G RECORD		ct Code: R09		Batch Size: 6,00	0,000 Tablets
		D A MATTERIA	10TDE 5/1		BPR.	No.: BPR/T/13	4-00	Batch No.: G	320100L
Proc	luct	RAMITHI	AZĮDE 5/1.		Custo	mer:		Generic Health	Care Pvt. Ltd.
33.	BATCH R	ECONCIL	ATION:				4.	2	A- 1 500
A	Batch Size	3	<u> </u>						6,00,000 Nos.
В	Quantity r	eceived for p	acking					5	76000
С	Total quar	ntity packed		<u> </u>			. 1 5	2.	28440
D	Control sa	ımples)_ = . 		, ,	SO 0
Е	Analytica	l Samples							120
F	In process	samples		= 5 y v		×100			760
G	Others sar	nples if any	(Stability, R	egulatory Sam	ples, etc.)				M .
H	Packing L	oss = B - (C	+D+E+1	F+G)					36480
I	and the second second second second	S = A - (C +							50480
J	Packing y	ield % (C + 1	D + E + F+0	G) / B X 100 (Y	ield Limit 9	/6)*			93.66.1
K	Batch Yie	eld % (C + D	+ E + F +G)/AX100(Y	ield Limit %)'	*		89.92%
Chec	7.0	ablished .cking /Date ER OF FIN		ODS:	(30)	Ver	ified by IP	QA/Date:	Ti-20
	FGTN	The second secon	D 1 G1	No. of	No. of	Transferred	FGTN	FGTN	FGTN
Date	No.	Sales	Pack Size	Units in a shipper	Shippers	Quantity	Raised b		Received by Stores
110	50.50	Sala.	BAIDS	3=6×3×1=5	59	532H4	Ame	10	HITTER
111/2020	0989	Qu'les.	V.	200 × 3 × 103	0	600	iAine	. 80	Harva
	- To a series	Care and a		Total Qty. To	ransferred	53 844	Lind	- P	MON
35. Dur Sr. No.	ring proce	FION/ EXC ss if there is Stage	any Deviat	ion / Exception	/ Exception	NOTATE STREET TO THE PROPERTY OF	in below	No contract agreement of the contract of the Tract	Observed By
			E 1 4 Value 12 M						
w	y y				_ 12444	Children and Children		ANTI-CALLES CONTRACTOR	
Check Pac	cking:	VIEW DETA	AILS:	Verified Packing mana				Approved by Head QA:	
36.	HANGERGAL WASHINGTON	MARKET BEST PERMITTING	CONDUCTOR OF STREET	ALEGABRICAVED SAFE WAS BLOCK		PERSONAL PROPERTY OF THE PARTY	AND CONTRACTOR OF THE		
36.	Rev	iewed by		The Market State of the Control of t	Name			Sign. /Da	te
	Rev g Executi			Seth		on P		Sign. /Da	te \\2010
Packin					is show m	1 10 2		Sign. /Da	12020
Packin QA Ex	g Executive		er/ HOD		is show m	1 10 2	3	DODY 21/1	12020
Packin QA Ex Produc	g Executive	ve stant Manag	er/ HOD		is show m	on P INDAN'B WHAN. K.S	32	DODY 21/1	12000
Packin QA Ex Produc	g Executive	stant Manag			Nyhom Ruman VBRAME AMUR	1~29~ B	32	Aller 211 S. May	11/2020
Packin QA Ex Produc	g Executive ction Assis	ove Stant Manag OD Prepared t	py:	BALASL	Whome Rumpp JBRAMF AMUR Check	WAAN R.S		Palito 211 S. Mas	12020
Packin QA Ex Produc	g Executive ction Assis	stant Manag	oy:		Whome Rumpp JBRAMF AMUR Check	1~29~ B		Palito 211 S. Mas	11/2020 11/2020 11/12020 roved By:

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C/D	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, K Villianur Commune, Puc	Page 29 of 29	
SAI PRIMUS	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.: GIF 201004
Troduct	KANTITITADIDE S/12.5	Customer	Generic Health Care Put Itd

37. BATCH RELEASED FOR DESPATCH:

Total quantity released: 528440 No's

Head QA sign/ Date:

38. REVISION HISTORY:

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

	Prepared by:	Cho	ecked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	KOK.	rong	O paret vo
Date	31/10/2020	31/10/2000	24/17/20	1. 10

MASTER COPY

CALDDIALIC	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, K Villianur Commune, Pu	Curumbapet Industrial Estate,	Page 1 of 29
SAI PRIMUS	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 20/207
, oddet	TO WILLIAM STATES	Customer:	Generic Health Care Pvt. Ltd.

	CKAGING RECORD COVER SHEET
PRODUCT NAME	: RAMITHIAZIDE 5/12.5
GENERIC NAME LABEL CLAIM	: Ramipril and Hydrochlorothiazide Tablets Each Uncoated tablet contains: Ramipril BP
3 SA CONTRACTOR OF THE CONTRAC	Excipientsq.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	: GF201004/31/10/2020
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)	: mystrow
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: 20/12/2020 : 20/12/2020
MFG. DATE: 1.3/2020	EXP. DATE: 11 2023
ALLOTTED BY: QA SIGN/DATE:	COUNTER CHECKED BY: QA SIGN/DATE: S.
QUANTITY RECEIVED FROM PRODUCTION	: 597050 Tablety
DATE OF COMMENCEMENT: 27 12 2020	DATE OF COMPLETION: de 12/2010
QUANTITY	: 6,00,000 tallets
RELEASED QUANTITY OF PACKED TABLETS	: 596400 pholets
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	A TELININON

ved By:	Approved	ecked by:	* Ch	Prepared by:	
ity Assurance	Head Quality	Quality Assurance	Production	Production	Dept.
w X	8 km	inni	708	L Ko	Sign.
0637	mort pp (21/0/200	31/10/2020	773110120201	Date V
	rpoliten	2 Nova	31/10/2020) ((43/1/6/12/06/1) (C	Date VS



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

Batch No.: 67 F & 6 18 6 7

Product

RAMITHIAZIDE 5/12.5

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

Generic Health Care Pvt. Ltd.

1. INDEX

Sr. No.	Content	Page No.
Batch Pacl	kaging 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
1.1	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
19	Over printing details, Shipper Label specimen	19
20	Individual Strip weighing limit, Carton Weight Limit Setting, Weight Checks On Carton, Sample Drawn Record	20
21	Secondary Packing In process Checks	21-22
22	Shipper Weighing	23
23	Man power allocation	24
24	Product Counter Check Line Clearance	25-26
25	Packing material reconciliation	27
26	Excess packing material return to store	27
27	Destruction of rejected/unused printed packing materials and stereos	27
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
33	Revision History	29

	Prepared by:	Che	ecked by:	1.	Approved By:
Dept.	Production	Production	Quality A	ssurance	Head Quality Assurance
Sign.	L. Ka-	ACK	infin		Jung
Date V	31/10/2020	31/10/2020	21/	AMAYON'	TROVED CCSV
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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. 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 20 / 20 7 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

1.		(Yes/No/NA/No.*)
	No. of pages of BPR+ Additional pages (If any) *	m
2.	Line clearance and environmental record	MU
3.	Processing activity done by and checked by is signed	4/9
4.	Dispensing	
a)	Equipment clean tag and dispensing tag attached with batch record	40
b)	Packaging material is checked	45
5.	Packing	P
a)	Rinse water analysis report attached with BPR	7
b)	Approved specimen of printed foil, show box and shipper label are attached	4.2
c)	Control / Stability / Finished product analysis samples are withdrawn	4,0
d)	Reconciliation of packing materials is done	1/p
e)	Tablet reconciliation is done	45
f)	In process checks parameters done at regular interval and recorded into BPR	417
6.	Attachment	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
a)	Finished Goods Transfer Note	UB
b)	Certificate of analysis of finished product is submitted	V
c)	Stereo Impression Form and Destruction Record	400
7.	Complete set of BPR Submitted	MP

Checked By QA/Date:	
Toll Wind	
*Mention total number of pages.	
Remarks (If any)	

	Prepared by:	Chec	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Kom	DOP	whie	1 South 12
Date V	3110/2020	21/20/2020	4. Jahr	200 00 202
1000		(1) 001 1222	- 2NENCON	TROLLEDICCOV

SAI PRIMUS

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,

Villianur Commune, Puducherry-605009.

BATCH PACKING RECORD

Product Code: R09

Customer:

Page 4 of 29

Product

RAMITHIAZIDE 5/12.5

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

Batch Size: 6,00,000 Tablets Batch No.: 67 F801207

Generic Health Care Pvt. Ltd.

PACKING MATERIAL SPECIFICATION AND INDENT: 3.

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	m n	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:	Cho	ecked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko	100	orps.	o- fred ac as
Date v	31/10/2020	31/10/2000	21/10/2 TINO	NTRALLEU COLI
	C. A FRANCE NEEDS OF THE CO.			UITING

SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009. 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.: SF201207 Customer: Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS

Date 25/12/2000 Time 15:35

Sr.	CHECKC	Observa	ation*
No.	CHECKS	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.		1
2	Check and ensure that display stand and weighing balance are clean.	1	/
3	Check and ensure that SS trolley are clean.		/
4	Check and ensure that area (floor, walls, ceiling, doors and windows) are clean.	1	1
5	Check and ensure that Magnehelic gauges, tube light fixtures, supply grills, return riser grills and filters, electrical fixture are clean.	1	/
6	Check and ensure that all the sides of Mobile Laminar Air Flow is clean	1	/
7	Check all the gauges of Mobile Laminar Air flow before switching ON.	1	-
8	Check and ensure that weighing balances and pressure gauges to be used are within calibration due date.	1	1
9	Check that the daily records (Balance Logbook, RH & Temp. record) are updated and signed.	1	
10	Equipment status is updated for Cleaned and Preventive maintenance.	/	/

Mobile Laminar Equipment Weighing Balance Area Air Flow Full Store ID No. MA STIBALION M4M STILDE DO Previous Product T9/028-12 B. No. THOOPLL Cleaned by Sign/Date Checked by Store Sign/Date Verified by IPQA Sign/Date

ENVIRONMENTAL CONDITIONS: Date At Land Time: 15'48	Observation	Checked by Store	Verified by IPOA
(For Reference SOP No.: QAGN/011)	u chruce je sa	Sign/Date	Sign/Date
Temperature (Limit: NMT 25°C)	53,C	M22/Whore	Balan
Differential Pressure across the booth Limit: 5 to 20 mm Water	12mm	My My May	Patrolaro

APPROVAL FOR DISPENSING BY IPQA: Si	gnI	Date: 1 Macro	w)
Dispensing start Time	End Time 16:35		

	Prepared by:	Che	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L·Ka	ROY	infri	O John Lie
Date	31/10/2020	31/10/2020	21/19/2020	1-150/19
I I WA			TINCO	ALDOLIED OCH

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

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.: FRO 12 07
Customer: Generic Health Care Pvt. Ltd.

		2 4 2 4 3		Custo			. 121,50	are Pvt. Ltd
5. DISPENSIN	G RECORD OF	PACK	ING MATER	IALS:	Date 2 VINhord St	iftTime		
Material Name	Item code	UOM	Req. Qty. for 6.0 Lac	Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified b
252mm Ramithiazide 5/12.5 Printed foil	PPF/SP/R009	Kg	, , , , , , , , , , , , , , , , , , , ,	28.80	Pm9/00531	02	25/12/2000	15 12 ha
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	153.000 (To be established)	क्रवेग	Pm410=766	07	25th horo	25 12/20
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	20400		Pm4 (005/8 Pm4 (005/8		25/12horo	25/12/201
Ramithiazide Printed Leaflet	PPL/SP/R002	No	20400	20400	12500 /5md	03	whos	B who
Shrink Sleeves (PVC)	PPS/SP/P001	No	2040				r 16 -	
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	75	47	Pm4100639	08	2 Mohan	25/27
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	10	10	Pmg100036	02	28/12/20	E Prin
3' Plain BOPP Tape	PUB/SP/B001	No	3	2ء	Puls/26/2/2/2		28/11/20	231
Strapping role.	PPR/SP/S001	Mtrs	300	300	Pmylosogn	٥٢,	28/when	25/12/20
Shipper Label	NA	No	76			Nn	3	—18t

	Prepared by:	Che	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	701	infrio	O hours
Date	31/10/2020	31/10/2000	-tall 0/2010	
VAC	MONTHONITON			CONTROLLENCE

S	Factory:	R.S. No. 4/3,	JS LIFE BIO Plot No.33, F ommune, Pu	Kurumbap	et Industri	al Est	ate,	Page 7 of	29	•	
SAI PRIMUS	BATCH	PACKING F	V 1		ct Code:	R09		Batch Size	e: 6.00.0	00 T	ablets
LIFE BIOTECH PVT LTD	2.2.02		ti do tio	7	No.: BPR	1110		Batch No.			
Product	RAMITHIA	ZIDE 5/12.5		Custo	-	7 1/13		Generic F			
6. LINE CLEA	RANCE CHEC	CKS:	Ž.	Custo	illet.	ilit i z		Generic I	icanii C	are r	Yı. Dia.
6.1 PRIMAI	RY PACKING:		Date/				7	·28.)1	2.1.20.20	oĢ	}
Previous Product:	Calilmax	P		Batc	h No.: 5	1435	2023P	01	7.		
r.	a-	Checks				Time	09:00	Obsc	rvation eq.	10	
0.		Checks				rinc	Packing	IPQA			IPQA
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	sure the differer				ecified lim	it	1	V	1	1	~
	sure that waste l				.~	-4	1	/	13		_
	perature and re				ecitied lim	iit	1-1	1	1-7		<u></u>
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	uct /batch are re		elected totis	, empty (Lores of R	on or	1 9	~			1
Check the sur	Toundings of th		d free from t	he previo	us product	ts and			17		
8. batch		Marie 1		1 × 4 ×		350	1	~	5		1
	printing stereo							V	15		1
	e daily records	(log book, b	alance, temp.	. & RH) a	are update	d and		1			
signed.	sure the Cleanli	ness followi-	a change nad	of Al. A	lu otrin	- 12 - 1	1	10	19		1
1. packing mach		ness tollowin	g change part	ot Aiu A	iu sirip		5	V		1	1
	absence of prev	ious batch/ p	roduct at mac	chine conv	evor belt.	T	1 /	100	1)		
Check Hoppe	r from Top, bot						1	1			
side of convey	yor belt and coll	lating unit.		** *	1.55		5	V			1
								and the second second second	10		
Check for cle	aning of hopper	r, feeding cha	nnel, vibrato	r plate, in	feed rolle	er and			17		.1
sweep brush.			nnel, vibrato	r plate, in	feed rolle	er and	1	~	7		1
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sweep brush. c) Check tool be Note: Tick mark (x/) Cleaning satisfacto Checked by Packin #In case the cleanin echeck the area / lir 6.2 AREA A Previous Product S. Equipmen 1. Alu Alu Pa 2. Alu Alu Pa 6.3 ENVIRO Check the environment Refer to SOP No.: SOP: QAGN/011 Temp °C Limit: NM RH % Limit: NMT DP Limit: NLT 10 I Primary Packing S APPROVAL FOR	ox, thinner and in if Complies are ry/Not-satisfacing (Sign. /Date) ing is not satisfacine and record. IND EQUIPMING: (Alumen) it / Area Name acking Area acking Machine DIMMENTAL CONMENTAL CONMENTAL CONMENTAL CONMENTAL CONTACT	nk box nd (X) if does tory : : : : : : : : : : : : : : : : : :	not comply INDED Cleaning Type A/B B S: acking area and acking area and acking area and acking area and acking by B Packing Sign/Date B Y 991121 B Y 991121 Complete	Clea Verithen investigated by the clean SOP PDOP/02 the start Verities Sign Sop	ning satisfied by IP tigate the output of process ified by PQA n/Date of process ified by PQA	ozol and F Date Obs	y/Not-satising. /Date/Tin Date/Tin Date	sfactory): re and tak ne: 26 12 Chec (Par Sign Bign/D Packi Sign/D Packi Sign/D	ked by cking) Doba	Verification of the state of th	ified by PQA) gn/Date ided by QA //Date
sweep brush. c) Check tool be Note: Tick mark (x) Cleaning satisfacto Checked by Packin #In case the cleanin echeck the area / lin 6.2 AREA A Previous Product S. Equipmen 1. Alu Alu Pa 2. Alu Alu Pa 6.3 ENVIRO Check the environmen Refer to SOP No.: SOP: QAGN/011 Temp °C Limit: NMT DP Limit: NLT 10 I Primary Packing S APPROVAL FOR	ox, thinner and in if Complies are ry/Not-satisfacing (Sign. /Date) ing is not satisfacine and record. IND EQUIPMING: (Aluma) it / Area Name acking Area acking Machine ONMENTAL Cental conditions Da Of MT 25°C 60% Pascal Started Date/Ti PRIMARY PA Prepared by:	nk box nd (X) if does tory ctory / line is ENT CLEAR P Eq.ID. /Area. No. spunpplacula PDI ALUR CONDITION of primary printe 241121-205 bservation 24 C Soy, lo me:27112122-3-4 ACKING: IP	not comply	Clea Verithen investigation in Clean SOF PD PDOP/02 the start Dec Verithen investigation in Clean SOF PD PDOP/02 the start Dec	ning satisfied by IP tigate the output of process ified by PQA n/Date of process ified by PQA	factor QA (Scause NG PL & Date Obs	y/Not-satising. /Date/Tin Date/Tin Date/	sfactory): re and tak ne: 26 12 Chec (Par Sign Bign/D Packi Sign/D Packi Sign/D	ked by cking) h/Date table) 11.0 h/2022 Approv	Verification of the state of th	ified by PQA) gn/Date ided by QA //Date

*

Material Name	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	Pm4/00531 Pm4/00731	02,	84	2
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	pm6 100766	LO L	84	Q.
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	Pmg 1007ds	02 07	8y,	B
Ramithiazide Printed Leaflet	PPL/SP/R002	No	pm G 100521	03	- Ry	Q
Shrink Sleeves (PVC)	PPS/SP/P001	No				
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	Pmg 100639	08	84	Q-
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	Pmg 1 00036	02	84	Q.
3' Plain BOPP Tape	PUB/SP/B001	No	PMB 241019/02	0)	84	Q
Strapping role.	PPR/SP/S001	Mtrs	pm61 100032	0)	84	@
Shipper Label	NA	No	The Later of the Control of the Cont	N		

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.	84 1/2/2020	Man'	84 Juliano	Swinhow

9. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift. 27 112 12020 G., Time: 191.15. (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	84	(8)
2.	Relative Humidity observed on display (Limit: NMT 60%)	58%	84_	2
3.	Bulk product containers are of the required product/Batch number and is approved by QC	yes	84	@
4.	Status label of machine/ line is for same product	ye,	84	8
5.	Printed foil/Base rolls are of the required product.	Yes	84.	(2)
6.	All secondary packing materials are of the required product	ye,	81	(3)

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	200 mg.	811-	(A)
2.	Colour of Tablet	Pink colour	84	(A)
3.	Quantity (Net Qty.in Kg)	119.410	84	Q.
4.	Number of Containers	04	BU	D

	Prepared by:	Che	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	100	in	0 mg 13
Date	31/10/2020	31/10/2020	21/10/20	COMPOST EDICE
1 / You	1) ([1, 1, 1()SIF M()) M	8	UN	CONTROLLED COL

	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, F Villianur Commune, Pu	Curumbapet Industrial Estate,	Page 9 of 29
SAI PRIMUS	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.: 67 F 201207
	KAMITHIAZIDE 3/12.3	Customous	Canadia Maalth Cana Part 141

11. WEIGHT VERIFICATION RECORD OF RECEIVED SEMI-FINISHED PRODUCT: Balance I.D. No.: PD | B AL | 614

- 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
Pamithearide	GF201207	12/202	11/2023.	119,410 Kg Equivalent to 5 97000Nos.	From Container No. 0 To Container No. 04 Total No. of Containers taken 04
Checked by Packing (Sign. /Date):				Verified By IPQA	(Sign. /Date):

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	Torish	(1)_	11			* ***
2	22.610	Jorish	8	12		- x.5 ₀	Sax
3	.33.220	Torish	CD/	13		and the street	1
4	29.880.	Jerish	(2)	14		ARE TAIL A	
5	with the set			15		F	
6			7 1 -	16			3° 1' 1
7		A district	×	17	- 7	1 11 11 11 11	AL
8		lat		18		WA	
9				19			
10	18,	90.00		220			

13. CONTAINER CONSUMPTION DETAILS:

CN	Ti	ime	Container	·Consumed	0.31	Tit	ne	Container	Consumed
S. No	From	То	No.	by S. No	From	To	No.	by	
1	09:10	12110	0)	Ham'	11		CARLONA MONOMES MANAGES		
2	12:15	15'00	02	Ham!	12			osii Ti	
3	09!20	14:45	03	Mari	13				
4	14:50	18:30	<u>O</u> s	Hari	14		16.		
5	V				15	_ = [-			R S C SE
6					16	X.11			
7	_ # #i				17		7	ο Υ	
8			- Tro		18				
9	r The Wes	9 1	1 20	2 (20)	19 🦏 👸		m1 170	n tradit	,
10			1	The Property	7084		1 20	2.0%	11 45 /

Checked By Packing (Sign. /Date): Deligion Verified by IPQA (Sign. /Date):

	Prepared by:	Check	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko-	ACA.	myne	O Kut I
Date	31/10/2020.	31/10/2020	21/10/200	1. (0)
Corl	《新祖、夏、黄星原居、巴州(美),郑七子 《		INCON	TDOTI FD CCOV

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SAI PRIMUS LIFE BIOTECH PVT LTD Product

SAI PRIMUS LIFE BIOTECH PVT LTD

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

lustrial Estate, Page 10 of 29

BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

RAMITHIAZIDE 5/12.5

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

Batch No.: On FODIZOT 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	6r	Ok
Batch No.:	GIF 2012 D 7	OŁ.
Mfg. Date:	12/2020	Ok
Exp. Date:	1112023	ok
Item Code: 13/0232	014	Clara Okoca Carlo
Pack size (3 x 10's)- Carton	ok	0k
Other instructions if any	NA	r4
Initiated by	Hany's	Manjo
Checked by Packing (Sign. & Date)	84271121200	8127/12/2020
Verified by IPQA (Sign. & Date)	(8 27/12/2020	7 (3) 24/12/2020

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	May's	0427/12/2020.	8-2+/12/201-0
		· 自己的	V .	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	hall the second
			A	4 3 30	Service
			1	NA	

16. PACKING INSTRUCTIONS:

- 1. Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
- 2. Issue the stereos 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 IPOA.
- 10. Pack 10 tablets per Alu Alu strip.

Time record for packing detail

		Primary	y packing	Seconda	Checked by		
Sr. No.	Date/Shift	Started at	Completed at	Started at	Completed at	(Packing) Sign. & Date	
0)	24/12/2020	69110	15:00	09:20	15!10	8427/12/20	
02	20 112 202	09:20	18:30	20130	18:40	8/28/12/20	
			avi			10.	
						187	

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

In process checks frequency for packing and IPOA. (As per SOP No · OAGN/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:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	DOK.	infrie	Q mot .v
Date	31/10/2020	31/10/2020	21/0/25011	CONTROL TENENCE
SV- AND	MANADATIAN	M s		CUNTRULLAN) (LIC

	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, k Villianur Commune, Puo	Curumbapet Industrial Estate,	Page 11 of 29		
SAI PRIMUS	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.: GF201207		
Troduct	KANTITITIZION 3/12.3	Customer:	Generic Health Care Pvt. Ltd.		

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	BPE GE 10'	Ok	842-111212020	(1) 3/12/20
Sealing Temperature	(160 °C - 200°C) To be established	190°C	84 27/12/2020	25/12/200
Leak test to be performed onAlu Alu strip	Nil (No Alu Alu strip should fail in leak test)	ok,	8427/12/2020	Any 202
Machine Speed	To be established	28	81 27/12/22	~ 1. 1

Sr. No	Proc	ess instruc	ctions	16.3		TO THE	45	7.1	- 10	-	
1.	Testi	ng freque	ncy: Startup	, End of the	activity and	after every	break	Jr.	114	, ,	
2.					Empty Packe cted & reject		rticle, Colou	r variation	, Foreign N	Matter, Dual	Tablets /
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
2/12/20	1	~	1	1	V	5	1	raje ital	Mon	84 ,	8
e4:120	2	V	- House	5 Mg	V	W 10	5	Royled	Man'	Qi-	10 b
8/17/20 8/10/20 10/10/20	3	· · · ·	1	· ·	~	9	W.	kulad	mani	64	6
04:00	4	~		~	-		~	Regular	Mari	84	1 10
18:30	5		70 ap.	ALC:	44.3	10 10 10 T	3/4	d	- 10	. srodli	
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	14	N. CO.				- 1 0			- Interpr		
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*1	16		<i>B</i>								
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	19	10, 100k -			00 1 29 to	- 0		- Y		7 - 1	
	20	in it		1 1 1 1 1						v.	1

1	Prepared by:	Chec	eked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	(III (SATIA(SONE))	31/10/200	Throw the state of	DOLLED CC 34

	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, k Villianur Commune, Puo	Curumbapet Industrial Estate,	Page 12 of 29
SAI PRIMUS	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 F201207
roduct	KAMITHIAZIDE 3/12.5	Customer	Generic Health Care Pyt Ltd

20. MACHINE IN-PROCESS CONTROL: 24 12 2020 G. 28/12/202 Date/Shift Hanilcandan Machine Operator Name 1230 Time of inspection 130 3:40 67:30 11:20 3 20 10.20 1119 2130 ØC Sealing Temperature 185 190' 190'c 2000 900 185 100,0 1840 1900 900 190'C (To be established) 190'L Leak test on Alu Alu Strips* No Yo de OIC EK. de de Olc Oc (Qty.: ob ote de 100 DIL bk DA Knurling /Sealing OK ok cle or ric OK de gc ok ok de oce ob OK OK de ok vil **Pocket Formation** OU 012 30 00 BK. 20 OC Olc de 06 ni OK di Horizontal cutting bu 0/0 0/2 OK de de oc Dic ok 3/0 ola OC ou D OK OA DL de Vertical cutting OIC Dic de OL rle 25 ole ou 06 OK Quality of Over printing OC ot ok Ele OF de OK 20 0/0 Ole 06 or cic OK OC: PON/DRUGS/ 00 OK Code No .: DE cic ole 0/0 OK ER ole ok Oil Ok Ok ok 19 13 4323 ou OC B. No.: 06 OC GF201207 06 Ole 20 Ele ole ole-06 Oli de Oil OE Mfg. Date OL 20 Ole ole ou OK olc 00 12/2020 ob cle 06 or ok ou oci oh Exp. Date ole. Olc ole bh Ok cle 04 11/2023. de cie Ok oli or ok Machine Speed 27 00 00 dã 28 28 20 28 30 20 2-8 201 28 38 (To be established) 8 18 84 Sy 84 NA Checked by (Packing) 84 84 NA 81 NID-Checked by (IPQA) () 100

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:	Chec	Checked by:				
Dept.	Production	Production	Quality Assurance	Head Quality Assurance			
Sign.	L.Ka	JOL	in in	1 July 100			
Date	31/10/2020	31/10/2020	31/2/	UNITED IN THE SY ON			

0	1100
C.	
SAI	PRIMUS
	IOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,

Villianur Commune, Puducherry-605009.

Product Code: R09

Batch Size: 6,00,000 Tablets

Page 13 of 29

Product RAMITHIAZIDE 5/12.5

BATCH PACKING RECORD

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

Batch No.: 57 F2 01867

Customer:

Generic Health Care Pvt. Ltd.

20.1 MACHINE IN-PROCESS CONTROL:

Date/ Shift		7 757	² مدود ا دا چ			- E	1 1	291 P	¢#	P. C.				polit re-			
Machine Op	erator Name	1	55) A 10	and						1.74	lok s	/4 -= \$	- 4 10				[" N
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Sealing Tem (To be estab		1390		1702		Mose	1900	1876			1.50	340	- 200				:
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Pocket Form	ation	oie	OV:	70	Cla	ひ	Oh	olc								E.	
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Vertical cutt	ing	de	90	90	ole	Oh	OR	ok		V.,)						1
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Exp. Date	4/2023	de	do	ou	cli	dr	on	Ole		29	24		_dh	- 4	10	pille i	
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Checked by	(Packing)	MA	84	84	No	SI	87	Na		1,0	Pal s		175		. '	81	
Checked by	(IPQA)	ቃ.	a	To	一州	m	M	刺		7	2002					1	. 3

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:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	, POP	infrig.	O boret w
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	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, R Villianur Commune, Pu	Page 14 of 29	
SAI PRIMUS	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 FOO 1207
	KANTITICABIDE SITE.S	Customer:	Generic Health Care Put I td

20.2 M	ACHINE IN-PRO	OCES	s cor	NTRO	L:						0 _ 1	i					
Date/ Shift				70		v					24 34 · · ·	-2 - JF					
Machine Ope	erator Name	1				-		- 1			1	# - 	4- p				e 3-1-14
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Leak test on Alu Alu Strips* (Qty.:)								Œ,			ij				·		
Knurling /Sealing				- 40			3.2	8 -	5			at i	0.5				F
Pocket Formation)*);							1.1	
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Vertical cutting						N	4	1	24			. 31				- 41	
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Code No.:	PON/DRUGS/ 19 13 4323	G					W man to the) - v		. Asc.				
B. No.:									0-	1			200	7	, -		
Mfg. Date						d	٥	1-	-,1	e e e	J. 1	/	1.			4.	
Exp. Date							W = *	. 1	, j).				/	=			= 5,100
Machine Spe (To be estab					-				in-				+				
Checked by							- 123									/	
Checked by	(IPOA)						1 - 1										

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.

		Approved By:		
Production	Production	Quality Assurance	Head Quality Assurance	
L.Ko	Dir	infrio 1	O hat was	
37/10/2020	31/10/2020	2/1/2/200	ON THE PROPERTY.	
	L.Ko	L.Ko. POF	L.Ko De join	

CALDD		Factory: R.S	AI PRIMUS LII S. No. 4/3, Plot N Villianur Commu	lo.33, Ku	rumbapet Ind	ustrial Estat	e,	Page	15 of 29	at v
SAI PR		BATCH PA	CKING RECO	RD	Product Co	de: R09	tin an e-leas of the equition of	Batcl	ı Size: 6,00,0	000 Tablets
Prod	luct	RAMITHIAZI	DE 5/12 5		BPR. No.:	BPR/T/134	-00	Batch	1 No.: 67 F	2018.07
1100	luct	KAMITIMAZI		Customer:			Gene	ric Health C	are Pvt. Ltd.	
21. I	DEFOILIN	G OF ALU AL	U STRIPS:	,					<u>.</u>	,
11910	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	1 to	Dc-foiling Done by				ecked by/ e (Packing)	Verified by Date (QA)
1/12/2022 /	7: 30	17!50	4156	Jama	ki, Chid	ጉዓ		श्रीय	115/2000	DETIVION
					qИ					- 3
		otal Weight of foiled Tablets		l .	ed By / Date			Veri	ified By / Da	18y te (IPQA):
21.1	INCRECT	ON OF DE EO	II ED TADI ET							
Date	Inspect	ion Inspection		Quantity of Good Quantity of Good tablets		Qty. of Rejected Tablets Kgs Nos		by/ Date Verified by		
sto-locos	17155		Sivasanbani	Kgs 4 · 100	Nos 20SO	Kgs 0.05b	2s		(Packing).	
			Total Control							
			, is	-	~~~~		L. D.			
4. 66.10		Te la mais	-	* 111						19
T-4-1 0	-4:4CD	and making		4:100	2_050 ed By / Date	0.056	28		By / Date (I	704)-
100	. Kgs!K	ejected Tablets	Destroyed		128/12/2			er med	2 / 2/12/2	

	Prepared by:	Chec	Checked by:			
Dept.	Production	Production	Production Quality Assurance			
Sign.	L.Ko-	700	infin.	0 /20 /m		
Date	31/10/2020	31/10/2020	101/01/01	X. K. Olyan		
To the state of	NCONTROLLED CC		UNC	INTROLLED CC7Y		

								and the second s		
2	COL	SAI PRIMUS LIFE F Factory: R.S. No. 4/3, Plot No.33 Villianur Commune,	3, Ku	rumbapet	Industr		Page 16	6 of 29		
	I PRIMUS BLOTECH PVT LTD	BATCH PACKING RECORD		Produc	t Code:	R09	Batch S	Size: 6,00,00	0 Tablets	
	Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00			Batch I	No.: 07 F	301207	
		RAMITATION STEELS		Custom	er:	Generic Health Care Pvt. Ltd				
22.	LINE CL	EARANCE CHECKS – BATCH CO Date/ S	DIN Shift .	G: 26(12/20	<u>90</u>			МА		
Previ	ous Product:	Ultra vibamin D	Bat	tch No.:	002	0948	the section			
_		a ga magama ga					Obser	servation		
Sr. No.		Checks			Time	7 100				
						Packing	IPQA	Packing	IPQA	
1	Check and en product.	sure that the area is visually clean and f	free fi	rom previ	ous	~	✓ <u> </u>	I		
2	Check and en			~						
3	Check the Pallets and crates area clean and free from any leftovers of previous product /Batch.						~		* *	
4	Check and en	sure 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.						×	מנק		
7	Check and ensure the cleanliness of hatch for conveyor belt.					/			4. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2.	
8	Check and en	sure the cleanliness of conveyer belt wi	ith co	llateral bl	ock.		~		407 H 112 112 112 112 112 112 112 112 112 1	
9	Check and en	sure the dispensed secondary packing r	nater	ial.	dia .		~	1,		
10	Check and en	sure the Preventive maintenance record	ds and	l log book		/	V	a company and the	· d.	
Note	: Tick mark (√)	if Complies, (X) if does not comply an	nd (N.	A) if not a	pplicab	ole.				
Clean	ning Satisfacto	ary / Not satisfactory#				ry / Not satis	factory#	>		
		the cleaning is not satisfactory / line is r		QA)Sign.			se of the fai	ilure and tak	e necessary	
		area / line and record.						×	- 11000000000	
22. 1. 2. 3. 4. 5.	Check and e Transfer und Set and open Overprinting	EQUIPMENT CLEARANCE FOR Consure that the over printing area and macoded printed Carton to Overprinting area to Overprinting Machine. If you have a shall be in indelible ink. If you have a shall be checked by Packing a printing area.	achin ea.	e is cleare				eration.		
I	Equipment	Inkjet Machine		Co	nveyor	1	- IA	Area		
ID. N	lo.:	PD/Inploo2		PO IN	P 100	2	Batch Cod	ling		
Previ	ious Product:	ULtra Vitamin D		a quentav						
Batcl	h No.:	UD20949								
Clea	ned by:	S. manju 126/12/2020		a.					1 h 1	
Chec	ked by Packii	4. 4								

Prepared by:		Che	Checked by:			
Dept.	Production	Production	Quality Assurance	Head Quality Assurance		
Sign.	L. Kon	AP	nin	O hout wal		
Date	31/10/2020	31/10/2020	2)	VI CONTRACTOR		
MARCHAR				VTREALEDCACY		

Verified by IPQA:

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.: FROIRT

22.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)		
Batch No.:	G1F201207	012		
Mfg. Date:	12/2020	OLL		
Exp. Date:	11/2023	OL		
Item Code: 15/0362	15/0362	OK		
Code No.: PON/DRUGS/19 13 4323	Pon/DRUGS/1913 4323	OK		
Other instructions if any	NB	NA		
Initiated by Sign. & Date	S. manju 26/12/2020	S. manju 26/12/2000		
Checked by Packing Sign. & Date	Ard 20)101 200	dr 02 6/12/200		
Verified by IPQA Sign. & Date	@ topic	6 total		

22.3 TIME RECORD FOR BATCH CODING:

Sr.	3-3-		Batch	Coding	Checked by	Verified by	
No.	Date/Shift	Batch Coding Done By	Started at	Completed at	(Packing) Sign. & Date	(IPQA) Sign. & Date	
01	26/12/2020	S. manjo	04 KO	13:30	84 26/2/2020	W. M. Will	
in la	784			9,-1-4,-11	17	36/0	
				= = =			
Section 1				AU.		1.0	
a de la companya de l	- Hair	The second	0 - 1 - 12	197 V. 10 - 1 - 1		18-1	

22.4 CARTON OVERPRINTING SPECIMEN:

S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
ol.	26/10/0000	01	450/10/200	Ozdrine
15 7		NA		
		30,474		151,

Note - Attach specimen copy of over printed carton

Prepared by:		Che	Approved By:		
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	TOF	infrire	O prot In	

() ()		SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, F Villianur Commune, Pu	Kurumbapet Industri	al Estate,	Page 18	3 of 29					
	I PRIMUS BIOTECH PVT LTD	BATCH PACKING RECORD	Product Code:	R09 Batch Size: 6,00,000 Tablet							
1	Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPR	L/T/134-00	Batch l	Batch No.: 6-1 F 20 120					
	rioduct	RAWITHIAZIDE 5/12.5	Customer:	Generic Health Care Pvt. Ltd							
23.	3. LINE CLEARANCE CHECKS - SECONDARY PACKING: Date/ Shift 8 12 2020 9 / 28 12 20 20										
Previ	ous Product:			, PC 200							
C			er bili filmer i	1	Observation						
Sr. No.		Checks	Time	09:00		05100	1				
		12	1. 42.54	Packing	IPQA	Packing	IPQA				
1	Check and ensproduct.	sure that the area is visually clean and free	e from previous	5		5	>				
2	Check and en	sure that waste bin is emptied out and clea	ned		/	5	~				
3	Check the Pal product /Batc	lets area clean and free from any leftovers h.	s of previous	5	~	5	>				
4	Check and en	sure the Correct status board is written.		5	V		/				
5	Check and end cut into pieces	sure the stereo of the previous product/bat s.	ch removed and	5	V	7	/				
6		sure the Alu Alu strips, rejected Carton, Slof previous product/batch are removed.	hipper and	1	~	9	>				
7	Check and en	sure the cleanliness of hatch for conveyor	belt.		V	_	5				
8	Check and en	sure the cleanliness of conveyer belt with	collateral block.	4	~	1	>				
9	Check and en	sure the dispensed secondary packing mat	erial.	10	/	/	V				
10	Check and en	sure the cleanliness of documentation table	e.	5	V/	7	5				
11	Check and en	sure the Preventive maintenance records a	ind log book.	7.	\checkmark		1				
Note:	Tick mark (V)	if Complies, (X) if does not comply and ((NA) if not applicab	Ге.		5.0	Fig.				
	ing Satisfacto king) Sign. /Da		Cleaning Satisfactor IPQA)Sign. /Date:	ry / Not sati	sfactory#	(8) 27/12F	MA				
		he cleaning is not satisfactory / line is not area / line and record.	certified then invest	igate the cau	se of the fai	lure and tak	e necessary				

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	PDICOBlood	PDIBALlois	M	PDISTP1002	PDIBALLIS	Secondary Packing Hall
Previous Product:	Calama x	P		Garpeti	r	
Batch No.:	743 SPC 2023		et des di ti			
Cleaned by:	Sivasankar			12 12		
Checked by Packin		12/2020			-	
Verified by IPQA:		8	₹			

	Prepared by:	Che	Approved By:		
Dept. Production		Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	DOS	min	O hours	

31/10/2020 2/16/1

ST.

	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, k Villianur Commune, Puo	Page 19 of 29	
SAI PRIMUS	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.: 57 F 2 5 1 2 5 7
Troduct	KAMITHAZIDE SITE.S	Customer:	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)

	P. Cal	Date/Time: 27	12/2020.		Date/Time: 26/12/2020.				
Shift:		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	84	and labore	25'L	84.	Barran		

Secondary Packing Started Date/Time: 25/12/2020 591. 20mpleted Date/Time: 25/12/2020 16:44

APPROVAL FOR SECONDARY PACKING:

Approved by IPQA Sing/Date:

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	·OŁ		
Mfg. Date:	12/2020	OK	DC		
Exp. Date:	11/2023	OE	Ok		
Code No.: PON/DRUGS/19 13 4323	'ok	O/F	NA		
Pack size:	NA	3 x 10's	2 7 x 10 x 3 x 10 's		
Other instructions if any	ND.	M	30f×3×10		
Initiated by Sign. & Date	Hany'o	Mary's	Mayto		
Checked by Packing Sign. & Date	81 27112/20 20	842710/202	84 27/12/202		
Verified by IPQA Sign. & Date	Balana	27/172	Protos		

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	0)	N 27/12/2020.	100 T. 1000
	111111111111111111111111111111111111111			37119
			· · · · · · · · · · · · · · · · · · ·	184.

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	1. Ka-	AN.	infrig	O Wat wer
Date	31/10/2029	31/10/2020	21/10/20	7. 1/2
Y'n	A D COM LEGISLAND		() TIN	CONTROLLENCES
WAR BUT I	CALL A MAY VI	i i	UIV	CONTRODED COL

				US LIFE BIO					4.000	3	
		Factory	r: R.S. No. 4/3	, Plot No.33, I Commune, Pu			Estate,	Page 20 o	of 29		
SAI PR		BATCI	H PACKING			ict Code: R	09	Batch Si	ze: 6.00	,000 Tablets	
LIFE BIOTEC	2	4				No.: BPR/				F201207	
Prod	luct	RAMITHI	AZIDE 5/12.5	5	Custo		.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			Care Pvt. Ltd.	
			WEIGHING				or Transition of the second		17		
Weight 1.		3.	oty Alu Alu st	5.	i below:	7.	1.8	9		7.0	
2.	1.8	4.	1.9	6.	1.8		1.8		0.	118.	
Avg. Wei	ght of ten E ght of a Em	ipty Alu Alu	lu strips = / & strip (A): tot ed Alu Alu str	al weight of te	n Empty A	of the second	21.04			6)	
1.	3.8	3.	3.7	5.	38	7.	3.7	9	. 8	3.8	
2.	38	4.16	3.8	6.	3,7	8.	3 18			3.9	
Avg. Weight Limit (C) (Each mis	ght of a Fills sing tablet ghing Done	should be id	u strips = 38 strip (B): tota entified) angki LIMIT SET	l weight of ter	: <u>Q</u>	12/12/2	Verified				
Weight			y cartons are			and the second				*	
1.	8.9	3.	8.9	5.	8.8	7.	8.7	9	. 8	3.9	
2.	8.8	4	84	6. 8.8		8.	8. 6'9		0.	f. E.	
Average v	ght of ten e weight of a				Jan - Lai	ton/10= 8	'&s)	+ 1			
1.	2.5	3.	24	5.	2.4	7.	2.5	9	. 5	24	
2.	2.5	4	2.4	6.	2.5	8.	2.4	1	0.	2.5	
		aflet (E): to	24.5 tal weight of to ON CARTO			S. of Li		I Dec			
Weight of	ten empty	Carton:	88 1		Avera	ige weight o	f one empty	Carton (D):	8	1-8-1	
Weight of	ten filled A	lu Alu strip	38	0	Avera	Average weight of one filled Alu Alu strip (B): 2.80					
Weight of	ten Leaflet	s:	2	4.5	Avera	ige weight o	f one Leaflet	(E): 2	45	4	
Weight of	one filled (Carton F = (I	DIAD (E)	2.H		$G = F \pm 1$ e established					
Checked I	by Packing	/Date: () E DRAWN	11.21 8020	na PAP . o	Verif	ied by IPQ	A/Date:	1217ex	# 100 m		
Sr. No.		of Sample c			ty. of Sar	nole	47	Collected	by (Sign	n. /Date)	
1		ample (Initia			c 1015	. 41		7/12/2020	7 (~.6		
2		ample (Mide			oktol S		- 17.0	(2)	7-1		
3		ample (Fina					AR DE	Pur/12/2			
4	Stability		•,	TK OF THE STATE OF	(5)	. /-	10	28/12/2020) 	Programme and the second	
5			aT (121 (71154) -11	Y-11	15	2.7		1.13/13	No. 18.3	
6		Other Sample			- It			STA.			
								908 12/2	377		
			Total Qty.	3.7				Postin			
		Prepared by				ed by:				oved By:	
The state of the s		Production	. 1	Production		Quality Assuran					
Dept.				Kan	, ii	Quant	Assurance	1200	.u Quu		
Dept. Sign. Date		L. Ka.		200	0	Sugar	Assurance		Q. <i>V</i>	Assurance Value	

	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, K Villianur Commune, Pu	Curumbapet Industrial Estate,	Page 21 of 29
SAI PRIMUS	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.: 67 F201207
	TOTAL TITLE CONTROL STEELS	Customers	Canaria Haalth Cara Put Itd

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

Date/ Shift ,	27/12/2020.	9				9		10	12/20	10					
Parameters	Specification	/	observation												
Tatameters	Specification		Packing							- 15-51	IPQA				
Time		०५% ०	10:40	ANAS	12:30	1345	1425	ア	10.30	\		1-7			
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OF	de	01/2	o^∟.	ο'n	οŁ		च						
Carton Overprinting	Legible and readable	01=	OK	Ole	Ob	ok	0		ck	2 -		/			
No. of cartons in a shrink sleeves	10 packed cartons	M	15	W-	no	12	M		NI-			¥			k
Shrink wrapping temperature*		r4	m	ra-	169	r∕4-	<i>L</i> 37		NA		35		1	.,	
No. of shrink sleeves in a 5 ply shipper	27 shrinks	OK	ch	OL	Oh	oh	٥٢	4	of	4 7 m					
Shipper strapping	Proper strapping	oL	Ole	8	Dh	du	oh		α						
Label appearance and Shipper appearance	Legible and readable	ol	de	OL.	. ch	Oh-	. Oh	10 10 10	et.		19/41 19/41		40		
Sealing of the shipper with BOPP Tape	H type	oh	Ole	eh	On	Olu	0 k		<i>हिं</i> दि	-					
Checked by	ea	81	84	Ry	€Y.	84	84	1 1	D						17

*Temperature to be mentioned.

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

Date/ Shift	28/12/2020	7			P.		1, 4		1.	34	-4	Die.		A - 4	
Parameters	Specification		1		9.			obser	vation			TDO 4		,	
Time			-		ackin			m				IPQA	1		8.
	3 Alu Alu strip	0d7/s	10:30	八:大0	12:30	13:34	14:50	P. 120	10,00	12:30	11-00	17:00	+		
No. of Alu Alu strip in a carton	with 10 tabs each and one leaflet.	Oh	ole	OF	Gr.	Ole	ok	0/6	cic	olic	310	oll	1		
Carton Overprinting	Legible and readable	Oh	ol	0/2	de	OL	De	οte	cle	ole	oll	cu			
No. of cartons in a shrink sleeves	10 packed cartons	VA.	M	na	na.	n	AUD	25	ph)	No	Mn	Na	9		
Shrink wrapping temperature*	,the	n	Niv.	NA-	M	100	m	MA	NA	Ŋα	NA	MA			- 4.2
No. of shrink sleeves in a 5 ply shipper	27-shrinks	Ole	ok	0/5	0/c	ωk	oli	O'L	ole	ok	OK	di		14	
Shipper strapping	Proper strapping	OVE	ou	0,c	ok	تاد	OL	Ole	de	olc	ou	0h			
Label appearance and Shipper appearance	Legible and readable	Ole	oin	Olc	OK	وباد	d	9~	ole	ole-	ou	oll			
Sealing of the shipper with BOPP Tape	H type	Oli	or	010	O/c	oF	oh	04	oll	de	de	au			1
Checked by	**************************************	Q	87	Sy	SI	81	84	81	\$	TO	· 100 -	湖			

*Temperature to be mentioned.

	Prepared by:	Check	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.16	POP	infra	O play in.
Date	31/10/2020	31/10/2020	- tallaga	NTDALLED GY SV

PA

C/D	
SAI PRIMUS	

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,

Villianur Commune, Puducherry-605009.

BATCH PACKING RECORD

Product Code: R09

Customer:

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Product

RAMITHIAZIDE 5/12.5

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

Batch Size: 6,00,000 Tablets Batch No.: On FREILOT

Generic Health Care Pvt. Ltd.

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

Date/ Shift	28 12/202	70							4.4	1.010	HE	3.5		3.3	
Parameters	Specification	observation													
Tarameters	Specification			F	ackir	g			IPQA						
Time		1830	4:2	18:30	T	43 %	$\mathbb{N}_{\mathcal{J}T}$	7	2.11						
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	9/5	Ole		w.		43	7g -		f gr	18",		8		
Carton Overprinting	Legible and readable	Ofe	de	ou	#3:	1	¥.j.	io :		/		_			
No. of cartons in a shrink sleeves	10 packed cartons	æ	1 2€2	cba.	e.		75-7	-600			7	76			
Shrink wrapping temperature*	,	M	100	120	esta :	2/g	,F4	(Single				X			
No. of shrink sleeves in a 5 ply shipper	27-shrinks 30b courton	de	Ole	Ok-	49)	lg	Ja	-212	14	24.4	. 142	2			ŀ
Shipper strapping	Proper strapping	ole	on	ON.	13	- 60	hot	illy.				1 5 7	/		
Label appearance and Shipper appearance	Legible and readable	Ole	de	01	. Aller		1/2	.in	v						
Sealing of the shipper with BOPP Tape	H type	Opr	on	ΘZ	. Seg	100	sky.	dg						. /	\
Checked by	1	81	81	81	1/3.	19.	1	. 12				V 5			1

^{*}Temperature to be mentioned.

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

Date/ Shift	1.112		مباعد		100						united the second				
Parameters	Specification	_	observation												
12 X		Packing										IPQA			
Time		1	-	100	- 164	A 17	C (18)	A. An		5					
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.					43	en e	14		0					117
Carton Overprinting	Legible and readable	Y	12 s	13			15	<i>4</i> 81							
No. of cartons in a shrink sleeves	10 packed cartons				Mes:		Mit I	1773		1	7.8	×.			
Shrink wrapping temperature*	3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			re-	Esq.	Orași.	di y	Tus	- CO- CO- CO- CO- CO- CO- CO- CO- CO- CO			A		(m)	- 3
No. of shrink sleeves in a 5 ply shipper	27 shrinks			E :	all a	Va.	da	10	~1	Henry.	het.				
Shipper strapping	Proper strapping	i Spa		170	3	30	reg	20			/				
Label appearance and Shipper appearance	Legible and readable			- 1	- 1	dig-	203.	10							
Sealing of the shipper with BOPP Tape	H type			7		7,0		lês.							
Checked by						lá.	8								78

^{*}Temperature to be mentioned.

	Prepared by:	Chec	eked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko	DO.	infin,	O Mark War
Date.	31/10/2020	31/10/200	21/0/200	TO OF THE WAY
ing die	JUNIAN PUNI		UNCU	MIKULLLU GUTI

SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Page 23 of 29 Villianur Commune, Puducherry-605009. SAI PRIMUS Batch Size: 6,00,000 Tablets BATCH PACKING RECORD Product Code: R09 Batch No .: 67 F2 01207 BPR. No.: BPR/T/134-00 Product **RAMITHIAZIDE 5/12.5** Generic Health Care Pvt. Ltd. Customer: Date/Shift 27/12 2020 9. Time: 09.30. Balance L.D. No.: PDI BAC 019 27. SHIPPERS WEIGHING: Weight of ten Shrinks: Average weight of one filled Shrink (H): 2280 Weight of ten empty shippers: Average weight of one empty shipper (I): 1.326 12.260 Weight of one filled shipper (J) = (27H+I): Limit: $K = J \pm 1\% =$ 8.218 - 8.385 8.302. (to be established) 37/12/12× Checked by Packing/Date: 8427 12 2020. Verified by IPQA/Date: Gross Gross Gross Gross Shipper Weighed Weighed Shipper Weighed Shipper Shipper Weighed weight weight weight weight No. By No. By No. By No. By (Kg) (Kg) (Kg) (Kg) 1 20 39 58 2.320 win 2.319 8342 2,363 Marery vir Novem 2 40 59 21 2351 2.362 8.3,57 Uh z · 320 Daneis Whi Vonely 8:344 8,345 3 22 41 60 3.320 2.339 Navery My. win Willmen 2.330 4 23 42 61 2.330 2:345 344 Program Wh' Who Whi 354 5 2.315 24 43 62 WH 8345 8.300 Win 1943VI Tiral Vim 6 25 8:326 44 63 237 2365 nin 8-310 Apres-Min Whi 7 8.339 26 8.342 Usi 45 64 3.300 8.330 No won win 8.300 2341 8.340 65 8 27 46 Paron Mh. 2.356

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833 19 2-351 38 8.361 57 76 4 Varien Total No. of De-foiled tablets Checked by Sign / Verified by Loose pack details: shippers weighed: packed in Sign / Date: Date: Shipper No: ..6.6..... Shipper No: Quantity .. (0) X . 31.10 'S 66 66 04/01/2021 Weight...4:77(1/2)

353

8.360

8310

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2.361

8:351

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

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance,
Sign.	L. Ka-	ACP.	ortin,	a free las
Date	31/10/2020	37/10/2020	13/12/20	1.150/10
YS	NONTROLLING:	1	INC	ONTROLLED CG2Y

		Factor	y: R.S. No	RIMUS LIFE BIO7 o. 4/3, Plot No.33, Ki anur Commune, Pud	urumbap	et Industrial Estate,	Page 24 of 29		
SAI PRIM		BATC		ING RECORD		ict Code: R09	Batch Size: 6,00,000 Tablets		
Produc	. ,	O A MITTLE	IAZIDE A	IDE 5/12 5		No.: BPR/T/134-00	Batch No.: GI FQUIROT		
Troude	Product RAMITHIAZIDE 5		E 5/12.5		mer:	Generic Health Care Pvt. Ltd.			
		ER ALLO	CATION	1: 192 500	12 21	(M. 19)			
DATE:%7.	12/2020			1	DAT	TE: 25/12/2020	- ×		
SHIFT:	G	1			SHII	FT:9			
	IVITIES	4.9	344	DONE BY		ACTIVITIES	DONE BY		
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Insertion of A leaflet into car		rip and		Selvi cruof	Inser	rtion of Alu Alu strip into on	dutra, solvi Sarany		
Cartons weigh	ning		W. C.	bharth'	Cart	ons weighing	Miji Bharch.		
Insertion of ca	arton into	shrink	<u>¥1</u>	M	Inser	rtion of carton into shrink	Np.		
Insertion of shrink wrapped carton into shipper		ı	٠ <u>٩</u>	111000000000000000000000000000000000000	rtion of shrink wrapped on into shipper	no le			
Shipper Label Pasting		With Bhaves the		Ship	per Label Pasting	Vifibharha			
Shipper Weighing			'i Bhaith'	Ship	per Weighing	VitiBhilo			
Shipper Strapping		U	tiblan'	24	per Strapping				
Shipper packed F			to do .		per packed	From 20. to bo			
	Signature of Packing			4 27/12/2020		ature of Packing	87-25/12/2027		
DATE:				NEW TOTAL	DA	re:	- design is		
SHIFT:				del -		FT:	Wall of the second		
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Insertion of A leaflet into ca		rip and	- 1	ACT ACT OF THE STATE OF THE STA	Inse	rtion of Alu Alu strip into			
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Insertion of ca sleeve	arton into	shrink			Inse slee	rtion of carton into shrink ve			
Insertion of sl carton into sh		pped				ertion of shrink wrapped on into shipper	***		
Shipper Labe	l Pasting		-		Ship	oper Label Pasting			
Shipper Weig	ghing				Ship	oper Weighing			
Shipper Strap	Shipper Strapping		- V		Ship	oper Strapping			
Shipper packe	ed		From	to	Ship	oper packed	Fromto		
Signature of	Packing	x X			Sign	nature of Packing	\right		
					R		R		
n		repared b		B	Check		Approved By:		
Dept. Production Production				Production		Quality Assurance	Head Quality Assurance		

31/10/2020

Sign.

Date

	I						
	Factory: R.S. No. 4/3, Plot No.33	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.					
SAI PRIMUS	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.: ET F201207				
Troduct	KAMITIMAZIDE 3/12.5	Customer:	Generic Health Care Pvt. Ltd.				
PRODUC	CT COUNTER CHECK LINE CLEAD Date/ SI		ASSET,				
revious Product:		Batch No.:	7 - 1900 P				
		AL II	Observation				

Prev	ious Product:			Batch No.:		. Jane			
Sr.						Obser	vation		
No.		Che	eks	Tim					
i	Check and ensu	ure that the area is	Packing	IPQA	Packing	IPQA			
2	/	ire that waste bin i	s emptied out an		1000		, 1		
3	Check the Palle product /Batch	ets area clean and i							
4	Check and ensu	are the Correct stat	us board is writte	en.				1. ,2.4.	
5	cut into pieces.					t o	15		
6	shipper label of	are the Alu Alu str f previous product							
7	Check and ensu	are the cleanliness	of hatch for con-				10 J		
8	Check and ensi	are the cleanliness	of conveyor belt	No.			7 9 9 7 8		
9	Check and ensi	ure the dispensed s	econdary packin						
10	Check and ensu	are the cleanliness	of documentatio	n table.					
11	Check and ensi	ure the Preventive	maintenance rec			P			
Note	: Tick mark (√) i	f Complies, (X) if	does not comply	and (NA) if not appli	cable.				
	ning Satisfactor king) Sign. /Dat	y / Not satisfactor	-y#	Cleaning Satisfa (IPQA)Sign. /Da		factory#	- * III		
Rem	arks: # In case th	e cleaning is not sa ea / line and recor		is not certified then in		se of the fa	ilure and take	e necessar	
	Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighi Baland (shippe	e	Area	
ID. 1	Vo.:	* * *							
Prev	ious Product:		- 341 11-15						
Batc	h No.:	-	2 H.S.			X .	0		
Clea	ned by:			o ja o o osoja		11	4	5 ya	
Che	cked by Packing	:		, had decided to be		- 1 Was 4*			
Veri	fied by IPQA:								
Recl	hecking Started	Date/Time:		Completed Date	e/Time:			\ .	
ΑI	PROVAL FOR	COUNTER CHI	ECK:	Approved by IPQA S	Sing/Date:			>	
- Butter Alligh			***************************************	W				25 helm	
								Theh	

Prepared by:		Ch	Approved By:		
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L.Ka	ACK,	infin	0 100	
Date	31/10/2020	31/10/2020	2/1/2020	1. 10/10	

HNCONTROLLED CCRY

UNCONTROLLED CC7Y

On The			CAID	RIMUS LIFE BIO	теси р	VTTTD	
		Factor	ry: R.S. No		Curumbap	et Industrial Estate,	Page 26 of 29
SAI PRIMI		BATC	CH PACK	ING RECORD	Produ	ict Code: R09	Batch Size: 6,00,000 Tablets
Product		DAMITH	[AZIDE 5/12.5		BPR. No.: BPR/T/134-00		Batch No.: @ F201207
Troduct		KANILLI	IAZIDES		Custo	mer:	Generic Health Care Pvt. Ltd.
27.1 CO	UNTE	R CHECK	OF PACE	CED SHIPPERS:			E V
DATE:		l di		7	DAT	TE:	
SHIFT:					SHII	FT:	
	ACTIVITIES		I	OONE BY		ACTIVITIES	DONE BY
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Checking of A leaflet in carton		strip and				cking of Alu Alu strip and et in carton	d
Cartons weigh	ing			-201 -	Cart	ons weighing	7 - 5 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1
Printing Check Label	cing in	Shipper		onica o	Print Labe	ting Checking in Shipper	
Shipper Weigh	ning			100	Ship	per Weighing	
Shipper Strapping				Ship	per Strapping		
Shipper Checked From		From	to	Ship	per Checked	Fromto	
Checked By P	Packing				Che	cked By Packing	
Verified By IPQA				fied By IPQA			
* -,	1 K 10 L 1			Hapterson	\		
DATE:	********				DAT	re:	
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Checking of A leaflet in carto		strip and			Checking of Alu Alu strip and leaflet in carton		d
Cartons weigh	ing				Cart	ons weighing	
Printing Check Label	king in	Shipper			Prin Lab	ting Checking in Shipper	
Shipper Weigl	hing			= 9 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Ship	per Weighing	hy.
Shipper Strapp	ping				Ship	pper Strapping	
Shipper Check	ced		From	to	Ship	pper Checked	Fromto
Checked By I	Packing	<u> </u>			Che	cked By Packing	
Verified By I						ified By IPQA	- D
No. of De	linor:	dentified:					A Standard Contraction of the
2. M 3. Ci	lajor: ritical:						86
		or Despate	ch: Check	ed By:		Verified By:	
		Prepared b	oy:	7 - 4 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	Check	ed by:	Approved By:
Dept. Production Production			n	Quality Assurance	Head Quality Assurance		

Sign. Dato

CID	
SAI PRIMUS	

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,

Villianur Commune, Puducherry-605009.

BATCH PACKING RECORD

Product Code: R09

Page 27 of 29

Product

RAMITHIAZIDE 5/12.5

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

Batch Size: 6,00,000 Tablets

Batch No.: 57 F201207

Customer:

Generic Health Care Pvt. Ltd.

20	DAGGIRAGO	RELITERATION	DECOMPOSE FAMILIANT
311	PACKING	MAIRIAI	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	20100	20400	D.A	75	30dmly)	103,
В	Additional material received for the batch	NA	NA	NA	NA		NA	MA	М.А.
С	Total material received (A+B)	48.200	166.700	20400	20,400		45	300 (mtx)	02.
D	Quantity packed	21.700	98.100	19890	19890		65	csolmin	03
Е	Quantity rejected (Online) & Destroyed	8.998	11.989	497	A97		40	NA	M
F	Quantity Returned	17.500	56.510	NA	NA		lo	red nto	Ng-
G	Sample affixed on BPR	0.006	44	02	02.	Na	NA	W	ha
Н	QC samples	0.002	0.006	NA-	4.4		NA	20	Nn .
I	Other samples (If any)	0.003	ور وی	1)	11	i	NA	l/b	ha
J	Total accountable Quantity (D+ E+F+G+H+I)	A8 199	166.635	20400	20400		45	300 (2014)	02
K	Variation (C – J)	0.001	0.065	-0 -	-0		-0-	-0-	-6-
L	%Variation (K x 100)/C	0.002.	0.037.	_0_	-0-		-0-	_0-	-0-
M	Acceptable limit	±2%	±2%	±2%	±2%	±2%	L see		1965 a

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

-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	7A	NA	NA	lo	30 (50 Mg)	124
Material returned by packing Sign./Date	By 3/1/2/2	00 1 1 1 2 hs	3/11/21/12	2000	VA	Alm	you	M
Verified By IPQA Sign./Date	外	第1200	THE LOS	m			V	
Material received by Store Sign./Date	they love	महित्र इस्ति।	duy			~		

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)
08/12/2020	96	8.998	11.989	Agy	477	IVA-	ma-	M	m
<u> </u>				-NA -	1 10				1
Total Qty. Destroyed	06	9.998	11.989	A97	AJY	M	na	M4	r _{sa}
Destroyed by (Packing)	8428	12/2020		y 9 - 2	No.				
Verified by (IPQA)	- 1	219000			11				,

Prepared by:		Chec	Checked by:				
Dept.	Production	Production	Quality Assurance	Head Quality Assurance			
Sign.	1.Ko	494.	infro	O hope wor			
Date	31/10/2020	71/10/2020	July Jan	1. 5/1/2/			
1 2200	A PART & PAY SELLING AND PARTY IN						

: NOONTROLLED CC2Y

INCONTROLLED CC2Y

		Facto		./3, Plot No.33, ir Commune, F		et Industrial Esta	ite, P	age 28 of 29		
THE BUDGE	RIMUS	BATO		G RECORD		uct Code: R09	E	Batch Size: 6,0	0,000 Tablets	
		DANGTOON	TATTOE 5/11		BPR.	No.: BPR/T/134			1 F & 0 1 & 0	
P F C	duct	RAMITH	HAZIDE 5/1:	4.5	Customer:			Generic Health Care Pvt. Ltd.		
33.	BATCH I	RECONCIL	LATION:	\$ 						
A	Batch Siz	:e		ga a				5 7	6,00,000 Nos.	
В	Quantity	received for	packing	(#) 17					597050.	
С	Total qua	Total quantity packed							596700	
D	Control s	Control samples							200	
Е	Analytica	I Samples	17			71	1,4		120	
F	In proces	s samples	75		, left etg		1 4		880	
G	Others sa	mples if any	(Stability, R	egulatory Samp	oles, etc.)				NA	
H	Packing I	Loss = B - (C + D + E + I	?+G)	- ⁷ 6' _ y	31		· v	850	
ľ	Total Los	ss = A - (C - C)	+ D + E + F+0	G)					2100	
J	Packing y	/ield % (C +	D + E + F+C	G) / B X 100 (Y	ield Limit	%)*		Real Control	100-141.	
K	Batch Yie	eld % (C + I	O + E + F +G	/ A X 100 (Yi	eld Limit %	6)*			99.651,	
		cking/Date	e: HISHED GOO	84)121 DDS:	30 m.	Veri	fied by IP(QA/Date:		
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	Sales	3×1013	306x 1×160	65	306 x 3x 104	Sy	8	1~~	
100 15	0-19-19-19-19-19-19-19-19-19-19-19-19-19-				militar	mg-			0	
				Total Qty. Tr	ansferred	59670	81	8	100	
35.			CEPTION DI s any Deviati		ing the second	yad than record	in balow to	able		
Sr. No.		Stage	De	Deviation Viation / Exce	/ Exception	details	Action ta		Observed By	
Sr. No.	ced by			<u>Deviation</u>	/ Exception ption detail	ls details	ort de gratege sande			
Sr. No.	ced by	Stage		Deviation viation / Exce Verified	/ Exception ption detail	ls details	ort de gratege sande	Approved by		
Sr. No.	ced by cking: BPR RE			Deviation viation / Exce Verified	/ Exception ption detail	ls details	ort de gratege sande	Approved by	\$-28),	
Sr. No. Check Pa 36.	ced by cking: BPR RE	Stage VIEW DET		Deviation viation / Exce Verified Packing manage	/ Exception ption detail by ger:	a details	ort de gratege sande	Approved by Head QA:	B-28/1	
Sr. No. Check Pa 36.	ced by cking: BPR RE	Stage VIEW DET		Deviation viation / Exce Verified Packing manage	/ Exception detail ption detail by ger:	a details	ort de gestelesene	Approved by Head QA:	B-28/1,	
Sr. No. Check Pa 36. Packir	sed by cking: BPR REY Rev ng Executive	Stage VIEW DET	'AILS:	Deviation / Exce	by ger:	a details Is hy	ort de gestelesene	Approved by Head QA:	B-28/1	
Sr. No. Check Pa 36. Packir QA Ex	sed by cking: BPR REY Rev ng Executive	Stage VIEW DET iewed by	'AILS:	Deviation viation / Exce Verified Packing manage	by ger:	a details Is hy	Action ta	Approved by Head QA: Sign. /Da Postument	\$-28/1 te	
Sr. No. Check Pa 36. Packir QA Ex	ced by cking: BPR REY Rev ng Executive cction Assis	Stage VIEW DET iewed by ive	ger/ HOD	Deviation / Exce	by ger: Name Chama	n details Is Is In hy	Action ta	Approved by Head QA: Sign. /Da Post 11 12 22 22 22 22 22 22 22 22 22 22 22	\$-281, te	
Sr. No. Check Pa 36. Packir QA Ex Produ	Rev ng Executive action Assistanager/ H	Stage VIEW DET iewed by ive Stant Manag	ger/ HOD	Deviation Viation / Exce Verified Packing manage Lath Lath	by ger: Name Check	a details Is In Amage of the second of the	Action ta	Approved by Head QA: Sign. /Da Sign. /Da Approved by Head QA:	te Stalo	
Sr. No. Check Pa 36. Packir QA Ex	Rev Recutive ction Assistance H	Stage VIEW DET iewed by ive	ger/ HOD	Deviation / Exce	by ger: Name Check	n details Is Is In hy	Action ta	Approved by Head QA: Sign. /Da Sign. /Da Approved by Head QA:	\$-281, te \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	

	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, I Villianur Commune, Pu	Page 29 of 29	
SAI PRIMUS	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.: Of Fablasi
	KAMITHIAZIDE 3/12.3	Customer:	Generic Health Care Pvt. Ltd

37. BATCH RELEASED FOR DESPATCH:

Total quantity released: 596700 No's

Head QA sign/ Date:

38. REVISION HISTORY:

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

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	KA	July .	O know war
Date	31/10/2020	31/10/2000	Wall of land	1.

A. A.

CAD DIAM IS	SAI PRIMUS LIFE B Factory: R.S. No. 4/3, Plot No.33 Villianur Commune, 1	, K	urumbapet Industrial Estate,	Page 1 of 29	
SAI PRIMUS	BATCH PACKING RECORD		Product Code: R09	Batch Size: 6,00,000 Tablets	1
Product	RAMITHIAZIDE 5/12.5		BPR. No.: BPR/T/134-00	Batch No.: GF210317	1
Troduct	KAMITHAZIDE 3/12.5	a. A	Customer:	Generic Health Care Pvt. Ltd.	
*	BATCH PACKAG	GIN	G RECORD COVER SHEET		-
PRODUCT NAME		:	RAMITHIAZIDE 5/12.5		
GENERIC NAME			Ramipril and Hydrochlorothi	azide Tablets	
	Ø		Each Uncoated tablet contains:	4	
TARRE OF ANA			Ramipril BP		
LABEL CLAIM		:	Hydrochlorothiazide BP Excipients		
			Colour: Erythrosine Supra	q.s.	
CODE NO.		:	PON/DRUGS/19 13 4323		
DOSAGE FORM		:	Tablet		
BPR No.		:	BPR/T/134-00		
REVISION No.		:	00		
SUPERSEDE No		:	NIL		
EFFECTIVE BATCI	H. No. /DATE	:	GF201004/31/10	Lo 250	
MARKET		÷	Export		
SHELF LIFE		:	36 Months		
BATCH SIZE		:•	6,00,000 Tablets		
PACKING CONFIG	URATION	:	3 x 10 Tablets Sales Pack (Alu	Alu Packing)	
BPR ISSUED BY/D.	ATE (QA)	:	1/03/20°d		

BPR CHECKED & RECEIVED BY/DATE

(PRODUCTION)

: L. Kozilo3/2021

MFG. DATE: 03 2021

ALLOTTED BY: QA SIGN/DATE:

COUNTER CHECKED BY: QA SIGN/DATE:

QUANTITY RECEIVED FROM PRODUCTION

589300

DATE OF COMPLETION: 27/04/204

QUANTITY

: booop

RELEASED QUANTITY OF PACKED TABLETS

: 58 3320

RELEASE OF BATCH BY HEAD QA SIGN/DATE:

: Joulal

This BPR contains 29 Pages + . . Additional Pages

	Prepared by:	Che	ecked by:	Approved By:	
Dept. Production		Production	Quality Assurance	Head Quality Assurance	
Sign.	L.Ko	708	in	I hank has	
Date	31/10/2020	31/10/2020	21/9/22		
Consultation of the last	and the contract of the second		- INCO	NTROLLEDCCZY	



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

RAMITHIAZIDE 5/12.5

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

Batch No.: GR 210314 Generic Health Care Pvt. Ltd.

1. INDEX

Sr. No.	Content	Page No.
Batch Pac	kaging 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
19	Over printing details, Shipper Label specimen	19
20	Individual Strip weighing limit, Carton Weight Limit Setting, Weight Checks On Carton, Sample Drawn Record	20
21	Secondary Packing In process Checks	21-22
22	Shipper Weighing	23
23	Man power allocation	24
24	Product Counter Check Line Clearance	25-26
25	Packing material reconciliation	27
26	Excess packing material return to store	27
27	Destruction of rejected/unused printed packing materials and stereos	27
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
33	Revision History	29

	Prepared by:	Chec	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
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Da te	31/10/2020	31/10/2020	21/10/22	CONTROLLARIOCUTY
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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 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
Customer:

Batch No.: 67 F210317
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	tes
b)	Packaging material is checked	Yes
5.	Packing	A Name of the
a)	Rinse water analysis report attached with BPR	XVA-
b)	Approved specimen of printed foil, show box and shipper label are attached	Yel
c)	Control / Stability / Finished product analysis samples are withdrawn	Yes
d)	Reconciliation of packing materials is done	re
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	Ter.

Checked By QA/Date:	
*Mention total number of pages.	
Remarks (If any)	

	Prepared by:	Che	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign-	Mar Likona I	DOR	min	O Marine
Date	31/10/2020!	27/00/2020	Sille MORPON	NTDOXI FINALS
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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 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
Customer:

Batch No.: 616210311
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:	C	hecked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	J. Ko	700	orly IINC	NTROLLER (C.24
Date	13/11/202011	31 10 2020	21/10/11/10	DIVING COLUMN

C	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.							
SAI	SAI PRIMUS BATCH PACKING RECORD Product Code: R09 Batch Size							Tablets.
					BPR. No.: BPR/T/13	34-00 Batch N	0::G1F21	0314
F	roduct	RAN	MITHIAZIDE 5/12.5		Customer:		Health Care	
4.	DISPENS	ING I	LINE CLEARANCE C	HECKS	Date	24 04 2021 ime	12:30	, p
Sr.	13.3.1	Observa	ation*					
No.	1 1	Store	IPQA					
1	Check and waste bin of	~	~					
2	Check and e	V .						
3	Check and e	レ	1					
4	Check and e	nsure	that area (floor, walls, c	eiling, doors ar	id windows) are clean		~	
5			that Magnehelic gauges xture are clean.	, tube light fix	tures, supply grills, re	turn riser grills and	~	/
6	Check and e	nsure	that all the sides of Mob	ile Laminar Ai	r Flow is clean		U	.1
7	Check all th	e gaug	ges of Mobile Laminar A	ir flow before	switching ON.		~	
8	Check and due date.	ensure	that weighing balances	and pressure	gauges to be used are	within calibration	~	<i>></i> .
9	Check that t	he dai	ly records (Balance Log	book, RH & Te	emp. record) are update	ed and signed.	<i>-</i>	1
10			is updated for Cleaned a			1 =		1
	Note: *Tick	mark	() if Complies, (X) if $($	loes not compl	y and (NA) if not appl	icable.		
Equi	pment	Here	Mobile Laminar Air Flow	- Alphanil	Weighing Balance		Are	a
ID N	0.		STLAFIOOI	STABOLION	-22-	-69-	Holi S	OORE.

Equipment	Mobile Laminar Air Flow	referred and	Weighing Balance	1	Area
ID No.	STLAFIOOI	STABLY 011	-NA-	-69-	Hole Score.
Previous Product	Intoto Zinc			9	Table - Incl. I o t H
B. No.	FI 022101	D . 19-14	i vius		02 x
Cleaned by Sign/Date	Ellappon 2	404/2021.		1	
Checked by Store Sign/Date	b.	04/2021.	A	S to the important of the All Section And All	7 - 7
Verified by IPQA Sign/Date			- Paledra		

ENVIRONMENTAL CONDITIONS: Date: 15:35. (For Reference SOP No.: QAGN/011)	Observation	Store	IPQA
		Sign/Date	Sign/Date
Temperature (Limit: NMT 25°C)	24.50	24/24/04/3E3	· Day by ho
Differential Pressure across the booth Limit: 5 to 20 mm Water	15mm	क्ष्मा अपाया बद्य	76 JUL 04

Dispensing start Time	15:140	End Time	16;00:		·	
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1/	Prepared by:	Ch	ecked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	an 124 Kanna	RON	in	O booth is
Date	3111012020	31/10/2020	21/10/12	The parties of the pa
	STATE STATE AND STATE ST	7-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1		NIKIKLEDGGI

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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.

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.: The last of the content of the content

THE

DISPENSING RECORD OF PACKING MATERIALS: Date 04 20 Shift G. Time: 15:40 Issued and Req. Qty. for Issued No. of Verified by UOM Checked by A.R No. Material Name Item code 6.0 Lac Roll/Box **IPQA** Qty. Store 45.900 252mm Ramithiazide 51.240 Pmg/01158 OA PPF/SP/R009 (To be Kg 5/12.5 Printed foil established) 153.000 252 mm Alu Alu 0千 172.460 Pmg/00926 PPF/SP/A019 Kg (To be Base foil established) 3x10'S Ramithiazide 15 20400 Pm&101135 PPC/SP/R010 No 20400 5/12.5mg Carton Ramithiazide Printed Pm&100884 20400 02 PPL/SP/R002 20400 No Leaflet Shrink Sleeves Pmat PPS/SP/P001 No 2040 (PVC) 5 Ply 390x390x430 75 mm GHPL Printed PPS/SP/G002 No 75 Pm 6/00705 90 Shipper rapolit 3' GHPL Printed PPB/SP/B002 No 10 10 Pmalo036 03 Bopp Tape walroff Holoston SUN PUB/SP/B001 3' Plain BOPP Tape No 3 03 01 Pmg/00935 Strapping role. PPR/SP/S001 Mtrs 300 300 Pm6 00032 10 MA. NA No 76 Shipper Label

	Prepared by:	Chec	ked by:		Approved By:
Dept.	Production	Production	Quality Assur	ance	Head Quality Assurance
Sign.	L. Ko	401	infrio	TINC	NTDOI VERVO SV
Date 7	11 3 1 mal 2020	31/10/2020	- taile	128	THE PROPERTY OF THE PROPERTY O
III	ACCEPTATION AND A SECOND				7

		Facto		IMUS LIFE BIO 4/3, Plot No.33, I			ial Esta	te,	Page 7 of 2	9			
SA	I PRIMUS		Villia	nur Commune, Pu	iducherry-6	05009.							
	BIOTECH PVT LTD	BAT	CH PACKI	NG RECORD	- II	ct Code:		1367	Batch Size				
7	Product	RAMITI	HAZIDE 5/	12.5	BPR.	No.: BPR	VT/134						
É					Custor	ner:			Generic Ho	ealth Car	re Pvt. Ltd.		
	LINE CLEAD 6.1 PRIMAR	YPACKI	NG:	Date	/ Shift 2			<u>િ</u>	1. Do	Mrs. /0)		
Previ	ious Product:	fanto 1	Dury -D	3. <u> </u>	Batch	No.: g	7821	0323	Observation				
Sr.			Check	re .			Time	10.00	Obser	vation			
No.	11.6	L	0.100.				Line	Packing	g IPQA	Packin			
1.	Area status bo				- 1		iy.	V		V			
2.									V	N	•		
	3. Check and ensure the differential pressure of the area is within specified limit								~	~	- 1		
	4. Check and ensure that waste bin is emptied out and cleaned												
	Check the temperature and relative humidity of the area within specified limitCheck the tablets of the previous product/ batch removed.								700				
6.						C (C- 11 - C	<u></u>					
7.	previous produ	ct /batch a	re removed.	ng, rejected rolls	. 4	*	е -	U	1	-			
8.	batch	2 4	2 1 2 V	ne and free from			2° - 1)	1	/			
9.				of previous prod				V	/	~			
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.							<u></u>	_	/			
11.	Check and ensure the Cleanliness following change part of Alu Alu strip packing machine									~	-		
12.	Check for the	absence of		ch/ product at mad									
a)	Check Hopper from Top, bottom of machine, below the hopper, between bottom									~	1		
-	Check for cleaning of hopper feeding channel vibrator plate in feed roller and												
p)	sweep brush.				- 4 2 3 4		-			V			
c)	Check tool bo			A STATE OF THE PARTY OF THE PAR	E' a "	1	1 3 1		1		/		
	ning satisfactor			does not comply	Clean	ing satis	factor	/Not sati	sfactory	1			
	ked by Packin			rt)				ign. /Date	stactory (2)	P[011] 300	1-1		
				ne is not certified					re and take	necessar	y action,		
	ck the area / lin	e and recor	d.	The second second		7# = # -	(1) - X				17.		
-			PMENT CL	EARANCE OF				Date/Ti	me: 28/04	hay 1	Wat		
Pro	evious Product	: () an	to from -	-D	Batch No			333		This A	Man t		
S.			Eq.1			ition and		Cleaned b	Check		Verified by		
No	I Railinmeni	:/Area Na	(A)			ng as pei number	r	Sign/Dat			(IPQA) Sign/Date		
1.	Alu Alu Pa	aking Araa	€ 52 NS	THE BOOK B		3N/006		Janylo			The second secon		
2.	Alu Alu Pa			14/00/ B	PDOP/02			Jens	7		टिंग १६/०म/ २०		
	6.3 ENVIRO				11 01702	0,1000	020	26/200			CON ECIDAL SO		
(Checl	k the environme	ntal condit		ary packing area a		f process							
		ter B	Date 2:61.01	1/201. Time		.41.1	Date.	27 lugher	Time:?1		i b the gar		
The second secon	r to SOP No.:			Packing		ied by	0.		Packin	g	erified by		
SOP	QAGN/011		Observati	on Sign/Date	, I II	QA /Date	Obse	ervation	Sign/Da	ta	IPQA Sign/Date		
Tem	o °C Limit: NM	1T 25°C	23°C	D	100 26 10 10 10 10 10 10 10 10 10 10 10 10 10	The state of the s	0	3°C	200	1-	ने भारति रेटम		
	6 Limit: NMT		521	D	St 21 10	1.1.1		521	D	11	M orlandra M		
	Limit: NLT 10 P		11	12	- Perselo			ll 5 <u>~,1</u>	60		भग्राहिमारिक		
Prin	ary Packing S	tarted Dat	e/Time:2b.	ohlzy Comp	pleted Date			54/34	13 Lw	0	ALDUM		
APP	ROVAL FOR	PRIMARY	Y PACKING	G: IPQA Sign. /D	Date:	tlog(non	11	rwe !	Paparlas	Carlotter our Landing day, and			
		Prepared			Checke				100	Approve	d By:		
D	Dept. Production Production Quality Assurance Head Quality Assurance												

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SAI PRIMUS

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,

Villianur Commune, Puducherry-605009.

BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Page 8 of 29

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: 61F210317

Customer:

Generic Health Care Pvt. Ltd.

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	8-211011 mg	04	4	Sel.
252 mm Alu Alu Base foil	PPF/SP/A019	Kg	pmhlooged	דים	À.	W.
3x10'S Ramithiazide 5/12.5mg Carton	PPC/SP/R010	No	pmh/0135	15	8	Spel
Ramithiazide Printed Leaflet	PPL/SP/R002	No	Pmy/00834	02	8	Toly
Shrink Sleeves (PVC)	PPS/SP/P001	No				0
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	pmh/ 00005	0-3	2	Ay.
3' GHPL Printed Bopp Tape	PPB/SP/B002	No	Dmn (00) 31	ગ્2	B	Carlot
3' Plain BOPP Tape	PUB/SP/B001	No	Pmy 100935	0)	P	CAR!
Strapping role.	PPR/SP/S001	Mtrs	pmy/00032	a)	P	Stay
Shipper Label	NA	No				0

STEREO ISSUANCE AND SETTING RECORD 8.

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	da	1/2/2/21	Polonin	ham	R	(26/26/ph)2021

RECEIPT OF PRODUCT AND MATERIALS: Date/Shift 2 Loylon Time: 11 (Check the following before start of packing activity and record the observation.)

S. No.	Check Points	Observation	Done by (Packing)	Verified By
1.	Temperature observed on display (Limit: NMT 25°C)	234	d	Sel.
2.	Relative Humidity observed on display (Limit: NMT 60%)	\$21	R	Tel
3.	Bulk product containers are of the required product/Batch number and is approved by QC	cy's	1	Sist.
4.	Status label of machine/ line is for same product	Y	P	· 1
5.	Printed foil/Base rolls are of the required product.	cys	8	Con
6.	All secondary packing materials are of the required product	gr	1	O Roy

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	200	of a second	नियः
2.	Colour of Tablet	Pine	L	O Fee
3.	Quantity (Net Qty.in Kg)	117-260	L	264
4.	Number of Containers	04	R. C.	STEP

	Prepared by:	Che	cked by:		Approved By:
Dept.	Production	Production	Quality Assur	ance	Head Quality Assurance
Sign.	r con L. Ko	700	sum	UNC	NTROLLED CC?Y
Date 1	3111012020	32/10/2020	Silvan	200	1-10

SAL BRI	0	Fac		.S. No. 4/3,	US LIFE BIO , Plot No.33, K Commune, Puo	urumbapet Inc	lustrial	Estate,	Page 9 of 29	
SAI PRI		BA	TCH P	ACKING	RECORD	Product C	ode: R	.09	Batch Size: 6,00,0	00 Tablets
Prod	uct	DAME	rura 7	IDE 5/12.5	in a fregue	BPR. No.:	BPR/	Г/134-00	Batch No.: (5)	10317
1100	uct	KAWII	IIIIAZ	IDE 3/12.3		Customer:			Generic Health C	are Pvt. Ltd.
1. Verify th	ne semi-fi	nished T	ablets b	els affixed o	ng the packing	iners against th	THE STATE OF	ective BMR a	and record the details	in below
Produc	t Name	Batc	h No.	Mfg. Date	Exp. Date	Qty. recd.		No. of	No. of Containers taken for packing	
Ramishio	naid 12:5	N 621	0317		02/2024	1) 7.860 Equivalent to	Kg	To Contain	ainer No. 01 er No. 04 of Containers taken _	04
Checked		ng (Sign	./Date)): 47 g	in	Verified By	IPQA	(Sign. /Date	hall de	
12.	CONTAIN	VER WE	EIGHT	DETAILS	•				C 20/04/12/	
Container No.	Gross V	Weight	Weig	ghed By cking	Checked By IPQA	Container No.	Gro	ss Weight in Kg	Weighed By Packing	Checked By IPQA
1	30-1		Mo	ent	They	11				1
2		200	IV	ant	- Vicey	12	15		e "e " d'an dier land dere land de belon " " "	а буд
3	25.	- 610	W	×1^	CARM	13				0.00
4	30	-450	128	an	- The	14			- In tende	
5	1					15	And His		1	
6	on to pull of the	<u> </u>				16	3-1/- 1/		, lot	10 1 12 12 12
7			1	- 1		17			x 10	78
8	1,25	Dull, Al	, ,			18	11-7			
9	4 1995		19			19		773		
10		12.0				20			a from the contract of	1

C N	Tit	me	Container	Consumed	en en en en en en	Ti	me	Container	Consumed
S. No	From	To	No.	by	S. No	From	To	No.	by
1	12,00	14-30	01	man	11				06.
2	14131	17200	02	man	12				
3	9530	10/30	03	mori '	13				- 4 4 4
4	10:31	1230	04	New,	14	0 -		D 4 4 1 1	1 4 6 9
5			· ·	N , I	15	1	The second second		
6		_	1		16		an and the same	M	
7			2		17	West to a con-			
8	ı jakılı				18			1.2	
0	£/4 = 11 in	NO. 10.			10		4 1		

Checked By Packing (Sign. /Date): Verified by IPQA (Sign. /Date):

CONTAINER CONSUMPTION DETAILS:

13.

-	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	101 L. Ko	184	min	hit was
Date IV	144131110/2020	31/10/2020	21/4/14	NTRALITACE 2V

Product

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

Customer:

Batch Size: 6,00,000 Tablets

RAMITHIAZIDE 5/12.5

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

Batch No.: Gr F210317

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/ DE UGS / 19/3 4323	ρ¢	
Batch No.:	" UF210317	ot o	
Mfg. Date:	03/2021	. Ob	
Exp. Date:	02/2024	Se	
Item Code: 13/0232	13/0232	6 k	
Pack size (3 x 10's)- Carton	3 2105	Ole	
Other instructions if any	V/0	M	
Initiated by	mam)	man:	
Checked by Packing (Sign. & Date)	And 26 bylon	- Am26/34/2	
Verified by IPQA (Sign. & Date)	(26 OH 2021	< किंश श्रीकार अरुथ	

15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
(0	16/04/2021	তা	many	RA	1000 Holde 185
	TOTAL CONTRACTOR OF THE CONTRA		i i i i i i i i i i i i i i i i i i i	1 1 1 1 C	
	A COLUMN TO A COLU		1	X20182007	
5 6.	1 40 4 5 4 5 K		TW NO THE	TEN YOU	

16. PACKING INSTRUCTIONS:

- 1. Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
- 2. Issue the stereos 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

	10 mg - 10 mg	Primary	packing	Seconda	Checked by	
Sr. No.	Date/Shift	Started at	Completed at	Started at	Completed at	(Packing) Sign. & Date
	26/04/2021/07	12.30	19100	1250	19.00	Sulla
2.	27/04/2021	09.00	1/3',00	09:00	1440	P
	W 1,					
			~			

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:	Checl	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.) (II I SOUPIUS VIII) (31/10/2020	Jaho MCC	NTROLITED CC3V

Carl	
	RIMUS ECH 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

Customer:

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: 616210317
Generic Health Care Pvt. Ltd.

18. ALU ALU PACKING MACHINE PARAMETERS:

Date/Shift 26/64/2 Time: 1.2.200.

	THE PRODUCTION ATTACKLING	L DAGO.	Dato office	1 1110. 4.2
Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	rear Table		27.12	1 11 1 1 1 1 1 1
Sealing Temperature	(160 °C - 200°C) To be established	180'C	P	100 26 horles
Leak test to be performed onAlu Alu strip	Nil (No Alu Alu strip should fail in leak test)	ue	· in Ly by	FM 26/04/2021
Machine Speed	To be established	30	- 1	Post 26/01/2021

19. CHALLENGE TEST FOR NON FILLING DETECTION SYSTEM:

Sr. No	Proc	ess instru	ctions	r X.3	177	131 1995	1 1				
1.	Testi	ng freque	ency: Startu	p, End of the	activity and	d after every	break	4.2			
2.	Acce Caps	ptance Ci ules and a	riteria: Bro Il defects sh	ken Tablet, ould be dete	Empty Pack cted & rejec	et, Black Parted.	ticle, Colou	r variation	, Foreign M	Matter, Dual	Tablets /
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
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12:00	2′	V	V	V,	- V	100	17 144	Cons	mary	1 Lon	· soce
to	3	~	<u></u>	U	e	V	L .	pus	mour.	P	-Visi
16:60	4		7. 4. 5.		1	4.5		1		A CANAL PARTY	01
	5	- My C	12	and the second second	1. A 2. 2	34		1.0	- 20/20	HAD I	1
27 642	6	い	· ·	~		V	V	pas	Moro	Ä	The !
dr.10	7	V	V	V	V	V	\sim	por	non	a	्रक्टिं।
	8	Vited at	7	1 1 1	# 1	展生等成	Park March	Page 1	The late	X	
13.00	9	3 = 1		- Artelior A	1.71	The Aut	(85 Mg)	A	Year 1		
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	19										
	20	And the section of th									

	Prepared by:	Che	ecked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	restricted and the second seco	D80	min	O fret
Date	31110120201	31/10/2000	The NEO	TROXILDECKEN



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

20.

Exp. Date

Machine Speed

(To be established)

Checked by (Packing)

Checked by (IPQA)

62 2024

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RAMITHIAZIDE 5/12.5

MACHINE IN-PROCESS CONTROL:

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

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NA

OF

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NA

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Batch No.: (7F 210317

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NA

Customer:

Generic Health Care Pvt. Ltd.

Date/Shift		The Hand		26	OL	15	202	1		- F" "	i	27	OH	120	120		
Machine Op	erator Name		1	gau	re	,					Ma	nì'					ŕ÷
Time of insp	ection	1210	12:15	13-15	14.35	W:30	15:30	16-45	16:50	a .30	T:50	10/30	11.35	11.50	W30		1
Sealing Tem (To be estab		1900	4,30°C	1300					i.	1	1950				195°C	-	3.2
Leak test on (Qty.:	Alu Alu Strips*	0 &	OU	6le	Q19	OIL	00	οŧ	Oh	OR	Cir-	कंक	00	OF	cl	1	1 1
Knurling/Se	ealing	e (c	QK	00	00	<u>Eil</u>	06	06	Ol	06	CV	OCT	OR	ol	68		a Program
Pocket Form	nation	OR	Da	06	86	Oll	08	363	DV-	OF	01	do	0 K	1 OK	00	61.11	1700
Horizontal c	utting	ok	Oa	60	OL	DB-	04	06	Ch	00	01-	συ	02		ot		
Vertical cutt	ing	90	DN-	Ob	OL	0k-	Ob	Ob	Ď'n−	06	04	Och	OR	0	500		
Quality of O	ver printing	tic	Or	ob	OL	OF	ok	at	Ch-	00	O/-	gφ	ob	OK	012		
Code No.:	PON/DRUGS/ 19 13 4323	ole	Oll	ok	ok	9-	6b	06	On	OR	Or-	O.	ok	SE SE	08		
B. No.:	61F210317	de	(Th	ob	06	Ol	co	OR	LR-	90	01	77	00	080	00	4	
Mfg. Date	63/2021	06	Clo	OR	Ole	04	ob .	de	ch	06	DV	a	Ob	080	Ole		

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.

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	Prepared by:	Che	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	not ikamuan	. Agr	inc.	1 Total
Date 11	U34/10/2020	31/10/2020	21/2/1	NTRALLENYCZYT

SAI PRIMUS
CINE BIOTECH PVI CID

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

Customer:

Batch Size: 6,00,000 Tablets

Product **RAMITHIAZIDE 5/12.5** BPR. No.: BPR/T/134-00

Batch No.: 61 F21 0317 Generic Health Care Pvt. Ltd.

20.1 MACHINE IN-PROCESS CONTROL.

Date/ Shift	en a V	סומ	4/21	x11112-111-1112-1112-1112-1112-1112-111	,							1	2			
Machine Op	erator Name	14														
Time of insp	pection	12.35	12.40	12.46	12.50											
Sealing Terr (To be estab		2000	1300	2000		-	1								£	ži.
	Alu Alu Strips*	4	4	di	5k										aī -	2 14 U/CO
Knurling/Se	ealing	61-	ok	et	ok					No. Line		0				
Pocket Form	nation	di	d	d	of											584
Horizontal c	utting	ef-	d	of	d		٠		\	(4)(11 - 9 15			2	e livie sace	
Vertical cutt	ing	ek	of	ok	ok								- ,			
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Code No.:	PON/DRUGS/ 19 13 4323	ek-	A	of	d							- 0 d				
B. No.:	GF210317	51-	ck	ot _e	d			- 14		-	/					
Mfg. Date	07/2021	61-	ರ	0(ર્											3,24
Exp. Date	orfrory	4	4	d	EF								ne			
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Checked by	(Packing)	·4	NY	47	NF											
Checked by	(IPQA)	10	b	80	10										11111210	1

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:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L, Ko	JOF.	in min	O Contraction of
Date	31/10/2020:	31/10/2020	Q VIII	TROLLED CC3Y

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SAI PRIMUS
12178

Product

SAI PRIMUS LIFE BIOTECH PVT LTD

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

Product Code: R09

Customer:

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

Page 14 of 29

BATCH PACKING RECORD

Batch Size: 6,00,000 Tablets

RAMITHIAZIDE 5/12.5

Batch No.: 67 F210317 Generic Health Care Pvt. Ltd.

Date/ Shift		1								į	11/1		, i			
Machine Op	erator Name	,	/					- 01				U. A.		1	1 -	
Time of insp	pection					-10							İ	•		
Sealing Tem (To be estab	nperature														p = =	-
	Alu Alu Strips*					1			-	STP ;		Š			1.	
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Checked by	y (IPQA)										4.1	17			1 7 -	

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:	Che	ecked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign	L. La	Por	sific 1	O hat
Date	3/1/0/2020	11/10/2020	7 2/1/2	IN KUAHLEGY

CALD	SAI PRIMUS LIF Factory: R.S. No. 4/3, Plot N Villianur Commu				rumbapet Ind	lustrial Estate	e, l	Page 15 of 29		
	ECH PVT LTD	BATCH PAG	CKING RECO	RD	Product Co	ode: R09 .	5 1 0 x	Batch Size: 6,00,0	00 Tablets	
Pre	Product RAMITHIAZIDE 5/12.5			BPR. No.:	BPR/T/134-	00 1	Batch No.: GF	210317		
Time v					Customer:	-		Generic Health C	are Pvt. Ltd.	
21.	DEFOILIN	G OF ALU ALU	STRIPS:	72		_	1912	, i		
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)	
क्षा ०५/२०	16230	11:50	0-250		Doger	2001		A 121	or Del	
	A STATE OF THE STA		rg = to to to the		0	100 Marie 1	4	י אין דעי	027/04/2	
4 4				- 60						
hdie		1 4		181					77. 1.5	
1 -1 -1	17			1	1	3- J			1	
		otal Weight of foiled Tablets	in W - a -a	Checke	ed By / Date			Verified By / Da	te (IPQA):	
21.1	INSPECTI	ON OF DE-FOI	LED TABLETS	S:	20	हिप 11		ं भाग		
Date	Inspect			Quantity of Good Qty. of Rejector Tablets			Checked by/ Date	Verified by		
10.00 (0.000,000)		at completed a	at Done by	Kgs	Nos	Kgs	Nos	(Packing).	Date (QA)	
27/54/2	4 11-58	12:10	maler	0.200	1000	620.0	250	D D D D D D D D D D D D D D D D D D D	(20) 104/4	
-	1500	1,100		- k			AND THE STREET	18 104	ייייסן רנף כיי	
		81 W 42 P								
1			9	4)	M				Franks J	
- 10iz	y xementus ig	4	Total		terem i -					
	uantity of Re	ejected Tablets Do	estroyed	Check	ed By / Date		Ver	rified By / Date (I	PQA):	

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko-	700	mym	O WOV
Date	3,11012020	31/10/2020	TON JONE ON	TRUINTERCES
U. A. A. CYCE	arm pen and an arm of the		/ ONCOI	INCLUDIO COM I

		SAI PRIMUS LIFE B Factory: R.S. No. 4/3, Plot No.33 Villianur Commune, 1	, Kurumbapet Industr	ial Estate,	Page 16	of 29		
	I PRIMUS BIOTECH PVT LTD	BATCH PACKING RECORD	Product Code:	R09	Batch S	ize: 6,00,00	0 Tablets 🖾	
*	Product	RAMITHIAZIDE 5/12.5	BPR. No.: BPI	R/T/134-00	Batch N	10.: G1F2	F210317	
	Trouder	KANTITITALIDE 5/12.5	Customer:	To a constant	Generic	Health Ca	re Pvt. Ltd.	
22.	LINE CL	EARANCE CHECKS – BATCH CO Date/ S	DING: hift 26/04/9	202) /	<u>U</u>			
Previ	ous Product:	Pantopral	Batch No.: OF				Vog 2000	
			4		Obser	vation		
Sr. No.		Checks	Time	Packing	IPQA	Packing	IPQA	
1	Check and en	sure that the area is visually clean and f	ree from previous	~	/		7 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	
2		sure that waste bin is emptied out and c	leaned	~	V			
3		lets and crates area clean and free from		/			restore .	
4		sure the Correct status board is written.			1			
5	Check and en	sure the previous batch details are delet	ed from the inkjet	/	/			
6	Check and entremoved.	sure the rejected Cartons of previous pr	oduct/batch are		· \			
7	Check and en	sure the cleanliness of hatch for convey	or belt.	~				
8	Check and en	sure the cleanliness of conveyer belt wi	th collateral block.	1				
9	Check and en	sure the dispensed secondary packing n	naterial.	~			de and the terms	
10	Check and en	sure the Preventive maintenance record	s and log book.	-				
Note:	Tick mark (√)	if Complies, (X) if does not comply an	d (NA) if not applicat	ole.	(
Clear (Pac	ning Satisfacto king) Sign. /Da	ory/Not satisfactory# ate: D. A. 21/4/2011	Cleaning Satisfacto (IPQA)Sign. /Date:		factory#			
Rema	irks: # In case t	the cleaning is not satisfactory / line is narea / line and record.	ot certified then inves	stigate the caus	se of the fai	lure and take	e necessary	
	Check and e Transfer und Set and open Overprinting	EQUIPMENT CLEARANCE FOR Observed that the over printing area and made oded printed Carton to Overprinting area to Overprinting Machine. It is shall be in indelible ink. It is observed by Packing and Details shall be checked by Packing and Detai	achine is cleared from ea.			eration.		
I	Equipment	Inkjet Machine	Conveyor		#0 <u>1</u> 2 ₁₀₀	Area	Constitution of the	
ID. N	. No.: PD/B-004				Batch Cod	ling		
Previ	ous Product:	PantoPral		= =	7.00			
Batcl	n No.:	C172 1033	75 22-					
Clea	ned by:	Magavalli	and the second s	And the second second second second	-		>	
Chec	eked by Packir	ig: De offult						
Veri	fied by IPQA:						·	
i. 1		WE DAY NY						

Prepared by:		Ch	Checked by:		
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign	L. Ka) DOD	THE TANK	and division	
Date /	31/10/2020	31/10/2020	2 July Water	ONIKUELDCUM	
IRAA DYTT	The same of the sa		7.0	J' J	

	Factory: R.S. No. 4	MUS LIFE BIO 4/3, Plot No.33, K or Commune, Puo	Curumbapet In	dustrial Estate,	Page 17 of 29
SAI PRIMUS	BATCH PACKING RECORD		Product Code: R09		Batch Size: 6,00,000 Tablets
Product	RAMITHIAZIDE 5/12	2.5	BPR. No.	: BPR/T/134-00	Batch No.: (7 F 2 10317
	Kumini Kimizibi 3/12		Customer:		Generic Health Care Pvt. Ltd.
22.2 OVERR	RINTING DETAILS:				\$ - 1 - 1 - 1 - 1 - 1
Overprinting Details		Overprint	Overprinted Text Carton (OK/		/ Not OK)

22.2 OVERRRINTING DETAILS:	34 - 1	
Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.: C1 F210314	8 1 4° 1 1 15°	in the second
Mfg. Date: 63/2021	.= ;	
Exp. Date: 62/2024	E 199	9.1
Item Code: 15/0362	1	*
Code No.: PON/DRUGS/19 13 4323	8 \$ mr.	20 ft .
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.		K 7	Batch	Coding	Checked by	Verified by
	Date/Shift	Batch Coding Done By	Coding Done By Started at Comple		(Packing) Sign. & Date	(IPQA) Sign. & Date
4 5					2 7 7 X ***	
1-5	, T			4	= =	
* 4 14						
eec 5 .51		Maria e di	L	1		St. Care
3.		No. No. of the second second	3			Commence of the Commence of th

22.4 CARTON OVERPRINTING SPECIMEN:

S. No.	Date	Carton Specimen No. Checked by Packing (Sign & Date)		Verified by IPQA (Sign & Date)		
		- 1-1-				
- 5 7						
<u> </u>	40	V . 2 - 0				
de var entradispor	par ransantin	The second secon				

Note - Attach specimen copy of over printed carton

Prepared by:	Chec	cked by:	Approved By:		
Production	Production	Quality Assurance	Head Quality Assurance		
La Land Land	JOH	infin	0		
31/10/2020	31/10/2020	- Tallalien	TROLLED CGY		
	Production	Production Production	Production Production Quality Assurance		

CALIDIALIC	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Ku Villianur Commune, Pudu	rumbapet Industrial Estate,	Page 18 of 29
SAI PRIMUS	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.: 61721031-
	ACCOUNT TO STATE OF THE STATE O	Customer:	Generic Health Care Pvt. Ltd.

23. LINE CLEARANCE CHECKS - SECONDARY PACKING:

23.	BIND CE	EARANCE CITE	Date/	Shift 26 5 Hiller	?	/				
Previ	ious Product:	pantogral	- D	Batch No.: \	1F2	10333	[*]	4 . IF !	11"	1
					•		Obser	vation	- 45	A W
Sr. No.		Che	cks	7	ime	11:00	48 %	a 10	0	
			·			Packing	IPQA	Packi	ng	IPQA
1	Check and ens product.	sure that the area is	us	\	~	レ				
2	Check and ens	sure that waste bin	ure that waste bin is emptied out and cleaned					0	1	~
3	Check the Pal product /Batch	lets area clean and	free from any lefto	vers of previous		V	~	~	1	
4	Check and ens	sure the Correct sta	tus board is writter	n.		V		Ĺ		
5	Check and ens	sure the stereo of the	e previous produc	t/batch removed a	nd	レ	~	L	1	
6		sure the Alu Alu str of previous product				V	V	C	1	/
.7	Check and ens	sure the cleanliness	of hatch for conve	eyor belt.		V			1	
8	Check and ens	sure the cleanliness	of conveyer belt v	with collateral blo	ck.	レ			1	~
9	Check and ens	sure the dispensed s	secondary packing	material.		7	~	C	1	
10	Check and ens	sure the cleanliness	of documentation	table.		C		C		V
11	Check and ens	sure the Preventive	maintenance reco	rds and log book.		V =		し	/	
Note	: Tick mark (√)	if Complies, (X) if	does not comply a	and (NA) if not ap	plicab	le.	7	_,		
(Pac	king) Sign. /Da	ry / Not satisfacto		Cleaning Sat (IPQA)Sign.	/Date:				1202	
		ne cleaning is not s		not certified ther	inves	tigate the cau	ise of the fa	ilure and	d take	necessary
The state	Equipment	rea / line and recor Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	S	trapping	Weighi Balan (shippe	ce		Area
ID. N	lo.:	P0/0087004	PD/ BRUTOIT	M		M	PP1 BOD	4032		ndary ing Hall
Previ	ous Product:	Pamtopoul	- D							
Batcl	Batch No.: Cn f 210333									
Clea	ned by:	Brotha		4 _ 4 4			4 14 25			- i - i
Chec	ked by Packin	g: 1, 2) 26/2	4 (224		1					
Veri	fied by IPQA:	Lestablonles	124		. 210					

Sign	roved By:
C: au Biddelines Consenses and	lity Assurance
THICARINDON	my actor
Date 31 10 2020 1 31 10 2020 2 10 2010	IND CONT

v	SAI PRIMUS
6	

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

Customer:

Batch Size: 6,00,000 Tablets

Product

RAMITHIAZIDE 5/12.5

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

Batch No.: Ct [-21031]
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)

2 × 1		Date/Time: 2	26 6541 hoz	11.80	Date/Time: 9	27 lo4 loy	69va.
Shift:		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	23'7	१६/०५/१५	10 kg	23°C	2164/4	Stel Souly

Secondary Packing Started Date/Time: 26 Date 1 2001 12:85. Completed Date/Time: 27 12 11 15 100

APPROVAL FOR SECONDARY PACKING:

Approved by IPQA Sing/Date: 12 25 011 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.: GHF210314	OK	014	DV
Mfg. Date: 03 (2024	OK	OK	OK
Exp. Date: 02 2024	OK.	Ol	OF
Code No.: PON/DRUGS/19 13 4323	OK.	ok	NA
Pack size: NA	NA	3 x 10's	27 x 10 x 3 x 10's
Other instructions if any	13/0232	15/03/2	16/0255 NA
Initiated by Sign. & Date	NA	Manju	Malini
Checked by Packing Sign. & Date		OA	1
Verified by IPQA Sign. & Date	Tel 26/04/2021	26/6/1/2021	Jest Horlow

24.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
	26/04/2021	0	a-	Wel 26/04/2021
			~	0

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign. Dale	1. K=	31/10/2020	WINCO!	VTROLLED CCŻY

LOE

					77 19			
	3	Factory: R.S. No. 4/3	IUS LIFE BIOT 3, Plot No.33, Ku Commune, Pudu	ırumbapet In	dustrial E	Estate,	Page 20 of 2	29
SAI PR		BATCH PACKING		Product C)	Batch Size:	6,00,000 Tablets
	TA TA			BPR. No.:		700		G1F210317
Proc	luct R	RAMITHIAZIDE 5/12.	5	Customer				alth Care Pvt. Ltd.
		L STRIP WEIGHING				for the		1 A.2 W
1. /	, &	3. 1.7	5. [·	and the second second	7.	1.7	9.	1.8
2.	.7	4. 1.8	6. 1	·	8.	1.8	10.	1.7
Avg. Wei	ght of a Emp	pty Alu Alu strips = \ \frac{1}{2} ty Alu Alu strip (A): tot idual Filled Alu Alu stri	al weight of ten		Alu strip/1	0= (14)	A)	
	-8	3. 3.8		8.8	7.	3.7	9.	3.8
2. 3	3.7	$\begin{array}{ c c } \hline 4. & 3.8 \\ \hline \text{led Alu Alu strips} = 3.5 \\ \hline \end{array}$		8	8.	3.7	10.	3.8
Avg. Wei Limit (C) (Each mis	ght of a Filled = 3.73 ssing tablet sh	d Alu Alu strip (B): tota 40 3.80 could be identified) By: Pracyca	l weight of ten F		u strip/10	= S, F.	P	
		- W - X			١		By: Tes	
25.1		WEIGHT LIMIT SET		ift.公占[见报.	[Ti	ime:		
Weight	of ten indivi	dual empty cartons are	given below:			* · · · · · · · · · · · · · · · · · · ·	* 9 ,	
1. 8	٠. ٦	3. 8.6	5. 6	8.6	7.	8.6	9.	8.7
<u> </u>	2,7	4 8-6	74 C - 10-104 C - 1	8.7	8.	8-6	10.	0 1
Total weig	ght of ten em weight of an e	1 0-0	weight of ten en	SAUC STREET	Service Comment			8.6
1,). =	39.1.	5. 2,	1	7.	9.1	9.	2,4
2.	0 -	0.4	~		8.	2.6		2'4
0	ght of ten Lea	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	16. 2	• 4	0.	2.5	10.	2.6
	ght of a Leaf	let (E): total weight of t CHECKS ON CARTO		2.5				- 1 a · 1
Weight of	ten empty Ca	irton: 86.3	ween wedge. In	Average w	veight of o	one empty	Carton (D):	8.63
Weight of	ten filled Alu	Alu strip: 37.7	1 = 4 1	Average w	veight of o	one filled A	Alu Alu strip (I	
Weight of	ten Leaflets:	25	4.5	Average w				'n
	•	rton F = (D+3B+E) = c	22.414	Limit: G =	F <u>+</u> 1 %		(X	
Checked l	by Packing/L	Date: \$ 21 1017 of	1021	100		Date:	29 27 WAL	2021
25.3		DRAWN RECORD:	131 = 23 - 1 -	1111	· · · · · · · · · · · · · · · · · · ·	0	1	
Sr. No.	Stage of	Sample collection	Qty	of Sample	t trace	n The	Collected by	(Sign. /Date)
1	Control San	nple (Initial)	7 xw	8		The	126 Copt 20 c	â.
2	Control San	nple (Middle)	b x loi			Cita	1 27/calone	1
3	Control San	nple (Final)	7 Riol				u ortopicoe	1
4	Stability Sa	mple	D.OA			0	MA	A Paris
5	Other Samp	ole	N(a)	. 20- 1		-	AlA	
6	Analytical s	sample	12 × 10	5		Copy 1	26/01/20	21
		Total Qty.	32 XV			E.	24/01/2021	
	Pr	epared by:		Checked b	y:		A	approved By:
Dept.	P	roduction	Production	P-	Quality .	Assurance		Quality Assurance
Sign.		1.1/2	500		`.\ `-			- July . UP
Date 7	HO JOY ALCE	131/10/2020/1	7 1 1 -	- 5	Ti of	1 - NE	NCHNTX	MANUE Y
Settleman general and a set		7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	31/10/2	000	>11	120/20	HALLIN	IMPLIA COLT

CALDRIANIC	SAI PRIMUS LIFE BIO Factory: R.S. No. 4/3, Plot No.33, F Villianur Commune, Pu	Page 21 of 29	
SAI PRIMUS	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.: 676210317
roduce	KARATOE SI 12.5	Customer:	Generic Health Care Pvt Ltd

SECONDARY PACKING IN-PROCESS CHECKS: (Please keep √ mark if found "Ok") Date/Shift 20 outry & G observation 2 **Parameters** Specification IPQA Packing 192) NAVO 16-49 Time 12:22 15:25 13:00 3 Alu Alu strip No. of Alu Alu strip in with 10 tabs each 01 of or or OV a carton th and one leaflet. Legible and 06 Carton Overprinting OR ou 04-00 Qu readable NA 12/1 No. of cartons in a NA 10 packed cartons na no 00 per shrink sleeves Shrink wrapping AP. Na noa polit na na temperature* No. of shrink sleeves in 27 shrinks 306 Covelors ob 00 OR OF Ok-OLL a 5 ply shipper 0400 Shipper strapping Proper strapping OR or 24 en

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*Temperature to be mentioned.

Legible and

readable

H type

Label appearance and

Sealing of the shipper !

Shipper appearance

with BOPP Tape

Checked by

26.1 SECON	DARY PACKING IN-P	ROCESS CHECKS: (Please)	keep √ mark if found "Ok")
Date/ Shift		woyly 8 G	25/04/2001/
Danamatana	C:G4:-		observation

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San Control of the Co			109	14			- Toronto (S.)	X	IIOF	アレンし	211-	to			
Parameters	CaraiGaraia		1						vation		(1			
rarameters	Specification	A		F	ackin	g						IPQA	, i		
Time		91.45	NHS	12.30	19,30	4530	- 1	75	bloc	13.00	9.00				
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	1	- 17	ole	- 1	a	2 ¹ C		ch	082	OR	Siplet Siplet	. —		
Carton Overprinting	Legible and readable	ob	ob	Ole	JIE.	a	1		OK	DK	改权	194		1	2.5
No. of cartons in a shrink sleeves	10 packed cartons	pá	na	ha	M	N			na	012	off	- 51=			
Shrink wrapping temperature*		Na	na	na	na	M			no	OR	欧			\	
No. of shrink sleeves in a 5 ply shipper	27 shrinks	gb-	06	00	ce	ou			on	0E	012				V 4
Shipper strapping	Proper strapping	06	ob	ole	ac	a			on	012	OK	31			1
Label appearance and Shipper appearance	Legible and readable	06	Ole	OR	ve	υζ			on	OK	OK				
Sealing of the shipper with BOPP Tape	H type	ok	00	ole	0e	a			Ok	ok	OK			-	
Checked by		100	64.	DE.	1	0			A B	Say	S.				

*Temperature to be mentioned.

	Prepared by:	Check	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign	Lola	DOB	infra	o bet
Date VS	31/10/2020	31/10/2020	- tollar	NTRALITATES
	AN MARKETH LINE		((0110)	MINORIDO COLI

No.	48 1
-	
SAI	PRIMUS
LIFE BIC	DTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

BATCH PACKING RECORD

Product Code: R09

Batch Size: 6,00,000 Tablets

Page 22 of 29

Product **RAMITHIAZIDE 5/12.5** BPR. No.: BPR/T/134-00

Batch No.: G1F210317

Customer:

Generic Health Care Pvt. Ltd.

SECONDARY PACKING IN-PROCESS CHECKS: (Please keen √ mark if found "Ok")

Date/ Shift				-	En E		1991				- 12				
Parameters	Specification		observ Packing							IPQA					
Time		_ \range			. 14	ýz :	41.	M.		V	H.			•	
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.			/	/	. A. I.	ō.	J.	, 1 . h		10				
Carton Overprinting	Legible and readable						2	10							
No. of cartons in a shrink sleeves	10 packed cartons			- 1		3.	\								
Shrink wrapping temperature*	87 1 1 1 1				E,	7	E	a			- 4	-			
No. of shrink sleeves in a 5 ply shipper	27 shrinks			-		٥.	F				- 1/2 =		_	1 2	4
Shipper strapping	Proper strapping	me II	E. S. SANCETTO		- 2	7 1							7		
Label appearance and Shipper appearance	Legible and readable		- -	- -								N			
Sealing of the shipper with BOPP Tape	H type		Į.			9:	7		7			1			6
Checked by	Market Commencer		F		1	4		1.							

^{*}Temperature to be mentioned.

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

Date/ Shift	_ hg														
Parameters	Specification	-	observation Packing							IPQA					
Time					Leith		41	A 12.55							
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.					1 .5		iz t				0.75			5
Carton Overprinting	Legible and readable	× -						NO.				190 - 1 - 1973			
No. of cartons in a shrink sleeves	10 packed cartons							4	 x		×				
Shrink wrapping temperature*	ed a	in i					3	1	r_						
No. of shrink sleeves in a 5 ply shipper	27 shrinks	e 3				Th.	lient.		1			- "			
Shipper strapping	Proper strapping					÷	. l	4 K -				1			
Label appearance and Shipper appearance	Legible and readable					1 2		3							
Sealing of the shipper with BOPP Tape	H type					31	3								
Checked by				1		1.8		W T							

^{*}Temperature to be mentioned.

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assuranc	e Head Quality Assurance
Sign. Date) ([] & [[] (2626)V	31/10/2020	W. W.	ONTROBLEDCERY

SAI PRIMUS LIFE BIOTECH PVT LTD Page 23 of 29 Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009. SAI PRIMUS BATCH PACKING RECORD Product Code: R09 Batch Size: 6,00,000 Tablets BPR. No.: BPR/T/134-00 Batch No .: (7/ 2/03/ Product **RAMITHIAZIDE 5/12.5** Generic Health Care Pvt. Ltd. Customer: Date/Shift Z6/04 Man Time: 12-15 Balance I.D. No. 10/ Backeg SHIPPERS WEIGHING: Weight of ten Shrinks: Average weight of one filled Shrink (H): Weight of ten empty shippers: Average weight of one empty shipper (I): Weight of one filled shipper (J) = (27H+I): Limit: $K = J \pm 1\% =$ 8.023 8.104 8 180 (to be established) fouly Checked by Packing/Date: Verified by IPQA/Date: Gross Gross Gross Gross Shipper Shipper Shipper Weighed Weighed Weighed Weighed Shipper weight weight weight weight No. By No. By No. By No. By (Kg) (Kg) (Kg) (Kg) 1 8-179 R-Madhu 8.140 Prive 58 8-175 8.170 2 40 8.165 P. March 21 8.150 Paris 59 20165 3 22 41 60 IRO R. Madho 7713

0	18.191	11 K-Madew	21	0-165	4417	40	12 -149	MILLER	.03		
9	8.135	L. Madh.	28			47	25-155	Prises	66		· _ dress_
10	2.015	7. Madh	29	8-145		48			67		
11	8:191	P. March	30	8.155		49			68		
12	8.17	1 R-Madh	. 31	8.170	Priya	50			69	\	
13	8.180	R. Madhy	32	8-185	Priga	51	8-170	Priga	70		
14		R. Madhe	- 33	2-170	PAHE	52			71	1	S 1
15	8-160	R. Meellu	34	8.150	PRINC	53	All the second	10 (1	72		$\frac{\lambda^{b}}{\lambda}$
16	8.165	RModelin	35	8-140	Privas	54		0 . []	73		. 44
17	8.145	- R.modh	36	8-140	Prince	55		- 11	74		
18	2.160	Ragher	37	8-145	Park	56	8-180	Part	75		
19	8.170	RMadh	38	2.165	Pringa	57	8,745	Riya	76	=	
Total	No. of	De-foiled	tablets	Checked	by Sign /	Verif	ied by	Loose pa	ck details:)	- 1
	9 10 11 12 13 14 15 16 17 18	9 8.135 10 2.015 11 2.190 12 2.170 13 3.180 14 8.165 15 8.160 16 8.165 17 8.145 18 3.160	9 8.135 f. Madh. 10 2.075 R. Madh. 11 2.190 R. Madh. 12 2.170 R. Madh. 13 8.180 R. Madh. 14 8.165 R. Madh. 15 8.160 R. Madh. 17 8.145 R. madh. 18 2.160 R. Madh. 19 8.170 R. Madh.	9 8.135 f. Madh. 28 10 2.075 R. Madh. 29 11 2.190 R. Madh. 30 12 2.170 R. Madh. 31 13 8.180 R. Madh. 32 14 8.165 R. Madh. 33 15 8.160 R. Madh. 34 16 8.165 R. Madh. 35 17 8.145 R. madh. 36 18 2.160 R. Madh. 37 19 8.170 R. Madh. 38	9 8.135 f. Madh. 28 8.150 10 2.075 R. Madh. 29 8.145 11 8.190 R. Madh. 30 8.155 12 8.170 R. Madh. 31 8.170 13 8.180 R. Madh. 32 8.185 14 8.165 R. Madh. 33 8.170 15 8.160 R. Madh. 34 8.150 16 8.165 R. Madh. 35 8.140 17 8.145 R. madh. 36 8.140 18 8.160 R. Madh. 37 8.145 19 8.170 R. Madh. 38 8.165	9 8.135 p.Madh: 28 8.150 Paya 10 8.075 R.Madh: 29 8.145 Raya 11 8.190 p.Madh: 30 8.155 Paya 12 8.170 R.Madh: 31 8.170 Paya 13 8.180 R.Madh: 32 8.185 Paya 14 8.165 R.Madh: 33 8.150 Paya 15 8.160 p.Madh: 34 8.150 Paya 16 8.165 R.Madh: 35 8.140 Paya 17 8.145 R.madh: 36 8.140 Paya 18 8.160 R.Madh: 37 8.145 Paya	9 8.135 p. Madh. 28 8-150 Parisa 47 10 8.075 p. Madh. 29 8-145 Parisa 48 11 8.190 p. Madh. 30 8.155 Parisa 49 12 9.170 p. Madh. 31 8.170 Parisa 50 13 8.180 p. Madh. 32 8.185 Parisa 51 14 8-165 p. Madh. 33 8.150 Parisa 51 15 8-160 p. Madh. 34 8.150 Parisa 53 16 8.165 p. Madh. 35 8-140 Parisa 54 17 8.145 p. madh. 36 8-140 Parisa 55 18 8.160 p. Math. 37 8-145 Parisa 56 19 8.170 p. Math. 38 8.165 parisa 57	9 8.135 p.Madh. 28 8.150 Parso 47 8.155 10 2.075 p.Madh. 29 8.145 Parso 48 8.160 11 2.190 p.Madh. 30 8.155 parso 49 8.160 12 2.170 p.madh. 31 8.170 parso 50 8.155 13 8.180 p.Madh. 32 8.185 parso 51 8.170 14 8.165 p.Madh. 33 8.170 parso 52 8.165 15 8.160 p.Madh. 34 8.150 parso 53 8.190 16 8.165 p.Madh. 35 8.140 parso 54 8.720 17 8.145 p.madh. 36 8.140 parso 55 8.795 18 2.160 p.madh. 37 8.145 parso 56 8.795 19 8.170 p.madh. 38 8.165 parso 57 8.795	9 8.135 f. Madh. 28 8.150 Parisa 47 8.155 Parisa 10 8.075 R. Madh. 29 8.145 Parisa 48 8.160 Parisa 11 8.190 p. Math. 30 8.155 Parisa 49 8.160 Parisa 12 8.170 P. Madh. 31 8.170 Parisa 50 8.155 Parisa 13 8.180 R. Madh. 32 8.185 Parisa 51 8.170 Parisa 14 8.165 R. Madh. 33 8.170 Parisa 51 8.170 Parisa 15 8.160 p. Math. 34 8.150 Parisa 53 8.190 Parisa 16 8.165 R. Madh. 35 8.140 Parisa 54 8. Not Parisa 17 8.145 R. math. 36 8.140 Parisa 55 8.795 Parisa 18 9.160 R. Math. 37 8.145 Parisa 56 8.787 Parisa 19 8.170 R. Math. 38 8.165 Parisa 57 8.795 Parisa	9 8.135 p. Madh. 28 8.150 Party 47 8.155 Party 66 10 8.075 R. Madh. 29 8.145 Raya 48 8.160 Party 67 11 2.190 p. Madh. 30 8.155 Party 49 8.160 Party 68 12 9.170 p. madh. 31 8.170 Party 50 8.155 Party 69 13 8.180 p. Madh. 32 8.135 Party 51 8.170 Party 70 14 8.165 p. Madh. 33 8.170 Party 52 8.165 Party 71 15 8.160 p. Madh. 34 8.150 Party 53 8.165 Party 72 16 8.165 p. Madh. 35 8.140 Party 54 8. Not Party 73 17 8.145 p. madh. 36 8.140 Party 55 8.715 Party 74 18 8.160 p. Math. 37 8.145 Party 56 8.787 Party 75 19 8.170 p. Math. 38 8.165 Party 57 8.715 Party 76	9 8.135 f. Madh. 28 8.150 Party 47 8.155 Party 66 10 8.075 R. Madh. 29 8.145 Party 48 8.160 Party 67 11 2.190 p. Madh. 30 8.155 Party 49 8.160 Party 68 12 9.170 p. madh. 31 8.170 Party 50 8.155 Party 69 13 8.180 p. Madh. 32 8.135 Party 51 8.170 Party 70 14 8.165 p. Madh. 33 8.170 Party 52 8.165 Party 71 15 8.160 p. Madh. 34 8.150 Party 53 8.190 Party 72 16 8.165 p. Madh. 35 8.140 Party 54 8. Not Party 73 17 8.145 p. madh. 36 8.140 Party 55 8.715 Party 74 18 8.160 p. Math. 37 8.145 Party 56 8.787 Party 75 19 8.170 p. Math. 38 8.165 Party 57 8.795 Party 76

42

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45

16

Sign / Date:

61

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63

64

Shipper No: ...6.4....

Weight. 5:672

Quantity 1664 3x 151

2171

2.157

5-670

150

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

Date:

23

24

25

26

packed in

Shipper No:

HJ

155

8.150

8.160

8.075 P. Nach

P.085 R. Made

4

5

6

7

shippers weighed:

GY

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign,	L.Ko	AQ.	in.	
Date VC	MIT Biliologo VI	31/10/2020	- Talla MAYEN	NTDMIFACOV
I I II.	O REGULERATE CONTR	1 1/0/8	UNCU.	HINGTIFF COLI

C/O	Facto	SAI PRIMUS LIFE BIO ry: R.S. No. 4/3, Plot No.33, K Villianur Commune, Pud	urumbapet Industrial Estate,	Page 24 of 29
SAI PRIMUS	BATO	CH PACKING RECORD	Product Code: R09	Batch Size: 6,00,000 Tablets
	DAMITTI	TATTOE EILO E	BPR. No.: BPR/T/134-00	Batch No.: 67 F210314
Product	KAMITH	IAZIDE 5/12.5	Customer:	Generic Health Care Pvt. Ltd.
28. MAN PO	WER ALL	OCATION:	- 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
28. MAN POY DATE: 26. OH 2	<i>i</i> /	with the state of	DATE:	
SHIFT:		ant a	SHIFT:	for any
ACTIVITII	ES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checki	ng	Janose, Sevasanby	Alu Alu strip Checking	1//
Printing Checking in strip	Alu Alu	Jarak Drolling	Printing Checking in Alu Alu strip	
Alu Alu strip weighii	ng	molar	Alu Alu strip weighing	
Insertion of Alu Alu leaflet into carton	striptand	Selvi. Korkar	Insertion of Alu Alu strip into carton	
Cartons weighing	N ,	Chanapyer	Cartons weighing	72.71.11
Insertion of carton in sleeve	to shrink	NA	Insertion of carton into shrink sleeve	M
Insertion of shrink w carton into shipper	rapped	ND	Insertion of shrink wrapped carton into shipper	,
Shipper Label Pastin	g	Heertha	Shipper Label Pasting	
Shipper Weighing	3	Vierta	Shipper Weighing	
Shipper Strapping		CrisoTha	Shipper Strapping	
Shipper packed		From. D. 1 to. 29	Shipper packed	Fromto
Signature of Packin	g	A.	Signature of Packing	Y-
DATE: 97/04/2	.))		DATE:	A'S
ACTIVITI	es	DONE BY	SHIFT:ACTIVITIES	DONE BY
Alu Alu strip Checki			Alu Alu strip Checking	Dombbi
Printing Checking in		Danob, Sivalanti	Printing Checking in Alu Alu	
strip		Daramet sori Sal	strip	
Insertion of Alu Alu leaflet into carton	strip and	moler	Insertion of Alu Alu strip into carton	0
Alu Alu strip weighi	ng	Selv KashMni	Alu Alu strip weighing	- T. A.
Cartons weighing	Special Community	Dharotryg	Cartons weighing	
Insertion of carton in sleeve	nto shrink	<i>\$</i> √4	Insertion of carton into shrin sleeve	k A
Insertion of shrink w carton into shipper	тарреd	NA	Insertion of shrink wrapped carton into shipper	Į ^t
Shipper Label Pastin	ng	fratha	Shipper Label Pasting	
Shipper Weighing		hota	Shipper Weighing	
Shipper Strapping		Mantha	Shipper Strapping	
Shipper packed		From. 2.1to 1.4	Shipper packed	Fromto
Signature of Packin	ng	10	Signature of Packing	

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	PO)	infri	O WITH THE
Date \	1 3 1/10/2020 11:	31/10/2020	191/0/WO	VIRALIAN CERV
The state of the s	Contraction of the contraction o		011001	VI NOULLED YOU I

(Factory: R.	AI PRIMUS LIFE S. No. 4/3, Plot No.	.33, Kuruml	papet Indus		Page 25	5 of 29	
	AI PRIMUS		Villianur Commune ACKING RECOR		oduct Code	. P/19	Ratch 9	Size: 6,00,00	M Tableta
LIFE	BIOTECH PVT LTD					R/T/134-00			210317
	Product	RAMITHIAZI	DE 5/12.5		stomer:		Generic	c Health Ca	re Pvt. Ltd.
29.	PRODUC	T COUNTER C	HECK LINE CLE	EARANCE: / Shift	26/04/2	1/6/		NT	
Previ	ious Product:	Pamilla on	*			210323		2 1	Programme and the second
Sr.			1 0-1	0			Obser	vation	
No.		Ch	ecks		Time	10000	1 1 2	1	
	Ch. It I	1 11	- Marie			Packing	IPQA	Packing	IPQA
1	product.	sure that the area i	s visually clean and	d free from	previous				_
2	Check and ens	sure that waste bir	is emptied out and	d cleaned	3				- 1
3	Check the Pal product /Batcl		I free from any lefto	overs of pre	vious	0			1.6. 48
4	Check and ens	sure the Correct st	atus board is writte	en.		5			
5	Check and ens	0							
6			trips, rejected Carto		and	C	/		
7	Check and ens	sure the cleanlines	s of hatch for conv	eyor belt.		0			ed
8	Check and ens	sure the cleanlines	s of conveyer belt	with collate	ral block.	<u></u>			
9	Check and ens	sure the dispensed	secondary packing	g material.		~	/		1
10	Check and ens	sure the cleanlines	s of documentation	ı table.	- EM (2-7-	0	/		
11	Check and ens	sure the Preventiv	e maintenance reco	ords and log	book.	0	/		
Note	: Tick mark (√)	if Complies, (X)	f does not comply	and (NA) if	not applica	ble.			
Clear (Pac	ning Satisfacto king) Sign. /Da	ry/Notsatisfacti	ity#		g Satisfact Sign. /Date	ory / Not satis		26/104/5	Lory
Rema	arks: # In case tl	ne cleaning is not	satisfactory / line is	s not certifie	d then inve	stigate the cau	se of the fai	lure and take	e necessary
	n, re check the a	Packing Conveyor	Weighing Balance (Carton)	Shrink S	leeve S	Strapping	Weighir Balanc (shippe	ee	Area
ID. N	lo.:	N	PO)BALIT	20	12.2.2	M	POBON	092	1 L 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Previ	ous Product:	pantofra			d	\ \			
Batcl	n No.:	CAF2163			O I W I				

	Prepared by:	Che	cked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	Bronk ike	DOX.	infin	0 - 240 - 003
Date	12 81 4012020	31/10/2020	21/2017	WALKE LOKENO

Approved by IPQA Sing/Date: This is the same

Rechecking Started Date/Time: 26 ohlow 15 ... Completed Date/Time: 21 6 4 1001 17630

Cleaned by:

Checked by Packing:

Verified by IPQA:

AU26/04/2021

APPROVAL FOR COUNTER CHECK:

CD)	Factor	y: R.S. No	RIMUS LIFE BIOT . 4/3, Plot No.33, Ku Inur Commune, Pudu	rumbape	et Industrial Estate,	Page 26 of 29
SAI PRIMUS	BATC		ING RECORD			Batch Size: 6,00,000 Tablets
Product	RAMITH		4 2	15 A	No.: BPR/T/134-00	Batch No.: 618210314
Product	KAWIIII	IAZIDES	712.3	Custo	mer:	Generic Health Care Pvt. Ltd
		OF PACE	CED SHIPPERS:	2	55/61/1000	\$
DATE: . 2.61.0H	M			and Hilliam	E. 27 10 4 120	. 1
SHIFT:			CANA DAY	SHIE	T:	DOME DAY
ACTIVITI			OONE BY	A 1	ACTIVITIES	DONE BY
Alu Alu strip Checking in		Untlivia	-, parameshway		Alu strip Checking ing Checking in Alu Alu	Shabana Don pry
strip	ı Alu Alu	Pan	ames hway	strip	ing Checking in Alu Alu	Kamah Maraneth
Alu Alu strip weighi	ing		nadan	Alu	Alu strip weighing	moler
Checking of Alu Alu leaflet in carton	strip and		malon		king of Alu Alu strip and et in carton	
Cartons weighing		111 2 22-12-2	malon	Carto	ons weighing	Viellyc
Printing Checking in Label	Shipper	Vı	the	Print Labe	ing Checking in Shipper I	Vially
Shipper Weighing		Ví	dh	Ship	per Weighing	vielly
Shipper Strapping		W	zlen	Ship	per Strapping	vidly
Shipper Checked		Fromº.	to3₽	Ship	per Checked	From. 3.1. to6.
Checked By Packin	ıg		R		cked By Packing	
Verified By IPQA		2		Veri	fied By IPQA	
DATE:			18 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -		`E:	
ACTIVITI		I	OONE BY		ACTIVITIES	DONE BY
Alu Alu strip Check	ing			Alu	Alu strip Checking	
Printing Checking in strip	n Alu Alu			Print strip	ting Checking in Alu Alu	
Alu Alu strip weigh	ing			Alu	Alu strip weighing	
Checking of Alu Alu leaflet in carton	u strip and				cking of Alu Alu strip and et in carton	d
Cartons weighing		1	0/2	Cart	ons weighing	M
Printing Checking in Label	n Shipper	-y	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Prin Labo	ting Checking in Shipper el	
Shipper Weighing				Ship	per Weighing	
Shipper Strapping				Ship	per Strapping	
Shipper Checked	,	From	to	Ship	per Checked	Fromto
Checked By Packin	ng	100		Che	cked By Packing	n 1
Verified By IPQA		L	٧/	Ver	ified By IPQA	4 /
No. of Defects 1. Minor: 2. Major: 3. Critical Batch Allowed	N4 N4 N5	ch: Check	ced By: April Solo	114	Verified By:	3) Joyh
	Prepared b		1	Check		Approved By:
Dept.	Productio	on	Production		Quality Assurance	Head Quality Assurance
Sign. Date III	1. Ka 1317101:	2920	31/10/2	ο <u>λ</u>	INCOM	ROLLIN CLASS

CID)
SAI PRIMU	
7	

SAI PRIMUS LIFE BIOTECH PVT LTD

Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,

Villianur Commune, Puducherry-605009.

BATCH PACKING RECORD

Product Code: R09

Customer:

Page 27 of 29

Product

RAMITHIAZIDE 5/12.5

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

Batch Size: 6,00,000 Tablets Batch No.: (71-210317

Generic Health Care Pvt. Ltd.

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	20200	20400	Nā	75	300	.10
В	Additional material received for the batch	NE	NA	M	M	M	NA	NA.	N
С	Total material received (A+B)	51.2ho	112-260	ગ્રાહ્ય લ્	20 how	No	75	312	0
D	Quantity packed	23.330		19444	19444	NA.	64	300	po
Е	Quantity rejected (Online) & Destroyed	5.591	13.448	948	47	WŁ	b	NS	W
F	Quantity Returned	22.300	7 1.500	NE	948	AM	5	100	W
G	Sample affixed on BPR	6-00-0	Ng	1	1	M	NA	NA-	No
Н	QC samples	0.001	0.005	nΑ	M	N	M	M	M
I	Other samples (If any)	6.010	0:020	7	4	M	M	M	M
J	Total accountable Quantity (D+ E+F+G+H+I)	51.240	1712 febo	20 hro	20 hes	M	75	300	าอ
K	Variation (C – J)	NA	M	M	NA-	M	M	M	M
L	%Variation (K x 100)/C	L/A	CA-	M	M	M	M	M	M
M	Acceptable limit	<u>+</u> 2 %	<u>+</u> 2%	±2%	±2%	±2%	M	M	M

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

31. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. 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)
Quantity Returned	22-300	71.500	Not	94-0	- 44	60	N	M
Material returned by packing Sign./Date	AND YNDO	(6)	2	A Dura	^	136		
Verified By IPQA Sign./Date			NO	रही स्त्रीय	N			
Material received by Store Sign./Date	(OD.	-6 D -		Spork				~

DESTRUCTION OF REJECTED/JINISED PRINTED PACKING MATERIALS AND STEDEOS.

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)
29/04/201	L	5-591	13.448	948	N	NJ-	76	M	M
Total Qty. Destroyed	6	5.57.	(13-448	948					
Destroyed by (Packing)	Spring	alouise1	<u>.</u>	Я	II +			·	.
Verified by (IPQA)	0	offica	4		V			2	

Prepared by:		Chec	Approved By:	
Dept.	Production Production		Quality Assurance	Head Quality Assurance
Sign.	1.Ko	404.	infin	1 Lav
Date) (3 8 / 10 / 2020)	71/10/2020	- Silva Danis	VERNITED AND I

	13	Factory	: R.S. No.	IMUS LIFE BIO 4/3, Plot No.33, K ur Commune, Puo	Curumbap	et Industri	al Esta	ite,	Page 28 of 29		
SAI PR							Batch Size: 6,00,000 Tablets				
Dua	Product RAMITHIAZIDE 5/			BPR. No.: BPR/T		JT/134	1-00	Batch No.: 61-21031			
Fro	duct	KAWIITHI	ALIDE 3/1	Customer:				Generic Health Care Pvt. Ltd			
33.	BATCH F	RECONCIL	ATION:				96	- 1			
A,	Batch Size	e		36 						6,00,000 Nos.	
В	Quantity received for packing								589300		
C	Total quantity packed									583320	
D	Control sa	Control samples 200									
Е	Analytica	l Samples		7) j = 1	T			13.5		120	
F	In process	samples			The Reserved April 1984	ilea e		4 1 4		560	
G	Others sai	mples if any (Stability, R	Legulatory Sample	es, etc.)	Ä.				NA	
Н	Packing L	Loss = B - (C	+D+E+	F+G)		9= 1				5100	
I	Total Los	s = A - (C +	D + E + F+	G)				1		15800	
J	Packing y	ield % (C + I) + E + F+0	G) / B X 100 (Yie	ld Limit 9	6)*	12 =		99.18	
K	Batch Yie	eld % (C + D	+ E + F +G) / A X 100 (Yiel	d Limit %)*	11 10/ X 5/1=1	-	97.36	
		ablished icking /Date: ER OF FINI	28/84				Veri	fied by IP	QA/Date:	25/104/2021	
Date	FGTN No.	Sales	Pack Size	No. of	No. of Shippers	Transfe Quant	(2)(1)(2)(2)(3)	FGTN Raised b Packing		FGTN Received by Stores	
linhow	0 569	Sali	3×101	366 73×11	63	57 23	4	1	501	1528/04/2	
				166 73410	1	49		8	C FOLLY	24: 28/46/20	
				Total Qty. Trai	nsferred	58 33		2	Tou	At 28/04/2	
1	ring proce		any Deviat	ion / Exception a <u>Deviation / I</u>	Exception	details	ecord	Confederate sharp armitted			
Sr. No.		Stage	D.	eviation / Except	ion detail	S		Action t	aken	Observed By	
) NH .	-/2-				1		
	1		<u> </u>		1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -		F-1	Her Street			
Check Pac	cking:	VIEW DETA	ILS:	Verified b Packing manage		A- 1			Approved by Head QA:		
	Rev	iewed by			Name				Sign. /D	ate	
Packin	g Executi	ve	A Prv1HARK			7777 100777	A 1 28/04/2021				
QA Executive Rankuman					20/0	ala A					
Produ	ction Assis	tant Manago	er/ HOD	BOUASU	BRA	MONTO	NA	5a	lasn	~ 5 (Bu)	
QA M	QA Manager/ HOD			R Slipter				Miroks			
	Prepared by:			Checked by:				Approved By:			
Dept.	- 5 m	Production	ı	Production Quality Assurance			surance	Head Qu	uality Assurance		
Sign.		1.Ko	THE CONTRACTOR BY A LAND BY A	JOH JOH		June 1	ū		0	Tark I	
Date	VCDD	731/10/	2011	31/10	2020		61/	AMERICA	ONTRALI	MYZY	

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 SAI PRIMUS BATCH PACKING RECORD Product Code: R09 Batch Size: 6,00,000 Tablets BPR. No.: BPR/T/134-00 Batch No.: 61 F21031 Product **RAMITHIAZIDE 5/12.5** Customer: Generic Health Care Pvt. Ltd.

37. BATCH RELEASED FOR DESPATCH:

Total quantity released:

Head QA sign/ Date:

REVISION HISTORY:

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

	Prepared by:	Check	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	10x	him	0
Date	31/10/2020	31/10/2000	10/10/16	NTKOLEDICERY