

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

Page 1 of 24

BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: 6 F 200501

Customer:

Generic Health Care Pvt. Ltd.

BATCH PACKAGING RECORD COVER SHEET

P	RC	טו	U	N	AN	1E	

: Amloperin 5mg/5mg

GENERIC NAME

Amlodipine Besilate and Perindopril Erbumine Tablets

Each uncoated tablet contains: Amlodipine Besilate BP

LABEL CLAIM

Equivalent to Amlodipine...... 5 mg Perindopril Erbumine BP 5 mg

Excipients.....q.s

CODE NO.

PON/DRUGS/19 13 4323

DOSAGE FORM

Tablet

BPR No.

BPR/T/107-00

REVISION No.

00

SUPERSEDE No

EFFECTIVE BATCH. No. /DATE

GF 200405 /22104/2020

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)

FN 60 92/05/2020

BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)

\$0\$22/05/200

MFG. DATE: 05 2020

EXP. DATE: 04 2023 2023

COUNTER CHECKED BY: QA SIGN/DATE

QUANTITY RECEIVED FROM PRODUCTION

591150 tablets

.........

DATE OF COMMENCEMENT: 25 05 20 20

DATE OF COMPLETION: 27/05/2020

QUANTITY

6,00000 tables

RELEASED QUANTITY OF PACKED TABLETS

387790 Tabley

RELEASE OF BATCH BY HEAD OA

SIGN/DATE:

This BPR contains 24 Pages + . M. .. Additional Pages

' - ,	Prepared by:	Check	ced by:	Approved By:
Dept.	Production	Production ()	Quality Assurance	Head Quality Assurance
Sign.	L. Ko-	Zaleny	P. K. John	O hard who
Date	20/04/2020	21/04/2020	22/04/2020	J. 150 124
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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.

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets Batch No.: GF200501

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00 Customer:

Generic Health Care Pvt. Ltd.

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1.	INDEX

Sr. No.	Content	Page No.
Batch Pacl	kaging cover sheet	I was
1 '	Index	2
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Dept.	Production	Production	Quality Assurance	Head Quality Assurance
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Date	20/04/2020	21/04/2020	42/04/202	27
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-	LIFE E	BIOTEC	H PVT L	TD

Product

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00
Customer:

Batch No.: GF200501
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) *	MA
2.	Line clearance and environmental record	Yus
3.	Processing activity done by and checked by is signed	Yag
4.	Dispensing	, M
a)	Equipment clean tag and dispensing tag attached with batch record	Yey
b)	Packaging material is checked	Yes
5.	Packing	NE
a)	Rinse water analysis report attached with BPR	Yay
b)	Approved specimen of printed foil, show box and shipper label are attached	Y.23
c)	Control / Stability / Finished product analysis samples are withdrawn	Yag
d)	Reconciliation of packing materials is done	Yes
e)	Tablet reconciliation is done	Yy
f)	In process checks parameters done at regular interval and recorded into BPR	Yaq
6.	Attachment	NA
a)	Finished Goods Transfer Note	Yes
b)	Certificate of analysis of finished product is submitted	Yes
c)	Stereo Impression Form and Destruction Record	+
7.	Complete set of BPR Submitted	Yes

Checked By QA/Date:	
1276	
*Mention total number of pages.	
Remarks (If any)	

	Prepared by:	Check	ted by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko	3alaluny	P. W. Josicor	O. Mat. no
Date	20/04/2020	21/04/2020	22/04/	
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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,
Villianur Commune, Puducherry-605009.

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00
Customer:

Batch No.: 6 F200501

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.	% Over ages	Qty. Required 6.0 Lac with overages
1	188 mm Amloperin 5 mg/5 mg Printed Foil	PPF/GH/ A001	Width – 188 ± 1 mm Thickness – 0.025 mm Total GSM: 66.93 gsm – 78.57 gsm Language – English/French	Kg	30.000	2	30.600
2	188 mm Alu/Alu Base Foil	PBF/GH/A001	Width – 188 ± 1 mm Plain non-printed (text matter) aluminum foil. Total GSM: 233.96 gsm – 272.41 gsm Thickness: Total: 125μ - 144μ OPA: 25.99μ - 30.51μ PVC: 56μ - 63.6μ	Kg	90.000	2	91.800
3	Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	Size – 98 x 46 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 4 colour Language – English/French	No	20000	2	20400
4	Amloperin packing inserts	PPI/GH/100	Size – 280 x 200 mm (L x w) Specification – 60 gsm Maplitho white Paper. Colour – 2 colours Language – English/French	No	20000	2	20400
5	Shrink Sleeves (PVC)	PPS/GH/ P001	Plain PVC Shrink Sleeves Length-290 Height-260	No	1250	2	1275
6	5 Ply 390x390x260 mm C/Boxes	PUS/GH/C	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 260 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	90	- 100	90
7	GHPL Ptd Bopp Tapes	PPB/GH /B001	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	18		18
8	Strapping Role	2 2 4 - 4 - 2 - 2	White or milky white colour. Width - 12 mm Thickness - 0.6 mm	Mtrs	250	-	250
9	Shipper Label		Half A4 size Computer printed label	No	91	-	91

	Prepared by:	Check	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko	Balalung	P. M. Dubiloop.	met 10h
Date	20/04/2020	21/04/2020	22	TOTAL CANAL
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LIFE DI	OTECH P	VILID

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

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00 Customer:

Batch No.: GF 200501 Generic Health Care Pvt. Ltd.

4. DISPENSING LINE CLEARANCE CHECKS

Date Time of 135

Sr.	CHECKS	Observ	ation*
No.		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.	2	1
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.	~	/
6	Check and ensure that all the sides of Mobile Laminar Air Flow is clean	V	1
7	Check all the gauges of Mobile Laminar Air flow before switching ON.	1	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
10	Equipment status is updated for Cleaned and Preventive maintenance.	~	1

Equipment	Mobile Laminar Air Flow		Weighing Bal	Area			
ID No.	ST LAP /001	NA	NA	STIBALION	Foil Store		
Previous Product	Telayle -	-40	110000000000000000000000000000000000000				
B. No.	T 130001 E		a management of the second		Ψ. Carlotte and the second se		
Cleaned by Sign/Date	Rayilts /25/	2020 /4					
Checked by Store Sign/Date	25/05/200		0	n p			
Verified by IPQA Sign/Date	82405 2020						

ENVIRONMENTAL CONDITIONS: Date: 25 15 Time: 9.40	01	Checked by	Verified by
(For Reference SOP No.: QAGN/011)	- Observation	Store Sign/Date	IPQA Sign/Date
Temperature (Limit: NMT 25°C)	23°6	17 Sans	835/05/2010
Differential Pressure across the booth Limit: 5 to 20 mm Water	limm	2000	(8) 25 05 20 to

APPROVAL FOR DISPENSING BY IPQA: Sign	Date:	25 05 2000	
Dispensing start Time 9!45 E	nd Time		

	Prepared by:	Check	ted by:	Approved By:
Dept. Production		Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	3alaluty	P. W. 62 1202) O met land
Date	20/04/2020	21/04/2020	22/04/2	X 12 20
B WAY FOR	ted and harring	7/7/	D	INCONTROLLER
	TOO TO WATER THE TOTAL TO	3210		OMCOMMENT OF

CAD DILLAND	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Kur Villianur Commune, Pudue	umbapet Industrial Estate,	Page 6 of 24
SAI PRIMUS	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.: GF200501
	74moperm sing/sing	Customer:	Generic Health Care Pvt. Ltd.

5. DISPENSIN	G RECORD OF	PACK	ING MATE	ERIALS:	Date 21 25 25	Shift.4Ti	me: 4:45	
Material Name	Item code	UOM	Req. Qty. for 6.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
188 mm Amloperin 5 mg /5 mg Printed Foil	PPF/GH/A001	Kg	30.600	12-1 (9/10)	PMG/100005	02	25/05/2020	25 85/202
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	91.800		PMG 100008	04	25/05/200	25/05/2020
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	20400	20,400	pm& /00004	9	4 300	25 05 200
Amloperin packing inserts	PPI/GH/I001	No	20400	20400	PM4 (2007	04	25/03/2020	25 05 70LO
Shrink Sleeves (PVC)	PPS/GH/P001	No	1275		0 1-		Wilder I	22/07
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	90	88 88 2 *	PMG/0002	09	25/05/200	25/05/2002
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	18	IS	PMG (00010	104	4 Just 25/05/200	25 06 JOEW
Strapping Role	PSR/CH/Sou	Mtrs	250	1000	PMG loocoi	01	25/05/202	· 25/05/2000
Shipper Label	N4	No	91	24: 11				100

	Prepared by:	Checke	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	3ala Sunty	P.K. 63 1707	O but "
Date	20/04/2020	121/64/2020	22/04	X
INMAS	TITA ONDVIN		IINC	NTROLE

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LIFE BIOTECH PVT L		ATCH PA	CKING	RECORD	P	roduct Co	de: A0	8	Batch Size: 6,00,000 Tablets			
Product		В	PR. No.: I	3PR/T	/107-00	Batc	h No.:	G1200	501			
Product Amloperin 5mg/5mg					C	ustomer:		Generic Health Care Pvt				
6 LINE CI	EARANCE	CHECKS	Hick	24 2 m s . 2	100000							
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Previous Produ	ct: TDAL	CHEN		Butor	Bat	ch No.: T	70000	ODE	./	4.0.3	124.74.101	.14.730
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No.		Checks Time)			1 344
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	d ensure the di					ecified lin	nit	V	V	_	/	/
	d ensure that v							س	100	/	U	1./
	temperature a					pecified lin	nit	V			レ	/
Charle th	tablets of the					- C (C- :1 C	~		<u> </u>	V.	/
	e loose Alu A product /batch			ejected rolls	, empty	cores of f	1011 01	V			V	1
Check the	surroundings			d free from	the previo	ous produc	ts and					
8. batch				d Hoo Hom	dio provid	ous produc	is and	V	V		V	/
9. Check the	foil printing	stereos, La	bels of p	revious prod	uct/batch	are remove	ed.	<u></u>		/		/
10 Check the	t the daily re	cords (log	book, b	alance, temp	. & RH)	are update	ed and		ija .	_		
signed.	1157				1 77.12		1,516	V	,		V	V
	d ensure the C	leanliness	followin	g change par	t of Alu A	Alu strip			,	/		
packing n		<u> </u>	1 1 1						3.25		~	
12. Check for	the absence of	r previous	of machi	roduct at mad	chine con	veyor belt.						Service con a
a) clieck Ho	pper from To nveyor belt an	p, bottom d collatin	or macni	ne, below the	e nopper,	between b	ottom				V.	/
Check for	cleaning of h	opper fee	eding cha	nnel vibrato	or plate i	n feed roll	er and		10.0	_		
b) sweep bri		oppor, re-	odnig circ	mioi, viorate	n plate, i	ir iccu rom	ci aliu	11			V	1
	l box, thinner	and ink b	ox	TARK IT	1 2 300		-201	1	1	/	V	/
Note: Tick mark	(√) if Compl	ies and (X	() if does	not comply			/			200	156	
Cleaning satisf	ctory/Not sa	isfactory	Cal	escapt out as	Clea	ning satis	factor	y/Not-sat	isfacto	ory-	EP - P-0	~
Checked by Pa	cking (Sign. /	Date):	4	25/05/2020	Ver	ified by IP	QA (S	ign./Dat	e):		172/02/	
#In case the cle	aning is not s	atisfactory	/ line is	not certified	then inve	stigate the	cause of	of the fail	ure an	d take	necessary a	ction,
recheck the area	A AND EQU		CLEAD	ANCEOFI	DDYNGAD	V D L CIVI	INIC	D-4- (T.		(P - N - 52)		
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No. Equip	nent / Area N	ame	/Area. No.	Type		ing as per		Sign/Date		(Pack		(IPQA)
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2. Alu Alı	Packing Ma	chine pD	AULOO	\mathbb{Z}	PDOP/0	20, PDCL/	020	Mani		QU		Postoso
	IRONMENT				4 41		- J D		1. 1.1		(-1.1.)	7
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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.

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BATCH PACKING RECORD

Product Code: A08

Customer:

Batch Size: 6,00,000 Tablets

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: GF 200501

Generic Health Care Pvt. Ltd.

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
188 mm Amloperin 5 mg/5 mg Printed Foil	PPF/GH/A001	Kg	PMG 1 00003	01	84	Q
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	PMG 100008	04 01	Set	0
Ptd Carton Amloperin 5 mg/5 mg	PPC/GH/A001	No	PMG 10004	09	84	@
Amloperin packing inserts	PPI/GH/I001	No	PMG 00 00 7	04	Soy .	@
Shrink Sleeves (PVC)	PPS/GH/P001	No	r.is	NA	AU.	NA
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	PMG 100003	09	84	Q
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	PMG 000 10	04	84	2
Strapping Role	PSP/9H/500)	Mtrs	PMG 00001	0)	84	@
Shipper Label	NA	No	NA	NA	A1A	N4-

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	08	R. Hackar justo	2 Lange 23/05/2020	Mani	Sof	(2) 5/05/100 m

RECEIPT OF PRODUCT AND MATERIALS: Date/Shift. 25/25/2020. G... Time: 16.115. (Check the following before start of packing activity and record the observation.)

S. No.	Check Points	Observation	Done by (Packing)	Verified By (IPQA)
1.	Temperature observed on display (Limit: NMT 25°C)	25°C	Soy	0
2.	Relative Humidity observed on display (Limit: NMT 60%)	58./.	Bu	Q-
3.	Bulk product containers are of the required product/Batch number and is approved by QC	Yes	34	MA
4.	Status label of machine/ line is for same product	yes	Cay	2
5.	Printed foil/Base rolls are of the required product.	Yes	84	8
6.	All secondary packing materials are of the required product	405	Boy	8

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	141, 25 mg	84	2
2.	Colour of Tablet	Hatfoff White colour	- CSU	2
3.	Quantity (Net Qty.in Kg)	82.500	84	Q
4.	Number of Containers	0.4	84	2

25/4

	Prepared by:	Check	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Enaluly	P. K. 600 200	o met
Date	201041202	0121/04/2020	90/04/0	
H	TED.A.K.MINY		TINCO	NTDOLLE

CAL DRIVALIS	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Kur Villianur Commune, Pudue	Page 9 of 24	
SAI PRIMUS	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.: G1 200501
A founct	Amtoper in Sing/Sing	Customer:	Generic Health Care Put I td

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

Balance I.D. No.: PD | BAL | 0 14-1. 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

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Amloperin	GIF 200 501	05/2020	04/2023	13.500 Kg Equivalent to S91150 Nos.	From Container No. 0 To Container No. 04 Total No. of Containers taken 04
Checked by Packi	The second second): 84	25/05/2020	Verified By IPQA	(Sign. /Date): 25 05 2020

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	23.480	Gopal	2	11		The result of the	- 1705/1915
2	28.440	Glopal	(Q)	12	Salar	-mv agregi 1999	
3	20.320	Gopal	2	13 0 000		- AKRET	atak:
4	20.460	Giopal	(g)	14	M.C.	- Mary 2	ULIA.
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6	INTO C			16	A A STATE OF THE PARTY OF THE P	124	
7				17			1 - 1 - 1 - 1 - 1 - 1
8				18			
9	E STATE OF THE STA	2	011	1105/219			\.
10		e de la la grandada de la compansión de la	88	20		Land to the second second	105

13.	CONTAINER CONSUMPTION DETAILS:	
10.	CONTAINER CONSOMITION DETAILS.	

	Tir	ne	Container	Consumed	ntainer Consumed		Tit	me	Container	Consumed
S. No	From	To	No.	by	S. No	From	To	No.	by /	
111	16:20	18:00	01	Mam'	11		Electron-Sk	Land Design Kinata	A Ballanda Sa	
2	09 1 40	13:40	02	Mani	12					
3	13:45	18100	03	Man'	13					
4	07135	12.00	04	Man'	14			LA Francisco		
5 .	14		n degrada de la	per mak men a Kessa	15	1 . I see weed	1 2 2 2 2	Transite Addis		
6	1				16					
#7					17	The control of the last	1		- A	
8	Alian carang				18	The street of the street of the	7		1	
9	e elvelació.	B	124 -		1105/29	46 -	4.	11 /4 3	84271051	
10	tidelar U.E.		1 × 1 × 1	107	20		79.6	123	194	

Checked By Packing (Sign. /Date): (2) Checked By Packing (Sign. /Date): (2)

	Prepared by:	Checke	d by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko	Zalalung	P. W. 60 11,000	laster O
Date	20/04/2020	2 allow lacas	22/00	A
	CA PARTITION		TINO	ONTOOLIFE



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

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Product

BATCH PACKING RECORD

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Product Code: A08

Batch Size: 6,00,000 Tablets Batch No.: GF 200501

Customer:

Generic Health Care Pvt. Ltd.

14. OVERPRINTING OF PRIMARY PACKAGING MATERIALS:

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.:	PON/DRUGS/19 13 4323	ok
Batch No.:	GF200501	ok
Mfg. Date:	05/2010	· Ok
Exp. Date:	04/2023	οV
Pack size (3 x 10's)- Carton	NA	OF NA
Other instructions if any	NA	NA INTERNATIONAL
Initiated by	Mani	120 Mam'
Checked by Packing (Sign. & Date)	PH 25/05/2020	8425/05/2020
Verified by IPQA (Sign. & Date)	Q 5/05/2020	(8) 00-105-2020

SPECIMEN OF PRINTED FOIL:

fied by IPQA (& Date)	Verified by (Sign & Da	ed by g (Sign & Date)	Checked Packing	Done By Sign & Date	Specimen No.	Date	S. No.
125/05/2020	18/25/05	25/05/2020.	dy:	Man 25/05/2020	01	25/05/2020	01
26/15/2020	20/05	26 105 1 20 100	84	Haniellusian	02	26/05/2020	02
27/05/2020	327/05	27/04/2020	84,	Har 27/15/202	01	27/05/2020	63
2		27/05/2020	37	Har 27/105/202	Property of the second	27/05/202	63

PACKING INSTRUCTIONS:

- 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.
- Set and operate Alu Alu Packing Machine as per SOP No. PDOP/020.
- Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.
- Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.
- Perform Leak Test as per Table or during change of Printed foil rolls & plain film rolls and after every start of operation or when machine is stopped due to some break down.
- 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.

		Primary packing		Seconda	Checked by	
Sr. No.	Date/Shift	Started at	Completed at	Started at	Completed at	(Packing) Sign. & Date
01	25 05 2020 G	16:20	161 18:00	16:25	13.00	842505/2020
02	26/05/2020 G	09.140	(8 !00	09!45	19:05	8426/05/20
63	27/05/20206	04.1.35	12:00	07:40	1210	8427105120
			NA			
114						1842M1

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.

4.	Prepared by:	Check	ked by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka-	Salalung	P. H. John 1002	0 hust son!
Date	- 20/04/2020	21/04/2020	22	- X-1
	A second		2771001	TOTAL TEN

34

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD

Product Code: A08

Customer:

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: GF 20050 | Generic Health Care Pvt. Ltd.

18. ALU ALU PACKING MACHINE PARAMETERS: Date/Shift. 25/05/2020 G ... Time: 16! 20 Checked by Packing Checked by IPQA **Parameters** Standard and Limits Observation Sign. / Date Sign. / Date BPM GE 10 Change Parts Details ex 8 2/25/05/2020 Checkoth (160 °C - 200°C) Sealing Temperature 199'6 To be established Leak test to be performed on Nil (No Alu Alu strip OL 04 Alu Alu strip should fail in leak test) Machine Speed To be established 25

Date/ Shift		21-	105/20	220 6	en er	. 1	26/05	1100-	Con	TEN							i de
Machine Op	erator Name	Ma			21) (70		26/05	(2020	<u> Lvene,</u>		84		h	Y			
Time of insp	pection	161,20	16:35	17:20	09 ¹ A ⁶	10,00	10:40	11240	12,00	12:30	13:35	14:15	W:30	15:20	16:15	16:30	וז:א
Sealing Ten (To be estab	perature	1982	196	199°c		199	1982	1984	OL	/	1982	Tributes of		1996	1982	199'0	199
	Alu Alu strips*	OK.	ok	ove	OK	01-	0/2	OK	010	0/ك	OLL	cic	DIE	Oil	ole	OV.	OK
Knurling /Se	ealing	OL	rile	or	OL	ole	OL.	OK	ok	or	or	0E-	ok	ዕኒ	016-	ove	ou
Pocket Forn	nation	OL	ol-	OK.	ماد	010	OK	OK	9 0 t	OL	ok	ot_	06	OK	ماد	OL.	Dic
Horizontal o	cutting /	OK	ole	OK	OK	. o i-	OL	90 'Yo	ole	016	ok:	ole	OL	ok	ok	OK	OL
Vertical cutt	ing /	OL	ole_	OVL	OL	oic	OV	OK	ole	OV	ok	olc	104	ok	010	OL	O'C
Quality of C	over printing	ok	ole	OK	OL	ob	OL	OK	0 k	210	OK	ole_	ok	OLL	016	ok	OK
Code No.:	PON/DRUGS/ 19 13 4323	ok	ر ال	OK	6k	ole	OL	οk	ole	010	OK	oje	OK	OL	ok-	OV	OK
B. No.:	G1F200501	ok	ols	OE	OIL	ole	OL	OL	ok	Ole	OL	016-	OL	OK	عام	OK	oc
Mfg. Date	05/2020	OK	ole	OK	OK	ob_	OL	OIL	ole	OV	ac	06-	ok	OK	olu	ok	ok
Exp. Date	04 2023	OL	01:-	OŁ	OK	06-	OLL	OŁ	ok-	012	or	0 l=	cle	OK	ole.	on	OLL
Machine Sp To be establ		24	25	85	24	25	24	25	25	25	24	9대-	24	28	27	27	18
Checked by	(Packing)	८५	-NN-	84	84	NA	4.B	84	NA	39.	84	'Mn	87	84	NA	Sy	81
Checked by	(IPQA)		2			2	-		2			2			0	Vη.	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.

- 1 - 3	Prepared by:	Checke	ed by:	Approved By:
Dept.	Production	Production (Quality Assurance	Head Quality Assurance
Sign.	L.Ka-	Eallung	F. N. Job.	O Mart 10
Date	20/04/2020	- 21/04/802m.	22/04/200	ONTO LETA
MAACT	ED CAMBUTURY	ALL I	TUNC	UN TRULLED VOL!

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	MUS	

Product

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: 6, F 200 501

Customer:

Generic Health Care Pvt. Ltd.

Date/ Shift		27	105/	2020	6	iene	ا اعر	de.									
Machine Op	erator Name	Ma	m'	20/20				£.	1.7/1.5	17/1.5	H1/2/s	11.5	n Á				
Time of insp	ection	07:35	65.50	08:35	0940	q:5°	10:40	11:25	11:35	11:40 H:50	11:55	H: 5/ 41.5	1		10 - 10 - 10 - 10 - 10 - 10 - 10 - 10 -		
Sealing Tem (To be estab	perature	1966	350	199'c	124			· 1000	U	10.0	- Trans.	220					
	Alu Alu strips* 0수	OL	olc	612	ok	ob	OK	ok	Ole	ol-	010	ok-					
Knurling /Se	ealing	ok	ote	OV	ok	00	ok	ماد	ole	ole	ole	OK	70				
Pocket Form	nation	οŁ	01=	ok	OIL	ck-	OK	OK	ok	0 lc_	υĿ	06-	ericid.	I.A.			
Horizontal c	utting	OK	ok	ox	Ole	ole	.ok	OK	012	٥١٤-	ok	10h		417	1 (12 TOK) 10 NOS		
Vertical cutt	ing	ok	ne	OK	OK	cle	OL	ole	014	ou	Dlc	۔ اه					
Quality of O	ver printing	06	ole	ok	06	ple	ok	OK	Ok	٠ ال	OK	ئا ن			1.1		
Code No.:	PON/DRUGS/ 19 13 4323	ok	cle	014	OK	ols-	30	OIL	6 iL	Clc_	0k	(a)		AQ.		oute oute	K 3.
B. No.:	G1220501	ole	ok	OL	ok	oli	oh	OL	ماد	واد	ok	ok			121	• openings -	
Mfg. Date	05/2020	OL	ole	010	ok	- 10 V	OL	ok	ال ال	ok_	ole	01		4			
Exp. Date	04/2023	OK	ole	olu	o'V	06	ok	Ole	٥١٤	ou	016	06		ia			
Machine Sp To be establ		26	26	26	27	94	28	28	310	35	10	35		Q			\ \
Checked by	(Packing)	84	i-lli	84	84	MV	84	Sy	Non	Nn	F1A	NA		13.			7
Checked by	(IPQA)	4 Cy along	82			Q	-		2	2	0	2		in.	1.00	8	11/2

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.

Date Date 20104/2020

POULTONITONI

3.4 105 /2 21 105 /2

	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Ku Villianur Commune, Pudu	rumbapet Industrial Estate,	Page 13 of 24
SAI PRIMUS LIFE BIOTECH PVT LTD	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.: GF 200501
All I de la la	Amoperm Sing/Sing	Customer:	Generic Health Care Pvt. Ltd

Date/ Shift	ACHINE IN-PR	,	169 Mya 1														7 - Ait
Machine Ope	erator Name	X															
Time of inspe	ection	机	1			cage/P		Maga.	What	P. (*)	pi	1.0		ra de la	11	01	d
Sealing Temp (To be establ	perature ished)		40,7007-0000			and the second					Days				the second second		and the same of the
Leak test on A	Alu Alu strips*													Lands		10 m	
Knurling /Sea	aling				9	(i)	Ita.	(7)			100				14.5	66	- 17
Pocket Forma	ation	- 1				1	100				ari i	- 48				1 a	
Horizontal cu	utting		1 - 3-12	1 530		Ti.,	1				100		7(4) 2 15 15				2F2
Vertical cutti	ng	v.0:		47.5		Times.	Taj.										
Quality of O	ver printing			1-12-	1	ala tata		1	LVE	NV.	G.	14		30 - NA		2.8	C4 88
Code No.:	PON/DRUGS/ 19 13 4323	white man		- And Deposit Annal States	1 1 1 1 manufacture of the second	ena iga internación con	Landardin	and the second of the second	/	and the second	was to from the Grand of	deur (strong)	and the same of			san year area.	
B. No.:				a B	141	N-g		T. K.L.	2 de ja	1							
Mfg. Date											121					-W	
Exp. Date		× .					10 - 1	To-				1					
Machine Spe To be establi												70	1				
Checked by	(Packing)						1 84,6							1		* j	
Checked by	(IPQA)	44.20 378.4					- 55		100	MgN Lights Tank Line			21.0	Towns	1	84	1105

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.

<u> </u>	Prepared by:	Checke	d by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko	Zerlung	Por but you	O Most 10m1
Date	20104/2020	721/04/2020	22/04	
MASI	EE LIGHTAL NOON	7	TW	CONTROLLED CO.

		Factory: R.	AI PRIMUS LII S. No. 4/3, Plot N Villianur Commu	lo.33, Kuri	ımbapet Ind	lustrial Estate),	Page 14 of 24			
	RIMUS ECH PVT LTD	BATCH	PACKING REC	ORD	Produc	t Code: A08		Batch Size: 6,00,000 Tablets			
Dro	oduct	Amloperin 5mg	·/Ema		BPR. N	o.: BPR/T/1	07-00	Batch No.: GF	100501		
111	duct	Amioperia Sin	3/3/ling		Custom	er:		Generic Health C	are Pvt. Ltd.		
20.	DEFOILI	NG OF ALU AL	U STRIPS:								
Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets		De-foiling	Done by		Checked by/ Date (Packing)	Verified by Date (QA)		
7/05/202	11110	11:35	0.989	Blvara	ny'ini,	Ponni,		By 27/05/200	(3) 57 pt)20:		
		East The River Control					7				
	gl sh	12 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			-3			22 (100)	84 74 los		
		otal Weight of foiled Tablets	0.989	Checked	i By / Date التركا			Verified By / Da	te (IPQA):		
20.1	INSPECT	ION OF DE-FO	ILED TABLET	S:		1					
Date	Inspect		The second of the second secon	TO A SECURIOR STREET,	y of Good blets	Qty. of	Rejecte blets	d Checked by/ Date	Verified by		
	Started	l at completed	l at Done by	Kgs	Nos	Kgs	No	- 67	Date (QA)		
27/05/2	020 11! 35	11:45	Sattiya.	0.975	6902	0.014	99	8y २७१०डीन	5 (3/105) 20		
 -											
	- 100 VIII			2	4			189	1105/2020		
	- postilist		Total	0.975	6902	0.014	99	. 04			
	antity of R	ejected Tablets	Destroyed		d By / Date			erified By / Date (I	PQA):		

1	Prepared by:	Check	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	Ealaluky	P. W. D. Ison	" O hust wo
Date	20/04/2020	21/04/2020	22/09/	7
INIACT	-FOTHHUMMON		TIN	CONTROLLE
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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate. Villianur Commune, Puducherry-605009.

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Product

Amloperin 5mg/5mg

Product Code: A08 BPR. No.: BPR/T/107-00 Batch Size: 6,00,000 Tablets Batch No.: 6 200501

Customer:

Generic Health Care Pvt. Ltd.

21. LINE CLEARANCE CHECKS - SECONDARY PACKIN	21.	LINE CLEARAN	CE CHECKS -	- SECONDARY	PACKING
--	-----	--------------	-------------	-------------	---------

BATCH PACKING RECORD

Date/ Shift . 25/05/2020 16:20 /... 24/05/2020 . G .. 09: 20 Batch No.: 7090003E **Previous Product:** RANSNERV Observation and the acoust alice Sr. Checks Time 16:22 09:22 No. IPQA Packing Packing IPQA Check and ensure that the area is visually clean and free from previous 1 product. 2 Check and ensure that waste bin is emptied out and cleaned Check the Pallets area clean and free from any leftovers of previous 3 product /Batch. 4 Check and ensure the Correct status board is written. Check and ensure the stereo of the previous product/batch removed and 5 cut into pieces. Check and ensure the previous batch details are deleted from the inkiet 6 Check and ensure the Alu Alu strips, rejected Carton, Shipper and 7 shipper label of previous product/batch are removed. . 8 . Check and ensure the cleanliness of hatch for conveyor belt. 9 Check and ensure the cleanliness of conveyer belt with collateral block. 10 Check and ensure the dispensed secondary packing material. 11 Check and ensure the cleanliness of documentation table. Check and ensure the Preventive maintenance records and log book. 12

Note: Tick mark $(\sqrt{})$ if Complies, (X) if does not comply and (NA) if not applicable.

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

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

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

21.1 AREA AND EQUIPMENT CLEARANCE FOR CODING:

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

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	PD COBLOOF	PD/BALLO18	NA	PDISTRIGOI	PD1 BA4020	Secondary Packing Hall
Previous Product:	TRANSMER	- 1 1 2 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		Maria de la compansa del compansa de la compansa del compansa de la compansa de l	y my wys y retor	
Batch No.:	7090003F					and the second s
Cleaned by:	Sathy on.				Particular Con-	
Checked by Packin	ng: old wlor	2000	. /e-s			

Verified by IPQA: Que 12020

	Prepared by:	Check	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	Za a Quenos	P. H. 60000	a hart
Date.	20/04/2020	21/04/2020	2404	1. 14.50
LAACT	on Addition	MILIM	TINC	ONTROLLET

J/3
I PRIMUS

Product

SAI PRIMUS LIFE BIOTECH PVT LTD

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

Page 16 of 24

BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: 6 F 200501

Customer:

Generic Health Care Pvt. Ltd.

21.2 ENVIRONMENTAL CONDITIONS:

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

		Date/Time: 25	105/2020	16:30	Date/Time: 26/05/2020 09:45					
Shift: Giene	89	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	25°C	84	2	24°C	84	Q-			

Secondary Packing Started Date/Time: 25. 105 12020 16:25. Completed Date/Time: 27 05 2010. 12100

APPROVAL FOR SECONDARY PACKING:

Approved by IPQA Sing/Date:

21.3 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 16 filled carton in a Shrink Sleeve.

Place 14 Shrink sleeves in each 5 ply shipper.

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

22. 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.:	GF200501	ok	0اد		
Mfg. Date:	05/2020	OK	. ok		
Exp. Date:	04/2023	0.F	ال ال		
Pack size:	NA	(3 x 10's Tablets)	14 x 16 x 3 x 10's		
Code No.:	PON/DRUGS/19 13 4323	ok	NA		
Other instructions if any	NA	NA	N.A.		
Initiated by Sign. & Date	Hani	Mani	Chamelessh!		
Checked by Packing Sign. & Date	72365/2020	Mani 725/05/2002	80/25/05/20		
Verified by IPQA Sign. & Date	B23/05/2020	23 05 202	Q 16x 2020		

22.1 Carton Overprinting Specimen:

S. No.	Date	Carton Specimen No.	Packing (Sign & Date) (Sign & Da					
. 1	23/05/2020	with There	728(05/2020	(8 23 05 2020				
	**************************************		+ min = 20.00 - 25 - 25 - 25 - 25 - 25 - 25 - 25 -	The second secon				
· Commercial Commercia		——NA		Second profession of the				

Note - Attach specimen copy of over printed carton

	Prepared by:	Check	Checked by:					
Dept.	Production	Production	Quality Assurance	Head Quality Assurance				
Sign.	L.Ko	Salaludy	P. W. Johnson	O. Must som				
Date	2010412020	21/04/2020	22/04	J V V V V V				
A A A A A A A	TEN A WINTIMO	VINT !	TINC	ONTROLLE				

	6		.S. No. 4/3,	S LIFE BIOT Plot No.33, Kur ommune, Pudu	umbapet I	ndustrial Estate,	F	Page 17 of 24		
	RIMUS TO	ВАТСН	PACKING			ct Code: A08	ī	Batch Size: 6	00,000 Tablets	
						No.: BPR/T/107	HE DAY			
Pro	duct	Amloperin 5m	g/5mg		Custo				th Care Pvt. Ltd.	
22.2	Shipper I	Label Specimen:		Kara Ja						
S. N	The state of the state of the state of	Date		Label Specime		Checked by		Verifie	by IPQA	
01	and the state of t		The second second	No.		king (Sign & Da			& Date)	
		5/05/2020	The second secon	01 NA		94 25/05/202	-	6-75	18424/cs	
Weight	of ten inc	N WEIGHT LIM		iven below:	25 05 20	. W.	3.0.,			
	5.8	3. 6	7.6	5. 5	<u>, H</u>	7. 5 8	3	9.	5.7	
• •	5.6	empty cartons =	5.8	6.	9	8. <u>C</u> .	٦	10.	5.6.	
Veight o		an empty carton (vidual Alu Alu s 3.				7. 2	2	9.	2.4	
- 110	THE RESERVE			6. 2.	and the second second		14	10.	2.3	
Total we	ight of ten	Alu Alu strips =	23.4					10.	<u>د: ح</u>	
23.1		eaflet (C): total	N CARTON			veight of one one		ton (A):		
		Alu Alu strip:	57.2			weight of one em			5.72 .	
	f ten Leafle		23.4		The second second	weight of one Le	A CONTRACTOR			
	100000000000000000000000000000000000000	Carton $C = (A+3)$	2 · b BB+C) [b	.00	Limit: D	0.10/	Low Yorker	:): 3.2 ·- 16.16	b assumed to	
hecked	by Packir	ig/Date:	4 25/05/2	03v		by IPQA/Date:	(2)	25/05/204		
2 44				Was Alf				12/1		
23.2	100	LE DRAWN RE			SIA ALE	T-		A.A.		
r. No.		e of Sample colle	ection	Qty.	of Sample	ACT U.A.	Co	llected by (S		
1		Sample (Initial)		3 x	3×10 5	NAME OF THE PARTY	200	(2) 26 05 21		
2		Sample (Middle)		3 ×	3×10	(0.15) II 35(L 35)		(D=105)		
3		Sample (Final)		1 ×	2 ×10	and the second second		(\$) 27/05		
4.	 	Sample		14	ሽ 10×32				4/05/200	
5	Other Sa			. и) ' ¢	- 40 To		NO		
5	1 MIIalyllo	cal sample		62 62	10 - 62	D N	(3)	25/05/2020	7.	
5 6	The state of the s		otal Qty.	32×10'	· 32	o Tablets	(3	24/05/20	120	
	*	T		J/ / 10						
6		Prepared by:			Checked l	oy:			proved By:	
					Checked I		ince		proved By:	
6		Prepared by:	Sa			Oy: Quality Assura		Head Qu	ality Assurance	
6 Dept.		Prepared by: Production			$\mathcal{Q}_{\mathbf{a}}$,	oy: Quality Assura		Head Qu		

SAI PRIMUS LIFE BIOTECH PYT LTD	

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

Page 18 of 24

BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00 Customer:

Batch No.: GF 200501 Generic Health Care Pyt. Ltd.

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

Date/ Shift	25/05/2020	(20	me;	41	26/0	5/20	10 G	2:	5/05/	2020	126	105/2	טבט		
Parameters	Specification	-Curt	Early VI C Lacking				observation IPQA								
Time		16:30	17:30	09:45	10:50	11:35	12:30	13:25	16:45	10:05				(
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OL	OF	Ok	ok	OK	OV	ok	ole	داد	ole-	Ok.	012	/	
Carton Overprinting	Legible and readable	ok	ok	ole	OK	OL	OV	OK	OL	0/4	012	ok	ok	l.	1
No. of cartons in a shrink sleeves	16 packed cartons	NA	MAY	NA	NA	NA	NA	NA	MA	МА	NA	- 1	LIA	rin .	NA
Shrink wrapping temperature*	NA	NA	NA	NA	NA	AU	MA	NA	NA	NA	NA	MA	NA	AM	M
No. of shrink sleeves in a 5 ply shipper	14 strinks, 232 Cortons	OK	ok	0k	OK	OIL	OL	OK	ok	ok	01-	ok-	01-		
Shipper strapping	Proper strapping	OŁ	ok	OK	OK	OL	OL	OIL	01:_	nk	06-	ok-	ولا		Fr. L.
Label appearance and Shipper appearance	Legible and readable	ok	Ok	٥٢	OK	OŁ	OK	OIL	0k_	OK	ok-		ا م	\$ 100 miles	L'ar
Sealing of the shipper with BOPP Tape	H type	OK	OK	OŁ	OK	OK	OK	ok	-dd	ok.	ok-	ok	OF		
Checked by		84	31	84	ઉપ	84	81	.89	@	2	2	0	Q		

*Temperature to be mentioned.

SECONDARY PACKING IN-PROCESS CHECKS: (Please keep \(\sqrt{mark} \) if found "Ok") 24.1

Date/ Shift	26/05/2020 h	en er	a) /	271	05/20	20 (4	9	7/05	0000	1. M. B.	ALIPHES.			
Parameters	Specification	ification			ackin	S - 2-4		obser	vation		IPQA				
Time E. T.		14:25	15:30	i i	T #15 - 000		08:NO	09:40	2.00	10:05	,	1	v 17		
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	ck:	ok	ble	OF	OK	Oll	OVL	olc.	E C	ole		1	* \	+ 100
Carton Overprinting	Legible and readable	ok	ole	ou	ou	ole	or	OL	20	داد	ملا				
No. of cartons in a shrink sleeves	16 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	MA	MA	NN	MA	NA-	Nu
Shrink wrapping temperature*	NA	NIA	MA	MA	NA	NA	MA	MA	Mn	ŊА	Hn-	MA	NA	NA	I-AJ
No. of shrink sleeves in a 5 ply shipper	14 shrinks 282 cortons	OK	OVE	OV	de	OL	olc	Oli	ok-	ok	06	1			
Shipper strapping	Proper strapping	ok	016	Ole	010	ol	OK	OL	016	NIC	010	1			
Label appearance and Shipper appearance	Legible and readable	οŁ	OK	ble	ve	ole	OE	ok	ole	OL	0 lt		12.00	12	
Sealing of the shipper with BOPP Tape	H type	OL	OK	OK	OL	OV	OV	OL	cie	06-	OK			1	
Checked by		84	84	St	83	84	89	84	2	2	0				1

*Temperature to be mentioned.

	Prepared by:	Chec	ked by:	Approved By:
Dept.	Production	Production (Quality Assurance	Head Quality Assurance
Sign.	L.Ka-	Salasuna	17. K. D. 1,507	o byt on
Date	-20/04/2020	21/04/2020	2210	7.1
LMAST	EB CUDATIVITY		TR	CONTROLLE"

34 26/05/2

ONCONTROLLES ~

	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Kur Villianur Commune, Puduc	umbapet Industrial Estate,	Page 19 of 24	
SAI PRIMUS	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets	
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.: GF 200501	
rioduct	Annoperin Sing/Sing	Customer:	Generic Health Care Pvt. Ltd.	

SECONDARY PACKING IN-PROCESS CHECKS: (Please keep √ mark if found "Ok") Date/ Shift Ciene ra 1 27/05/2020 observation Specification **Parameters** IPQA Packing (O) AY 11: A3 Time عديل 3 Alu Alu strip No. of Alu Alu strip in with 10 tabs each a carton 06 Ob. DL and one leaflet. Legible and Carton Overprinting OL OC readable Ob No. of cartons in a 16 packed cartons shrink sleeves MA NA MA Shrink wrapping NA temperature* AM 44 NA No. of shrink sleeves in 14 shrinks 282 cortons OL a 5 ply shipper ole DL Proper strapping Shipper strapping OLL ac 06 Label appearance and Legible and OL Shipper appearance readable de OL Sealing of the shipper H type 210 with BOPP Tape OL Ok 84 84 Checked by *Temperature to be mentioned.

SECONDARY PACKING IN-PROCESS CHECKS: (Please keep \(\sqrt{\text{mark if found "Ok"}} \)

24.3

Date/ Shift			H.12.	ten liki	Pike.		14.	1 199	1-1		Per :		4	4.00	LY III
	Cassification	1	77 M.	- 110	observation										
Parameters	Specification	Packing					VIII I	Notice and				IPQA			
Time								15	P-12			+44		e ta	
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	l white	88.6							engelieb engelieb engelieb engelieb					* 4 4
Carton Overprinting	Legible and readable	T.	def			1.4		21	1874			1-0.52		Anti)	L
No. of cartons in a shrink sleeves	16 packed cartons					/		5.7	10.5					2.5	
Shrink wrapping temperature*		W.						1 #	15 - 23	10 4-743		tal.		41,	100
No. of shrink sleeves in a 5 ply shipper	14 shrinks							1							
Shipper strapping	Proper strapping						JKE J	1. The second	1	P.				30	
Label appearance and Shipper appearance	Legible and readable		į				P h								
Sealing of the shipper with BOPP Tape	H type			gur	31/4			-		31	adh 			BY	105
Checked by			Kurj .		N/A		1 7	6.15	4.5				907	By	3,

*Temperature to be mentioned.

	Prepared by:	Check	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko	Zalowy	P.K. Al Spore	O. Must , on!
Date	20/04/2020	21/04/2025	22/0	777
NAAC	CONTRACTOR		TINIC	ONTDOLLE

डपू भाजी

SAI PR	RIMUS CH PVT LTD	BAT	TCH PAC	KING RE	CORD	Produ	ct Code: A	108	Batch Siz	e: 6,00	,000	Tablets
2.5				221.1976			No.: BPR/					The second second second second
Pro	duct	Amloperi	n 5mg/5m	g		Custo	2002		Batch No.: GF 200 501 Generic Health Care Pvt. Ltd.			
25.	SHIPPER	S WEIGH	INC:	Date/	Shift. 25/11			16120	ALCOHOLDS TO THE		No. of the last	A THE RESERVE AND A STREET OF THE PARTY OF T
	ten Shrink			-30	NA NA			ne filled SI		7 W. m.		THE RESERVE
	ten empty			E - In this gall and	1				hipper (F):		13	NA
to the second		,		0.820	NA		$= G \pm 1\% =$		mpper (1).	1 ~	6 -82	+v4
Weight of	one filled:	shipper (G)	= (14E+F)):-	AM .	(to be est		N4				
Checked	by Packing	g/Date: 8	54 27/05/	ശവ		Verified I	by IPQA/I	Date: 1/2	Joshan -	7		
Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No. Gross weight (Kg) Weighed By No. Weighed No.		Gro weig (Kg	ght Weighed			
1	5.874	Dhaire blat	26	5.899	Dha naldhhi	.51	5.895	Donably	76	7		- or think
2	the same and the same of the same	Dhoralath	27		Dhanalalahi	52		Shamalah	77			
3		Plandalle	28	5.882.	Shornolahi'	53	1.00	Morrish	78		K [7]	
4		Bhonalath	29		Dlang lath!	54	Sura v	Oho ro lah	79	3		- North
5	5.889	10 hamlel	30	5.914	Phoinglahi	55	To Charge Ties to	aboundleh.	80	1 de		
6	5'882	10 handlat	31	5. 914	Mariah	56	5.887	Chandle	81	P.C.	14	
7	5.885	Dhamlable.	32	5 . 858	Dha nalahi	57	100	Donaley	82		-152	
8	5.886	Dhamald	33	5.908	Obernalch'	58	5.824	elombly'	83	1.0		
9	2.888	Charalah	34	5.1872	Ohanalahh'	59	5.834	Olamballi	84	1		
10	5.898	Ohernalahh'	35	2.846	Dorokhi'	60	5.84-1	domlahm'	85			
11	51914	Dha na lath	. 36		Dhamloh'	61	5.814	Daraluh'	86			1 1 1 1 1 1 1
12	2.862	Phondath'	37	5.862	Dhamalah	62	5.814	Rhandleh'	87			
13	5.887	Dlambla	38		Dharalah!	63	2,849	Planalati'	88			
14	5.914	Dhamili'	39	2 ,846	Dhairalah'	64	2.893	Dlaralahi	89 .			
15	5.924	10 langlath	40	5.911	Dhandley'	65		Charaluh!	90			HE CANTERNA
16	5.915	Chamlath'	41	5.852	Dharakh	66		"Storah"	91			
17	5.901	Dha ratch'	42	2.89 0	Dharalah '	67		Clarelahi'	92	1.0		40
18	5.878		43		Dhanalek	68	35	Nonalah	93			
19		Dandely!	44	14	Dlawilch!	69	VC	Ohomala	94			
20	8-1896	Marolaluh			Dlamlub'	70	4.438	Dhanalain	95			
21	and the second s		46		Dhamlah !	71	1.		96			
22	The state of the s	Dlanalath'	47	088.2	Dlamlath		44	The state of the s	97			**************************************
23	5.882	Dhanabh	48	5.884	Alamalah.	7 73	Maria I		98	4-47	- 57	
24	5.878	Dhanolahi	49	5.904	Do rolah	74	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	X -	99			7
25	5.873	Dhamlah	50		Shanih!	75		90x 3000	100			01 51
Total N nippers w	veighed:	pac	ed tablets ked in per No:	Checked Da	21.7%		Date:	Shipper I Quantity	ick details: No:Fo .91.X.13.5.	 ⊁ 35	/61×	८५०मा

CALDDIMILE LIFE DIOTECH DUTLITO

Weight of Ten filled corton! 168.30 Average weight of one Hilled Corton (E): Weight of Ten empty shipper: 10.820 Avorage weight of one empty shipper (+)! 1.082

Weight of one filled Shipper(G) (282 EtF): 5.828 Shipper that han checked for all shipper Checked by:

Approved By: No of corton per

Prepared by: Dept. Production Production Quality Assurance Head Quality Assurance Sign. progl 21/04/2020

				. •	
4 - 2		1			
SAI PRIMUS	Factor	SAI PRIMUS LIFE BIO ry: R.S. No. 4/3, Plot No.33, I Villianur Commune, Pu	Kuru	ımbapet Industrial Estate,	Page 21 of 24
LIFE BIOTECH PVT LTD	BAT	TCH PACKING RECORD		Product Code: A08	Batch Size: 6,00,000 Tablets
Product Amloperin 5mg/5mg				BPR. No.: BPR/T/107-00	Batch No.: 6 - 200501
the second of th				Customer:	Generic Health Care Pvt. Ltd.
26. MAN POV	VER ALL	OCATION:			
DATE: 25/05/20. SHIFT: Cone				DATE: 205/202 SHIFT: Ceneral	
ACTIVITIE	S - Trans	DONE BY		ACTIVITIES	DONE BY
Alu Alu strip Checkin	ig (Sathya, Indra.	0.54	Alu Alu strip Checking	Biva santari, Indra
Printing Checking in a strip	Alu Alu	Sivagneari, Lahami	(4)	Printing Checking in Alu Alu strip	
Alu Alu strip weighin	g , sharing	Maheshwari, Dhamapri		Alu Alu strip weighing	Makeshwari Dhanap
Insertion of Alu Alu s leaflet into carton	trip and	Caranya, Sivaranjini	10	Insertion of Alu Alu strip into carton	Baranya, Si varanji
Cartons weighing		Sugarith.	da	Cartons weighing	
Insertion of carton inte sleeve	o shrink	NA NA	14	Insertion of carton into shrink sleeve	C Oddavim.
Insertion of shrink wra carton into shipper	apped All	NA ALA		Insertion of shrink wrapped carton into shipper	9 (2) 32-21 NA
Shipper Label Pasting	+ A16	Dhana kuhu his	N.	Shipper Label Pasting	Dhama lahihi
Shipper Weighing	AIA	Suganth'	0	Shipper Weighing	
Shipper Strapping	daw	Ohanalak h.	Si or	Shipper Strapping	Dhanglahah.
Shipper packed	100	From01to03		Shipper packed	Marie 1 To 1 Vis Vis Vis Visit and Astron

DATE:27./25./.20%	A PART OF THE PART	DATE:	
SHIFT: Crem. Etg.)		SHIFT:	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking	Bivasanhari, Indra.	Alu Alu strip Checking	
Printing Checking in Alu Alu strip	Bathya, Lohs lm'	Printing Checking in Alu Alu strip	\$\(\sigma\)
Insertion of Alu Alu strip and leaflet into carton	Makeshusu Dlamoperin	Insertion of Alu Alu strip into carton	(1 ₅) (2.
Alu Alu strip weighing	Baranya, Sivaranyin.	Alu Alu strip weighing	
Cartons weighing	Paratha	Cartons weighing	
Insertion of carton into shrink sleeve	NA	Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper	и.,	Insertion of shrink wrapped carton into shipper	LA
Shipper Label Pasting	Dhama laks hi	Shipper Label Pasting	1000 \ (0.000)
Shipper Weighing	The state of the s	Shipper Weighing	
Shipper Strapping	Suganthi' Dhonalahih'	Shipper Strapping	1001 4
Shipper packed	From.5.8to7.tz	Shipper packed	Fromto
Signature of Packing	80124105/2020	Signature of Packing	1170

By 25/05/2020

Signature of Packing

8424/05/202

Signature of Packing

12 1 1 -	Prepared by:		Check	ed by:	Approved By:
Dept.	Production	F. W.	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka-	30	July	P. N. Johnson	O. Must when
Date :	20104/2020	21	104/2020	22/04/201	2
I MAS.	TER COMMING	1/17		TINI	CONTROLLE
		1010		3 1110	I I I I I I I I I I I I I I I I I I I

C	M3
	PRIMUS OTECH PVT LTD
	4 To V

Product

SAI PRIMUS LIFE BIOTECH PVT LTD

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

Page 22 of 24

BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: 6, F 200501

Customer:

Generic Health Care Pvt. Ltd.

27. PACKING MATERIAL RECONCILIATION.			
7/ PACKING MATERIAL DEGRANGED LATITANI.	27	DICTION CIMEN	 ~
	, ,	PACKING	I A TITLANI.

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)
Α	Quantity received for the batch	36.880	89 1940	20400	20400	.NA	88504	250 mirs	01
В	Additional material received for the batch	NA	NA	NIA	NA	ИА	NA	NA	NIA .
С	Total material received (A+B)	36.880	39. 940	20400	20400	NA	. 88	250(mtr)	01,
D	Quantity packed	15:047	56.251	19593	19593	NA	& Towns	0,980 131	DI
Е	Quantity rejected (Online) & Destroyed	6.001	16.998	294	NA	NA	. NA	0.012	NA
F	Quantity Returned	15.350	16.370	500	795	NA	13	4.008	AM
G	Sample affixed on BPR	0.002.	NA	02	0102	NA	NA	NA	MA
Н	QC samples	0.003	D:DII	+204	04	NA	NA	NA	AM
I	Other samples (If any)	36.405	0.019	07	07	NA.	I NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	36.408	89.649	-0-	-0-	NA	HAMA	NA	NA
K	Variation (C – J)	0.472	0.291	-0-	-0-	MA	INNA	NA	AIA
L	%Variation (K x 100)/C	1.27.1.	0.321	-0-	-0-	NA	INA	NA	AIA
M	Acceptable limit	<u>+</u> 2%	± 2.%	±2%	±2%	±2%			

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

18/-----

28. EXCESS PACKING MATERIAL RETURN TO STORE: MRN 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	15.350	16.370	500	AM	NA	NA	NA	. 41
Material returned by packing Sign./Date	84271051202		0	NA	NA	AU	NA	· NA
Verified By IPQA Sign./Date	(2) 105/2010	(3) 05/20V	304/05/300	NA	NA	NA	NO	NA
Material received by Store Sign./Date	4 6	400			NA	24	NA	· Au

29. DESTRUCTION OF REJECTED/UNUSED PRINTED PACKING MATERIALS AND STEREOS

Date	Stereos	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
21/05/2020	03	6.001	16.998	295 -NA -	NA	Na	NA	10.012	NA 84
Total Qty. Destroyed	08	6.001	16,998	295	NA	NA	N.	0:012	The second secon
Destroyed by (Packing)	Sy	2 1/05/202	- ∞			-	77 - 43		
Verified by (IPQA)	2:1	05/2020					in Inc. Po	2	The second secon

	Prepared by:	Check	ted by:	Approved By:
Dept.	Production	Production _	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	3abbury	P.M. Gallon	O My
Date	20/04/2020	21/04/2020	22/041	7 1 2 70

UNCONTROLLE

SAI PR			ry: R.S. No. 4	r Commune, 1	3, Kurumbar Puducherry-	oet Industrial Estate, -605009.		age 23 of 24	0.000 57.3
LIFE BIOTE	CH PVT LTD	BAI	CII FACKII	NG KECUKI		roduct Code: A08		Batch Size: 6,00,000 Tablets Batch No.: 6 - 200 50 1	
Pro	duct	Amloperi	n 5mg/5mg			PR. No.: BPR/T/107-			
30.	BATCU I	RECONCIL	ATTON.		The same of the sa	ustomer:	6	eneric Healtr	Care Pvt. Ltd.
Α .	Batch Siz		LATION.					13 5, 5 - 17 10 C 1805 140 , 17 14 14	6,00,000 Nos.
В	- AL SCHOOL SECTION				A Medical Annual An				
C	Quantity received for packing Total quantity packed								591150
D	Control sa								567790
E	Analytica								200
F	In process								120
G		*	(Stability, Re	aulatory Sam	inles etc.)			Maria da de la composición dela composición de la composición de la composición de la composición dela composición dela composición dela composición de la composición de la composición dela composición de la composición dela composición	080
Н	Company and the same		C + D + E + F		ipies, etc.)		8 04 :		NA
I	The second secon		D + E + F+C					1961	water and the second district and
J			Silver		Violat L	% NLT 95%)*			10810
K	THE RESERVE AND THE		1000		tions when the con-	THE RESERVE OF THE PARTY OF THE	Trock.		99.664,
					ieid Limit %	*(לֵרףוּלִאַיאַ)*			98119.1.
Chec	ked by Pa	cking /Date	Sy 27			Verified	by IPQ	A/Date:	HO5 2020
Date	FGTN No.	Sales	Pack Size	No. of Units in a shipper	No. of Shippers	Quantity Rai	GTN sed by cking	FGTN Checked by IPQA	FGTN Received by Stores
72-1 lost 2	- 245	Su les	3×1015	282× 3×10k	70	69 x282x 3x1016 (20	8	M. Sava
77 1 (USTO-									
321(0\$65-						Olx125x3x104	<u> </u>	0	4. Sam
		CION/ EVC		Total Qty. To	ransferred	18772 1x10	5	2	4. Sam
32.	DEVIAT		EPTION DE	TAILS:	n are obser / Exception	ved then record in boardeails	\$\frac{1}{2}	ble	المركب ا
32. Dur Sr. No.	DEVIAT	ss if there is	EPTION DE any Deviation	TAILS: on / Exception Deviation	n are obser /Exception eption detai	ved then record in boardeails	Specification take	ble	4.500
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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.

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BATCH PACKING RECORD

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Product Code: A08

Batch No.: 6, F200501

Customer:

Generic Health Care Pvt. Ltd.

34. BATCH RELEASED FOR DESPATCH:

Total quantity released: 584490

Head QA sign/ Date:

REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
i	BPR/T/107-00	New Document	Nil

Checked by: Approved By: Prepared by: Head Quality Assurance Production Production Quality Assurance Dept. P. K. bol Sign. 22/04/2 21/04/2020 Date-

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: A08 Batch Size: 6,00,000 Tablets Product Amloperin 5mg/5mg BPR. No.: BPR/T/107-01 Batch No.: 67 F 2 CO 70 4 Customer: Generic Health Care Pvt. Ltd.

BATCH PACKAGING RECORD COVER SHEET

PRODUCT NAME	: Amloperin 5mg/5mg
GENERIC NAME	: Amlodipine Besilate and Perindopril Erbumine Tablets Each uncoated tablet contains:
LABEL CLAIM	Amlodipine Besilate BP : Equivalent to Amlodipine
CODE NO.	: PON/DRUGS/19 13 4323
DOSAGE FORM '	: Tablet
BPR No.	: BPR/T/107-01
REVISION No.	: 01
SUPERSEDE No	: BPR/T/107-00
EFFECTIVE BATCH. No. /DATE	: GF200704/27/01/2000
MARKET	: Export
SHELF LIFE .	: 36 Months
BATCH SIZE	: 6,00,000 Tablets
ACKING CONFIGURATION	: 3 x 10 Tablets Sales Pack (Alu Alu Packing)
BPR ISSUED BY/DATE (QA)	: - 125/6-11/201
BPR CHECKED & RECEIVED BY/DATE PRODUCTION)	: L. Ka- 28/07/2020
(FG. DATE: 07/10)-	EXP. DATE: 06/Lo 23
LLOTTED BY: QA SIGN/DATE:	COUNTER CHECKED BY: QA SIGN/DATE:
UANTITY RECEIVED FROM PRODUCTION	: S99713 Tablets
ATE OF COMMENCEMENT: 31/67/2626	DATE OF COMPLETION: 3/61/262
UANTITY	: 6,00,000 Pablet
ELEASED QUANTITY OF PACKED TABLETS	: 580380 Tabley
ELEASE OF BATCH BY HEAD QA GN/DATE:	: 13/2/2020

Prepared by:		Chec	Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
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Date Date	SIENdiller	2-1104/2000	21	19268/250

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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.

Product Code: A08

Batch Size: 6,00,000 Tablets

Page 2 of 26

Product

Amloperin 5mg/5mg

BATCH PACKING RECORD

BPR. No.: BPR/T/107-01

Batch No.: GF200704

Customer:

Generic Health Care Pvt. Ltd.

Sr. No.	Content	Page No
Batch Pac	kaging cover sheet	
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	8
9	Receipt of product and materials,	8
10	Detail of the product as per BMR	8
11	Weight verification record of received semi-finished product	9
12	Container weight details	9
13	Container consumption details.	9
14	Over printing of primary packing	9
15	Specimen of printed foil	10
16	Packing instruction, time record for packing detail	10
17	Packing In-process checks for primary packing	10
18	Alu Alu packing machine parameters	10
19	Machine In-Process control	11-13
20	Defoiling of Alu Alu strips, Inspection of defoiled Tablets	14
21	Line clearance for Batch Coding, Area and equipment clearance for coding, overprinting details, time record for batch coding, Carton overprinting specimen	15-16
22	Line clearance for secondary packing, Packing Details	17
23	Over printing details, Shipper Label specimen	18
24	Carton Weight Limit Setting, Weight Checks On Carton, Sample Drawn Record	19
25	Secondary Packing In process Checks	20-21
26	Shipper Weighing	22
27	Man power allocation	23
28	Packing material reconciliation	24
29	Excess packing material return to store	24
30.	Destruction of rejected/unused printed packing materials and stereos	24
31	Batch reconciliation	25
32	Transfer of finished goods	25
33	Deviation Detail	25
34	BPR review details	. 25
35	Batch released for Despatch, Revision History	26

Prepared by:	Check	ed by:	Approved By:
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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.

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-01 Customer:

Batch No.: GF 200704 Generic Health Care Pvt. Ltd.

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) *	Yey .
2.	Line clearance and environmental record	Yes
3.	Processing activity done by and checked by is signed	Yes
4.	Dispensing	
a)	Equipment clean tag and dispensing tag attached with batch record	Yes
b)	Packaging material is checked	Yes
5.	Packing	2
a)	Rinse water analysis report attached with BPR	Yes 1
b) .	Approved specimen of printed foil, show box and shipper label are attached	Yes
c)	Control / Stability / Finished product analysis samples are withdrawn	Yes
d)	Reconciliation of packing materials is done	Yes
e)	Tablet reconciliation is done	Yeg
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	Yeg
7.	Complete set of BPR Submitted	Ta

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

	Prepared by:	Chec	ked by:	Approved By:
Dept	Production	Production	Quality Assurance	Head Quality Assurance
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Date	TEN 27/97/2620	24/04/10000	27/	29621202



Product

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 26

Amloperin 5mg/5mg

Product Code: A08 BPR. No.: BPR/T/107-01

Customer:

Batch Size: 6,00,000 Tablets

Batch No.: GF 200 TO4

Generic Health Care Pvt. Ltd.

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.	% Over ages	Qty. Required 6.0 Lac with overages
1	188 mm Amloperin 5 mg/5 mg Printed Foil	PPF/GH/ A001	Width – 188 ± 1 mm Thickness – 0.025 mm Total GSM: 66.93 gsm – 78.57 gsm Language – English/French	Kg	30.000	2	30.600
2	188 mm Alu/Alu Base Foil	PBF/GH/A001	Width – 188 ± 1 mm Plain non-printed (text matter) aluminum foil. Total GSM: 233.96 gsm – 272.41 gsm Thickness: Total: 125μ - 144μ OPA: 25.99μ - 30.51μ PVC: 56μ - 63.6μ	Kg	90.000	2	91.800
3	Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	Size – 98 x 46 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 4 colour Language – English/French	No	20000	2	20400
4	Amloperin packing inserts	PPL/GH/100 1	Size – 280 x 200 mm (L x w) Specification – 60 gsm Maplitho white Paper. Colour – 2 colours Language – English/French	No	20000	2	20400
5	Shrink Sleeves (PVC)	PPS/GH/ P001	Plain PVC Shrink Sleeves Length-290 Height-260	No	1250	2	1275
6	5 Ply 390x390x260 mm C/Boxes	PUS/GH/C 001	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 260 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	.90	•	- 90
7	GHPL Ptd Bopp Tapes	PPB/GH /B001	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	18	<u> </u>	18
8	Strapping Role	PPR/GH/ S001	White or milky white colour. Width - 12 mm Thickness - 0.6 mm	Mtrs	250	-	250
9	Shipper Label	NA	Half A4 size Computer printed label	No	91	2	91

Prepared by:	Check	ed by:	Approved By:
- Production	Production	Quality-Assurance	Head Quality Assurance
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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.

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BATCH PACKING RECORD

Product Code: A08

BPR. No.: BPR/T/107-01

Batch Size: 6,00,000 Tablets

Batch No.: G F 200 70 4

Product

Amloperin 5mg/5mg

Customer:

Generic Health Care Pvt. Ltd.

DISPENSING LINE CLEARANCE CHECK		DISPENSING	LINE	CLEARANCE	CHECK
---------------------------------	--	------------	------	-----------	-------

Date-30/04/2022 Time 15:00

Sr.	CHECKS	Observ	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.		~
2	Check and ensure that display stand and weighing balance are clean.	THE STATE OF THE S	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
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	Marine Marine	/
7	Check all the gauges of Mobile Laminar Air flow before switching ON.	The second secon	
8	Check and ensure that weighing balances and pressure gauges to be used are within calibration due date.		~
9	Check that the daily records (Balance Logbook, RH & Temp. record) are updated and signed.		~
10	Equipment status is updated for Cleaned and Preventive maintenance.		/

Note: *Tick mark ($\sqrt{}$) if Complies, (X) if does not comply and (NA) if not applicable. Mobile Laminar Equipment Weighing Balance Area Air Flow ID No. STIBALION STILAFLOOL Foil Store NA NA Previous Product TelMIPTIME H B. No. TobooobG Cleaned by Sign/Date lory 13010 +12020 Checked by Store Sign/Date Verified by IPOA Sign/Date

ENVIRONMENTAL CONDITIONS: Date 3007 100 Time 157.05	Observation	Checked by	Verified by
(For Reference SOP No.: QAGN/011)	 Observation 	Store Sign/Date	. IPQA Sign/Date
Temperature (Limit: NMT 25°C)	23°C	100/3det/2500	कार्वाक्रिक
Differential Pressure across the booth Limit: 5 to 20 mm Water	13mm	10830107 /2020	

APPROVAL FOR DISPENSING BY IPQA: Si	gn d		30 0 7 17070
Dispensing start Time 15:10	End Time	12:28	

Carlo Million	Prepared by:	Check	ed by:	Approved By:
Dept	Production -	Production	- Quality Assurance	Head Quality-Assurance
Sign.	L.Ka	April.	12/1/00	m'm
Date	22/2/2/20	2-110-1100	21/10	Leaponor





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

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-01

Batch No.: GF 200704

Generic Health Care Pvt. Ltd.

DISPENSING RECORD OF PACKING MATERIALS: Date 30/67/2020 Shift. Time: 15:10

Material Name	Item code	иом	Req. Qty. for 6.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
188 mm Amloperin 5 mg/5 mg Printed Foil	PPF/GH/A001	Kg		-1.	Pmg Googs	<u>08</u>	30/07/2020	30/01/2020
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	91.800	163.60 143.60	ProcHootant	0 g 0 2	30/24/2020	The lost
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	20400	20400	Pm41 0000 4	۰ 90	30/07/200 30/07/200	20 July or
Amloperin packing inserts	PPI/GH/I001	No	20400	20400	Procificocoff	6 A	30/04/2000	To Non
Shrink Sleeves (PVC)	PPS/GH/P001	No	1275		17 3.			30012
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	90	٥١٥	Pma) 00148	09/	30/07/2020	30/1/200
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	18	18	pm4100134	• • •	30/07/2020	30/07/200
Strapping Role	PPR/GH/S001	Mtrs	250	250	Pmc((0000)	0	. 667 30/07/2020	30/07/200
Shipper Label	NA NA	No	91			- √ C	h 3	30

	Prepared by:	Che	cked by:	Approved By:
Dept	Production	Production-	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Jung	Didnov	whice
Date	27/07/2020	مد صا الما المر	25/0	109/02/2020

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SAI PRIMILY Product Product Product Product Product Product Product Product Amloperin Smg/Smg Product Product Product Amloperin Smg/Smg Product	6	COL	Facto	ory: R.S.	No. 4/3	Plot No.33	IOTECH PVT I , Kurumbapet Inc Puducherry-60500	lustrial Es	state,	Page 7 of 2	26	\$
6. LINE CLEARANCE CHECKS: 6.1 PRIMARY PACKING: Date/ Shift 3.3 b+ b-2a_c Gt			BA	TCH PA	CKING	RECORI	Produc	Code: A	208	Batch Size	: 6,00,000	Tablets
6. LINE CLEARANCE CHECKS: 6.1 PRIMARY PACKING: Date/ Shift 3.3 b+ b-2a_c Gt		Duadwat	BPR. No.: BPR/T/107-01 Batch No.: GIF No.						GF 200	3 704		
6. LINE CLEARANCE CHECKS: C1 PRIMARY PACKING: Date/ Shift: 31 b+lbsha. G1 Previous Product: U tyo. Vi-lococin S Sr. No. Checks Time Packing IPQA Packing I		Product	Amioper	perin 5mg/5mg								
Sr. No. Check and ensure that the area is visually clean and free from previous product. Check and ensure that the area is visually clean and free from previous product. Check and ensure that the area is visually clean and free from previous product. Check and ensure that the area is visually clean and free from previous product. Check and ensure that the area is visually clean and free from previous product. Check and ensure that the area is visually clean and free from the previous product with a control of the contro	6	LINE CLEA	DANCE C	HECKS.	or, fra	4		National Control				- A 15
Sr. No. Checks Time Of 12ac Packing IPQA Packing IPQA Packing IPQA Check and ensure that the area is visually clean and free from previous product Check and ensure the differential pressure of the area is within specified limit A Check and ensure the waste bin is emptied out and cleaned Check the temperature and relative humidity of the area within specified limit A Check and ensure the waste bin is emptied out and cleaned Check the tabeles of the previous product batch removed. Check the surroundings of the machine and free from the previous products and batch Check the surroundings of the machine and free from the previous products and batch Check the surroundings of the machine and free from the previous products and batch Check that the daily records (log book, balance, temp. & RH) are updated and signed. Check that the daily records (log book, balance, temp. & RH) are updated and signed. Check the surroundings of previous batch product at machine conveyor belt. Check the (hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit. Check hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit. Check hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit. Check hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit. Check hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit. Check hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit. Check the proper from Top, between bottom side of conveyor belt and collating unit. Check the proper from Top, between bottom side of conveyor belt and collating unit. Check the proper from Top between bottom side of conveyor belt and collating unit. Check the proper from the from the proper from the proper from the proper from the prop		6.1 PRIMAR	RY PACKI	NG:		Dat	e/ Shift .31 07	10206	TO C	/ <u>R</u>	JA	
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Sign.

Date

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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.

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-01
Customer:

Batch No.: 67 F 200 704)
Generic Health Care Pvt. Ltd.

7. VERIFICATION OF DISPENSED PACKING MATERIALS: Date 31 lot 120 Shift. Gr..... Time: .07.35

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
188 mm Amloperin 5 mg/5 mg Printed Foil	PPF/GH/A001	Kg	Pmg 100005	03	84	0
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	pm4/00008	0 g	dy	0
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	Pmg /00004	09	Sy	3
Amloperin packing inserts	PPI/GH/I001	No	PmC 100007	04	Set .	(B)
Shrink Sleeves (PVC)	PPS/GH/P001	No	- Prof Bank ja gar	4 <u></u>	W-100-12-12	
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	pmc/00/78	09	Set.	8
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	PmG100134	04	Sy	@
Strapping Role	PPR/GH/S001	Mtrs	Pma100001	Ó1	Qñ .	8
Shipper Label	NA	No		-NA -	. 5 mm 1989 (com	- 0

Blorba

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	08	Royporo	Haling's	Hon'	A430/001/2	2 30/07/202

RECEIPT OF PRODUCT AND MATERIALS: Date/Shift...3! 1ヵキーシー・Time: ロボームの (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)	216	Ny	(2)
2.	Relative Humidity observed on display (Limit: NMT 60%)	58./,	Sulle	2
3.	Bulk product containers are of the required product/Batch number and is approved by QC	NA	N4	NA
4.	Status label of machine/ line is for same product	Yes	By	2
5.	Printed foil/Base rolls are of the required product.	. yy	O'y	2
6.	All secondary packing materials are of the required product	uje de la	Ry	8

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	139,50mg.	Bu	a
2.	Colour of Tablet	White colour.	O'T	一里
3.	Quantity (Net Qty.in Kg)	83.660	Sy	(B)
4.	Number of Containers	06	dy .	1-4-AD

V	Prepared by:	Chec	cked by:	Approved By:
Dept	Production	_ Production	Quality Assurance	· Head-Quality Assurance
Sign.	L.Ko	Anny	12/2000	aprico
Date	07-27/07/2020	250110110	21/1	27/07/22

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

Page 9 of 26

Product

Amloperin 5mg/5mg

Product Code: A08 BPR. No.: BPR/T/107-01

Batch Size: 6,00,000 Tablets Batch No.: 01 F 200 704

Customer:

Generic Health Care Pvt. Ltd.

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

BATCH-PACKING RECORD

Balance I.D. No.: PDIBALLD 14

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

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Amloparin 5mg/smg	G1F200 704	0=(2020	06 2623	83. bb o Kg Equivalent to 도 역 역 및 및 Nos.	From Container No. ol To Container No. ol Total No. of Containers taken bl
Checked by Packi	ng (Sign. /Date): Sy	3/07/2020	Verified By IPQA	(Sign. /Date): 21/07/2020

12. CONTAINER WEIGHT DETAILS:

Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA	Container No.	Gross Weight in Kg	Weighed By Packing	· Checked By IPQA
1	26.690	Hanny	30	11	1		
2	24.630	Manny	10	12	1	44 144119	46700
3	14.190	Mahnu	4	13 .	America Company		1 20
4	15.880	Mapu	() () () () () ()	14	Cheffel attracting to the state of the state	Control of the Contro	
5	9.240	MACHA	一张 一	15			1 00 00 to 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
6	6:250	Mann	7	16		- Aug	
7				17			
8			150g/ - 150g	18			
9		NA -		19		1/18/2007	7
10	A hour specific		Admire	20	The state of the s		3 63

S. No	Ti	me	Container	Consumed		Ti	me	Container	Consume
5.110	From	То	No.	by	S No	From	То	No.	by
1	08:20	69120	01	Hani	11 L				
2	091.25	10:30	٥٧_	Hani	12			Company of the State of the	· Carlot man on the
3	10:35	11 1 30		Nani	13		-N.	Market and the	1.000
4	11110	13150	04	Mam'	14		,		1479.703
5	13155	15120	05	Man'	15				to the same
6	15:30	17:40.	O.L	nam'	16		1 1 2 2 2 2 2	Simon Shell	
7	American St.	28 K	and the		17	TOTAL STATE OF THE	1374/3570		4. 7.4.13
8	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	AND	-NA	ica - icalizate	18		-tv valski	100 mm 10	1
9			7		19			Principle of	0
10	THE MESTIGNAN A	48 - T		841	20	a manager of the contract of		District Commence	Dy

7-	Prepared by:	Checke	ed by:	Approved By:
_ Dept	. Production	Production	-Quality Assurance	-Head Quality Assurance
Sign.	L. Ko	Jup	A Novo	mm
Date	27/07/2020	24/04/1020	100	1286812020

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CD)	SAI PRIMUS LIFE BIOT: Factory: R.S. No. 4/3, Plot No.33, Kur Villianur Commune, Puduc	Page 10 of 26	
SAI PRIMUS	BATCH PACKING RECORD Product Code: A08		Batch Size: 6,00,000 Tablets
Product		BPR. No.: BPR/T/107-01	Batch No.: 67 F 200 704
	Amloperin 5mg/5mg	Customer:	Generic Health Care Pvt. Ltd.

OVERPRINTING OF PRIMARY PACKAGING MATERIALS: 14. Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)
Code No.:	PON/DRUGS/19 13 4323	OK
Batch No.:	GP200704	OŁ
Mfg. Date:	M7/2020	ەلد
Exp. Date:	06/2024 06/2023	Ok
Pack size (3 x 10's)- Carton	OL '	ok and and
Other instructions if any	NA LEIL DE	DA complete
Initiated by	Hanî	Hani
Checked by Packing (Sign. & Date)	84301071200	Sy 20 107/2020
Verified by IPQA (Sign. & Date)	(3) 20/01/2020	(3) 20/01/2020

SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
0)	30/67/2020	ΟÍ	Mani 30/04/2020	By 31/07/2020	(3)-3B/01/2020
California (N	Α		The second secon
127					[3,5730]04]

PACKING INSTRUCTIONS: 16.

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

Issue the stereos to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.

Set and operate Alu Alu Packing Machine as per SOP No. PDOP/020.

Verify the status label of overprinted packaging materials and transfer to the packing line in secondary packing hall.

5. Perform Leak Test as per SOP No. QAGN/045 and enter the observations in respective table.

Perform Leak Test as per Table or during change of Printed foil rolls & plain film rolls and after every start of operation or when machine is stopped due to some break down.

Attach proof of printed foil from each roll dispensed as and when used on machine.

Overprinting Details on printed foil shall be checked by Packing and cross-checked by IPQA before starting the operation as per given in the respective Table.

Affix first overprinted Al. foil, Carton, Shipper and shipper label duly checked by Packing and verified by IPQA.

10. Pack 10 tablets per Alu Alu strip.

200		Primary packing		Secondar	Checked by	
Sr. No.	Date/Shift	Started at	Completed at	Started at	Completed at	(Packing) Sign. & Date
01	31/0+/2020	08:30	17:40	08-32	04:10	8431/07/202
<u> </u>		The second secon	A STATE OF THE STA			
			NA	06 364 - 15 - 17 A	A Territoria	
			A CONTRACTOR CONTRACTO		- W 32 53 53 53 53 53 53 53 53 53 53 53 53 53	1343110

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

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.

11	Prepared by:	Checke	Approved By:	
Dept	- Production -	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko	Pemple	1 Jorlyou	- surje
Date	07577/27/2020	ocan/polks	211	22/02/2000

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

Villianur Commune, Puducherry-605009.

Product Code: A08

Batch Size: 6,00,000 Tablets

Page 11 of 26

Product

Amloperin 5mg/5mg

BATCH PACKING RECORD

BPR. No.: BPR/T/107-01 Customer:

Batch No.: G F 200 764
Generic Health Care Pvt. Ltd.

Date/Shift. 31.107-12020. G. Time: . 08:3.0. 18. ALU ALU PACKING MACHINE PARAMETERS:

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	BPM GE 10	ok	843107/2020	(8) 31/01/2020
Sealing Temperature	(170 °C - 210°C)	182°C	3431/04/2020	31/07/2020
Leak test to be performed on 02 Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	ok	8431/07/2020	331/04/2020
Machine Speed	(10 – 35 cycles)	28	Q431/07/2022	@31/04/2020

Date/ Shift		3/1	07/2	مده	Gir	enero	18							L F A			
Machine O	perator Name		1 /-	mda	n					a right			d _{is}		L.7	٠, ٣٦	H-
Time of ins	pection	08;30	Q!AS	09:3°	10130	10:50	11/25	12:30	13.00	435	15.3	15.35	16:25	. 71.30	17.50	17.5	15.4
Sealing Ten (170°C - 21	nperature	(gyt	WE F		185 c	1862	185°C	100		<i>الاد</i> ر	184	1850	184'0	1300	"C	1700	
Leak test or (Qty.: 02)	n Alu Alu strips*	Ok	010	O.C.	04	ok.	OL	di	olc	or	oh	والت	OL	oh	eic	at	66
Knurling /S	ealing	OK	010-	ok	015	oV.	ON	OK	ok	oh	oh	ot	ioh	oh	ct	ek	ek
Pocket Forn	mation	04	01-	04	OK	ok	Ol	OK	ok	Oh	Oh	elc	Oh.	015	ele	jo	ot.
Horizontal o	cutting	ok	ok-	οĶ	0K)	olc.	OL	oh	0)=	oh	OL	50	OR	043	St.	eit	ei
Vertical cut	ting	ok	ok	015	OK	OK	OK	oh	ok	Oh	OL	ok	ok	015	de	ck	ck
Quality of C	Over printing	ok	ole	οK	OL	ole	ol	Dh	ok	ch	ok	el	OK	OK	oi	eli	ċ.k
Code No.:	PON/DRUGS/ 19 13 4323	ok	ok-	оĶ	OL	ole	Oh	Oh	ōΚ	On	01ـ	ak	ok	οų	di	ok	ئان
B. No.:	G18200 704	ok	nk	045	OL	ble	Oh	oh	ok.	Oh	oh	ck	ok	014	EK	ci	ck
Mfg. Date	07/2020	014	ok	04	0h	0 k	DL	Oh	ok	oh.	OL	d	ok	OK	di	EİL	oli
Exp. Date	06 2023	016	ok	σk	Ok	ok	oh	oh	014	oh	ok	라	OK	6h	di	ok	cic
Machine Spe (10 – 35 cyc	eed les)	18.	28	30	So	3ô	30	go.	36	. 30	· Qo	340	35	30	10	35	aj
Checked by	(Packing)	Sig	144	Qy,	St	NA	87	&	W.	红	·SI	NE	ર્વેછ	Lej.	72	水	28.
Checked by	(IPQA)		0			3_			2		5	0	100		6	The state of the s	P

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:	Check	Approved By:	
Dept	Production	Production	- Quality Assurance	Head Quality Assurance
Sign.	L. Ko.	Eugh	2/19/1/20	sinci.
Date NAA	STED-ALONDUS L	27/07/1220	211	129681202

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SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Ku Villianur Commune, Pudu	Page 12 of 26				
	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets			
Product	A 1	BPR. No.: BPR/T/107-01	Batch No.: GF 200 704			
	Amloperin 5mg/5mg		Carrie III alth Carre Dat I tal			

	IACHINE IN-PE	1			OL:			11000									
Date/ Shift	. Dest configuration of the state of the sta																
Machine Op	perator Name	27.1	9/	Mix	ukano	lan	Ver										
Time of insp	pection	18-2	1	19		2 ° 4	8-1					-1			Same	8	
Sealing Ten (170 °C - 21	nperature .0°C)	200	0/19			•	*	new Year		K							
Leak test on (Qty.: 02)	Alu Alu strips*	ot.	-unff)	11/2	/											- 54-	
Knurling /Se	ealing	ok						proj	4.214		0.00	ea[]	PE				te.
Pocket Form	nation	ونزد	1						Marie T	VYA.	er sid	Sept. 18	1			<u> </u>	* p3
Horizontal c	cutting	it.		107				Lur		Tage:	15	112	,		20 m	1 2	× 12
Vertical cutt	ting	Je Je	7.6				1	1					1,614		isi.		
Quality of C	ver printing	st.			*	1	rh ar		V.X	1	10:		1			a li gi	
Code No.:	PON/DRUGS/ 19 13 4323	OK			ec				7	1			1				
B. No.:	GF200704	oj-		121730				1		1	/		4,5		ilkari Vita	3.4	
Mfg. Date	on/2=20	ct	,	1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -						A)	1	1			100	
Exp. Date	06/2027	ster.	1 /				7)		3 4						
Machine Spe (10 – 35 cyc		35				Topical I				14.4	7	, N	3				
Checked by	(Packing)	439														religión a d'ass	
Checked by	(IPQA)	B					- m vil					1 2				10	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	Checked by:						
Dept	Production	Production	Head Quality Assurance						
Sign.	1.40	April	1000	Contin					
Date MA	STER MOTIVE 20	27/04/2000	n'i	12 Sport or so					
0003	1015110011		TRIC	AMEDOLLE					

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: A08

Customer:

Page 13 of 26 Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-01

Batch No.: G F 200 704 Generic Health Care Pvt. Ltd.

MACHINE IN-PROCESS CONTROL:

Date/ Shift		1			tende i			arian da			I				. Tiga		2164-76
Machine O	perator Name	CA are	/		Ē.												Energy (Francisco)
Time of ins	pection					TIBA		1 Take		1 2					410	1	
Sealing Ter (170 °C - 21	nperature 10°C)		1 (2) 1 (2) 1 (2) 1 (2) 1 (2) 1 (2)				-	AH						x - 141 151	2 2 22 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		
Leak test or (Qty.: 02)	n Alu Alu strips*							W-5-2-10		9							
Knurling/S	ealing			#15			1	100	2		10			1 100			
Pocket Form	nation						1	21.5									
Horizontal o	cutting			This			11.57							L	1516		×.
Vertical cut	ting (tall tall t		1.6		71Q		e C	T ROAL	4	1	y carr	35	P21		106	, , ,,,	. His
Quality of C	Over printing				*2				6/								
Code No.:	PON/DRUGS/ 19 13 4323							/ M. all		1							
B. No.:			- NF-41						L. L.		1				1972		
Mfg. Date			No.		10 E	:Ji	112	- 12.25 V- 12.25				1			K		1.20
Exp. Date					1								/				
Machine Spe (10 – 35 cyc	eed les)					2 3 7 2 3 2 3			Ki.								ie e
Checked by	(Packing)	- 1 10 11 11													X		4.13
Checked by	(IPQA)		0.000			nh.z.			UK-K		T4	- Line			84	3/04	1000

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.

A T THE RE	Prepared by:	Check	Approved By:	
. Dept.	- Production	Production	Quality Assurance	Head Quality Assurance.
Sign.	L. Ko	Any	De la las	Confin
Date	CTER 2/20/20	محمالمالح	27/	28/02/200
IVIA	ASIER CUPY	0		

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C	10	Factory: R.	AI PRIMUS LII S. No. 4/3, Plot N Villianur Commi	Jo.33, Ku	rumbapet Ind	dustrial Esta	te,	Page	14 of 26	
	RIMUS ECH PVT LTD	BATCH	PACKING REC	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			Batch Size: 6,00,000 Tablets			
J. T. T. V					BPR. N	o.: BPR/T/	107-01	Batc	h No.: G F &	100704
Pro	oduct	Amloperin 5mg	g/5mg		Custom	ier:	Color Eq.	Gene	eric Health Ca	re Pvt. Ltd.
20.	DEFOILI	NG OF ALU AL	U STRIPS:	* *						
Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets		De-foiling	Done by			hecked by/ te (Packing)	Verified by Date (QA)
31/04/2020	16:40	17,00	31/66	Jara	la, Amb	(Ambi'ka		8:	431/07/2020	(8) 31/04/20
		3		- NA	4.000			11.1851.		
						7	V			St.
		otal Weight of foiled Tablets	3.160	Checke	d By / Date	(Packing):		Ver	ified By / Date	(IPQA):
20.1	INSPECTI	ON OF DE-FO	ILED TABLETS	S:	d X					
Date	Inspect	ion Inspectio	n Inspection	Quanti ta	ty of Good blets	Ta	Rejecte blets	by/ Date		Verified by Date (QA)
is a life			at Done by	Kgs	Nos	Kgs	No	S	(Packing).	
31/07/202	12100	17/20	Vang's	31100	22,222	0.060	430		Q731/04/20	(8)31/07/20
- t-				NA					All some state	
			1/1							70
1.00			Total	- 10g						1917 V
Total Qu	antity of Re . Kgs A. 2	jected Tablets I Nos.	Destroyed		d By / Date		Ve	erified	By / Date (IP	

	Prepared by:	Checke	ed by:	Approved By:
_Dept.	Production	Production	-Quality-Assurance -	Head Quality-Assurance
Sign.	L.Ka	Sprif	A CAN	infrie
Date AA	TFF27/20120	27/07/1020		22/02/2020
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W)
SAI PRIMUS LIFE B!OTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

BATCH PACKING RECORD

Villianur Commune, Puducherry-605009.

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-01 Customer:

Cleaning Satisfactory / Not-satisfactory#

(IPQA)Sign. /Date:

Batch No.: GF 200 764 Generic Health Care Pvt. Ltd.

LINE CLEARANCE CHECKS - BATCH CODING: 21.

Date/ Shift . 30107 1200 (4)

Page 15 of 26

Sr.			Observation					
No.	Checks	Time	12-55					
فليت		The variable of the state of th		IPQA	Packir	10	IPQA	
1	Check and ensure that the area is visually clean a product.	and free from previous	4	/	1			
2	Check and ensure that waste bin is emptied out a	nd cleaned	V		-			
3	Check the Pallets and crates area clean and free f previous product /Batch.	from any leftovers of	5	/		A. A.	7 15 17 1	
4	Check and ensure the Correct status board is writ	tten.	~	1				
5	Check and ensure the previous batch details are of machine.	deleted from the inkjet	<u>.</u>	/	V . Y			
6 .,	Check and ensure the rejected Cartons of previous removed.	s product/batch are	<u></u>			419		
7	Check and ensure the cleanliness of hatch for con	iveyor belt.	ー				7	
8	Check and ensure the cleanliness of conveyer bel	t with collateral block.			282 6		1	
9	Check and ensure the dispensed secondary packing	ng material.	S	1				
10	Check and ensure the Preventive maintenance rec	cords and log book.	0		3	-1-1		

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

21.1AREA AND EQUIPMENT CLEARANCE FOR CODING: 1. Check and ensure that the over printing area and machine is cleared from previous products.

Transfer uncoded printed Carton to Overprinting area.

Set and operate Overprinting Machine.

Overprinting shall be in indelible ink.

Cleaning Satisfactory / Not satisfactory#

(Packing) Sign. /Date:

5. Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Equipment	Inkjet Machine	Conveyor	Area	
ID. No.:	Ividado PD/105/001	Polenelool	Batch Coding	
Previous Product:	FTO100029 FTO100020	The late of the second		
Batch No.:	FI01000 217		1	
Cleaned by:	Draller			
Checked by Packin	g: SympaoloTinas			
Verified by IPQA:	(8) 30/04/2022			

Prepared by:	Check	ked by:	Approved By:
Production	Production	- Quality Assurance	Head Quality Assurance
2.20	Auri	A AND	- min
	27/10/120	N. C.	12967200
	Production	Production	Production — Quality Assurance — Quality — Qua

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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. SAI PRIMUS LIFE BIOTECH PVT LTD BATCH PACKING RECORD Product Code: A08 Batch Size: 6,00,000 Tablets BPR. No.: BPR/T/107-01 Batch No.: C1 F 200 T04

21.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.:	GF20704	Φb
Mfg. Date:	07/2020	06
Exp. Date:	0612023	υė
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS / 19 13 43 23	d
Other instructions if any	N'A	ν <u>α</u> .
Initiated by Sign. & Date	Brothy	de .
Checked by Packing Sign. & Date	1930/07/2029	Aprilo 100 :
Verified by IPQA Sign. & Date	(B) 30/07/2020	(5) 30/07/00

21.3 TIME RECORD FOR BATCH CODING:

			Batch	Coding	Checked by	Verified by
Sr. No.	Date/Shift	Batch Coding Done By	Started at	Completed at	(Packing) Sign. & Date	(IPQA) Sign, & Date
10	30121200/14	#ndhu.	18:10	19:00	Ahre took	35/07/20
-	Name of the				, 31	
			TOPE			
				Addition to the second		<u> 4 y</u>

Customer:

Generic Health Care Pyt. Ltd.

21.4 CARTON OVERPRINTING SPECIMEN:

S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	30/07/2020		osa110100 broke	320107 2020
07	31/07/2020	∞ _	May los los	Datostos
02	01/08/200	03	12 01/08/2020	100/08/20
A control of the second		NA NA		184

Note - Attach specimen copy of over printed carton

	Prepared by:	Checke	ed by:	Approved By:
Dept	Production	Production	_ Quality-Assurance	Head Quality-Assurance-
Sign.	1. Ko.	ruph	Matter	Contra
Date //	TED27/2020	24/04/2020	2.1	29/07/2020

SAI PRIMUS	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Ku Villianur Commune, Pudue	Page 17 of 26			
LIFE BIOTECH PVT LTD.	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets		
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-01			
		Customer:	Generic Health Care Pyt Itd		

22. LINE CLEARANCE CHECKS - SECONDARY PACKING: Date/ Shift ... 31/07/2020 C. / Batch No.: UD20505 **Previous Product:** Ultra. 10 Observation Sr. Checks Time No. 08:00 Packing IPOA Packing IPOA Check and ensure that the area is visually clean and free from previous 1 2 Check and ensure that waste bin is emptied out and cleaned Check the Pallets area clean and free from any leftovers of previous 3 product /Batch. 4 Check and ensure the Correct status board is written. Check and ensure the stereo of the previous product/batch removed and 5 cut into pieces. Check and ensure the blisters, rejected Carton, Shipper and shipper label 6 of previous product/batch are removed. 7 Check and ensure the cleanliness of hatch for conveyor belt. 8 Check and ensure the cleanliness of conveyer belt with collateral block. 11 9 Check and ensure the dispensed secondary packing material. 10 Check and ensure the cleanliness of documentation table. 11 Check and ensure the Preventive maintenance records and log book. Note: Tick mark (1) if Complies, (X) if does not comply and (NA) if not applicable. Cleaning Satisfactory / Not satisfactory# Cleaning Satisfactory / Not-satisfactory# (IPQA)Sign. /Date: (Packing) Sign. /Date: 31/01/2020 Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record. Weighing Weighing Packing Equipment Balance Shrink Sleeve Strapping Balance Conveyor Area (Carton) (shipper) ID. No .: Secondary PDILOB OU PAIBAL/018 PDI BALLOO2 PD BAL 02 Packing Hall NA Previous Product: ultra A Batch No .: UD20505 Cleaned by: Checked by Packing:

Prepared by:	Che	Checked by:							
Dept Production	Production	- Quality Assurance	Approved By: Head Quality Assurance						
Sign.	Loud	N. Mar							
Date/ACTER 67991262	0 24/04/20 20	21/0	2268/20						

Verified by IPOA:



SAI PRIMUS

SAI PRIMUS LIFE BIOTECH PVT LTD

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

Estate, Page 18 of 26

BATCH PACKING RECORD

Product Code: A08

Customer:

Batch Size: 6,00,000 Tablets

Product Amloperin 5mg/5mg

BPR. No.: BPR/T/107-01

Batch No.: 67 F 200 704
Generic Health Care Pvt. Ltd.

21.5 ENVIRONMENTAL CONDITIONS:

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

		Date/Time: 3	1/07/201	08/00	Date/Time: NA				
Shift: Giene	20)	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	SAL	्रवे	3		NA	- Isy		

APPROVAL FOR SECONDARY PACKING:

Approved by IPQA Sing/Date: 3 21/2:1/2020

21.6 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 16 filled carton in a Shrink Sleeve.

Place 14 Shrink sleeves in each 5 ply shipper.

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

23. 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.:	ITF200704	OL	OK		
Mfg. Date:	0712020	OL MARKET	OL W		
Exp. Date:	06/2623	- You'll	<u> ا</u>		
Pack size:	NA	(3 x 10's Tablets)	14 x 16 x 3 x 10's		
Code No.:	PON/DRUGS/19 13 4323	ol .	NA		
Other instructions if any	NA	NA	NA X		
Initiated by Sign. & Date	· Droller	<u>Drolhei</u>	Labshi		
Checked by Packing Sign. & Date	dys	23	9731/04/00%		
Verified by IPQA Sign. & Date	A 31107/2020	31/04/2020	2 31/07/2020		

22.1 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
Ol	30/07/120	01	Arrant day	(20 31/04/202
		NA -	Z-100 - 100	184

P	repared by:	Cl	necked by:	Approved By:			
Dept.	Production	- Production -	Quality Assurance	Head-Quality Assurance			
Sign.	L. Ka	Jung	3/1/20	- Silving			
Date	27.407626	24/07/202	0 21	29/01/20			

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E	B	Factory: R.S.	I PRIMUS No. 4/3, P Villianur Co	lot No.33	, Kurun	nbapet l	Industrial	Estate,	Page 19 of 26				
SAI LIFE B	PRIMUS OTECH PVT LTD	BATCH PA			-		uct Code:	A08	Batch Size: 6,00,000 Tablet.				
	Product	Amlonovin Emal	Fina		Na A	BPR.	No.: BP	R/T/107-01	Batch No.: GF 200 To				
in the second	Tounct	Amloperin 5mg/	omg			Custo	omer:				Ith Care Pvt. Lt		
24. Wei		UAL STRIP WEIG lividual Empty Al		ALL PRINCIPAL PR	on holo				la.				
1.	1.1	3. 1.2		1 -	li Jeio	w.	7.	1.0		9.			
2.	1.7	4.	g Cleba	6.	Control of the Real Property	2	8.			10.	1:0		
		Empty Alu Alu strip			W.H.	King to	Au delfry			1.4	4 - 1 - 2 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1		
Avg. V	Weight of a En	npty Alu Alu strip ((A): total v	veight of t	ten Emp	oty Alu	Alu strip/	21 ، ا = 1					
Wei	ght of ten ind	lividual Filled Alu	Alu strins	are giver	n helow								
1.	2.4	A section to the section of the sect	2 · A	5.	2		7.	214		9.	0.3		
2.	2.4	4.	2.3	6.	2	3	8.	2.2		10.	2 4		
		illed Alu Alu strips			ALL R	6.2	a and						
Avg. v Limit (veight of a Fil	led Alu Alu strip (E						= 2.34			To the second		
		should be identified	d) .	4 3.1		AF 9 X	un in old selection				4 4		
	veighing Don			hecked By	v: Su	21/24	1000	Verified B	ev. C	2	4/2020		
3 7 4						m./a.				31/0	7/2020		
23.1	I CARTON	WEIGHT LIMI	T SETTIN	G: Date	/Shift	31/07	1.1020T	ime: . 9. 8	20				
S. C. Leave Contract		vidual empty carto	2011 80	A DEPRES		7.7							
1.	5.8	3. 5 17		5.	5.8		7.	5. ₽	9).	2.8		
2.	reight of ten er	mpty cartons =	4.25	-6. yes	$\varsigma \cdot \gamma$	1 /	8.	8.2		10.	5 .8		
Average	e weight of an	empty cartons =	Total weight	ght of ten	empty	carton /	10= 5	76.					
Shephy Carter Shephy		dual Leaflets are g											
1.	2.2	3. 2.		5.		0	7.	15677	C).	The design of the second secon		
2.	2.2	4 2	1.4	6.	<u>91</u>		8.	24		0.	214		
	eight of ten Le			e yanne				2.2		0.	24		
Avg. W	eight of a Lea	flet (E): total weig	ht of ten Le	eaflets/10=	= 2 .	31							
23.2	WEIGHT	CHECKS ON CA	ARTON:			Tayla:	12 m -1						
Weight o	of ten empty C	arton: 57	Ь	/	Ave	erage w	eight of o	ne empty Ca	rton (D):	5	-7-6		
Weight o	f ten filled Al	u Alu strip: ع	514	7.0	CALL TO STATE OF THE STATE OF T	Average weight of one empty Carton (D): 5 . 7 6 Average weight of one filled Alu Alu strip (B): 2.3 4							
Weight o	f ten Leaflets:			17		Average weight of one Leaflet (E): 2:31							
Weight o	f one filled Ca	arton F = (D+3B+E)	15.00	9		T: :- O - D : 1 av							
	by Packing/I	a	104/202		and the second s	Verified by IPQA/Date: (4) $3t/b1/2020$							
		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			7 01	med b	y II QA/L	ate. (3)	<u>- 3710</u>	1/120	10		
23.3	AND THE RESERVE OF THE PARTY OF	DRAWN RECOR											
Sr. No.	del Company of the Co	Sample collection	1		y. of Sa	ample	t Ave	THE RESERVE OF THE PERSON.	186 45 17		n. /Date)		
1		nple (Initial)		7	1×10/3				3167/20	70	44.00		
2		nple (Middle)	19 ,319 1	ك أماد ع	סו אךי	5 .			P 21/07/	70 to			
3	Control San			6	105	la di				12020			
4	Stability San	2 2		D4 1781	NA	15			47				
5	Other Samp	A CONTRACTOR OF THE PARTY OF TH		N. AM	MA	9 - 116	740 T		M·A				
6	Analytical s	tical sample				, 2	n killa	(5	131/1	7/20	20		
		Total Q	ety.	2×10	1 _	320'	Tablets	6	2	l-			
	Pre	epared by:			A STATE OF THE PARTY OF THE PAR	ked by:		1	SHITTENEY.	4 7 7 2			
Dept.		roduction	· · P.r	oduction-			uality As	surance			oved By:		
Sign.							Dr/ 1.	,\"		\ \	-J Modulance		
Date,	5	7/07/2020	۸	the.		\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	2/2/1	7 7 110	Con	tw			
IMA	STERC	OPYTO	2	J LOJ K	مدما	L	·V.	71		103	x/oxform		
				-				TTV ~ ~ ~			7		
		W# 1 77						UNCONI	ROLL	RD	COPY		
									A CILI	عاد سطا	0011		

S	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Ku Villianur Commune, Pudue	Page 20 of 26			
SAI PRIMUS	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets		
Product		BPR. No.: BPR/T/107-01	Batch No.: GF 200 704		
	Amloperin 5mg/5mg	Customer	Generic Health Care Pvt. Ltd.		

SECONDARY PACKING IN-PROCESS CHECKS: (Please keep √ mark if found "Ok") 25. 31/01/2000 Date/Shift 31/07/2020 observation Specification Parameters IPQA Packing 09:05 19.30 17.40 11:10 Time 09,20 09/50 11/10 3 Alu Alu strip No. of Alu Alu strip in OC with 10 tabs each elc a carton OL OK OK 04 OK ot OF and one leaflet. 04 OK OF Legible and ek de Carton Overprinting OL OL 6K readable 014 Ok ok 06 OB OLE NA No. of cartons in a 16 packed cartons elu NA NA NA NA NA shrink sleeves NA NA MA MA Shrink wrapping VI 24 AU NA NA N4-ALA ALA temperature* AM MA MA No. of shrink sleeves in 14 shrinks eic OL ok a 5 ply shipper Oh OK 014 014 OK 010 0/4 oic Proper strapping Shipper strapping Oh ek 0/4 OL ok 012 ck OL 03 DK ok Die Label appearance and Legible and et 61L Shipper appearance readable Oh 04 OL OL ols 06 OL Sealing of the shipper H type oh OF ok 6 K DK with BOPP Tape OL ók 04 oh ole-Checked by 3) Q⁷ QY

*Temperature to be mentioned.

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

The second secon	La contract		11117	BC K				observation							
Parameters `	Specification		Packing					1,000	11	S. M.		IPQA			
Time		15139	16.40	* \Xº	1		W 71351	1			-0 2 2 3 3 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4				
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	ᅄ	DΚ	οk					1	170	72				
Carton Overprinting	Legible and readable	OK	οk	Ol					27/01	1 5		24V		8.5	TVI-V
No. of cartons in a shrink sleeves	16 packed cartons	2	24	2			12/	21		<u> </u>			110 to 11		
Shrink wrapping temperature*	*	24	NA	3	T Wante		71 100 100 100	1	I Joseph						
No. of shrink sleeves in a 5 ply shipper	14-shrinks 282 Cartors	ok	ЬЦ	04,					Jan.			N.	1 1 5 5 4		
Shipper strapping	Proper strapping	015	ols	th			12		Tak	1	v 74	- 10	4 9 10		
Label appearance and Shipper appearance	Legible and readable	oк	οĶ	OK			ı		145) 1961	1		,			
Sealing of the shipper with BOPP Tape	H type	014	οŀj	oh	- Win-			P					•	***	
Checked by		84	84	Sy		_	-		- 12			/	12.		

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1/2020 2ª 1 - 3/00/2000
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SAI PRIMUS	Factory: R.S. No. 4	SAI PRIMUS LIFE BIOTE Factory: R.S. No. 4/3, Plot No.33, Kuru Villianur Commune, Puduch					ndust		tate,	P	Page 21 of 26					
LIFE BIOTECH PVT LTD	BATCH PACKING RECORD					Produ	uct Co	de: A	.08	В	Batch Size: 6,00,000 Tablets					
Product	Amloperin 5mg/5mg				37	BPR.	No.:	BPR/	Г/107-0	1 B	atch	No.: (FF	200	704	
I per CP1 CPC	Darig Steel See See See See See See See See See					Custo	mer:			G	eneri	c Hea	Ith C	are P	vt. Ltd	
24.2 SECOND Date/ Shift	ARY PACKING IN-PI	ROCE	ESS C	CHEC	KS:	Pleas	e keej	o√ma	ark if fo	und	"Ok"	')				
Parameters	Specification	Observation Packing				1	IPQA									
Time	the control of the co		1						1	7-	T d					
No. of Alu Alu strip in a carton	and one leaflet.					7	1 5 6				9_10 0 x 3 1 4 1					
Carton Overprinting	Legible and readable	Life	a			1		a Tr			Į.	M	20.07	j. 3		
No. of cartons in a shrink sleeves	16 packed cartons	FF.				1			7		1.45	a det		42. 1.3		
Shrink wrapping temperature* No. of shrink sleeves in		2.种寺			10	A Alega N				1 - 12 3/2		i ka	424	19.		
a 5 ply shipper	14 shrinks	- 46	4			Art.	1 4				- suite		183	4. H		
Shipper strapping	Proper strapping					1 EAT 1			128							
Label appearance and Shipper appearance	Legible and readable	- vo	1 14 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		100					\	1		7. es	7 L		
Sealing of the shipper with BOPP Tape	H type	11	d		# (5 m) (5 m)	l land	1	1).	pa so	Y = 1				1.12		
Checked by				1	1 7 7 10	April 1919 Liberary		T MAN			145	lar.	1012	802	1/07/2	
	ure to be mentioned. ARY PACKING IN-PR	OCES	SS CI	HECK	KS: (I	Please	keen	√ma	rk if for	ınd "	Ok")	64Q 14	1.30		200	
Date/ Shift	L Saft et al.	Amb -				ick 9	*	26.46			1 h	April 1	100	a spekt		
Parameters	Specification				Packii	n or		obse	vation	p Marie	IPQA					
Time		V	d _e		acki	Shepe on l	1 10	As A C				IF QA	17 Ag			
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.		/			Separal Separal sales sal					- 1-26 - 1-1-20 - 6-50		4 13 14 14 14 14 14 14 14 14 14 14 14 14 14 1			
Carton Overprinting	Legible and readable			1				i i	ETAN.			di		71		
No. of cartons in a shrink sleeves	16 packed cartons				1	340					Alde 1 / Alde	ka	沙克	Day 1		
Shrink wrapping temperature*				C topics			4.1		reformation of the second							
No. of shrink sleeves in a 5 ply shipper	14 shrinks					£ ' e	50							in it.		
Shipper strapping	Proper strapping	7 - 1 p	**************************************			7	70 /J	H			r d			14		
Label appearance and Shipper appearance	Legible and readable				0 		- 1			1					# 12 m	
Sealing of the shipper with BOPP Tape	H type								10-4							
Checked by						lx ·					1	×	8	31/2	#1202	
*Temperatur	re to be mentioned.		angel je					- 16.5					— 1 2			
Pre	pared by:	gis manifest		C	hecke	d by:						Appr	oved	By:		

- Dept. -

Sign.

Date ASTE

-Production

· Production

24/24/2020

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Head Quality-Assurance

_Quality Assurange -

S	SAI PRIMUS LIFE BIOT: Factory: R.S. No. 4/3, Plot No.33, Kur Villianur Commune, Puduc	Page 22 of 26	
SAI PRIMUS	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product		BPR. No.: BPR/T/107-01	Batch No.: 6, F 200 704
	Amloperin 5mg/5mg	Customer:	Generic Health Care Pvt. Ltd.

Date/Shift..311.07.)2020 Ch... Time: OK. 56... Balance I.D. No.:. P.D. 18AU 010 SHIPPERS WEIGHING: 26. Average weight of one filled Shrink (E): [A .O Weight of ten Shrinks: cartor> 170.00 Average weight of one empty shipper (F): 0.887 Weight of ten empty shippers: K+8,8 Weight of one filled shipper (G) = (14E+F): Limit: $H = G \pm 1\% =$ 5.624 5.681 5. 437 Verified by IPQA/Date: (8) 31/07/2020 Checked by Packing/Date: Of 4 31 10 7 2020 Gross Gross Gross Gross Weighed Weighed Shipper Weighed Weighed Shipper Shipper Shipper weight weight weight weight By No. By By No. By No. No. (Kg) (Kg) (Kg) (Kg) 51 76 1 26 5.721 5.705 5.701 52 77 27 191, 5.688 700 5.709 28 53 78 3 5.696 54 79 4 29 5.684 5.683 5.688 55 80 30 5 hash 5.702 56 81 31 5.662 6 5.652 Minabur 57 82 32 7 5.669 668 58 83 33 8 59 84 9 34 60 85 10 35 5.661 61 36 86 11 5.678 5.668 62 87 12 37 5.687 63 88 13 38 5.669 64 89 14 39 5-668 5.685 40 65 90 15 tehnabl. 5.694 5.676 Pholes WA 41 66 Dhy 91 16 5-654 = 6th 67 92 17 42 5-674 68 93 43 18 5.700 5-692 the boke 5.660 69 94 19 44 4.532 5.698 5.677 70 95 45 20 5.664 5.669. 71 96 21 46 22 72 97 22 47 5.714 73 98 48 23 5.691 674 74 99 49 halsh 24 5.668 5.701 Dy 100 Showlatch 75 50 25 5, 691 Loose pack details: De-foiled tablets Checked by Sign / Verified by Total No. of Shipper No: ...6 9.... packed in Date: Sign / Date: shippers weighed: Shipper No: Quantity 170 /3x1013 Sylo# 100h 69 69 -

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

P P	repared by:	Chec	ked by:	Approved By:
_Dept	Production	Production	- Quality-Assurance	Head Quality Assurance
Sign.	L-Ko-	Ant	20100	Suhy
Date AARTER	26,0940620	2410410000	214	2969/20

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Calla	Fact		I PRIMUS LIFE BIO . No. 4/3, Plot No.33,		H PVT LTD papet Industrial Estate,	Page 23 of 26
SAI PRIMUS		V	illianur Commune, Pu	ducher	ry-605009.	and the second second second second
LIFE BIOTECH PVT LTD	BA	TCH P.	ACKING RECORD		Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloper	in 5mg/	5mg		BPR. No.: BPR/T/107-01	Batch No.: GF 200 704
The state of the s			and Market		Customer:	Generic Health Care Pvt. Ltd.
27. MAN PO		LOCAT	ION:			
DATE: .31)9.71/20:					OATE:	
SHIFT: GIENEY		Total organization	DOME DV	S	HIFT:	COP As which common and the Copy and the Cop
ACTIVITIE		-	DONE BY	0	ACTIVITIES	DONE BY
Alu Alu strip Checkin		dat	hya, Vanay'a		lu Alu strip Checking	
Printing Checking in strip		Si	lvasankuri		rinting Checking in Alu Alu rip	
Alu Alu strip weighir	BETT BEST MITTER	Jah.	shin's Makes bywar	A	lu Alu strip weighing	
Insertion of Alu Alu s leaflet into carton	strip and	100	6-4 JASPA	and the second	sertion of Alu Alu strip into arton	201 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Cartons weighing	A VA	10	analalihi'	C	artons weighing	
Insertion of carton int	o shrink		A Land	1	sertion of carton into shrink	
Insertion of shrink wr carton into shipper	apped		SA AM HAR		sertion of shrink wrapped urton into shipper	
Shipper Label Pasting	Alexa territoria	0	hana lahi	SI	ripper Label Pasting	
Shipper Weighing	H left of the second		Lanculahi	Sì	nipper Weighing	
Shipper Strapping			Shanuh'	1	ripper Strapping	The state of
Shipper packed		1000	1to69	A Contract of	nipper packed	Fromto
Signature of Packing		8	43107/2021	Si	gnature of Packing	to diversity in the first of the state of
DATE:		- 4	¥31[00((2-2-3)	קו	ATE:	8y
A STATE OF THE STA						
SHIFT:ACTIVITIES		- A	DONE BY	SI	ACTIVITIES	DONE DV
Alu Alu strip Checkin	5	And I	BONEBI	41		DONE BY
	77. 2.2				u Alu strip Checking	A The second of
Printing Checking in A strip			the dynaids	Pr	inting Checking in Alu Alu ip	(a) (b) (a) (a) (b) (a) (b) (a) (b) (a) (b) (a) (b) (b) (a) (b) (b) (b) (b) (b) (b) (b) (b) (b) (b
Insertion of Alu Alu st leaflet into carton	rip and	The state of the s		7	sertion of Alu Alu strip into	A 1 30 .
Alu Alu strip weighing				Al	u Alu strip weighing	
Cartons weighing	1974 Z T.	79.9%	· · · · · · · · · · · · · · · · · · ·	Ca	rtons weighing	
Insertion of carton into sleeve	shrink	to a	\ a		sertion of carton into shrink	
Insertion of shrink wra carton into shipper \	pped				ertion of shrink wrapped ton into shipper	
Shipper Label Pasting	V 5000	1 -1	114		ipper Label Pasting	The physical results
Shipper Weighing			The state of the s	-	ipper Weighing	
Shipper Strapping	3.44		13, 40	-	ipper Strapping	4 4
Shipper packed	1-1-1737	From.	to	_ —	pper packed	Fromto
Signature of Packing	* 100 200 200 200 200 200 200 200 200 200				nature of Packing	7.000
1.4			dy			
	epared by			Check	ed by:	Approved By:
Dept P	roduction	**	Production	5 ·	Quality-Assurance	- Head Quality Assurance .
Sign	· Ko	wa .	April		100 m	whi
Date 14 7 7 2	7607(2	920	021101100	20	277	arkete s

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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.

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-01

Batch No.: G F 200 704

Customer:

Generic Health Care Pvt. Ltd.

Sr. No.	8. PACKING MATERIAL Material	Printed Alu. Foil (Kg)		Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
À	Quantity received for the batch	31.200	94.000	20400	20400	NA	90	osomtra	18
В	Additional material received for the batch	NA	NA	NA	NA	NA.	44	NA	. מא
С	Total material received (A+B)	31.200	97.000	20400	20400	NA	90	Rompa	{ & ·
D	Quantity packed	14.857	55.542	19346	19346	NA	69	Isomtra	ly
Е	Quantity rejected (Online) & Destroyed	7.456	32.001	1016	NA	NA	NA	AU	U ja
F	Quantity Returned	8-349	8.998	NA	9-561016	NA	21	Loo mirs	Na
G	Sample affixed on BPR	0.001	NA	ol	01	NA	U-NA	NP	AG
Н	QC samples	0.003	0.011	NA	ANA	NA	NA	49	NA
I	Other samples (If any)	0.005	0.019	07	FO	NA	NA_	Np	מא
J	Total accountable Quantity (D+ E+F+G+H+I)	30.671	96.571	<u>-0-</u>	-0-	2 2	NA	24	, NA
K	Variation (C – J)	0.529	0.A29	-0-	-0-	NA	NA	NA	. NA
L	%Variation (K x 100)/C	1.69%	0 44%	-0-	-0-	NA	NA.	Nh	
M	Acceptable limit	<u>+2%</u>	±2%	±2%	±2%	±2%		J	

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

29. 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	8.349	8.998	NA	9561046	NA	21	100 mirs	NA.
Material returned by packing Sign./Date	84/08/202	8 4 3/08/202	44	84 Capar	Nh	Og as por	121	44
Verified By IPQA Sign./Date	(13/08/2000	2/3/08/22	NA	23/08/24	NA-	(15/00/22	13/28/20	No
Material received by Store Sign./Date	Dot: 105/2020			"Sodii por	AU	Det: poi	· Sel: Joslow	, NA

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)
3107 20%	08	7.456	32.001	956	NA	NA	NA	NA	NA
		-44 / Zyz -41 /		NA	The second state				154
Total Qty. Destroyed	08	7.456	32.001	956	NA	NA	NA	NA	NA
Destroyed by (Packing)	8स्त्री	17 20h	1						
Verified by (IPQA)		31/04/2020			- X			133	

As on great	Prepared by:	Check	ted by:	Approved By:
Dept.	Production	- Production	_ Quality-Assurance _	Head Quality-Assurance
Sign.	L.Ka	Syring	A Solver	my .
Date	ACTER 7/2/2000	2+104/2020	ν) ·	12 10 2000
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	1717		UN	CUNIKULLE

SAPEMIUS Product Amloperin Smg/Smg BR.No.: BPR/VIO7-01 Batch No.: Gr 200 70-1 Customer: Generic Health Care Pvt. Lit Generic Health Care Pvt. Lit Customer: Generic Health Care Pvt. Lit Generic Health Care Health Care Health Care Generic	- 11 I	DRIANI IS		ory: R.S. No. Villian	ur Commune,	3, Kurumb Puducherr	apet Industrial Es	tate,	Page 25 of 26	
31. BATCH RECONCILATION: A Bach Size Generic Haslith Care Pv. Lit. B Quantity received for packing C Total quantity packed D Control samples E Analytical Samples C Analytical Samples D Charros samples (Subbility, Regulatory Samples, etc.) F In process samples G Others samples if any (Subbility, Regulatory Samples, etc.) J Packing Loss = B - (C+D+E+F+G) J Packing yield % (C+D+E+F+G) / A X 100 (Yield should not less than 98.00%) J Packing yield % (C+D+E+F+G) / A X 100 (Yield Limit) %. Med 12.0. C Checked by Packing /Date: Other Samples Total Coss = A - (C+D+E+F+G) / A X 100 (Yield Limit) %. Med 12.0. TRANSFER OF FINISHED GOODS: TRANSFER OF FINISHED GOODS: Total Qty. Transferred Silpers Tota			BA	TCH PACK	ING-RECOR	D 1	Product Code: A	.08	Batch Size: 6,	00,000 Tablets
31. BATCH RECONCILATION: A Batch Size 6,00,000 No. 6 B Quantity received for packing 549 7 1 2 5 8 0 3 2 0 Control samples 5,80 3 2 0 E Analytical Samples 1,20 B Quantity packed 5,80 3 2 0 E Analytical Samples 1,20 B Total quantity packed 5,80 3 2 0 E Analytical Samples 1,20 B Total Cass = B - (C+D+E+F+G)	Pr	oduct	Amloper	in 5mg/5mg]	BPR. No.: BPR/	Г/107-01	Batch No.: G	F200 701
Besch Size B Quantity received for packing C Total quantity packed D Control samples E Analytical Samples E Analytical Samples In process samples G Others samples in grocess in groce						(Customer:	- 00 a	Generic Healt	h Care Pvt. Ltd
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Checked by Packing /Date:	K	Batch Yie	eld % (C + I) + E + F +G	/ A X 100 (Y	ield Limiț	%. N너- 95%.)			Yes a service of the
Date No. Sales Pack Size Units in a shipper Shippers Quantity Raised by Checked by IPQA Stores Sales Pack P							Ver	ified by II	PQA/Date: (31/04/2020
Total Qty. Transferred 580 %	Date		Sales	Pack Size	Units in a		- Park The Indiana Committee of the edited on a field of	Raised b	y Checked	Received by
Total Qty. Transferred 580 %. Sy Jugan. 33. DEVIATION/EXCEPTION DETAILS: During process if there is any Deviation / Exception are observed then record in below table Deviation / Exception details Sr. No. Stage Deviation / Exception details Sr. No. Stage Deviation / Exception details Checked by Packing: Packing manager: Approved by Head QA: 34. BPR REVIEW DETAILS: Reviewed by Name Sign. Date Packing Executive Ranking Executive Rankin	108 /2625	0444	Sales	3×10/2	28243116	69	68×282×3×10	13 . Br	77.500.00.00	0 4 GH 54s
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C/D	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Kur Villianur Commune, Puduc	umbapet Industrial Estate,	Page 26 of 26
SAI PRIMUS	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
	A - la - via 5	BPR. No.: BPR/T/107-01	Batch No.: GF 200704
Product	Amloperin 5mg/5mg	Generic Health Care Pyt. Ltd.	

35. BATCH RELEASED FOR DESPATCH:

Total quantity released: \(\frac{580.380}{180} \) No's Head QA sign/ Date: \(\frac{150.380}{180} \)

36. REVISION HISTORY:

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/107-00	New Document	Nil
2.	BPR/T/107-01	Revision after three validation batches	BPR/T/107-00

1457 - 1	Prepared by:	Che	cked by:	Approved By:
Dept	Production	~ Production -	Quality Assurance	-Head Quality Assurance
Sign.	L.Ko	Ann	12/2/200	man -
Date	27/07/20120	27/07/12020	1/2	100000 m

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CAL DRIANCE	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Kur Villianur Commune, Pudue	rumbapet Industrial Estate,	Page 1 of 24
SAI PRIMUS	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.: GFdoor 02
roduct	Annoper in Sing/Sing	Customer:	Generic Health Care Pvt. Ltd.
	BATCH PACKAGING	RECORD COVER SHEET	
PRODUCT NAME		Amloperin 5mg/5mg	
GENERIC NAME		Amlodipine Besilate and Perin	dopril Erbumine Tablets
	그 그리다는 아이들은 아이들 아이들 때문에 가장 아이들 때문에 가장 아이들 때문에 가장 아이들 때문에 다른 사람이 되었다.	Each unageted tablet container	

PRODUCT NAME	: Amloperin 5mg/5mg
GENERIC NAME	: Amlodipine Besilate and Perindopril Erbumine Tablets Each uncoated tablet contains:
LABEL CLAIM	Amlodipine Besilate BP : Equivalent to Amlodipine
CODE NO.	: PON/DRUGS/19 13 4323
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/107-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: GF 200405/22/04/2020
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)	: 12/2/2010
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: L. Ko- 23/05/2020
MFG. DATE:os.lagae	EXP. DATE: CHILDRED 04/2023.
ALLOTTED BY: QA SIGN/DATE:	COUNTER CHECKED BY: QA SIGN/DATE:
QUANTITY RECEIVED FROM PRODUCTION	59 63 19 Rilly
DATE OF COMMENCEMENT: 27/05/2020	DATE OF COMPLETION: OF OV 2000
QUANTITY	: 60000 pabley
RELEASED QUANTITY OF PACKED TABLETS	: 5922000 thely
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	2 Toplor ono

	Prepared by:	Check	ted by:	Approved By:
Dept.	Production	Production ()	Quality Assurance	Head Quality Assurance
Sign.	L.Ko-	3 alexy	P. K. John	O hard w/
Date	20/04/2020	21/04/2020	22/04/2020	2. 150 /211

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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 24

BATCH PACKING RECORD

Product Code: A08

Customer:

Batch Size: 6,00,000 Tablets

Generic Health Care Pvt. Ltd.

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: GF200502

1. INDEX

Sr. No.	Content	Page No.
Batch Pacl	kaging cover sheet	
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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	8
9	Receipt of product and materials,	8
10	Detail of the product as per BMR	8
11	Weight verification record of received semi-finished product	9
12	Container weight details	9
13	Container consumption details.	. 9
14 .	Over printing of primary packing	9
15	Specimen of printed foil	.10
16	Packing instruction, time record for packing detail	10
17	Packing In-process checks for primary packing	10
18	Alu Alu packing machine parameters	10
19	Machine In-Process control	11-13
20	Defoiling of Alu Alu strips, Inspection of defoiled Tablets	14
21	Line clearance for secondary packing, Area and equipment clearance for coding, Packing Details	15
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23	Carton Weight Limit Setting, Weight Checks On Carton, Sample Drawn Record	17
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25	Shipper Weighing	20
26	Man power allocation	21
27	Packing material reconciliation	22
28	Excess packing material return to store	22
29	Destruction of rejected/unused printed packing materials and stereos	22
30	Batch reconciliation	23
31	Transfer of finished goods	23
32	Deviation Detail	23
33	BPR review details	23
34	Batch released for Despatch	24
35	Revision History	24

	Prepared by:	Checke	ed by:	Approved By:
Dept.	Production	Production Production Quality Assurance		Head Quality Assurance
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Date	- 20 do 4/20 20	21/04/2020	m2/04/2020	7
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CAL DELANCE	Factory: R.S. No. 4/3, Plot No.33, Kur	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: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.: 61Fdov502
	- Ambreway	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) *	'NA
2.	Line clearance and environmental record	Yes
3.	Processing activity done by and checked by is signed	Yes
4.	Dispensing	
a)	Equipment clean tag and dispensing tag attached with batch record	Yes
b)	Packaging material is checked	Yes
5.	Packing	
a)	Rinse water analysis report attached with BPR	NA
b)	Approved specimen of printed foil, show box and shipper label are attached	Yey
c)	Control / Stability / Finished product analysis samples are withdrawn	Yug
d)	Reconciliation of packing materials is done	Yieg
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	Yee
b)	Certificate of analysis of finished product is submitted	Yes
c)	Stereo Impression Form and Destruction Record	Ye,
7.	Complete set of BPR Submitted	Yes

	TO L
Checked By QA/Date:	- Dadono
	X

*Mention total number of pages.

Remarks (If any)

Prepared by:	Check	Checked by:		
Production	Production	Quality Assurance	Head Quality Assurance	
L.Ko	3alaluny	P. W. Job isor	O. Mat. no	
20/04/2020	21/04/2020	100/1	7 - 2	
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Product

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD

Product Code: A08

Customer:

Batch Size: 6,00,000 Tablets

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: GFAULOL
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.	% Over ages	Qty. Required 6.0 Lac with overages
1	188 mm Amloperin 5 mg /5 mg Printed Foil	PPF/GH/ A001	Width – 188 ± 1 mm Thickness – 0.025 mm Total GSM: 66.93 gsm – 78.57 gsm Language – English/French	Kg	30.000	2	30.600
2	188 mm Alu/Alu Base Foil	PBF/GH/A001	Width -188 ± 1 mm Plain non-printed (text matter) aluminum foil. Total GSM: 233.96 gsm -272.41 gsm Thickness: Total: $125\mu - 144\mu$ OPA: $25.99\mu - 30.51\mu$ PVC: $56\mu - 63.6\mu$	Kg .v	90.000	2 5	91.800
3	Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	Size – 98 x 46 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 4 colour Language – English/French	No	20000	2	20400
4'~	Amloperin packing inserts	PPI/GH/100	Size – 280 x 200 mm (L x w) Specification – 60 gsm Maplitho white Paper. Colour – 2 colours Language – English/French		20000	2	20400
5	Shrink Sleeves (PVC)	PPS/GH/ P001	Plain PVC Shrink Sleeves Length-290 Height-260	No	1250	2	1275
6	5 Ply 390x390x260 mm C/Boxes	PUS/GH/C	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 260 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm ²	No	90		90
7	GHPL Ptd Bopp Tapes	PPB/GH /B001	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	18		18
8	Strapping Role		White or milky white colour. Width - 12 mm Thickness - 0.6 mm	Mtrs	250		250
9	Shipper Label		Half A4 size Computer printed label	No	91		91

, T Vog.	Prepared by:	Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ke	3alalung	P. M. Duby 2000	O Met 10H
Date	20/10/4/12020	21/04/2020	2210	7-1-7-1
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UNCONTROLLED CO.

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTH Factory: R.S. No. 4/3, Plot No.33, Kur Villianur Commune, Puduc	Page 5 of 24	
	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.: GFdoct 02
	Amioper in Sing/Sing	Customer:	Generic Health Care Put I

4. DISPENSING LINE CLEARANCE CHECKS

Date. 27/05/2020 Time. 091: 35

Sr.	OTTE OVE	Observ	ation*
No.	CHECKS		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.	V	1
3	Check and ensure that SS trolley are clean.	1	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.	V	/
6	Check and ensure that all the sides of Mobile Laminar Air Flow is clean		/
7	Check all the gauges of Mobile Laminar Air flow before switching ON.	V	V
8	Check and ensure that weighing balances and pressure gauges to be used are within calibration due date.	~	/
9	Check that the daily records (Balance Logbook, RH & Temp. record) are updated and signed.		/
10	Equipment status is updated for Cleaned and Preventive maintenance.	V	./
de e	Note: *Tick mark $()$ if Complies (X) if does not comply and (NA) if not applicable	A PARTY OF THE PAR	

Equipment Mobile Laminar Air Flow Weighing Balance Area

ID No. STIKAF (OU) NA NA STIKALION FOIL Store

Previous Product Anional Structure

B. No. Expansion Sny Ing

Cleaned by Sign/Date Rnight 27/07/2020

Checked by Store
Sign/Date

Verified by IPQA
Sign/Date

Checked by Store

21 05 2000

Sign/Date

ENVIRONMENTAL CONDITIONS: Date: 2# CS/2" Time: OA: AD

Observation Checked by Store IPQA
Sign/Date Sign/Date

Temperature (Limit: NMT 25°C)

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

1 mm | 23°C | 20°C
APPROVAL FOR DISPENSING BY IPQA: Sign. Date: 27 05 2012

Dispensing start Time 09.145 End Time 10.145

L. L	Prepared by:		Check	ed by:	Approved By:
Dept.	Production	Pr	oduction (Quality Assurance	Head Quality Assurance
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Date	20104/2020	2110	4 2020	22/04/1	The state of the s
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	SAI PRIMUS LIFE BIOTI Factory: R.S. No. 4/3, Plot No.33, Kur Villianur Commune, Puduc	umbapet Industrial Estate,	Page 6 of 24
SAI PRIMUS	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6
Product	Amlonerin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.:

Batch Size: 6,00,000 Tablets

BPR. No.: BPR/T/107-00 Batch No.: GFLOOS OF Customer: Generic Health Care Pvt. Ltd.

Material Name	Item code	UOM	Req. Qty. for 6.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by 'Store	Verified by IPQA
188 mm Amloperin 5 mg/5 mg Printed Foil	PPF/GH/A001	Kg	30.600	41.500	pmigliocost	04	27/05/2020	24/05/2020
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	91.800		P44120008 P44100004	04 03	27/05/200	2 05 2010 JET 05 2010
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	20400	26400	PMG/ccoc4	09	27/05/300	27/05/202
Amloperin packing inserts	РРІ/GН/1001	No	20400	20460	PMellocco+	04	21/25/2020	24/05/202
Shrink Sleeves (PVC)	PPS/GH/P001	No	1275				1V	- Antho
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	90	90	PMG /00178	09	H. 800 21/05/200	2=100-1200
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	18	18	PM 4/coolo	03	21/05/2020	2 504 05 20°
Strapping Role	PPR/ 4H/5001	Mtrs	250	250 1000	PMGloocoi	01	21/05/2020	9:4/05/200
Shipper Label	NIL	No	91				\(\frac{1}{2} \)	13/05/

	Prepared by:	Checke	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
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Date	20/04/2020	131/64/2020	22 INCO	NTRALL
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	I PRIMUS BIOTECH PVT LTD		-	Villianur C	Commune, Pu	ducherry	pet Industrial -605009. roduct Code	er yer ree	- 1 - 1 - 1 - 1	Page 7 of 2 Batch Size	44.4	0 Ta	hlete
		201 H					PR. No.: BP	114114					
	Product	Amloper	in 5m	ıg/5mg				K/1/	107-00	Batch No.			
				- A			ustomer:			Generic H	ealth Ca	re P	vt. Ltd.
The	6.1 PRIMAI	RY PACKI	NG:		Date/	Shift A.	11.05/20.20	G.e.	nera!	123.0.5.	20.30(Cier	n gral
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5.	Check the ten						pecified limit		V	1	u	1	NA
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7.	Check the lo previous prod				rejected rolls	, empty	cores of foil	of	~	1			NO
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	batch	. Juniumigs	or tile	macimic al	La nec nom	ne brevio	ras products i	and	V		-		NB
).	Check the foil	printing st	ereos,	Labels of p	revious produ	uct/batch	are removed.		~	1	- L	,	NA
0.	Check that th	e daily rece	ords (log book, b	alance, temp	. & RH)	are updated	and				- 11/1-	
185°	signed.					and the same		1.1	· • · · ·	11 /	19. V		/
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	IOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: GF200502

Customer:

Generic Health Care Pvt. Ltd.

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
188 mm Amloperin 5 mg /5 mg Printed Foil	PPF/GH/A001	Kg	PMG 100005	OF	34	2
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	PMG 100003	04 03	८५	8
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	PMG 100004	0407	Sy	2
Amloperin packing inserts	PPI/GH/I001	No	P MG 0000 Y	64	Sy.	2
Shrink Sleeves (PVC)	PPS/GH/P001	No	N.A.	NA	NA	NIA
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	PMG 100178	09	Sy	2
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	PMG 100010	03	<i>ઉ</i> પ્ર	2
Strapping Role	PPR/ G+/2001	Mtrs	PMG 100001	01	By.	8
Shipper Label	MA	No			-m_ 7	- 10

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	08	H' Markevi ,	Pary 105/202	Mam'	8427105/2020	Q77 05 2020

P. RECEIPT OF PRODUCT AND MATERIALS: Date/Shift: At 27/09/2020 GTime: 12:145

(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)	252	89	8
2.	Relative Humidity observed on display (Limit: NMT 60%)	584.	84	8
3.	Bulk product containers are of the required product/Batch number and is approved by QC	Yes	Sy	NA
4.	Status label of machine/ line is for same product	Yes	84	2
5.	Printed foil/Base rolls are of the required product.	414	84	(2)
6.	All secondary packing materials are of the required product	yes ups	84	2

10. DETAIL OF THE PRODUCT AS PER BMR:

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	139.7 mg,	<i>8</i> પુ	· 2
2.	Colour of Tablet	White colour	84	Q-
3.	Quantity (Net Qty.in Kg)	88.310	84	3
4.	Number of Containers	04	By	2

	Prepared by:	Checke	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Ealaluly	P.W. Do	o hust
Date	2010412020	21/04/2020	a storting	ON THE STATE OF STATE

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CAL DELANGE	Factory: R.S.	PRIMUS LIFE BIO No. 4/3, Plot No.33, K illianur Commune, Puc	urumbapet Industrial Estate,	Page 9 of 24
SAI PRIMUS LIFE BIOTECH PVT LTD	BATCH PA	BATCH PACKING RECORD Product Code:		Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5	ma	BPR. No.: BPR/T/107-0	0 Batch No.: GF200502
X Todate	Amioperiu Sing/S	illig	Customer:	Generic Health Care Pvt. Ltd
Balance I . Verify the semi-f	D. No.: PD IRA	re starting the packing		DUCT: R and record the details in below
Product Name		Mfg. Exp. Date	Qty. recd. For No. o	f Containers taken for packing

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Amloperin	G1P200502	02/3000	04/2013	23.310. Kg Equivalent to C94349. Nos.	From Container No. 0 To Container No. 04 Total No. of Containers taken 64
Checked by Packi	ng (Sign. /Date)	: (Sy.	27 105/2020	Verified By IPQA	(Sign. /Date): Silos 2000

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	17.480	Gopal	(8)	11			
2	17.460	Gopal	9	12			
-3	29 1000	G1 D Pal	B-	13	(1)	15 1 - A 4.2 ji l	- PTC
4	28,600	Gopal	(g)	14			R C S C S S S S S S S S S S S S S S S S
5	1			15			
6	The state of the s		region _ex	16		J. R.	
7				17			
8		\ .	357 4.	18		5600 U V	
9		3		19		A STATE OF THE STA	
10				20		A CONTRACTOR OF THE PARTY OF TH	784280°

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C N	Ti	me	Container	Consumed	0.31	Tir	ne	Container	Consumed
S. No	From	To	No.	by	S. No	From	To	No.	by
11.5	13:40	16:30	01	Mani'	11 70				
2	16:35	19:00	02	Hom'	12				4 44
3	071.30	11:10	03	Mani	13		1100 California		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
4	11/15	1A:05	04	Mam'	14				
5	1				15	Alexander Control		A SHEET A	
6	/	143	- Na distant	i i i i i i i i i i i i i i i i i i i	16		12	A District Control of the	
7	(Company to set)		Lee' X		17				
8	Constitution (Constitution)				18			1	
9	- Charatan A	1.1	2	34.33.1	19	10 - 1 7 - m - m - m	84, 1	#	105
10	that he to	3- 12		(SH 18/05)	20		e): (\$) 02 To		1 (3 g)

	Prepared by:	Checke	d by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ko	Zalalun	oralled. H.T	a ton
Date	20/04/202	a allow lacas	22/6 1710	NITTO OLI ETT
Date	20104/202	0 21/04/2020	22/11/10	ONTROLLECT

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: A08 Batch Size: 6,00,000 Tablets Product Amloperin 5mg/5mg BPR. No.: BPR/T/107-00 Batch No.: 4 Fdou 502 Customer: Generic Health Care Pvt. Ltd.

14. OVERPRINTING OF PRIMARY PACKAGING MATERIALS:

Initial checks of Overprinting Details

Overprinting Details	Overprinted Text	Printed AL. Foil (OK/ not OK)		
Code No.:	PON/DRUGS/19 13 4323	ρk		
Batch No.:	G1200502.	O.K.		
Mfg. Date:	05/2020	OIL_		
Exp. Date:	0412023	OL		
Pack size (3 x 10's)- Carton	NA HARIAN	CALL MANAGER AND THE COLUMN		
Other instructions if any	NA	NA ,		
Initiated by	Mam'	Hani		
Checked by Packing (Sign. & Date)	८०० (२०१००)	8427 105 2020		
Verified by IPQA (Sign. & Date)	\$ 25/05/2020	(D)=105/2020		

15. SPECIMEN OF PRINTED FOIL:

S. No. Date		Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
(b)	27/05/2020	01	Man'27/05/2020	8427/05/2020	8 5 2020
02	28/05/2020	02	Man' 23/05/200	84 25/2020	252/05/2000
1 7 7 1 1					Sy 25

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

		Primary	packing	Seconda	ry packing	Checked by
Sr. No.	Date/Shift	Started at	Completed at	Started at	Completed at	(Packing) Sign. & Date
01	29/05/2020 6	13:40	11:00	13:45	19105	Sof 21/05/201
02	28/05/2020 G	07! 30	17:05	P7137	14:10	8428/05/202
			<u> </u>	12 g/s v ₁₋₁₀ , d		
1		allow atoms and mile the	**************************************			84,38 05 16

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
Transary packing Secondary Lacking	At start of the batch, every one hour	checks by IPQA per batch.

	Prepared by:	Check	Checked by:				
Dept.	Production	Production	Quality Assurance	Head Quality Assurance			
Sign.	L.Ko	Balany	P.H. John War	0 knot 200)			
Date	20/04/2020	21/04/2020	22	X			
1 11 11 11 11 11	Constituting of	112000	TINCO	NTROLLE			

SAI PRIMUS LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD

Product Code: A08

Customer:

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: GF266502

Generic Health Care Pvt. Ltd.

18. ALU ALU PACKII	NG MACHINE PARAMET	ERS:	Date/Shift. 27/05/2022. G. Time: 13.14.a.			
Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date		
Change Parts Details	BAMBER	. ble	4-1-24/05/200	-4-micsi was		
Sealing Temperature	(160 °C - 200°C) To be established	198'	5427/05/202	Q27/05/202		
Leak test to be performed on Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	ok	8427/05/22	24/05/2020		
Machine Speed	To be established	21	Strictor	Det 105 12020		

Date/ Shift		24	1051	212 24	13	27/05/2020 General				1	28	1051	2000	Cien	nero	x	
Machine Op	erator Name		ani	~ 76	14	ene	~1				- Alexand	lam	Mar.	de o			
Time of insp	pection	3:45	14.15	MAS	15.745	16:20	16120	17:10	18:10	18:40	o7:30	01.55	od: Ac	04.30	Cai. re	10,30	11:35
Sealing Tem (To be estab		198'L	20	190'c	(-vs.)	4 THE R		199'L				1950		E 25	00	199'c	
Leak test on (Qty.:	Alu Alu strips*	οŁ	olc	ove	OK	Ole	010	OK	оК	ماد	cx	0 K	οk	OV	e i-/	OK.	0/د
Knurling/Se	ealing	ok	ok	Ove	OL	ole	ص الا	OL	OK	OK	OL.	ок	OL	61c	دانــ	.ok	الم
Pocket Form	nation	OL	ele	OK	OL	c le	011	OL	nx	OK	ok	nΥ	OL	OK	06-	OL	ok
Horizontal c	cutting	OL	0 P	OL	014	و له	OK	ok.	026	OK	OK	976	OK	25	ole	Ok	ok
Vertical cutt	ting	ملا	die	ok	ok	04	OK	OK	ox	Ole	yo	616	OL	0/2	06-	Ok	010
Quality of C	over printing	OL	di	OK	OK	داف	OK	ok	01	ok	CL	0.X	OŁ	. Ok	ole	0k;	ove
Code No.:	PON/DRUGS/ 19 13 4323	ok	ole	OK	OL	ole	6k	ole	9×	dŁ	OL	016	ok	OVL	01	OL.	ole
B. No.:	GF200502	ok	210	ەلد	OK	0k-	ok	Ole	つみ	OIL	ole	04	OŁ	ok	ر ان	OK	016
Mfg. Date	05/20%	Ok	ole	OL	ok	10 kg-	OŁ	ok	оχ	OK	OK	016	OK	ەلا	ا نان	ok_	o\c
Exp. Date	04/2023	d٤	No	OK	OL	el	616	OK	ОН	CK	ok_	016	OK	Ole	ه لا	ok	ok
Machine Sp To be establ		24	24	24	24	28	28	28	23	98	26	26	28	28	30	26	29
Checked by	(Packing)	84	- Tr	Qu	CS4	NA	8,4	Sij	NA	9	84	. NA	Sy	८५	MA	Sy	9
Checked by	(IPQA)	9.4	0			2		Silly mys	0			B.			9	,T _a '	

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.

34	Prepared by:	Checke	ed by:	Approved By:		
Dept. Production		Production	Quality Assurance	Head Quality Assurance		
Sign.	L.Ka-	Balluly	P. N. Job.	0 met "		
Date	20/01/20 20,	21/04/2020	22/04/2020	1.150 V		
HAAC	TED ANDWITCH!		FINO	OMEDOLLER		
. 1911			UNC	UNIKULLED OUR!		

CAL DELALIS	SAI PRIMUS LIFE BIOTE Factory: R.S. No. 4/3, Plot No.33, Kuru Villianur Commune, Puduc	ımbapet Industrial Estate,	Page 12 of 24		
SAI PRIMUS	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets		
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.: GF20502		
	7tmoperm Sing/Sing	Customer:	Generic Health Care Pvt. Ltd.		

Date/ Shift		28/	05/2	020	Cre	ner	q l				7 - L - S - J A - J /						
Machine Op	erator Name	Ma	m'		17/15	L.7/1.5	HI.T.	H.7/	s			. A.					
Time of insp	pection	11:45	12:35	13'25	96		-3	in the second									* *
Sealing Tem (To be estab	perature	1990	ally:	1992		4 8	219.5	n deswern	\								
Leak test on (Qty.:	Alu Alu strips*	06-	OL	or	014	014	ole-	01-	u -		·						
Knurling /Se	ealing	ou	OLL	ok	6le	OK	ole	O.C.	(= 74, 1)	14)	100	781	W.T.	17/3	X		
Pocket Form	nation	ou	ok	olc	ole	niL	OK	ol_		Här			-total to	3379			
Horizontal c	utting	06	OK	حالا	0/4	:010	ا ه	οt_	Tager .			10	The p	*77			
Vertical cutt	ing	014	OŁ	oc	06_	ok	ok	٥١٥			10						
Quality of O	over printing	0k-	OL	OE	OK	ole	0ائ	0اد_	11=0								
Code No.:	PON/DRUGS/ 19 13 4323	0b-	ok.	or	OL	OK	ال ال	ok_					MA	Vά			4
B. No.:	GF200502	ou	OK	or	Ole	ok	ok	داد					20-14 17				
Mfg. Date	01/2020	06-	Ole	OK	.ob_	OK	0 k_	<i>ا</i> ور				J. T.					
Exp. Date	04/2023	ck	OK	0,6	ole	010	ble	ok				enge kir	100	The state of			
Machine Sp To be establ		30	29	29	10	35		35				1			1		, , , , , , , , , , , , , , , , , , ,
Checked by	(Packing)	MA	84	84	NA	LIA	NA	NÁ				Ya	£ 4	6			
Checked by	(IPQA)	0			0	@	-02	Q	201			l di		74	2 25 7 104 A 2 25 7 C 2 25 25 2 26 27	भूज	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.

Par E	Prepared by:	Checke	ed by:	Approved By:
Dept.	Production	Production _	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	3alung	P.K. Col	O Love In
Date	20/12/4/2020	21/04/2020	22/04/2020	DOI Div

MASTED CODY INVENT

CAD DIVINIS	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Kur Villianur Commune, Pudue	umbapet Industrial Estate,	Page 13 of 24
SAI PRIMUS	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.: GFLOUS OL
	Transporting Single Sing	Contamo	C TY III C D TY

19.2 M	ACHINE IN-PR	OCE	SS CC	ONTRO	DL:									-44		
Date/ Shift		/					n diamen			Year	r Lydel		30	160	rivalo en	
Machine Ope	rator Name	/	\										le. 1	1 1		
Time of inspe	ection					Lyan		ns , 13							7	146
Sealing Temp (To be establ	perature ished)				- un							p. Server				
Leak test on A	Alu Alu strips*						*							e R		
Knurling /Sea	aling				1	Tung.				725		_ Hf				
Pocket Forma	ation		ex est		1					1946		langer of				
Horizontal cu	ıtting				2			4					· FeI			
Vertical cutti	ng					ile (735	1000				温聚	11/2	
Quality of Ov	er printing				1		/									
Code No.:	PON/DRUGS/ 19 13 4323												-			
B. No.:	(1) (1) (2) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4		(feet sel)		XI ZZ	14						142-1				
Mfg. Date								1								
Exp. Date	i a Vicini								File							
Machine Spe To be establis	ed shed				- 0x0 - 421		70.5				/					
Checked by	(Packing)						line.	ji.				1				1209
Checked by	(IPQA)			Life of the			10020		7		A Mary			.5	4x11	, <u> </u>

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:	Checke	d by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	- L. Ko	Berklung	Py believe	O Met 1011
Date	20104/202071	21/04/2020	22/0-1	7
LMAS	IFE EMPAILS	AU I I I I I I I I I I I I I I I I I I I	TINICO	MTDOLLEY

CALD			Factory: R.S.	PRIMUS LII No. 4/3, Plot N Ilianur Commu	lo.33, Kur	umbapet Inc	lustrial Estate,		Page	14 of 24		
	RIMUS ECH PVT LTD		BATCH PA	CKING REC	ORD	Produc	t Code: A08		Batch Size: 6,00,000 Tablets			
Dro	duct	A	loperin 5mg/5			BPR. N	o.: BPR/T/10	7-00	Batch No.: GF20050L			
	duct	AIII	toperm smg/s	omg	Customer:					ric Health Ca		
20.	DEFOILI	VG (OF ALU ALU	STRIPS:								
Date	De-foiling started at		e-foiling mpleted at	Weight of De-foiled tablets		De-foiling	Done by			necked by/ e (Packing)	Verified by Date (QA)	
3/65/2020	13:10	i	3!24	2.200	Saran	ya, 8	ud hr.		84 28/05/2020		22 05 20	
	24.2	-				0						
	p)	-			List of the		- N-1		100	I = 20-14-10-10-15-1	- 0 -	
						—-₹	the same of the sa		- 1-31		18420	
- 19 E								,				
			Weight of ed Tablets	2.200	Checke	d By/Date	(Packing):		Ver	ified By / Date	e (IPQA): 2010	
20.1	INSPECT	ION	OF DE-FOIL	ED TABLET	S:		ore on America. Security					
Date	Inspect		Inspection	Inspection	The second second second second	ty of Good blets	Qty. of F Tab		l	Checked by/ Date	Verified by	
	started	at	completed a		Kgs	Nos	Kgs	Nos	1 5	(Packing).	Date (QA)	
18/ 29/	12 13 13	0	13:45	Sathya.	21150	15390	01050	35	1	84 13/05/20h	SEN 05 20	
				0		\$00 to 200 miles				A TO POSSO		
							3				- 1986/1412	
					1, 142, 113, 11	7 7 7					J 8473/05	
		- 1		Total	2.150	francisco de la	0.020				1 0426	
	antity of Ro		ed Tablets De		Checke	d By / Date 옵션 (25)	(Packing):	Ve	rified	By / Date (IP	QA):	

	Prepared by:	Check	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	Ealaluky	P. K. Od boro	" (me there)
Date	20/04/2020	2006/40/16-	> NOT TIME	ONTOOLET
BEART	THE MALLON FINAS	1217	UNC	UN PRULLED OVA!

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and Section .

3

		SAI PRIMUS LIFE I Factory: R.S. No. 4/3, Plot No.3 Villianur Commune,	3, Kuru	mbapet Industr	ial Estate,	Page 1:	5 of 24	
	A PRIMUS BIOTECH PVT LTD	BATCH PACKING RECOR	CD CD	Product Co	de: A08	Batch	Size: 6,00,00	0 Tablet:
	Product	Amloperin 5mg/5mg		BPR. No.: 1	3PR/T/107-00	Batch	No.: GFdoi	502
	7 Todalet	Atmoperin Sing/Sing		Customer:			c Health Car	
1.	LINE CI	LEARANCE CHECKS - SECONDAL Date/	RY PAC Shift 2.7	CKING:	uneral/	.28/05/	2020 Cor	i644 J
Prev	ious Product:		Batcl	h No.: GIR201	1020			
Sr.		· Calledate V. J		and our to		Obser	vation	
No.		Checks		Time	12:50	Alleria de la companya de la company	07:10	
	Check and ar	nsure that the area is visually clean and	Gran Gran	m manulana	Packing	IPQA	Packing	IPQA
1	product.	isure that the area is visually clean and	пее по	m previous	V	/	W	V
2	Check and er	nsure that waste bin is emptied out and	cleaned		レ	1/		/
3	Check the Pa product /Bato	llets area clean and free from any leftoch.	vers of p	orevious	· Wall	/		. ~
4	Check and er	nsure the Correct status board is written	1.		レ	/		/
5	cut into piece					1	1	/
6	machine.	nsure the previous batch details are dele			\cdot		1	
7	shipper label	nsure the Alu Alu strips, rejected Carton of previous product/batch are removed			W	/	~	/
. 8	Check and er	nsure the cleanliness of hatch for conve	yor belt				~	V
9	Check and er	nsure the cleanliness of conveyer belt w	vith colla	ateral block.	w.	/	V	1
10	Check and er	nsure the dispensed secondary packing	material		V	/	~	1
11	Check and en	nsure the cleanliness of documentation	table.	184 184	1	/	V	/
12	Check and er	nsure the Preventive maintenance recor	ds and I	og book.	1 V 3 4 4	113	V	1
Vote	: Tick mark (√) if Complies, (X) if does not comply a	nd (NA)	if not application	le.			
	ning Satisfacte king) Sign. /D	ory / N ot satisfacto ry# St 27/05/25	Clea (IPQ	ning Satisfacto A)Sign. /Date:	ry / Not-satis	factorý#	2.1 05 2020	× 1111
	arks: # In case n, re check the	the cleaning is not satisfactory / line is	not cert	ified then inves	tigate the caus	e of the fa	ilure and take	necessa

Set and operate Overprinting Machine.

Overprinting shall be in indelible ink.

Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	PDILOBIO04	PD/BALIO18	NA NA	PDISTRIOO1	PD/ BAYOZE	Secondary Packing Hall
Previous Product:	Amloppedi	smy/5 ma			A	
Batch No.:	G1P200501	0 0				
Cleaned by:	Sathyn					
Checked by Packin	1g: 84 271 05	- 1000	- 12 25 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 11 2 7 1			
Verified by IPQA:					Tar Services	

7.7	Prepared by:	Checke	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	Za a Dunin	P. N. De ior	a root is
Date	20104/2020	21/04/2020	220	1

SAI PRIMUS LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

Page 16 of 24

BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00
Customer:

Batch No.: GF20502

Generic Health Care Pvt. Ltd.

21.2 ENVIRONMENTAL CONDITIONS:

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

9.4		Date/Time: 2	7/05/2020	12:50	Date/Time: 2	7/05/2020	07:30
Shift: G. energ.).	n 4 / K 🗴	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	23'4	Set .	0	24'C	84	2

Secondary Packing Started Date/Time: 11/05/2012 13:45... Completed Date/Time: 28 05 2000 14:10

APPROVAL FOR SECONDARY PACKING:

Approved by IPQA Sing/Date: 2025

21.3 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 16 filled carton in a Shrink Sleeve.

Place 14 Shrink sleeves in each 5 ply shipper.

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

22. 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.:	GF2 00502	Ok	. الق
Mfg. Date:	05/2020	ok	, lok
Exp. Date:	04/2023	OV	yo
Pack size:	NA NA	(3 x 10's Tablets)	14 x 16 x 3 x 10's
Code No.:	PON/DRUGS/19 13 4323	OK	NA
Other instructions if any	NA	Na	MA
Initiated by Sign. & Date	Mam'	Mam*	Dhanalah h
Checked by Packing Sign. & Date	Rang 26/05/2420	Dange 26/05/202	8427105/2020
Verified by IPQA Sign. & Date	Q26 05 /2 02.0	8 26 0x 12022	Q2+105-12020

22.1 Carton Overprinting Specimen:

S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
	26/05/2020	0)	Damya 26/05/202	6 20 c5 200
, 02	27/05/2020	01	5 (84/27/05/2020)	(22105 2000
5 100	7.01	9 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	The second second is an in	By role.
		1.		1 a or or out to a

Note - Attach specimen copy of over printed carton

	Prepared by:	Check	ed by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	Balaludy	P.M. balings	O. Must son M
Date	2010412020	21/04/2020	22/04/	
BAACT	TOPANALIM	M. L. Committee of the		CONTROLL

23. CARTON WEIGHT LIMIT SETTING: Date/Shift. 2.7 2.62 Time: . 3 5 Weight of ten individual empty cartons are given below: 1. 5.8 3. 5.7 5. 5.9 7. 5.8 9. 5	
Product Amloperin Smg/Smg	
Customer: Generic Health Care F	Tablets
Customer: Generic Health Care F	502
S. No. Date Shipper Label Specimen Checked by Packing (Sign & Date) (Sign & Date) 27 25 25 25 25 25 25 25	e Pvt. Ltd.
District District No. Packing (Sign & Date) Symbol Date) O	
23. CARTON WEIGHT LIMIT SETTING: Date/Shift.A:7 esc 2x22Time:. 3:,5:2 Weight of ten individual empty cartons are given below: 5.8 3.5.7 5.5.9 7.5.8 9.5. C. 4 5.8 6.5.8 8.5.9 10.5. Total weight of ten empty carton (A) = Total weight of ten empty carton /10=5.77 Average weight of an empty carton (A) = Total weight of ten empty carton /10=5.77 Weight of ten individual Alu Alu strips are given below: 2.5 3.2 6 5.2.6 7.2.5 9.2.6 Avg. Weight of a Alu Alu strips = 2x-8 Avg. Weight of a Alu Alu strips = 2x-8 Avg. Weight of a Alu Alu strip (B): total weight of ten Alu Alu strip/10= 2.58 eight of ten individual Leaflets are given below: 3.2 3.2 4 3.4 5.3 5.3.2 7.3.4 9.3.2 Total weight of ten Leaflets = 22.7 Avg. Weight of a Leaflets = 22.7 Avg. Weight of a Leaflets = 22.7 Avg. Weight of ten Eaflets = 22.7 Avg. Weight of ten Eaflets = 22.7 Avg. Weight of ten Eaflets = 32.7 Average weight of one empty Carton (A): 5.77 Weight of ten filled Alu Alu strip: 25.9 Average weight of one empty Carton (A): 5.77 Weight of ten Eaflets: 32.7 Average weight of one Empty Carton (A): 5.77 Average weight of one Empty Carton (A): 5.77 Checked by Packing/Date: 32.7 Weight of one filled Carton C = (A+3B+C) 16.73 Checked by Packing/Date: 32.8 23.2 SAMPLE DRAWN RECORD: Sr. No. Stage of Sample collection Qty. of Sample Collected by (Sign. /Date) 1 Control Sample (Middle) 3.2.32 10.2 4 Stability Sample Alu Alu Stability Sample Alu Alu Stability Sample Alu Fill 10x.3 × 10.2 Other Sample (Middle) 3.2.32 10.32	
23. CARTON WEIGHT LIMIT SETTING: Date/Shift.27/less 2.62Time:.135.2 Weight of ten individual empty cartons are given below:	
23. CARTON WEIGHT LIMIT SETTING: Date/Shift. 27 25 26 25 26 25 25 25 25	3427105
Total weight of ten empty cartons = 5 7 · 7 Average weight of an empty carton (A) = Total weight of ten empty carton /10 = 5 · 7 7 Average weight of an empty carton (A) = Total weight of ten empty carton /10 = 5 · 7 7 Weight of ten individual Alu Alu strips are given below: 2 · 5 3. 2 · 6 5. 2 · 6 7. 2 · 5 9. 2 · 6 Avg. Weight of ten Alu Alu strips = 25 · 8 Avg. Weight of a Alu Alu strips (B): total weight of ten Alu Alu strip/10 = 2 · 5 8 eight of ten individual Leaflets are given below: 3 · 2 3. 3 · 3 5. 3 · 2 7. 3 · 4 9. 3 · 2 Total weight of ten Leaflets = 32 · 7 Average weight of an empty Carton (A): 5 · 7 · 7 Average weight of one empty Carton (A): 5 · 7 · 7 Average weight of one empty Carton (A): 5 · 7 · 7 Average weight of one filled Alu Alu strip (B): 2 · 5 Weight of ten Eaflets: 32 · 7 Average weight of one Eaflet (C): 3 · 27 Weight of ten Eaflets: 32 · 7 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Leaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Weight of one filled Carton C = (A+3B+C) 16 · 73 Checked by Packing/Date: 32 · 7 Average weight of one Leaflet (C): 3 · 27 Checked by Packing/Date: 32 · 7 Average weight of one Eaflet (C): 3 · 27 Checked by Packing/Date: 32 · 7 Average weight of one Eaflet (C): 3 · 27 Checked by Packing/Date: 32 · 7 Average weight of one Eaflet (C): 3 · 27 Checked by Packing/Date: 32 · 7 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average weight of one Eaflet (C): 3 · 27 Average	
S.	7
Total weight of ten empty cartons = $5.7.7$ Average weight of an empty carton (A) = Total weight of ten empty carton /10= 5.77 Weight of ten individual Alu Alu strips are given below: 2.5 3. 2.6 5. 2.4 7. 2.5 9. 2.4 2.4 4 2.6 6. 2.6 8. 2.6 10. 2. Total weight of ten Alu Alu strips = 25.8 Avg. Weight of a Alu Alu strip (B): total weight of ten Alu Alu strip/10= 2.58 eight of ten individual Leaflets are given below: 3.2 3. 3.3 5. 3.2 7. 3.4 9. 3.2 Total weight of ten Leaflets = 22.7 Avg. Weight of a Leaflet (C): total weight of ten Leaflets/10= 3.27 23.1 WEIGHT CHECKS ON CARTON: Weight of ten empty carton: $5.5.7.7$ Average weight of one empty Carton (A): $5.7.7$ Average weight of one filled Alu Alu strip: 25.9 Average weight of one Eaflet (C): 3.27 Weight of ten Leaflets: 32.7 Average weight of one Eaflet (C): 3.27 Weight of one filled Carton C = (A+3B+C) $1.6.73$ Checked by Packing/Date: $3.2.7$ Checked by P	5.7
Average weight of an empty carton (A) = Total weight of ten empty carton /10= 5.77 Weight of ten individual Alu Alu strips are given below: 2 5 3. 2 6 5. 2 6 8. 2 8. 2 8. 10. 2 Total weight of ten Alu Alu strips = 25 8 Avg. Weight of a Alu Alu strip (B): total weight of ten Alu Alu strip/10= 2 58 eight of ten individual Leaflets are given below: 3 2 3 5. 3 2 7. 3 4 9. 3 2 Total weight of ten Leaflets = 32 7 Avg. Weight of a Leaflet (C): total weight of ten Leaflets/10= 3 27 Avg. Weight of a Leaflet (C): total weight of ten Leaflets/10= 3 27 23.1 WEIGHT CHECKS ON CARTON: Weight of ten individual Leaflet (C): total weight of ten Leaflets/10= 3 27 Veight of ten empty Carton: 55 57.7 Average weight of one empty Carton (A): 5.77 Weight of ten Eaflets: 32.7 Average weight of one leaflet (C): 3.27 Weight of ten Leaflets: 32.7 Average weight of one Leaflet (C): 3.27 Weight of ten Leaflets: 32.7 Average weight of one Leaflet (C): 3.27 Weight of ten Leaflets: 32.7 Average weight of one Leaflet (C): 3.27 Weight of ten Leaflets: 32.7 Average weight of one Leaflet (C): 3.27 Weight of ten Leaflets: 32.7 Average weight of one Leaflet (C): 3.27 Weight of one filled Carton C = (A+3B+C) 16.73 Checked by Packing/Date: Qc 31 05 2020 Verified by IPQA/Date: Average weight of one Leaflet (C): 3.27 23.2 SAMPLE DRAWN RECORD: Str. No. Stage of Sample collection Qty. of Sample Collected by (Sign. /Date 22.20 Control Sample (Initial) 3. 3. 3. 3. 3. 3. 3. 3. 3. 3. 3. 3. 3.	
2 '5 3 2 '6 5 2 '6 7 2 5 9 2 '6 2 ' 4 4 2 6 6 2 6 8 2 2 6 10 Fotal weight of ten Alu Alu strips = 25 '8 Avg. Weight of a Alu Alu strip (B): total weight of ten Alu Alu strip/10= 2 '5 8 eight of ten individual Leaslets are given below: 3 2 3 3 3 5 5 3 2 7 3 4 9 3 2 2 Fotal weight of ten Leaslets = 22 7 Avg. Weight of a Leaslet (C): total weight of ten Leaslets/10= 3 2 2 23.1 WEIGHT CHECKS ON CARTON: Weight of ten empty Carton: 55 57 7 Average weight of one empty Carton (A): 5 7 7 Weight of ten filled Alu Alu strip: 25 9 Average weight of one Easlet (C): 3 2 7 Weight of ten Leaslets: 32 7 Average weight of one Leaslet (C): 3 2 7 Weight of ten Leaslets: 32 7 Average weight of one Leaslet (C): 3 2 7 Weight of one filled Carton C = (A+3B+C) 16 73 Checked by Packing/Date: 20 2 2 1 05 2000 23.2 SAMPLE DRAWN RECORD: 67. No. Stage of Sample collection Qty. of Sample Collected by (Sign. /Date 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
2 '5 3 2 '6 5 2 '6 7 2 5 9 2 '6 2 ' 4 4 2 '6 6 2 '6 8 2 '8 10 Fotal weight of ten Alu Alu strips = 25 '8 Avg. Weight of a Alu Alu strip (B): total weight of ten Alu Alu strip/10= 2 '58 eight of ten individual Leaslets are given below: 3 ' 2 3 3 ' 3 5 3 \ 2 7 3 \ 4 9 3 \ 2 Fotal weight of ten Leaslets = 20 ' 7 Avg. Weight of a Leaslet (C): total weight of ten Leaslets/10= 3 \ 24 23.1 WEIGHT CHECKS ON CARTON: Weight of ten empty Carton: 55 5 ' 7 ' 7 Average weight of one empty Carton (A): 5 ' 7 ' 7 Weight of ten filled Alu Alu strip: 25 \ 9 Average weight of one Leaslet (C): 3 \ 2 7 Weight of ten Leaslets: 32 \ 7 Average weight of one Leaslet (C): 3 \ 2 7 Weight of one filled Carton C = (A+3B+C) 16 \ 7 3 Checked by Packing/Date: 20 2 1 05 2000 23.2 SAMPLE DRAWN RECORD: So. No. Stage of Sample collection Qty. of Sample Collected by (Sign. /Date 1) Control Sample (Initial) 2 \ 2 \ 2 \ 2 \ 10 \ 2 \ 2 \ 2 \ 2 \ 2 \ 2 \ 2 \ 2 \ 2 \	
Fotal weight of ten Alu Alu strips = 25.8 Avg. Weight of a Alu Alu strip (B): total weight of ten Alu Alu strip/10= 2.58 Eight of ten individual Leaflets are given below: 3.2 3.3 4.3 5.3.2 7.3.4 9.3.2 Fotal weight of ten individual Leaflets are given below: 3.2 4.3 5.3.2 7.3.4 9.3.2 10.3.2 Avg. Weight of ten Leaflets = 32.7 Avg. Weight of a Leaflet (C): total weight of ten Leaflets/10= 3.24 23.1 WEIGHT CHECKS ON CARTON: Weight of ten empty Carton: 55.5 Weight of ten filled Alu Alu strip: 25.9 Weight of ten Leaflets: 32.7 Average weight of one empty Carton (A): 5.77 Average weight of one filled Alu Alu strip (B): 2.5 Weight of ten Leaflets: 32.7 Weight of one filled Carton C = (A+3B+C) 16.73 Checked by Packing/Date: 3.1 5.3 Checked by Packing/Date: 3.1 5.3 Control Sample collection Qty. of Sample Collected by (Sign. /Date 1) 2.3.2 Control Sample (Middle) 3.23×10.5 3.3 Control Sample (Middle) 3.23×10.5 3.3 Control Sample (Final) 1.2 × 10.5 4.5 Stability Sample 1.4 × 2.6 × 10.5 Checked Sample (Final) 1.4 × 2.6 × 10.5 Average weight of one empty Carton (A): 5.77 Average weight of one empty Carton (A): 5.77 Average weight of one filled Alu Alu strip (B): 2.5 Average weight of one filled Alu Alu strip (B): 2.5 Average weight of one Empty Carton (A): 5.77 Average weight of one	Alleman Alleman A
Total weight of ten Alu Alu strips = 25.8 Avg. Weight of a Alu Alu strip (B): total weight of ten Alu Alu strip/10= 2.58 sight of ten individual Leaflets are given below: 3.2 3.3 5.3.2 7.3.4 9.3.2 Total weight of ten Leaflets = 32.7 Avg. Weight of ten Leaflets = 32.7 Avg. Weight of a Leaflet (C): total weight of ten Leaflets/10= 3.27 23.1 WEIGHT CHECKS ON CARTON: //eight of ten empty Carton: \$\sum_{S\cup S} \cdot 5.7.7 Average weight of one empty Carton (A): \$\sum_{S\cup 7} \cdot 7.7 //eight of ten filled Alu Alu strip: 25.8 Average weight of one filled Alu Alu strip (B): 2.5.7 //eight of ten Leaflets: 32.7 Average weight of one Leaflet (C): 3.27 //eight of one filled Carton C = (A+3B+C)	
Average weight of an Alu Alu strip (B): total weight of ten Alu Alu strip/10= $\frac{2.58}{8}$ and $\frac{3.2}{3.2}$ and $\frac{3.3}{3.2}$ and 3.3	· .
eight of ten individual Leaflets are given below: 3.2 3.2 4.3.4 5.3.2 7.3.4 9.3.2 Fotal weight of ten Leaflets = 32.7 Avg. Weight of a Leaflet (C): total weight of ten Leaflets/10= 3.27 23.1 WEIGHT CHECKS ON CARTON: Weight of ten empty Carton: Ser. 57.7 Average weight of one empty Carton (A): Serial to ften filled Alu Alu strip: 25.8 Average weight of one filled Alu Alu strip (B): 2.5 Weight of ten Leaflets: 32.7 Average weight of one Leaflet (C): 3.27 Average weight of one Leaflet (C): 3.27 Limit: D = C ± 1 % = (To be established) 16.61 - 16.94 / Checked by Packing/Date: 23.2 SAMPLE DRAWN RECORD: Ser. No. Stage of Sample collection Qty. of Sample Control Sample (Initial) 2 Control Sample (Middle) 3 X 3 X 10 2 Zalos 2020 4 Stability Sample 5 Other Sample 1 X 2 X 10 2 Zalos 2020 5 Other Sample	*
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LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

Page 18 of 24

BATCH PACKING RECORD

Product Code: A08

BPR. No.: BPR/T/107-00

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

Batch No .: GFdoor 62 Generic Health Care Pvt. Ltd. Customer:

Date/ Shift	Y PACKING IN-PRO	/1	n ea	-	21				105/5			128/0	15/20	20	
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Carton Overprinting	Legible and readable	OL	de	OL	OK	OK	ok		ole	06-	ols	26-	حاء	ت لا	ore
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*Temperature to be mentioned.

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*Temperature to be mentioned.

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SAI PRIMUS LIFE BIOTECH PVT LTD			
LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOT Factory: R.S. No. 4/3, Plot No.33, Ku Villianur Commune, Pudue	Page 19 of 24	
	BATCH PACKING RECORD	Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00	Batch No.: GFdoos 02
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SECONDARY PACKING IN-PROCESS CHECKS: (Please keep √ mark if found "Ok") 24.3

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Production

Dept.

Sign.

Production

Quality Assurance

Head Quality Assurance

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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.

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

BPR. No.: BPR/T/107-00

Batch No.: GF200502

Customer:

Generic Health Care Pvt. Ltd.

27	DACTIVATO	N. W. A. PRINTER Y A. Y.	RECONCILIATION:	
1.1	PACKING	VIATERIAL	PHOTONOLI I ATTIONS	10

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)
À	Quantity received for the batch	41.500	105.010	20 100	20400	NA	90	1008	0118
В	Additional material received for the batch	NA	NA	NA	NA	МЧ	AIA	NA	NA.
С	Total material received (A+B)	41.500	105.019	20400	20400	NA	90	1.008	13.
D	Quantity packed	15.160	56.673	19740	19740	NA	70	0.958	18
Е	Quantity rejected (Online) & Destroyed	8.066	16.016	206206		MA.	NA	0.018	NA
F	Quantity Returned	18.128	32.04	440	647	NA	ALA	3.032	A1/4;
G	Sample affixed on BPR	0.002	NA	02	07 01	AM	NA	NA.	NA
H	QC samples	0.003	0 .011	01	04	MA	NA	NA	NA
I	Other samples (If any)	0.005	0.022	08	03	NA	NA	NA	NA .
Ĵ	Total accountable Quantity (D+ E+F+G+H+I)	11.364	104.766	-0-	-0-	NA	LI WA	NA.	NA
K	Variation (C – J)	0-196	0:244	-0-	-0-	NA	NA	NA	NA
Ĺ	%Variation (K x 100)/C	0.32 /	0.23.	-0-	-0-	MA	NA	NA	NA.
M	Acceptable limit	±2%	<u>+</u> 2.%	±2%	±2%	±2%			

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

Foil (Kg)

28. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. Printed Alu. Base Foil

(Kg)

Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
NA	NA	4.008	NA -
	The state of the s	to an add the free particular better the particular particular and the particular partic	the comment of the co

NIA NA Material returned by packing NA MA NX NA. Sign./Date Verified By IPQA Sign./Date AM Ma NIG MA Material received by Store NA NA Sign./Date

Leaflets

(Nos)

Cartons

(Nos)

DESTRUCTION OF REJECTED/UNUSED PRINTED PACKING MATERIALS AND STEREOS: 29.

Date	Stereos	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
28/05/2020	08	8.066	16.016	206 201	NA	NA	NA		いな、
	1	AT THE PART OF	11		NA-		VA		18
Total Qty. Destroyed	08	8.066	16.016	2007	NA	NA	NΔ		NA,
Destroyed by	0	20.00		L a		mg#.			

(Packing) Verified by (IPQA)

Material

Quantity Returned

Prepared by:		Check	Checked by:				
Dept.	Production	Production (Quality Assurance	Head Quality Assurance			
Sign.	L.Ka	Baleny	r. W. Golfon	C Kmy 0			
Date	20/04/202	0 21/04/2020	2204	X			

	0	Factor	y: R.S. No. 4	MUS LIFE BI /3, Plot No.33, ir Commune, P	Kurumbap	et Industrial Esta	te,	Page	e 23 of 24	
190	CH PVT LTD	BAT	CH PACKII	NG RECORD	Pr	oduct Code: A0	8	Bat	ch Size: 6,00	0,000 Tablets
Pro	duct	Amlonerii	n 5mg/5mg		В	PR. No.: BPR/T/	107-00	7-00 Batch No.: GFd00502		
		open			Cı	ıstomer:		Generic Health Care Pvt. Ltd.		
30.	The state of the s	RECONCIL	ATION:							
A	Batch Siz									6,00,000 Nos
В	Quantity	received for	packing							596349
С	Total qua	ntity packed							Vest de subtre	592200
D	Control sa	amples	1000		وبالمجال والمال					200
Е	Analytica	l Samples								20
F	In process	s samples							9	120
G	Others sa	mples if any	(Stability, Re	egulatory Samp	oles, etc.)		15 17 ¹		The section	30
Н	Packing I	Loss = B - (0)	C + D + E + F	F+G)					Č	2879
I	4 4 7	north-real-state and a second second	D + E + F+0							65 30
J	Packing y	vield % (C +	D + E + F+C	G) / B X 100 (Y	ield Limit	% NL7 95%)*		200	CONTRACTOR OF THE STATE OF THE	99.51%.
K	Batch Yie	eld % (C + I) + E + F +G)) / A X 100 (Y	ield Limit %	6. MLT 977)*			Tudosto, a serb. Tudosto entradapa	98.914.
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	FGTN	Sales	Pack Size	Units in a	No. of Shippers	Transferred Quantity	Raised Packi		Checked by IPQA	Received by Stores
Date	No.	Saics		shipper		, ,	racki	ng	by II QA	Stores
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SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Page 24 of 24 Villianur Commune, Puducherry-605009. SAI PRIMUS BATCH PACKING RECORD Product Code: A08 Batch Size: 6,00,000 Tablets BPR. No.: BPR/T/107-00 Batch No.: G FLOUSOZ Product Amloperin 5mg/5mg Generic Health Care Pvt. Ltd. Customer:

34. BATCH RELEASED FOR DESPATCH:

Total quantity released: 592200

Head QA sign/ Date:

35. REVISION HISTORY

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/107-00	New Document	Nil

	Prepared by:	Checke	d by:	Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ks_	Salaluny	P. W. boli	2 hours
Date	20/04/202	0-21/04/2020	29-10412	7.