 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 1 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b> Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00		Batch No.: GF 200501
	Customer:		Generic Health Care Pvt. Ltd.

### BATCH PACKAGING RECORD COVER SHEET

PRODUCT NAME	: Amloperin 5mg/5mg
GENERIC NAME	: Amlodipine Besilate and Perindopril Erbumine Tablets
LABEL CLAIM	: Each uncoated tablet contains: Amlodipine Besilate BP 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	: 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)	: P. J. Deb 22/05/2020
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: J. P. 22/05/2020
MFG. DATE: 05/2020	EXP. DATE: 04/2023
ALLOTTED BY: QA SIGN/DATE: P. J. Deb 22/05/2020	COUNTER CHECKED BY: QA SIGN/DATE: J. P. 22/05/2020
QUANTITY RECEIVED FROM PRODUCTION	: 591150 Tablets
DATE OF COMMENCEMENT: 25/05/2020	DATE OF COMPLETION: 27/05/2020
QUANTITY	: 6,00,000 Tablets
RELEASED QUANTITY OF PACKED TABLETS	: 587790 Tablets
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	: J. P. 27/05/2020

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	J. P.	P. J. Deb	J. P.
Date	20/04/2020	21/04/2020	22/04/2020	27/04/2020

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SAI PRIMUS  
LIFE BIOTECH PVT LTD

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

Page 2 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.: G1F200501

Customer:

Generic Health Care Pvt. Ltd.

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Prepared by:

Checked by:

Approved By:

Dept.

Production

Production

Quality Assurance

Head Quality Assurance

Sign.

L. Ka

3a. [Signature]

P. H. [Signature]

J. [Signature]

Date

20/04/2020


21/04/2020

22/04/2020

22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 24
	<b>BATCH PACKING RECORD</b>	Product Code: A08 BPR. No.: BPR/T/107-00 Customer:	Batch Size: 6,00,000 Tablets Batch No.: GF200501 Generic Health Care Pvt. Ltd.
<b>Product</b>	Amloperin 5mg/5mg		

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.	<b>Dispensing</b>	NA
a)	Equipment clean tag and dispensing tag attached with batch record	Yes
b)	Packaging material is checked	Yes
5.	<b>Packing</b>	NA
a)	Rinse water analysis report attached with BPR	Yes
b)	Approved specimen of printed foil, show box and shipper label are attached	Yes
c)	Control / Stability / Finished product analysis samples are withdrawn	Yes
d)	Reconciliation of packing materials is done	Yes
e)	Tablet reconciliation is done	Yes
f)	In process checks parameters done at regular interval and recorded into BPR	Yes
6.	<b>Attachment</b>	NA
a)	Finished Goods Transfer Note	Yes
b)	Certificate of analysis of finished product is submitted	Yes
c)	Stereo Impression Form and Destruction Record	Yes
7.	Complete set of BPR Submitted	Yes

Checked By QA/Date: 22/04/2020

\*Mention total number of pages.

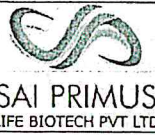
Remarks (If any) .....

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	3a. Lalitha	P. H. Reddy	S. Murthy
Date:	22/04/2020	22/04/2020	22/04/2020	

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	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 24
	<b>BATCH PACKING RECORD</b>		<b>Product Code: A08</b>
	<b>Product</b>		<b>Batch Size: 6,00,000 Tablets</b>
	<b>Amloperin 5mg/5mg</b>		<b>Batch No.: GF200501</b>
	<b>Customer:</b>		<b>Generic Health Care Pvt. Ltd.</b>


### 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	PPH/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/C001	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 <sup>2</sup>	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

<b>Prepared by:</b>		<b>Checked by:</b>		<b>Approved By:</b>
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	Saladur	P. H. Sub	
Date	20/04/2020	21/04/2020	22/04/2020	

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 5 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF200501 Generic Health Care Pvt. Ltd.

#### 4. DISPENSING LINE CLEARANCE CHECKS

Date: 25/05/2020 Time: 9:35

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

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

Equipment	Mobile Laminar Air Flow	Weighing Balance		Area
ID No.	ST/HAF/001	NA	NA	ST/BAL/011
Previous Product	Telnyl - 40			
B. No.	T130001E			
Cleaned by Sign/Date	Ranjith / 25/05/2020 / 14			
Checked by Store Sign/Date	S. S. / 25/05/2020			
Verified by IPQA Sign/Date	S. S. / 25/05/2020			


ENVIRONMENTAL CONDITIONS: Date: 25/05/2020 Time: 9:40	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	17/05/2020	25/05/2020
Differential Pressure across the booth Limit: 5 to 20 mm Water	11 mm	25/05/2020	25/05/2020

APPROVAL FOR DISPENSING BY IPQA: Sign: _____ Date: 25/05/2020
Dispensing start Time: 9:45 End Time: 10:05

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	3.4.2020	P. K. 22/04/2020	
Date	20/04/2020	21/04/2020		

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	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF200501 Generic Health Care Pvt. Ltd.

**5. DISPENSING RECORD OF PACKING MATERIALS:** Date: 25/05/2020 Shift: 4 Time: 9:45

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	11.090 25.790	PMG/00003 PMG/00005	01 02	M. Siva 25/05/2020	Q. Siva 25/05/2020
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	91.800	51.770 38.170	PMG/00008 PMG/00009	04 02	M. Siva 25/05/2020	Q. Siva 25/05/2020
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	20400	20400	PMG/00004	9	M. Siva 25/05/2020	Q. Siva 25/05/2020
Amloperin packing inserts	PPI/GH/I001	No	20400	20400	PMG/00007	04	M. Siva 25/05/2020	Q. Siva 25/05/2020
Shrink Sleeves (PVC)	PPS/GH/P001	No	1275				NA	Q. Siva 25/05/2020
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	90	88 88 2 *	PMG/00002 PMG/00178	09 01	M. Siva 25/05/2020	Q. Siva 25/05/2020
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	18	18	PMG/00010	04	M. Siva 25/05/2020	Q. Siva 25/05/2020
Strapping Role	PSR/CH/S001	Mtrs	250	1000	PMG/00001	01	M. Siva 25/05/2020	Q. Siva 25/05/2020
Shipper Label	NA	No	91				NA	Q. Siva 25/05/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	Sala Siva	P. S. Siva	S. Siva
Date	20/04/2020	21/04/2020	22/05/2020	22/05/2020


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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 8 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF 200501 Generic Health Care Pvt. Ltd.

**7. VERIFICATION OF DISPENSED PACKING MATERIALS:** Date 25/05/2020 Shift: G Time: 11:15

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 0000 3 PMG 1 0000 5	01 02	84	Q
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	PMG 1 0000 8 PMG 1 0000 8	04 02	84	Q
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	PMG 1 0000 4	09	84	Q
Amloperin packing inserts	PPI/GH/I001	No	PMG 1 00 00 7	04	84	Q
Shrink Sleeves (PVC)	PPS/GH/P001	No	NA	NA	NA	NA
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	PMG 1 0000 3	09	84	Q
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	PMG 1 000 10	04	84	Q
Strapping Role	PSP/GH/S001	Mtrs	PMG 1 0000 1	01	84	Q
Shipper Label	NA	No	NA	NA	NA	NA

**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. Mankar 23/05/2020	Mani 23/05/2020	Mani	84	Q 25/05/2020

**9. RECEIPT OF PRODUCT AND MATERIALS:** Date/Shift: 25/05/2020 G Time: 11:15

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

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

**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	Q
2.	Colour of Tablet	Hot off white colour	84	Q
3.	Quantity (Net Qty.in Kg)	82.500	84	Q
4.	Number of Containers	04	84	Q

20.08  
84  
25/05

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	R. Mankar	P. H. Babu	S. Anand
Date	20/04/2020	21/04/2020	22/04/2020	22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF 200501 Generic Health Care Pvt. Ltd.

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

Balance I.D. No.: PD/BAL/014

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

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Amloperin 5mg/5mg	GF 200501	05/2020	04/2023	<u>82.500</u> Kg Equivalent to <u>591150</u> Nos.	From Container No. <u>01</u> To Container No. <u>04</u> Total No. of Containers taken <u>04</u>
Checked by Packing (Sign. /Date): <u>Sy 25/05/2020</u>				Verified By IPQA (Sign. /Date): <u>Sy 25/05/2020</u>	

### 12. CONTAINER WEIGHT DETAILS:

Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA	Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA
1	23.480	Gopal	<u>Sy</u>	11			
2	28.440	Gopal	<u>Sy</u>	12			
3	20.320	Gopal	<u>Sy</u>	13			
4	20.460	Gopal	<u>Sy</u>	14			
5				15			
6				16			
7				17			
8				18			
9				19			
10				20			

### 13. CONTAINER CONSUMPTION DETAILS:


S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	16:20	18:00	01	Mam'	11				
2	09:40	13:40	02	Mam'	12				
3	13:45	18:00	03	Mam'	13				
4	07:35	12:00	04	Mam'	14				
5					15				
6					16				
7					17				
8					18				
9					19				
10					20				

Checked By Packing (Sign. /Date): Sy 25/05/2020 Verified by IPQA (Sign. /Date): Sy 25/05/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>S. S. S. S. S.</u>	<u>P. H. S. S.</u>	<u>S. S. S. S. S.</u>
Date	<u>20/04/2020</u>	<u>21/04/2020</u>	<u>22/04/2020</u>	<u>22/04/2020</u>

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF 200501 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.:	GF 200501	OK
Mfg. Date:	05/2020	OK
Exp. Date:	04/2023	OK
Pack size (3 x 10's)- Carton	NA	OK NA
Other instructions if any	NA	NA
Initiated by	Mami	Mami
Checked by Packing (Sign. & Date)	SY 25/05/2020	SY 25/05/2020
Verified by IPQA (Sign. & Date)	SY 25/05/2020	SY 25/05/2020

#### 15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	25/05/2020	01	Mami 25/05/2020	SY 25/05/2020	SY 25/05/2020
02	26/05/2020	02	Mami 26/05/2020	SY 26/05/2020	SY 26/05/2020
03	27/05/2020	01	Mami 27/05/2020	SY 27/05/2020	SY 27/05/2020

#### 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

Sr. No.	Date/Shift	Primary packing		Secondary packing		Checked by (Packing) Sign. & Date
		Started at	Completed at	Started at	Completed at	
01	25/05/2020 G	16:20	16:13:00	16:25	18:00	SY 25/05/2020
02	26/05/2020 G	09:40	18:00	09:45	19:05	SY 26/05/2020
03	27/05/2020 G	07:35	12:00	07:40	12:50	SY 27/05/2020

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


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

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	30/04/2020	P. H. 27/04/2020	
Date	20/04/2020	21/04/2020		

**UNCONTROLLED**



 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF 200501 Generic Health Care Pvt. Ltd.

18. **ALU ALU PACKING MACHINE PARAMETERS:** Date/Shift: 25/05/2020 G Time: 16:20

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	BPM GE 10	OK	84/25/05/2020	84/25/05/2020
Sealing Temperature	(160 °C - 200 °C) To be established	199 °C	84/25/05/2020	84/25/05/2020
Leak test to be performed on 04 Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	OK	84/25/05/2020	84/25/05/2020
Machine Speed	To be established	25	84/25/05/2020	84/25/05/2020

19. **MACHINE IN-PROCESS CONTROL:**

Date/ Shift	25/05/2020 General 26/05/2020 General																
Machine Operator Name	Mam																
Time of inspection	16:20	16:35	17:20	09:40	10:00	10:40	11:40	12:00	12:30	13:35	14:15	14:30	15:20	16:15	16:30	17:20	
Sealing Temperature (To be established)	198 °C	196 °C	199 °C	198 °C	197 °C	198 °C	198 °C	198 °C	199 °C	198 °C	199 °C	198 °C	199 °C	198 °C	199 °C	199 °C	
Leak test on Alu Alu strips* (Qty.: 04)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Knurling /Sealing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
B. No.: GF200501	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Mfg. Date 05/2020	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Exp. Date 04/2023	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Machine Speed To be established	24	25	25	24	25	24	25	25	25	24	24	24	28	24	24	28	
Checked by (Packing)	84	NA	84	84	NA	84	84	NA	84	84	NA	84	84	NA	84	84	
Checked by (IPQA)																	


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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka		P. N. Babu	
Date	20/04/2020	21/04/2020	22/04/2020	

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: G.F 200501 Generic Health Care Pvt. Ltd.

### 19.1 MACHINE IN-PROCESS CONTROL:


Date/ Shift	27/05/2020 General												
Machine Operator Name	Mami												
Time of inspection	07:35	08:50	08:35	09:40	09:50	10:40	11:25	11:35	11:40	11:50	11:55	12:00	
Sealing Temperature (To be established)	196°C	198°C	199°C	198°C	196°C	199°C	196°C	197°C	197°C	220°C	220°C		
Leak test on Alu Alu strips* (Qty.: 04)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Knurling /Sealing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
B. No.: G.F 200501	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Mfg. Date 05/2020	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Exp. Date 04/2023	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Machine Speed To be established	26	26	26	27	27	28	28	10	35	10	35		
Checked by (Packing)	84	144	54	84	NA	84	54	NA	NA	NA	NA		
Checked by (IPQA)													

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	32/04/2020	P.K. 22/04/2020	8/04/2020
Date	22/04/2020	22/04/2020	22/04/2020	22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF 200501 Generic Health Care Pvt. Ltd.

### 19.2 MACHINE IN-PROCESS CONTROL:

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

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	20/04/2020	21/04/2020	22/04/2020	22/04/2020

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

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### BATCH PACKING RECORD

Product Code: A08

**Batch Size: 6,00,000 Tablets**

## Product

**Amloperin 5mg/5mg**

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

Batch No.: GF 200501

Customer:

**Generic Health Care Pvt. Ltd.**

## 20. DEFOILING OF ALU ALU STRIPS:

Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	De-foiling Done by	Checked by/ Date (Packing)	Verified by Date (QA)
17/05/2020	11:10	11:35	0.989	Sivazanylini, Ponni.	Sy 27/05/2020	Sy 27/05/2020
<b>Total Weight of De-foiled Tablets</b>			0.989	<b>Checked By / Date (Packing):</b> Sy 27/05/2020		<b>Verified By / Date (IPQA):</b> Sy 27/05/2020

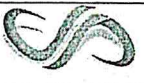
### 20.1 INSPECTION OF DE-FOILED TABLETS:

Date	Inspection started at	Inspection completed at	Inspection Done by	Quantity of Good tablets		Qty. of Rejected Tablets		Checked by/ Date (Packing).	Verified by Date (QA)
				Kgs	Nos	Kgs	Nos		
27/05/2020	11:35	11:45	Sathya	0.975	6902	0.014	99	Sg 27/05/20	Sg 27/05/20
				NA				Sg 27/05/2020	
Total				0.975	6902	0.014	99		
Total Quantity of Rejected Tablets Destroyed ...D: 04... Kgs ...9.9... Nos.				Checked By / Date (Packing): Sg 27/05/2020			Verified By / Date (IPQA): Sg 27/05/2020		

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	20/04/2020	21/04/2020	22/04/2020	22/04/2020

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	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: Gf 200501 Generic Health Care Pvt. Ltd.

21. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift .25/05/2020.....16:22.../...24/05/2020...G...09:20

Previous Product: TRANSNERV		Batch No.: T090003E				
Sr. No.	Checks	Time	Observation			
			16:22		09:22	
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	✓
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	✓
4	Check and ensure the Correct status board is written.		✓	✓	✓	✓
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	✓
6	Check and ensure the previous batch details are deleted from the inkjet machine.		✓	✓	✓	✓
7	Check and ensure the Alu Alu strips, rejected Carton, Shipper and 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.		✓	✓	✓	✓
12	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	✓

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

Cleaning Satisfactory / Not satisfactory# Scf 25/05/2020 Cleaning Satisfactory / Not satisfactory# Scf 25/05/2020  
 (Packing) Sign. /Date: (IPQA) Sign. /Date:

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

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.
3. Set and operate Overprinting Machine.
4. Overprinting shall be in indelible ink.
5. Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	RD/COB/004	PD/BAL/018	NA	PD/STR/001	PD/BAL/020	Secondary Packing Hall
Previous Product:	<u>TRANSNERV</u>					
Batch No.:	<u>T090003E</u>					
Cleaned by:	<u>Scf 25/05/2020</u>					
Checked by Packing:	<u>Scf 25/05/2020</u>					
Verified by IPQA:	<u>Scf 25/05/2020</u>					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ko</u>	<u>Scf 25/05/2020</u>	<u>P. H. 25/05/2020</u>	<u>Scf 25/05/2020</u>
Date.	<u>20/04/2020</u>	<u>21/04/2020</u>	<u>22/04/2020</u>	<u>22/04/2020</u>

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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

Batch No.: GF200501

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)

Shift:.....General.....		Date/Time: 25/05/2020 16:30			Date/Time: 26/05/2020 09:45		
		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	8	24°C	84	8

Secondary Packing Started Date/Time: 25/05/2020 16:25.. Completed Date/Time: 27/05/2020 12:00

### APPROVAL FOR SECONDARY PACKING:

Approved by IPQA Sing/Date:.....25/05/2020.....

### 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	OK
Mfg. Date:	05/2020	OK	OK
Exp. Date:	04/2023	OK	OK
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	NA
Initiated by Sign. & Date	Mani	Mani	Shameless
Checked by Packing Sign. & Date	23/05/2020	23/05/2020	23/05/2020
Verified by IPQA Sign. & Date	23/05/2020	23/05/2020	23/05/2020

### 22.1 Carton Overprinting Specimen:


S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
1	23/05/2020	1	23/05/2020	23/05/2020
		NA		

Note – Attach specimen copy of over printed carton

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	21/04/2020	22/04/2020	22/04/2020
Date	20/04/2020	21/04/2020	22/04/2020	22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF 200501 Generic Health Care Pvt. Ltd.

### 22.2 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	25/05/2020	01	84 25/05/2020	84 25/05/2020
		NA		84 24/05/2020

### 23. CARTON WEIGHT LIMIT SETTING: Date/Shift: 25/05/2020 G Time: 16.13.00

Weight of ten individual empty cartons are given below:

1. 5.8	3. 5.6	5. 5.7	7. 5.8	9. 5.7
2. 5.6	4. 5.8	6. 5.9	8. 5.7	10. 5.6

Total weight of ten empty cartons = 57.2

Average weight of an empty carton (A) = Total weight of ten empty carton / 10 = 5.72

Weight of ten individual Alu Alu strips are given below:

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

Total weight of ten Alu Alu strips = 23.4

Avg. Weight of a Alu Alu strip (B): total weight of ten Alu Alu strip / 10 = 2.34

Weight of ten individual Leaflets are given below:

1. 3.2	3. 3.3	5. 3.2	7. 3.3	9. 3.2
2. 3.3	4. 3.4	6. 3.2	8. 3.3	10. 3.2

Total weight of ten Leaflets = 32.6

Avg. Weight of a Leaflet (C): total weight of ten Leaflets / 10 = 3.26

### 23.1 WEIGHT CHECKS ON CARTON:

Weight of ten empty Carton: 57.2	Average weight of one empty Carton (A): 5.72
Weight of ten filled Alu Alu strip: 23.4	Average weight of one filled Alu Alu strip (B): 2.34
Weight of ten Leaflets: 32.6	Average weight of one Leaflet (C): 3.26
Weight of one filled Carton C = (A+3B+C) 16.00	Limit: D = C + 1% = 15.84 - 16.16 (To be established)
Checked by Packing/Date: 84 25/05/2020	Verified by IPQA/Date: 84 25/05/2020

### 23.2 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	3 x 3 x 10 <sup>6</sup> S	84 25/05/2020
2	Control Sample (Middle)	3 x 3 x 10 <sup>6</sup> S	84 25/05/2020
3	Control Sample (Final)	1 x 2 x 10 <sup>6</sup> S	84 25/05/2020
4	Stability Sample	NA 10 x 3 x 10 <sup>6</sup> S	NA 84 25/05/2020
5	Other Sample	NA	NA
6	Analytical sample	12 x 10 <sup>6</sup> S	84 25/05/2020
Total Qty.		62 32 x 10 <sup>6</sup> S = 320 Tablets	84 25/05/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	84 25/05/2020	P. K. 84 25/05/2020	84 25/05/2020
Date	20/04/2020	20/04/2020	22/04/2020	

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

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**BATCH PACKING RECORD**

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

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

Batch No.: GF200501

Customer:

Generic Health Care Pvt. Ltd.

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

Date/ Shift	25/05/2020	General							26/05/2020 G							25/05/2020 / 26/05/2020						
Parameters	Specification	observation																				
		Packing							IPQA													
Time		16:30	17:30	09:45	10:50	11:35	12:30	13:25	16:45	10:05	12:10	14:10	16:25									
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK									
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK									
No. of cartons in a shrink sleeves	16 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA							
Shrink wrapping temperature*	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA							
No. of shrink sleeves in a 5 ply shipper	14 shrinks 282 cartons	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK									
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK									
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK									
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK									
Checked by		SY	SY	SY	SY	SY	SY	SY	Q	Q	Q	Q	Q									

\*Temperature to be mentioned.

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

Date/ Shift	26/05/2020 General				27/05/2020 G				27/05/2020						
Parameters	Specification	observation													
		Packing								IPQA					
Time		14:25	15:30	16:30	17:35	07:45	08:40	09:40	12:00	10:05	12:10				
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
No. of cartons in a shrink sleeves	16 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Shrink wrapping temperature*	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
No. of shrink sleeves in a 5 ply shipper	14 shrinks 282 cartons	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Checked by		SY	SY	SY	SY	SY	SY	SY	Q	Q	Q				

\*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	S. K. S.	T. K. S.	S. K. S.
Date:	20/04/2020	21/04/2020	22/04/2020	23/04/2020

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

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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.: GF200501

Customer:

Generic Health Care Pvt. Ltd.

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

Date/ Shift	27/05/2020	Gene 491										
Parameters	Specification	Packing					observation					IPQA
		10:45 16/20	11:45 17/20	12:45								
Time												
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK								
Carton Overprinting	Legible and readable	OK	OK	OK								
No. of cartons in a shrink sleeves	16 packed cartons	NA	NA	NA								
Shrink wrapping temperature*	NA	NA	NA	NA								
No. of shrink sleeves in a 5 ply shipper	14 shrinks 282 cartons	OK	OK	OK								
Shipper strapping	Proper strapping	OK	OK	OK								
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK								
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK								
Checked by		84	84	84								

\*Temperature to be mentioned.

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


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

\*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	Zababur	P. H. Ab	S. N. N	
Date	20/04/2020	21/04/2020	22/04/2020	21/04/2020	

UNCONTROLLED



 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 20 of 24
	<b>BATCH PACKING RECORD</b>		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.

25. SHIPPERS WEIGHING: Date/Shift: 25/05/2020 Time: 11:30 AM Balance I.D. No.: P.D./B.A.L./020

Weight of ten Shrinks: 168.30 NA	Average weight of one filled Shrink (E): 16.83 NA
Weight of ten empty shippers: 10.820 NA	Average weight of one empty shipper (F): 1.082 NA
Weight of one filled shipper (G) = (14E+F): NA	Limit: H = G ± 1% = NA (to be established)

Checked by Packing/Date: Sy 27/05/2020 Verified by IPQA/Date: Sy 27/05/2020

Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By
1	5.874	Dhanalakshmi	26	5.899	Dhanalakshmi	51	5.895	Dhanalakshmi	76		
2	5.885	Dhanalakshmi	27	5.862	Dhanalakshmi	52	5.892	Dhanalakshmi	77		
3	5.880	Dhanalakshmi	28	5.882	Dhanalakshmi	53	5.846	Dhanalakshmi	78		
4	5.887	Dhanalakshmi	29	5.878	Dhanalakshmi	54	5.856	Dhanalakshmi	79		
5	5.886	Dhanalakshmi	30	5.914	Dhanalakshmi	55	5.837	Dhanalakshmi	80		
6	5.882	Dhanalakshmi	31	5.914	Dhanalakshmi	56	5.887	Dhanalakshmi	81		
7	5.885	Dhanalakshmi	32	5.858	Dhanalakshmi	57	5.854	Dhanalakshmi	82		
8	5.886	Dhanalakshmi	33	5.908	Dhanalakshmi	58	5.824	Dhanalakshmi	83		
9	5.888	Dhanalakshmi	34	5.872	Dhanalakshmi	59	5.837	Dhanalakshmi	84		
10	5.898	Dhanalakshmi	35	5.866	Dhanalakshmi	60	5.841	Dhanalakshmi	85		
11	5.914	Dhanalakshmi	36	5.870	Dhanalakshmi	61	5.816	Dhanalakshmi	86		
12	5.865	Dhanalakshmi	37	5.862	Dhanalakshmi	62	5.814	Dhanalakshmi	87		
13	5.887	Dhanalakshmi	38	5.895	Dhanalakshmi	63	5.866	Dhanalakshmi	88		
14	5.914	Dhanalakshmi	39	5.866	Dhanalakshmi	64	5.863	Dhanalakshmi	89		
15	5.924	Dhanalakshmi	40	5.911	Dhanalakshmi	65	5.867	Dhanalakshmi	90		
16	5.915	Dhanalakshmi	41	5.852	Dhanalakshmi	66	5.855	Dhanalakshmi	91		
17	5.901	Dhanalakshmi	42	5.860	Dhanalakshmi	67	5.843	Dhanalakshmi	92		
18	5.878	Dhanalakshmi	43	5.903	Dhanalakshmi	68	5.881	Dhanalakshmi	93		
19	5.904	Dhanalakshmi	44	5.893	Dhanalakshmi	69	5.863	Dhanalakshmi	94		
20	5.896	Dhanalakshmi	45	5.897	Dhanalakshmi	70	5.833	Dhanalakshmi	95		
21	5.882	Dhanalakshmi	46	5.909	Dhanalakshmi	71			96		
22	5.904	Dhanalakshmi	47	5.880	Dhanalakshmi	72			97		
23	5.882	Dhanalakshmi	48	5.884	Dhanalakshmi	73			98		
24	5.878	Dhanalakshmi	49	5.904	Dhanalakshmi	74			99		
25	5.873	Dhanalakshmi	50	5.894	Dhanalakshmi	75			100		

Total No. of shippers weighed: 10	De-foiled tablets packed in Shipper No: 10	Checked by Sign / Date: Sy 27/05/2020	Verified by Sign / Date: Sy 27/05/2020	Loose pack details: Shipper No: 70, Quantity: 9.135 X 3x10's, Weight: 4.438
-----------------------------------	--	---------------------------------------	--	---

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

Weight of Ten filled corton: 168.30 Average Weight of one filled corton (E): 16.83

Weight of Ten empty shipper: 10.820 Average Weight of one empty shipper (F): 1.082

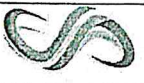
Weight of one filled shipper (G) (282 E+F): 5.823 Limit H = G ± 1% = 5.769 - 5.886

Total no. of corton per shipper has been checked for all 100 shippers

Prepared by: L. Ka		Checked by: P. K. K.		Approved By: Sy 27/05/2020	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.					
Date	20/04/2020	25/04/2020	22/04/2020		

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 21 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b> Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:		Batch No.: GF 200501 Generic Health Care Pvt. Ltd.

### 26. MAN POWER ALLOCATION:

DATE: 25/05/2020	
SHIFT: General	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Bathya, Indra
Printing Checking in Alu Alu strip	Sivasankari, Lakshmi
Alu Alu strip weighing	Maheshwari, Dhanapriya
Insertion of Alu Alu strip and leaflet into carton	Baranya, Sivarajini
Cartons weighing	Suganthi
Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Dhanalakshmi
Shipper Weighing	Suganthi
Shipper Strapping	Dhanalakshmi
Shipper packed	From 01 to 03
Signature of Packing	By 25/05/2020

DATE: 25/05/2020	
SHIFT: General	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Sivasankari, Indra
Printing Checking in Alu Alu strip	Bathya, Lakshmi
Alu Alu strip weighing	Maheshwari, Dhanapriya
Insertion of Alu Alu strip into carton	Baranya, Sivarajini
Cartons weighing	Suganthi
Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Dhanalakshmi
Shipper Weighing	Suganthi
Shipper Strapping	Dhanalakshmi
Shipper packed	From 04 to 07
Signature of Packing	By 26/05/2020


DATE: 27/05/2020	
SHIFT: General	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Sivasankari, Indra
Printing Checking in Alu Alu strip	Bathya, Lakshmi
Insertion of Alu Alu strip and leaflet into carton	Maheshwari, Dhanapriya
Alu Alu strip weighing	Baranya, Sivarajini
Cartons weighing	Suganthi
Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Dhanalakshmi
Shipper Weighing	Suganthi
Shipper Strapping	Dhanalakshmi
Shipper packed	From 08 to 10
Signature of Packing	By 27/05/2020

DATE: .....	
SHIFT: .....	
ACTIVITIES	DONE BY
Alu Alu strip Checking	
Printing Checking in Alu Alu strip	
Insertion of Alu Alu strip into carton	
Alu Alu strip weighing	
Cartons weighing	
Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper	
Shipper Label Pasting	
Shipper Weighing	
Shipper Strapping	
Shipper packed	From ..... to .....
Signature of Packing	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	S. Lakshmi	P. K. G. S.	S. Anand
Date:	20/04/2020	21/04/2020	22/04/2020	22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 22 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
	Product: Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF200501 Generic Health Care Pvt. Ltd.

### 27. PACKING MATERIAL RECONCILIATION:

Sr. No.	Material	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
A	Quantity received for the batch	36.880	89.940	20400	20400	NA	88	250 mtrs (5 kg)	01
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	36.880	89.940	20400	20400	NA	88	250(mtrs) (5 kg)	01
D	Quantity packed	15.047	56.251	19593	19593	NA	70	0.930 kg	01
E	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	NA
G	Sample affixed on BPR	0.002	NA	02	02	NA	NA	NA	NA
H	QC samples	0.003	0.011	04	04	NA	NA	NA	NA
I	Other samples (If any)	0.005	0.019	07	07	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	36.408	89.649	-0-	-0-	NA	NA	NA	NA
K	Variation (C - J)	0.472	0.291	-0-	-0-	NA	NA	NA	NA
L	%Variation (K x 100)/C	1.27%	0.32%	-0-	-0-	NA	NA	NA	NA
M	Acceptable limit	±2%	±2%	±2%	±2%	±2%			

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

### 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	NA	NA	NA	NA	NA
Material returned by packing Sign./Date	84/21/05/2020	84/21/05/2020	84/21/05/2020	NA	NA	NA	NA	NA
Verified By IPQA Sign./Date	84/21/05/2020	84/21/05/2020	84/21/05/2020	NA	NA	NA	NA	NA
Material received by Store Sign./Date	84/21/05/2020	84/21/05/2020	84/21/05/2020	NA	NA	NA	NA	NA


### 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	08	6.001	16.998	295	NA	NA	NA	0.012	NA
Total Qty. Destroyed	08	6.001	16.998	295	NA	NA	NA	0.012	NA
Destroyed by (Packing)	84/21/05/2020								
Verified by (IPQA)	84/21/05/2020								

Prepared by:	Checked by:	Approved By:
Dept. Production	Production Quality Assurance	Head Quality Assurance
Sign. L. Ka	30/04/2020	84/21/05/2020
Date: 20/04/2020	21/04/2020	22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF-200501 Generic Health Care Pvt. Ltd.

### 30. BATCH RECONCILIATION:

A	Batch Size	6,00,000 Nos.
B	Quantity received for packing	591150
C	Total quantity packed	587790
D	Control samples	200
E	Analytical Samples	120
F	In process samples	1080
G	Others samples if any (Stability, Regulatory Samples, etc.)	NA
H	Packing Loss = B - (C + D + E + F + G)	1960 8560
I	Total Loss = A - (C + D + E + F + G)	10810
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit %...95%...)*	99.66%
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %...95%...)*	98.18%

\*To be established

Checked by Packing /Date: Sy 27/05/2020

Verified by IPQA/Date: 27/05/2020

### 31. TRANSFER OF FINISHED GOODS:

Date	FGTN No.	Sales	Pack Size	No. of Units in a shipper	No. of Shippers	Transferred Quantity	FGTN Raised by Packing	FGTN Checked by IPQA	FGTN Received by Stores
27/05/2020	245	Sales	3X10's	23275	70	69 X 23275 3X10's	Sy	2	M. Sava
						01 X 25 X 3 X 10's	Sy	2	Y. Sava
Total Qty. Transferred						58779	Sy	2	Y. Sava

### 32. DEVIATION/ EXCEPTION DETAILS:

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

#### Deviation / Exception details

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

Checked by  
Packing:

Verified by  
Packing manager:

Approved by  
Head QA:

### 33. BPR REVIEW DETAILS:


Reviewed by	Name	Sign./Date
Packing Executive	A. PUVIARAW	27/05/2020
QA Executive	Ram Kumar	27/05/2020
Production Assistant Manager/ HOD	Balasubramanian B	27/05/2020
QA Manager/ HOD	Stephen B	27/05/2020

Prepared by:	Checked by:	Approved By:
Dept. Production	Production Quality Assurance	Head Quality Assurance
Sign. L. K.	T. K. G.	S. M.
Date 22/04/2020	22/04/2020	22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 24 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF200501 Generic Health Care Pvt. Ltd.

**34. BATCH RELEASED FOR DESPATCH:**

Total quantity released: 587790 No's

Head QA sign/ Date: [Signature] 27/04/2020

**35. REVISION HISTORY:**

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>[Signature]</u>	<u>P. K. [Signature]</u>	<u>[Signature]</u>
Date	<u>20/04/2020</u>	<u>21/04/2020</u>	<u>22/04/2020</u>	<u>21/04/2020</u>

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SAI PRIMUS  
LIFE BIOTECH PVT LTD

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

Page 1 of 26

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
		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:
		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/107-01
REVISION No.	:	01
SUPERSEDE No	:	BPR/T/107-00
EFFECTIVE BATCH. No. /DATE	:	GF 200704 / 27/07/2020
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)	:	<i>[Signature]</i> 28/07/2020
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:	L. Ke 28/07/2020
MFG. DATE: 07/10/19	EXP. DATE:	06/10/23
ALLOTTED BY: QA SIGN/DATE: <i>[Signature]</i> 28/07/2020	COUNTER CHECKED BY: QA SIGN/DATE:	<i>[Signature]</i> 28/07/2020
QUANTITY RECEIVED FROM PRODUCTION	:	599713 Tablets
DATE OF COMMENCEMENT: 31/07/2020	DATE OF COMPLETION:	31/07/2020
QUANTITY	:	6,00,000 Tablets
RELEASED QUANTITY OF PACKED TABLETS	:	580380 Tablets
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	:	<i>[Signature]</i> 13/08/2020


This BPR contains 26 Pages + ..... Additional Pages

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	27/07/2020	27/07/2020	27/07/2020	27/07/2020

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
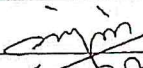
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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-01 Customer:	Batch No.: <u>GF200704</u> Generic Health Care Pvt. Ltd.

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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	27/07/2020	27/07/2020	27/07/2020	

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SAI PRIMUS  
LIFE BIOTECH PVT LTD

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

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**BATCH PACKING RECORD**

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

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

Batch No.: GF 200704

Customer:

Generic Health Care Pvt. Ltd.

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

**Instruction:**

Check the following points before submitting the documents for final Review

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

Checked By QA/Date:

\*Mention total number of pages.


Remarks (If any) .....

Prepared by:		Checked by:		Approved By:
Dept. ...	Production ...	Production.	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Apur	27/07/2022	27/07/2022
Date	27/07/2022	27/07/2022		

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	<b>BATCH PACKING RECORD</b>	<b>Product Code: A08</b>	<b>Batch Size: 6,00,000 Tablets</b>
<b>Product</b>	<b>Amloperin 5mg/5mg</b>	<b>BPR. No.: BPR/T/107-01</b>	<b>Batch No.: GF 200 704</b>
		<b>Customer:</b>	<b>Generic Health Care Pvt. Ltd.</b>

### 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	PPH/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/C001	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 <sup>2</sup>	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	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	-	91

Prepared by:		Checked by:		Approved By:
Dept. --	-- Production --	Production--	Quality Assurance --	Head Quality Assurance --
Sign.	L. Ke	Apur	27/07/2020	27/07/2020
Date	27/07/2020	27/07/2020	27/07/2020	27/07/2020

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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

Customer:

Generic Health Care Pvt. Ltd.

**4. DISPENSING LINE CLEARANCE CHECKS**

Date: 30/07/2020 Time: 15:00

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

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

Equipment	Mobile Laminar Air Flow	Weighing Balance			Area
ID No.	ST/LAF/001	ST/BAL/011	NA	NA	Foil Store
Previous Product	Telmisartan H				
B. No.	Tob 000607				
Cleaned by Sign/Date	Murali 30/07/2020				
Checked by Store Sign/Date	log 30/07/2020				
Verified by IPQA Sign/Date	[Signature] 30/07/2020				

ENVIRONMENTAL CONDITIONS: Date: 30/07/2020 Time: 15:05	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	log 30/07/2020	[Signature] 30/07/2020
Differential Pressure across the booth Limit: 5 to 20 mm Water	13 mm	log 30/07/2020	[Signature] 30/07/2020

APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature] Date: 30/07/2020

Dispensing start Time 15:10 End Time 15:25

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	[Signature]	[Signature]
Date	27/07/2020	27/07/2020	27/07/2020	27/07/2020

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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

Customer:

Generic Health Care Pvt. Ltd.

5. DISPENSING RECORD OF PACKING MATERIALS: Date: 30/07/2020 Shift: G Time: 15:15

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	31.200	PMG/00005	03	kg 30/07/2020	kg 30/07/2020
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	91.800	91.100 54.50 43.90	PMG/00008 PMG/00009	03 02	kg 30/07/2020	kg 30/07/2020
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	20400	20400	PMG/00004	09	kg 30/07/2020	kg 30/07/2020
Amloperin packing inserts	PPI/GH/I001	No	20400	20400	PMG/00007	04	kg 30/07/2020	kg 30/07/2020
Shrink Sleeves (PVC)	PPS/GH/P001	No	1275				kg 30/07/2020	kg 30/07/2020
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	90	90	PMG/00178	09	kg 30/07/2020	kg 30/07/2020
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	18	18	PMG/00134	04	kg 30/07/2020	kg 30/07/2020
Strapping Role	PPR/GH/S001	Mtrs	250	250	PMG/00001	01	kg 30/07/2020	kg 30/07/2020
Shipper Label	NA	No	91				kg 30/07/2020	kg 30/07/2020

Prepared by:		Checked by:		Approved By:
Dept. ---	--- Production	--- Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	kg	kg 27/07/2020	kg 28/07/2020
Date	27/07/2020	27/07/2020		

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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 200 704

Customer:

Generic Health Care Pvt. Ltd.

6. LINE CLEARANCE CHECKS:

6.1 PRIMARY PACKING:

Date/ Shift: 31/07/2020...G1...../.....NA.....

Previous Product: Ultra Vitamin D		Batch No.: UD20505				
Sr. No.	Checks	Time	Observation			
			07:20 Packing	IPQA	Packing	IPQA
1.	Area status board is updated for "CLEANED" status.		✓	✓		
2.	Check and ensure that the area is visually clean and free from previous product		✓	✓		
3.	Check and ensure the differential pressure of the area is within specified limit		✓	✓		
4.	Check and ensure that waste bin is emptied out and cleaned		✓	✓		
5.	Check the temperature and relative humidity of the area within specified limit		✓	✓		
6.	Check the tablets of the previous product/ batch removed.		✓	✓		
7.	Check the loose Alu Alu strip cutting, rejected rolls, empty cores of foil of previous product /batch are removed.		✓	✓		
8.	Check the surroundings of the machine and free from the previous products and batch		✓	✓		
9.	Check the foil printing stereotypes, Labels of previous product/batch are removed.		✓	✓		
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.		✓	✓		
11.	Check and ensure the Cleanliness following change part of Alu Alu strip packing machine		✓	✓		
12.	Check for the absence of previous batch/ product at machine conveyor belt.					
a)	Check Hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit.		✓	✓		
b)	Check for cleaning of hopper, feeding channel, vibrator plate, in feed roller and sweep brush.		✓	✓		
c)	Check tool box, thinner and ink box		✓	✓		

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

Cleaning satisfactory/Not-satisfactory

Checked by Packing (Sign. /Date):

Cleaning satisfactory/Not-satisfactory

Verified by IPQA (Sign. /Date):

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

6.2 AREA AND EQUIPMENT CLEARANCE OF PRIMARY PACKING

Date/Time: 31/07/2020. 07:25

Previous Product: Ultra Vitamin D				Batch No.: UD20505			
S. No.	Equipment / Area Name	Eq.ID. /Area. No.	Cleaning Type A/B	Operation and cleaning as per SOP number	Cleaned by Sign/Date	Checked by (Packing) Sign/Date	Verified by (IPQA) Sign/Date
1.	Alu Alu Packing Area	SPU/PFF/AW/01	B	PDGN/006	Hani	By	31/07/2020
2.	Alu Alu Packing Machine	PD/ALU/001	B	PDOP/020, PDCL/020	Hani	By	31/07/2020

6.3 ENVIRONMENTAL CONDITIONS:

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

Refer to SOP No.: SOP: QAGN/011		Date: 31/07/2020 Time: 07:30.....		Date:.....NA..... Time:.....NA.....	
Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	24°C	By 31/07/2020			
RH % Limit: NMT 60%	58%	By 31/07/2020			
DP Limit: NLT 10 Pascal	10	By 31/07/2020			

Primary Packing Started Date/Time: 31/07/2020. 07:30 Completed Date/Time: .....31/07/2020.....17:40


APPROVAL FOR PRIMARY PACKING: IPQA Sign. /Date: .....31/07/2020

Prepared by:		Checked by:		Approved By:	
Dept.	Production	- Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	By	By	By	
Date	31/07/2020	31/07/2020	31/07/2020	31/07/2020	

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	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-01 Customer:	Batch No.: <u>GF 200 704</u> Generic Health Care Pvt. Ltd.

**7. VERIFICATION OF DISPENSED PACKING MATERIALS:** Date 31/07/2020 Shift G 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	<u>PMG/00005</u>	<u>03</u>	<u>SH</u>	<u>Q</u>
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	<u>PMG/00008</u>	<u>02</u>	<u>SH</u>	<u>Q</u>
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	<u>PMG/00004</u>	<u>09</u>	<u>SH</u>	<u>Q</u>
Amloperin packing inserts	PPI/GH/I001	No	<u>PMG/00007</u>	<u>04</u>	<u>SH</u>	<u>Q</u>
Shrink Sleeves (PVC)	PPS/GH/P001	No	<u>NA</u>	<u>NA</u>	<u>SH</u>	<u>Q</u>
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	<u>PMG/00138</u>	<u>09</u>	<u>SH</u>	<u>Q</u>
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	<u>PMG/00134</u>	<u>04</u>	<u>SH</u>	<u>Q</u>
Strapping Role	PPR/GH/S001	Mtrs	<u>PMG/00001</u>	<u>01</u>	<u>SH</u>	<u>Q</u>
Shipper Label	NA	No	<u>NA</u>	<u>NA</u>	<u>SH</u>	<u>Q</u>

**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	<u>08</u>	<u>PMG/0012020</u>	<u>Mali/0012020</u>	<u>Mani</u>	<u>SH 30/07/2020</u>	<u>Q 30/07/2020</u>

**9. RECEIPT OF PRODUCT AND MATERIALS:** Date/Shift... 31/07/2020... Time: 07:10  
(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)	<u>24°C</u>	<u>SH</u>	<u>Q</u>
2.	Relative Humidity observed on display (Limit: NMT 60%)	<u>58%</u>	<u>SH</u>	<u>Q</u>
3.	Bulk product containers are of the required product/Batch number and is approved by QC	<u>NA</u>	<u>NA</u>	<u>NA</u>
4.	Status label of machine/ line is for same product	<u>Yes</u>	<u>SH</u>	<u>Q</u>
5.	Printed foil/Base rolls are of the required product.	<u>Yes</u>	<u>SH</u>	<u>Q</u>
6.	All secondary packing materials are of the required product	<u>Yes</u>	<u>SH</u>	<u>Q</u>

**10. DETAIL OF THE PRODUCT AS PER BMR:**

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	<u>139.50mg</u>	<u>SH</u>	<u>Q</u>
2.	Colour of Tablet	<u>White colour</u>	<u>SH</u>	<u>Q</u>
3.	Quantity (Net Qty.in Kg)	<u>83.660</u>	<u>SH</u>	<u>Q</u>
4.	Number of Containers	<u>06</u>	<u>SH</u>	<u>Q</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head-Quality Assurance
Sign.	<u>L.K</u>	<u>Amu</u>	<u>SH 31/07/2020</u>	<u>SH</u>
Date	<u>31/07/2020</u>	<u>31/07/2020</u>	<u>31/07/2020</u>	<u>31/07/2020</u>

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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.: 01F200704

Customer:

Generic Health Care Pvt. Ltd.

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

Balance I.D. No.: PD/BAL/014

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

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Amloperin 5mg/5mg	01F200704	07/2020	06/2023	83.660 Kg Equivalent to 599712Nos.	From Container No. 01 To Container No. 06 Total No. of Containers taken 06
Checked by Packing (Sign. /Date): Sy 31/07/2020				Verified By IPQA (Sign. /Date): Sy 31/07/2020	

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	Nanny	✓	11			
2	24.630	Nanny	✓	12			
3	14.190	Nanny	✓	13			
4	15.880	Nanny	✓	14			
5	9.240	Nanny	✓	15			
6	6.250	Nanny	✓	16			
7				17			
8				18			
9				19			
10				20			

13. CONTAINER CONSUMPTION DETAILS:

S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	08:20	09:20	01	Nani	11				
2	09:25	10:30	02	Nani	12				
3	10:35	11:30	03	Nani	13				
4	11:40	12:50	04	Nani	14				
5	13:55	15:20	05	Nani	15				
6	15:30	17:40	06	Nani	16				
7					17				
8					18				
9					19				
10					20				

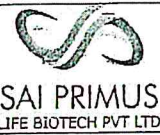
Checked By Packing (Sign. /Date): Sy 31/07/2020 Verified By IPQA (Sign. /Date): Sy 31/07/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Sy	Sy	Sy
Date	27/07/2020	27/07/2020	27/07/2020	27/07/2020

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	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-01	Batch No.: 61F200704
		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.:	61F200704	OK
Mfg. Date:	07/2020	OK
Exp. Date:	06/2021 06/2022	OK
Pack size (3 x 10's)- Carton	OK	OK
Other instructions if any	NA	NA
Initiated by	Mani	Mani
Checked by Packing (Sign. & Date)	Sy 31/07/2020	Sy 31/07/2020
Verified by IPQA (Sign. & Date)	Sy 31/07/2020	Sy 31/07/2020

#### 15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	31/07/2020	01	Mani 31/07/2020	Sy 31/07/2020	Sy 31/07/2020
1		NA			Sy 31/07/2020

#### 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

Sr. No.	Date/Shift	Primary packing		Secondary packing		Checked by (Packing) Sign. & Date
		Started at	Completed at	Started at	Completed at	
01	31/07/2020	08:30	17:40	08:50	18:10	Sy 31/07/2020
1			NA			Sy 31/07/2020

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

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

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	Sy 31/07/2020	Sy 31/07/2020	Sy 31/07/2020
Date	27/07/2020	27/07/2020	27/07/2020	27/07/2020

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

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BATCH PACKING RECORD

Product Code: 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.

18. ALU ALU PACKING MACHINE PARAMETERS:

Date/Shift: 31/07/2020 G Time: 08:30.

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

19. MACHINE IN-PROCESS CONTROL:

Date/ Shift	31/07/2020 General															
Machine Operator Name	Manikandan															
Time of inspection	08:30	08:45	09:30	10:30	10:50	11:35	12:30	13:00	14:25	15:30	15:35	16:25	17:30	17:50	18:15	18:45
Sealing Temperature (170 °C - 210°C)	182°C	185°C	185°C	185°C	186°C	185°C	184°C	OK	185°C	184°C	185°C	184°C	185°C	170°C	170°C	210°C
Leak test on Alu Alu strips* (Qty.: 02)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Knurling /Sealing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.: GF200704	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date 07/2020	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date 06/2023	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed (10 - 35 cycles)	28	28	30	30	30	30	30	30	30	30	30	30	30	10	35	10
Checked by (Packing)	31	31	31	31	31	31	31	31	31	31	31	31	31	31	31	31
Checked by (IPQA)	31	31	31	31	31	31	31	31	31	31	31	31	31	31	31	31

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

Prepared by:	Checked by:	Approved By:
Dept. - Production	Production - Quality Assurance	Head Quality Assurance
Sign. L. Ka	Sign. 27/07/2020	Sign. 27/07/2020
Date 27/07/2020	Date 27/07/2020	Date 27/07/2020

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LIFE BIOTECH PVT LTD

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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/107-01

Batch No.: GF 200 704

Customer:

Generic Health Care Pvt. Ltd.

**19.1 MACHINE IN-PROCESS CONTROL:**

Date/ Shift	31/07/2020	
Machine Operator Name	Minkandan	
Time of inspection	18:25	
Sealing Temperature (170 °C - 210°C)	210	
Leak test on Alu Alu strips* (Qty.: 02)	ok	
Knurling /Sealing	ok	
Pocket Formation	ok	
Horizontal cutting	ok	
Vertical cutting	ok	
Quality of Over printing	ok	
Code No.: PON/DRUGS/ 19 13 4323	ok	
B. No.: GF200704	ok	
Mfg. Date 07/2020	ok	
Exp. Date 08/2020	ok	
Machine Speed (10 – 35 cycles)	35	
Checked by (Packing)	PK	
Checked by (IPQA)	PK	

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	PK	27/07/2020	27/07/2020
Date	27/07/2020	27/07/2020		

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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.: G F 200704

Customer:

**Generic Health Care Pvt. Ltd.**

## 19.2 MACHINE IN-PROCESS CONTROL:

Date/ Shift																					
Machine Operator Name																					
Time of inspection																					
Sealing Temperature (170 °C - 210°C)																					
Leak test on Alu Alu strips* (Qty.: 02)																					
Knurling /Sealing																					
Pocket Formation																					
Horizontal cutting																					
Vertical cutting																					
Quality of Over printing																					
Code No.:	PON/DRUGS/ 19 13 4323																				
B. No.:																					
Mfg. Date																					
Exp. Date																					
Machine Speed (10 – 35 cycles)																					
Checked by (Packing)																					
Checked by (IPQA)																					

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance.
Sign.	L. Ko	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	22/02/2020	21/01/2020	21/07/20	20/02/2020

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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

Customer:

Generic Health Care Pvt. Ltd.

20. DEFOILING OF ALU ALU STRIPS:

Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	De-foiling Done by	Checked by/ Date (Packing)	Verified by Date (QA)
31/07/2020	16:40	17:00	3.166	Sarala, Ambika	S 431/07/2020	S 31/07/2020
Total Weight of De-foiled Tablets			3.166	Checked By / Date (Packing): S 31/07/2020		Verified By / Date (IPQA): S 31/07/2020

20.1 INSPECTION OF DE-FOILED TABLETS:

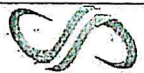
Date	Inspection started at	Inspection completed at	Inspection Done by	Quantity of Good tablets		Qty. of Rejected Tablets		Checked by/ Date (Packing)	Verified by Date (QA)
				Kgs	Nos	Kgs	Nos		
31/07/2020	17:00	17:20	Vang's	3.100	22222	0.060	430	S 431/07/2020	S 31/07/2020
Total									
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing): S 31/07/2020		Verified By / Date (IPQA): S 31/07/2020			
..0.060... Kgs ...430... Nos.									

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka				
Date	27/07/2020	27/07/2020	27/07/2020	27/07/2020	

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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

Customer:

Generic Health Care Pvt. Ltd.

21. LINE CLEARANCE CHECKS – BATCH CODING:

Date/ Shift 30/07/2020 / NA

Previous Product: INTOTO

Batch No.: FI01000204

Sr. No.	Checks	Time	Observation			
			14:55			
			Packing	IPOA	Packing	IPOA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓		
3	Check the Pallets and crates area clean and free from any leftovers of previous product /Batch.		✓	✓		
4	Check and ensure the Correct status board is written.		✓	✓		
5	Check and ensure the previous batch details are deleted from the inkjet machine.		✓	✓		
6	Check and ensure the rejected Cartons of previous product/batch are removed.		✓	✓		
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓		
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓		
9	Check and ensure the dispensed secondary packing material.		✓	✓		
10	Check and ensure the Preventive maintenance records and log book.		✓	✓		

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

Cleaning Satisfactory / Not satisfactory#  
(Packing) Sign./Date: 30/07/2020

Cleaning Satisfactory / Not-satisfactory#  
(IPQA) Sign./Date: 30/07/2020

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.

21.1 AREA AND EQUIPMENT CLEARANCE FOR CODING:

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


Equipment	Inkjet Machine	Conveyor	Area
ID. No.:	INTOTO PD/INS/001	PD/INS/001	Batch Coding
Previous Product:	INTOTO FI01000204		
Batch No.:	FI01000204		
Cleaned by:	Enam		
Checked by Packing:	30/07/2020		
Verified by IPQA:	30/07/2020		

Prepared by:		Checked by:		Approved By:
Dept.:	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	Amr	30/07/2020	30/07/2020
Date	27/07/2020	27/07/2020		

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	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-01 Customer:	Batch No.: GF 200 T04 Generic Health Care Pvt. Ltd.

### 21.2 OVERPRINTING DETAILS:

Overprinting Details	Overprinted Text	Carton (OK/ Not OK)
Batch No.:	GF 200 T04	OK
Mfg. Date:	07/2020	OK
Exp. Date:	06/2023	OK
Code No.: PON/DRUGS/19 13 4323	PON/DRUGS/19 13 4323	OK
Other instructions if any	NA	NA
Initiated by Sign. & Date	Snathu	OK
Checked by Packing Sign. & Date	30/07/2020	30/07/2020
Verified by IPQA Sign. & Date	30/07/2020	30/07/2020

### 21.3 TIME RECORD FOR BATCH CODING:

Sr. No.	Date/Shift	Batch Coding Done By	Batch Coding		Checked by (Packing) Sign. & Date	Verified by (IPQA) Sign. & Date
			Started at	Completed at		
01	30/07/2020/6	Snathu	18:10	19:00	30/07/2020	30/07/2020
1						
			NA			
						184

### 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	01	30/07/2020	30/07/2020
02	31/07/2020	02	31/07/2020	31/07/2020
03	01/08/2020	03	01/08/2020	01/08/2020
		NA		184

Note - Attach specimen copy of over printed carton

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Snathu	30/07/2020	30/07/2020
Date	27/07/2020	27/07/2020		

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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 200 704

Customer:

Generic Health Care Pvt. Ltd.

**22. LINE CLEARANCE CHECKS - SECONDARY PACKING:**

Date/ Shift ... 31/07/2020

Previous Product: Ultra D		Batch No.: UD20505				
Sr. No.	Checks	Time	Observation			
			08:00			
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	N/A	
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓		
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓		
4	Check and ensure the Correct status board is written.		✓	✓		
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓		
6	Check and ensure the blisters, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓		
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓		
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓		
9	Check and ensure the dispensed secondary packing material.		✓	✓		
10	Check and ensure the cleanliness of documentation table.		✓	✓		
11	Check and ensure the Preventive maintenance records and log book.		✓	✓		

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

Cleaning Satisfactory / Not-satisfactory#  
(Packing) Sign./Date: 31/07/2020

Cleaning Satisfactory / Not-satisfactory#  
(IPQA) Sign./Date: 31/07/2020

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

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	PD/LOB/004	PD/BAL/018	NA	PD/BAL/002	PD/BAL/021	Secondary Packing Hall
Previous Product:	Ultra D					
Batch No.:	UD20505					
Cleaned by:	Vargha					
Checked by Packing:	31/07/2020					
Verified by IPQA:	31/07/2020					

Prepared by:		Checked by:		Approved By:	
Dept. - - -	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.					
Date	24/07/2020	24/07/2020	27/07/2020	27/07/2020	

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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

Customer:

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)

Shift:.....General.....		Date/Time: 31/07/2020 08:00		Date/Time: NA	
		Observation	Checked by Packing	Verified by IPQA	Observation
Refer to SOP No.: SOP: QAGN/011	Temperature °C Limit: NMT 25°C	24°C	Se	Se	NA
Secondary Packing Started Date/Time: 31/07/2020 08:50 Completed Date/Time: 31/07/2020 13:10					
APPROVAL FOR SECONDARY PACKING: Approved by IPQA Sing/Date: 31/07/2020					

**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.:	GF200704	OK	OK
Mfg. Date:	07/2020	OK	OK
Exp. Date:	06/2023	OK	OK
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	NA
Initiated by Sign. & Date	Prothet	Prothet	Lakshmi
Checked by Packing Sign. & Date	Am	Am	31/07/2020
Verified by IPQA Sign. & Date	Se 31/07/2020	Se 31/07/2020	Se 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)
01	30/07/2020	01	Am 30/07/2020	Se 31/07/2020
1		NA		Se

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head-Quality Assurance
Sign.	L. Ka	Am	Se	Se
Date	27/07/2020	24/07/2020	27/07/2020	27/07/2020

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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.: GF200704

Customer:

Generic Health Care Pvt. Ltd.

24. INDIVIDUAL STRIP WEIGHING LIMIT:

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

1. 1.1	3. 1.2	5. 1.1	7. 1.2	9. 1.1
2. 1.2	4. 1.1	6. 1.2	8. 1.1	10. 1.2

Total weight of ten Empty Alu Alu strips = 11.15

Avg. Weight of a Empty Alu Alu strip (A): total weight of ten Empty Alu Alu strip/10 = 1.15

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

1. 2.4	3. 2.4	5. 2.3	7. 2.4	9. 2.3
2. 2.4	4. 2.3	6. 2.3	8. 2.2	10. 2.4

Total weight of ten Filled Alu Alu strips = 23.4

Avg. Weight of a Filled Alu Alu strip (B): total weight of ten Filled Alu Alu strip/10 = 2.34

Limit (C) =

(Each missing tablet should be identified)

Strip weighing Done By: Maheshwari  
Checked By: 31/07/2020  
Verified By: 31/07/2020

23.1 CARTON WEIGHT LIMIT SETTING: Date/Shift...31/07/2020...Time: 08.15

Weight of ten individual empty cartons are given below:

1. 5.8	3. 5.7	5. 5.8	7. 5.7	9. 5.8
2. 5.7	4. 5.8	6. 5.7	8. 5.8	10. 5.8

Total weight of ten empty cartons = 57.6

Average weight of an empty carton (D) = Total weight of ten empty carton /10 = 5.76

Weight of ten individual Leaflets are given below:

1. 2.2	3. 2.3	5. 2.2	7. 2.4	9. 2.4
2. 2.2	4. 2.4	6. 2.4	8. 2.2	10. 2.4

Total weight of ten Leaflets = 23.1

Avg. Weight of a Leaflet (E): total weight of ten Leaflets/10 = 2.31

23.2 WEIGHT CHECKS ON CARTON:

Weight of ten empty Carton: 57.6	Average weight of one empty Carton (D): 5.76
Weight of ten filled Alu Alu strip: 23.4	Average weight of one filled Alu Alu strip (B): 2.34
Weight of ten Leaflets: 23.1	Average weight of one Leaflet (E): 2.31
Weight of one filled Carton F = (D+3B+E) 15.69	Limit: G = F ± 1 % = 15.93 - 15.24
Checked by Packing/Date: 31/07/2020	Verified by IPQA/Date: 31/07/2020

23.3 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7x10 <sup>5</sup>	31/07/2020
2	Control Sample (Middle)	7x10 <sup>5</sup>	31/07/2020
3	Control Sample (Final)	6x10 <sup>5</sup>	31/07/2020
4	Stability Sample	NA	NA
5	Other Sample	NA	NA
6	Analytical sample	12x10 <sup>5</sup>	31/07/2020
Total Qty.		32x10 <sup>5</sup> = 320 Tablets	31/07/2020

Prepared by:	Checked by:	Approved By:
Dept. -- Production --	Production -- Quality Assurance --	Head-Quality Assurance
Sign. L. Ka	Sign. 27/07/2020	Sign. 27/07/2020
Date 27/07/2020	Date 27/07/2020	Date 27/07/2020

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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

Customer:

Generic Health Care Pvt. Ltd.

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

Date/ Shift	31/07/2020	31/07/2020													
Parameters	Specification	observation													
		Packing							IPQA						
Time		08:50	09:50	10:30	11:40	12:30	13:25	14:30	09:05	11:10	13:20	15:30	17:40		
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
No. of cartons in a shrink sleeves	16 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
Shrink wrapping temperature*	*	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
No. of shrink sleeves in a 5 ply shipper	14 shrinks 232 cartons	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Checked by		SY	SY	SY	SY	SY	SY	SY	SY	SY	SY	SY	SY		

\*Temperature to be mentioned.

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

Date/ Shift															
Parameters	Specification	observation													
		Packing							IPQA						
Time		15:30	16:40	17:40											
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK											
Carton Overprinting	Legible and readable	OK	OK	OK											
No. of cartons in a shrink sleeves	16 packed cartons	NA	NA	NA											
Shrink wrapping temperature*	*	NA	NA	NA											
No. of shrink sleeves in a 5 ply shipper	14 shrinks 232 cartons	OK	OK	OK											
Shipper strapping	Proper strapping	OK	OK	OK											
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK											
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK											
Checked by		SY	SY	SY											

\*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.					
Date	27/07/2020	27/07/2020	27/07/2020	27/07/2020	

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## Product Code: A08

Batch Size: 6,00,000 Tablets

**Amloperin 5mg/5mg**

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

Batch No.: GF 200704

Customer:

Generic Health Care Pvt. Ltd.

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

24.3 SECONDARY PACKING IN-PROCESS CHECKS: (Please keep  $\checkmark$  mark if found "Ok")

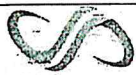
[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	28/07/2020	24/07/2020	27/07/2020	27/07/2020

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LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

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

Batch No.: 61F 200704

Customer:

Generic Health Care Pvt. Ltd.

26. SHIPPERS WEIGHING:

Date/Shift: 31/07/2020 Time: 08:55... Balance I.D. No.: P.D.(BA) 019

Weight of ten Shrinkers: cartons	170.00	Average weight of one filled Shrink (E):	17.0
Weight of ten empty shippers:	8.877	Average weight of one empty shipper (F):	0.887
Weight of one filled shipper (G) = (14E+F):	5.681	Limit: H = G ± 1% =	5.624 - 5.737
Checked by Packing/Date:	31/07/2020	Verified by IPQA/Date:	31/07/2020

Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By	Shipper No.	Gross weight (Kg)	Weighed By
1	5.701	Phanishu	26	5.705	Phanishu	51	5.721	Phanishu	76		
2	5.709	Phanishu	27	5.700	Phanishu	52	5.688	Phanishu	77		
3	5.696	Phanishu	28	5.672	Phanishu	53	5.671	Phanishu	78		
4	5.688	Phanishu	29	5.684	Phanishu	54	5.683	Phanishu	79		
5	5.701	Phanishu	30	5.653	Phanishu	55	5.702	Phanishu	80		
6	5.687	Phanishu	31	5.652	Phanishu	56	5.662	Phanishu	81		
7	5.669	Phanishu	32	5.668	Phanishu	57	5.668	Phanishu	82		
8	5.659	Phanishu	33	5.669	Phanishu	58	5.688	Phanishu	83		
9	5.708	Phanishu	34	5.671	Phanishu	59	5.662	Phanishu	84		
10	5.710	Phanishu	35	5.661	Phanishu	60	5.674	Phanishu	85		
11	5.690	Phanishu	36	5.678	Phanishu	61	5.668	Phanishu	86		
12	5.673	Phanishu	37	5.699	Phanishu	62	5.677	Phanishu	87		
13	5.693	Phanishu	38	5.671	Phanishu	63	5.669	Phanishu	88		
14	5.667	Phanishu	39	5.668	Phanishu	64	5.685	Phanishu	89		
15	5.676	Phanishu	40	5.674	Phanishu	65	5.671	Phanishu	90		
16	5.676	Phanishu	41	5.657	Phanishu	66	5.654	Phanishu	91		
17	5.663	Phanishu	42	5.674	Phanishu	67	5.680	Phanishu	92		
18	5.692	Phanishu	43	5.660	Phanishu	68	5.700	Phanishu	93		
19	5.698	Phanishu	44	5.677	Phanishu	69	4.532	Phanishu	94		
20	5.664	Phanishu	45	5.669	Phanishu	70			95		
21	5.667	Phanishu	46	5.701	Phanishu	71			96		
22	5.688	Phanishu	47	5.714	Phanishu	72			97		
23	5.674	Phanishu	48	5.691	Phanishu	73			98		
24	5.668	Phanishu	49	5.701	Phanishu	74			99		
25	5.672	Phanishu	50	5.691	Phanishu	75			100		
Total No. of shippers weighed:	69	De-foiled tablets packed in Shipper No:	69	Checked by Sign / Date:	31/07/2020	Verified by Sign / Date:	31/07/2020	Loose pack details: Shipper No.: 69.... Quantity: 170 x 3 x 10 <sup>1</sup> s Weight: A: 532..			

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	Apur	27/07/2020	27/07/2020
Date	27/07/2020	27/07/2020		

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

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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 200 704

Customer:

Generic Health Care Pvt. Ltd.

27. MAN POWER ALLOCATION:

DATE: 31/07/2020 SHIFT: General		DATE: ..... SHIFT: .....	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking	Sathya, Varaj'a	Alu Alu strip Checking	
Printing Checking in Alu Alu strip	Sivasankari	Printing Checking in Alu Alu strip	
Alu Alu strip weighing	Lakshmi, Maheshwari	Alu Alu strip weighing	
Insertion of Alu Alu strip and leaflet into carton		Insertion of Alu Alu strip into carton	
Cartons weighing	Dhanalaksi	Cartons weighing	
Insertion of carton into shrink sleeve	NA	Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper	NA	Insertion of shrink wrapped carton into shipper	
Shipper Label Pasting	Dhanalaksi	Shipper Label Pasting	
Shipper Weighing	Dhanalaksi	Shipper Weighing	
Shipper Strapping	Dhanalaksi	Shipper Strapping	
Shipper packed	From...1...to...69	Shipper packed	From.....to.....
Signature of Packing	31/07/2020	Signature of Packing	

DATE: ..... SHIFT: .....		DATE: ..... SHIFT: .....	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking		Alu Alu strip Checking	
Printing Checking in Alu Alu strip		Printing Checking in Alu Alu strip	
Insertion of Alu Alu strip and leaflet into carton		Insertion of Alu Alu strip into carton	
Alu Alu strip weighing		Alu Alu strip weighing	
Cartons weighing		Cartons weighing	
Insertion of carton into shrink sleeve		Insertion of carton into shrink sleeve	
Insertion of shrink wrapped carton into shipper		Insertion of shrink wrapped carton into shipper	
Shipper Label Pasting		Shipper Label Pasting	
Shipper Weighing		Shipper Weighing	
Shipper Strapping		Shipper Strapping	
Shipper packed	From.....to.....	Shipper packed	From.....to.....
Signature of Packing		Signature of Packing	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	Amey	31/07/20	
Date	27/07/2020	27/07/2020		27/07/2020

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LIFE BIOTECH PVT LTDSAI 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.: GTF 200704

Customer:

Generic Health Care Pvt. Ltd.

## 28. PACKING MATERIAL RECONCILIATION:

Sr. No.	Material	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
A	Quantity received for the batch	31.200	97.000	20400	20400	NA	90	250mtrs	18
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	31.200	97.000	20400	20400	NA	90	250mtrs	18
D	Quantity packed	14.857	55.542	19346	19346	NA	69	150mtrs	18
E	Quantity rejected (Online) & Destroyed	7.456	32.001	956	NA	NA	NA	NA	NA
F	Quantity Returned	8.349	8.998	NA	956/046	NA	21	100mtrs	NA
G	Sample affixed on BPR	0.001	NA	01	01	NA	NA	NA	NA
H	QC samples	0.003	0.011	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.005	0.019	07	07	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	30.671	96.571	-0-	-0-	NA	NA	NA	NA
K	Variation (C - J)	0.529	0.429	-0-	-0-	NA	NA	NA	NA
L	%Variation (K x 100)/C	1.69%	0.44%	-0-	-0-	NA	NA	NA	NA
M	Acceptable limit	±2%	±2%	±2%	±2%	±2%			

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

NA

## 29. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. NA

Material	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
Quantity Returned	8.349	8.998	NA	956/046	NA	21	100mtrs	NA
Material returned by packing Sign./Date	84/13/08/2020	84/13/08/2020	NA	84/13/08/2020	NA	84/13/08/2020	84/13/08/2020	NA
Verified By IPQA Sign./Date	84/13/08/2020	84/13/08/2020	NA	84/13/08/2020	NA	84/13/08/2020	84/13/08/2020	NA
Material received by Store Sign./Date	84/13/08/2020	84/13/08/2020	NA	84/13/08/2020	NA	84/13/08/2020	84/13/08/2020	NA

## 30. 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)
31/07/2020	08	7.456	32.001	956	NA	NA	NA	NA	NA
				NA					184
Total Qty. Destroyed	08	7.456	32.001	956	NA	NA	NA	NA	NA
Destroyed by (Packing)	84/13/07/2020								
Verified by (IPQA)	84/31/07/2020								

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head	Quality Assurance
Sign.	L. Ka	Amey	27/07/2020	Amey	27/07/2020
Date	27/07/2020	27/07/2020		27/07/2020	

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LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD		Product Code: A08	Batch Size: 6,00,000 Tablets
Product	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-01	Batch No.: G1F 200 704
		Customer:	Generic Health Care Pvt. Ltd.

### 31. BATCH RECONCILIATION:

A	Batch Size	6,00,000 Nos.
B	Quantity received for packing	599713
C	Total quantity packed	580380
D	Control samples	200
E	Analytical Samples	120
F	In process samples	680 340
G	Others samples if any (Stability, Regulatory Samples, etc.)	NA
H	Packing Loss = B - (C + D + E + F + G)	18333
I	Total Loss = A - (C + D + E + F + G)	18620
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield should not less than 98.00%)	96.94%
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %... 95%...)	96.89%

Checked by Packing /Date: 24/07/2020

Verified by IPQA/Date: 31/07/2020

### 32. TRANSFER OF FINISHED GOODS:

Date	FGTN No.	Sales	Pack Size	No. of Units in a shipper	No. of Shippers	Transferred Quantity	FGTN Raised by Packing	FGTN Checked by IPQA	FGTN Received by Stores
13/08/2020	0445	Sales	3x10's	232x3x10's	69	68x232x3x10's	84	84	M. Saurav
						01x170x3x10's	84	84	M. Saurav
Total Qty. Transferred						58038	84	84	M. Saurav

### 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	Action taken	Observed By
		NA		

Checked by  
Packing:

Verified by  
Packing manager:

Approved by  
Head QA:

### 34. BPR REVIEW DETAILS:


Reviewed by	Name	Sign./Date
Packing Executive	Santhya	24/07/2020
QA Executive	Ram Kumar	31/07/2020
Production Assistant Manager/ HOD	BALASUBRAMANIAN-B	31/07/2020
QA Manager/ HOD	Stephen	31/07/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Amr	27/07/2020	Amr
Date	27/07/2020	24/07/2020		27/07/2020

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	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-01 Customer:	Batch No.: <u>GF 200704</u> Generic Health Care Pvt. Ltd.

**35. BATCH RELEASED FOR DESPATCH:**

Total quantity released: 580380 No's

Head QA sign/ Date: [Signature]  
27/07/2020

**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

Prepared by:		Checked by:		Approved By:
Dept.:	Production.	Production.	Quality Assurance.	Head Quality Assurance
Sign.	<u>L. Ke</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>27/07/2020</u>	<u>27/07/2020</u>	<u>27/07/2020</u>	<u>27/07/2020</u>

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	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b> Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00		Batch No.: <u>61 Feb 05 02</u>
	Customer:		Generic Health Care Pvt. Ltd.

### BATCH PACKAGING RECORD COVER SHEET

PRODUCT NAME	: Amloperin 5mg/5mg
GENERIC NAME	: Amlodipine Besilate and Perindopril Erbumine Tablets
LABEL CLAIM	Each uncoated tablet contains:
	Amlodipine Besilate BP
	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	: NIL
EFFECTIVE BATCH. No. /DATE	: <u>GF 200405 / 22104 / 2020</u>
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets
PACKING CONFIGURATION	: 3 x 10 Tablets Sales Pack (Alu Alu Packing)
BPR ISSUED BY/DATE (QA)	: <u>By 23/05/2020</u>
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <u>L. Ko 23/05/2020</u>
MFG. DATE: <u>05/05/20</u>	EXP. DATE: <u>04/05/2023</u>
ALLOTTED BY: QA SIGN/DATE: <u>By 23/05/2020</u>	COUNTER CHECKED BY: QA SIGN/DATE: <u>By 23/05/2020</u>
QUANTITY RECEIVED FROM PRODUCTION	: <u>596349 Tablets</u>
DATE OF COMMENCEMENT: <u>27/05/2020</u>	DATE OF COMPLETION: <u>28/05/2020</u>
QUANTITY	: 600000 tablets
RELEASED QUANTITY OF PACKED TABLETS	: 5922000 tablets
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	<u>By 28/05/2020</u>

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ko</u>	<u>By 21/04/2020</u>	<u>By 22/04/2020</u>	<u>By 22/04/2020</u>
Date	<u>20/04/2020</u>	<u>21/04/2020</u>	<u>22/04/2020</u>	<u>22/04/2020</u>

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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 2 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.: GFd00502

Customer:

Generic Health Care Pvt. Ltd.

**1. INDEX**

Sr. No.	Content	Page No.
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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
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11	Weight verification record of received semi-finished product	9
12	Container weight details	9
13	Container consumption details.	9
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34	Batch released for Despatch	24
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Prepared by:

Checked by:

Approved By:

Dept.

Production

Production

Quality Assurance

Head Quality Assurance

Sign.

L. Ka

3a. Lalitha

P. N. J. S.

J. M. S.

Date

20/04/2020

21/04/2020


22/04/2020

22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 24
	<b>BATCH PACKING RECORD</b>	Product Code: A08 BPR. No.: BPR/T/107-00 Customer:	Batch Size: 6,00,000 Tablets Batch No.: G1Fdo0502 Generic Health Care Pvt. Ltd.
<b>Product</b>	Amloperin 5mg/5mg		

## 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.	<b>Dispensing</b>	
a)	Equipment clean tag and dispensing tag attached with batch record	Yes
b)	Packaging material is checked	Yes
5.	<b>Packing</b>	
a)	Rinse water analysis report attached with BPR	NA
b)	Approved specimen of printed foil, show box and shipper label are attached	Yes
c)	Control / Stability / Finished product analysis samples are withdrawn	Yes
d)	Reconciliation of packing materials is done	Yes
e)	Tablet reconciliation is done	Yes
f)	In process checks parameters done at regular interval and recorded into BPR	Yes
6.	<b>Attachment</b>	
a)	Finished Goods Transfer Note	Yes
b)	Certificate of analysis of finished product is submitted	Yes
c)	Stereo Impression Form and Destruction Record	Yes
7.	Complete set of BPR Submitted	Yes

Checked By QA/Date: *[Signature]*

\*Mention total number of pages.


Remarks (If any) .....

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ke</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	20/04/2020	21/04/2020	22/04/2020	22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 24
	<b>BATCH PACKING RECORD</b>	<b>Product Code: A08</b>	<b>Batch Size: 6,00,000 Tablets</b>
	<b>Product</b>	<b>Amloperin 5mg/5mg</b>	<b>Batch No.: GF 201902</b>
		<b>Customer:</b>	<b>Generic Health Care Pvt. Ltd.</b>

### 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 <b>Thickness:</b> 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/1001	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/C001	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 <sup>2</sup>	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

<b>Prepared by:</b>		<b>Checked by:</b>		<b>Approved By:</b>
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	Saladun	P. H. Sub	J. M. Sub
Date	20/04/2020	21/04/2020	22/04/2020	

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 5 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF200502 Generic Health Care Pvt. Ltd.

#### 4. DISPENSING LINE CLEARANCE CHECKS

Date: 27/05/2020 Time: 09:35

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

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

Equipment	Mobile Laminar Air Flow	Weighing Balance		Area
ID No.	ST/BAF/001	NA	NA	ST/BAL/001
Previous Product	Amloperin 5mg/5mg			
B. No.	GF200501			
Cleaned by Sign/Date	Rajil 27/05/2020			
Checked by Store Sign/Date	H. Sava 27/05/2020			
Verified by IPQA Sign/Date	27/05/2020			

ENVIRONMENTAL CONDITIONS: Date: 27/05/2020 Time: 09:40	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	H. Sava	27/05/2020
Differential Pressure across the booth Limit: 5 to 20 mm Water	11mm	H. Sava	27/05/2020

APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature] Date: 27/05/2020

Dispensing start Time: 09:45 End Time: 10:15

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	[Signature]	[Signature]	[Signature]	
Date	20/04/2020	27/04/2020	22/04/2020	22/04/2020	

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SAI PRIMUS  
LIFE BIOTECH PVT LTD

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

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BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

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

Batch No.: GFD00502

Customer:

Generic Health Care Pvt. Ltd.


5. DISPENSING RECORD OF PACKING MATERIALS: Date: 27/05/2020 Shift: 4 Time: 9.45

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	41.500	PMG/00005	04	H. S. 27/05/2020	Q 27/05/2020
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	91.800	45.330 59.650	PMG/00008 PMG/00004	04 03	H. S. 27/05/2020	Q 27/05/2020
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	20400	20400	PMG/00004	09	H. S. 27/05/2020	Q 27/05/2020
Amloperin packing inserts	PPI/GH/T001	No	20400	20400	PMG/00007	04	H. S. 27/05/2020	Q 27/05/2020
Shrink Sleeves (PVC)	PPS/GH/P001	No	1275					Q 27/05/2020
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	90	90	PMG/00178	09	H. S. 27/05/2020	Q 27/05/2020
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	18	18	PMG/00010	03	H. S. 27/05/2020	Q 27/05/2020
Strapping Role	PPR/GH/S001	Mtrs	250	250	PMG/00001	01	H. S. 27/05/2020	Q 27/05/2020
Shipper Label	N/A	No	91					Q 27/05/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	3. S. S. S. S. S.	P. S. S. S. S.	
Date	27/05/2020	27/05/2020	27/05/2020	

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 7 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>Amloperin 5mg/5mg</b>	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF200502 Generic Health Care Pvt. Ltd.

## 6. LINE CLEARANCE CHECKS:

### 6.1 PRIMARY PACKING:

Date/ Shift 27/05/2020... General... 23/05/2020... General

Previous Product: Amloperin 5mg/5mg		Batch No.: GF200501				
Sr. No.	Checks	Time	Observation			
			12:35 Packing	IPQA	07:16 Packing	IPQA
1.	Area status board is updated for "CLEANED" status.		✓	✓	✓	✓
2.	Check and ensure that the area is visually clean and free from previous product		✓	✓	✓	NA
3.	Check and ensure the differential pressure of the area is within specified limit		✓	✓	✓	✓
4.	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
5.	Check the temperature and relative humidity of the area within specified limit		✓	✓	✓	NA
6.	Check the tablets of the previous product/ batch removed.		✓	✓	✓	NA
7.	Check the loose Alu Alu strip cutting, rejected rolls, empty cores of foil of previous product /batch are removed.		✓	✓	✓	NA
8.	Check the surroundings of the machine and free from the previous products and batch		✓	✓	✓	NA
9.	Check the foil printing stereotypes, Labels of previous product/batch are removed.		✓	✓	✓	NA
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.		✓	✓	✓	✓
11.	Check and ensure the Cleanliness following change part of Alu Alu strip packing machine		✓	✓	✓	✓
12.	Check for the absence of previous batch/ product at machine conveyor belt.					
a)	Check Hopper from Top, bottom of machine, below the hopper, between bottom side of conveyor belt and collating unit.		✓	✓	✓	NA
b)	Check for cleaning of hopper, feeding channel, vibrator plate, in feed roller and sweep brush.		✓	✓	✓	✓
c)	Check tool box, thinner and ink box		✓	✓	✓	✓

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

Cleaning satisfactory/Not-satisfactory  
Checked by Packing (Sign./Date): 84/27/05/2020

Cleaning satisfactory/Not-satisfactory  
Verified by IPQA (Sign./Date): 84/27/05/2020

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

### 6.2 AREA AND EQUIPMENT CLEARANCE OF PRIMARY PACKING

Date/Time: 27/05/2020 12:46

Previous Product: <u>Amloperin 5mg/5mg</u>				Batch No.: <u>GF200501</u>			
S. No.	Equipment / Area Name	Eq.ID. /Area. No.	Cleaning Type A/B	Operation and cleaning as per SOP number	Cleaned by Sign/Date	Checked by (Packing) Sign/Date	Verified by (IPQA) Sign/Date
1.	Alu Alu Packing Area	<u>SPC/APP/ALU</u>	<u>B</u>	PDGN/006	<u>Mam</u>	<u>27/05/2020</u>	<u>27/05/2020</u>
2.	Alu Alu Packing Machine	<u>PD/ALU/001</u>	<u>B</u>	PDOP/020, PDCL/020	<u>Mam</u>	<u>27/05/2020</u>	<u>27/05/2020</u>

### 6.3 ENVIRONMENTAL CONDITIONS:

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


Refer to SOP No.: SOP: QAGN/011		Date: 27/05/2020 Time: 12:45		Date: 28/05/2020 Time: 07:16	
Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	25°C	84/27/05/2020	24°C	84/28/05/2020	84/28/05/2020
RH % Limit: NMT 60%	58%	84/27/05/2020	57%	84/28/05/2020	84/28/05/2020
DP Limit: NLT 10 Pascal	10 pascal	84/27/05/2020	10 pascal	84/28/05/2020	84/28/05/2020
Primary Packing Started Date/Time: 27/05/2020 12:46 Completed Date/Time: 28/05/2020 17:05					

APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: 84/27/05/2020

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ko	3. Lalitha	P. H. 22/04/2020		
Date	20/04/2020	21/04/2020			

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 8 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF200502 Generic Health Care Pvt. Ltd.

**7. VERIFICATION OF DISPENSED PACKING MATERIALS:** Date: 27/05/2020 Shift: G..... Time: 12:42

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   00005	04	SY	Q
188 mm Alu/Alu Base Foil	PBF/GH/A001	Kg	PMG   00003 PMG   00004	04 03	SY	Q
Ptd Carton Amloperin 5 mg / 5 mg	PPC/GH/A001	No	PMG   00004	04	SY	Q
Amloperin packing inserts	PPI/GH/I001	No	PMG   00007	04	SY	Q
Shrink Sleeves (PVC)	PPS/GH/P001	No	N/A	N/A	N/A	N/A
5 Ply 390x390x260 mm C/Boxes	PUS/GH/C001	No	PMG   00178	04	SY	Q
GHPL Ptd Bopp Tapes	PPB/GH/B001	No	PMG   00010	03	SY	Q
Strapping Role	PPR/GH/S001	Mtrs	PMG   00001	01	SY	Q
Shipper Label	N/A	No				Q

**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. Maran 27/05/2020	P. Maran 27/05/2020	Mouni	SY 27/05/2020	Q 27/05/2020

**9. RECEIPT OF PRODUCT AND MATERIALS:** Date/Shift: 27/05/2020 G Time: 12:45

(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	SY	Q
2.	Relative Humidity observed on display (Limit: NMT 60%)	58%	SY	Q
3.	Bulk product containers are of the required product/Batch number and is approved by QC	Yes	SY	N/A
4.	Status label of machine/ line is for same product	Yes	SY	Q
5.	Printed foil/Base rolls are of the required product.	Yes	SY	Q
6.	All secondary packing materials are of the required product	Yes	SY	Q


**10. DETAIL OF THE PRODUCT AS PER BMR:**

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	139.7 mg.	SY	Q
2.	Colour of Tablet	White colour	SY	Q
3.	Quantity (Net Qty.in Kg)	83.310	SY	Q
4.	Number of Containers	04	SY	Q

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Saladur	P. H. Sub	
Date	20/04/2020	21/04/2020	22/04/2020	

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: 61F200502 Generic Health Care Pvt. Ltd.

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

Balance I.D. No.: PD/BAL/014

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

Product Name	Batch No.	Mfg. Date	Exp. Date	Qty. recd. For packing	No. of Containers taken for packing
Amloperin 5mg/5mg	61F200502	05/2020	04/2023	83.310 Kg Equivalent to 596349 Nos.	From Container No. 01 To Container No. 04 Total No. of Containers taken 04
Checked by Packing (Sign. /Date): <u>Sy 27/05/2020</u>			Verified By IPQA (Sign. /Date): <u>Sy 27/05/2020</u>		

# 12. CONTAINER WEIGHT DETAILS:

Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA	Container No.	Gross Weight in Kg	Weighed By Packing	Checked By IPQA
1	17.480	Gopal	Sy	11	NA	NA	NA
2	17.460	Gopal	Sy	12			
3	29.000	Gopal	Sy	13			
4	28.600	Gopal	Sy	14			
5	NA	NA	NA	15			
6				16			
7				17			
8				18			
9				19			
10				20			

# 13. CONTAINER CONSUMPTION DETAILS:


S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	13:40	16:30	01	Mam	11	NA	NA	NA	NA
2	16:25	19:00	02	Mam	12				
3	17:30	19:10	03	Mam	13				
4	19:15	19:05	04	Mam	14				
5	NA	NA	NA	NA	15				
6					16				
7					17				
8					18				
9					19				
10					20				

Checked By Packing (Sign. /Date): Sy 28/05/2020 Verified by IPQA (Sign. /Date): Sy 28/05/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ke</u>	<u>Sy 28/05/2020</u>	<u>P. H. Bab</u>	<u>Sy 28/05/2020</u>
Date	<u>20/04/2020</u>	<u>20/04/2020</u>	<u>22/04/2020</u>	<u>22/04/2020</u>

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 24
	<b>BATCH PACKING RECORD</b>		<b>Product Code: A08</b> <b>Batch Size: 6,00,000 Tablets</b>
<b>Product</b>	<b>Amloperin 5mg/5mg</b>	<b>BPR. No.: BPR/T/107-00</b> <b>Customer:</b>	<b>Batch No.: GF200502</b> <b>Generic Health Care Pvt. Ltd.</b>

#### 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.:	GF200502	OK
Mfg. Date:	05/2020	OK
Exp. Date:	04/2023	OK
Pack size (3 x 10's)- Carton	NA	NA
Other instructions if any	NA	NA
Initiated by	Mani	Mani
Checked by Packing (Sign. & Date)	Sy 27/05/2020	Sy 27/05/2020
Verified by IPQA (Sign. & Date)	Sy 27/05/2020	Sy 27/05/2020

#### 15. SPECIMEN OF PRINTED FOIL:

S. No.	Date	Specimen No.	Done By Sign & Date	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	27/05/2020	01	Mani 27/05/2020	Sy 27/05/2020	Sy 27/05/2020
02	28/05/2020	02	Mani 28/05/2020	Sy 28/05/2020	Sy 28/05/2020
			NA		Sy 28/05/2020

#### 16. PACKING INSTRUCTIONS:

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

##### Time record for packing detail

Sr. No.	Date/Shift	Primary packing		Secondary packing		Checked by (Packing) Sign. & Date
		Started at	Completed at	Started at	Completed at	
01	27/05/2020 G	13:40	19:00	13:45	19:05	Sy 27/05/2020
02	28/05/2020 G	07:30	17:05	07:35	14:10	Sy 28/05/2020
						Sy 28/05/2020

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


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

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	3a/04/2020	P.H. 22/04/2020	Sy 22/04/2020
Date	20/04/2020	21/04/2020		

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF200502 Generic Health Care Pvt. Ltd.

18. **ALU ALU PACKING MACHINE PARAMETERS:** Date/Shift: 27/05/2020... Time: 13.14.20

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	BPM 110 (160 °C - 200 °C) To be established	OK	S 27/05/2020	S 27/05/2020
Sealing Temperature	198 °C	OK	S 27/05/2020	S 27/05/2020
Leak test to be performed on 4 Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	OK	S 27/05/2020	S 27/05/2020
Machine Speed	To be established	24	S 27/05/2020	S 27/05/2020

19. **MACHINE IN-PROCESS CONTROL:**


Date/ Shift	27/05/2020 / General										28/05/2020 General									
Machine Operator Name	Mani										Mani									
Time of inspection	13:15	14:15	15:15	16:15	17:15	18:15	19:15	20:15	21:15	22:15	01:30	02:30	03:30	04:30	05:30	06:30	07:30	08:30	09:30	10:30
Sealing Temperature (To be established)	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C	198°C
Leak test on Alu Alu strips* (Qty.: 4)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Knurling /Sealing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Code No.:	PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.:	GF200502	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	05/2020	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	04/2023	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed To be established	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24	24
Checked by (Packing)	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S
Checked by (IPQA)	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S

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

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	S. K.	P. N. S.	S. K.	S. K.
Date	20/04/2020	20/04/2020	22/04/2020	22/04/2020	22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg		BPR. No.: BPR/T/107-00 Batch No.: GF200502 Customer: Generic Health Care Pvt. Ltd.

### 19.1 MACHINE IN-PROCESS CONTROL:

Date/ Shift	28/05/2020 General							
Machine Operator Name	Mam' L.T/L.S L.T/H.S H.T/L.S H.T/H.S							
Time of inspection	11:45	12:35	13:20	13:30	13:40	13:50	14:00	
Sealing Temperature (To be established)	199°C	199°C	199°C	199°C	199°C	199.5°C	220°C	
Leak test on Alu Alu strips* (Qty.: 04)	OK	OK	OK	OK	OK	OK	OK	
Knurling /Sealing	OK	OK	OK	OK	OK	OK	OK	
Pocket Formation	OK	OK	OK	OK	OK	OK	OK	
Horizontal cutting	OK	OK	OK	OK	OK	OK	OK	
Vertical cutting	OK	OK	OK	OK	OK	OK	OK	
Quality of Over printing	OK	OK	OK	OK	OK	OK	OK	
Code No.: PON/DRUGS/ 19 13 4323	OK	OK	OK	OK	OK	OK	OK	
B. No.: GF200502	OK	OK	OK	OK	OK	OK	OK	
Mfg. Date: 05/2020	OK	OK	OK	OK	OK	OK	OK	
Exp. Date: 09/2023	OK	OK	OK	OK	OK	OK	OK	
Machine Speed To be established	30	29	29	10	35	10	35	
Checked by (Packing)	NA	84	84	NA	NA	NA	NA	
Checked by (IPQA)	Q			Q	Q	Q	Q	


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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	[Signature]	T.K. [Signature]	[Signature]
Date	20/04/2020	21/04/2020	22/04/2020	

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: 61F200502 Generic Health Care Pvt. Ltd.

### 19.2 MACHINE IN-PROCESS CONTROL:

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

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ka</i>	<i>21/04/2020</i>	<i>21/04/2020</i>	<i>21/04/2020</i>
Date	21/04/2020	21/04/2020	21/04/2020	21/04/2020

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LIFE BIOTECH PVT LTD

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

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**BATCH PACKING RECORD**

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

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

Batch No.: 6F2,050L

Customer:

Generic Health Care Pvt. Ltd.

**20. DEFOILING OF ALU ALU STRIPS:**

Date	De-foiling started at	De-foiling completed at	Weight of De-foiled tablets	De-foiling Done by	Checked by/ Date (Packing)	Verified by Date (QA)
28/05/2020	13:10	13:25	2.200	Sathya, Sudha	84 28/05/2020	84 28/05/2020
Total Weight of De-foiled Tablets			2.200	Checked By / Date (Packing): 84 28/05/2020		Verified By / Date (IPQA): 84 28/05/2020

**20.1 INSPECTION OF DE-FOILED TABLETS:**

Date	Inspection started at	Inspection completed at	Inspection Done by	Quantity of Good tablets		Qty. of Rejected Tablets		Checked by/ Date (Packing)	Verified by Date (QA)
				Kgs	Nos	Kgs	Nos		
28/05/2020	13:30	13:45	Sathya	2.150	15390	0.050	357	84 28/05/2020	84 28/05/2020
Total				2.150		0.050			
Total Quantity of Rejected Tablets Destroyed ...0.050. Kgs ...357.... Nos.				Checked By / Date (Packing): 84 28/05/2020			Verified By / Date (IPQA): 84 28/05/2020		

Prepared by:

Checked by:

Approved By:

Dept.

Production

Production

Quality Assurance

Head Quality Assurance

Sign.

L. Ka

Sathya

P. K. Sathya

P. K. Sathya

Date

20/04/2020

21/04/2020


21/04/2020

21/04/2020

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	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 15 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GF200502 Generic Health Care Pvt. Ltd.

21. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift 27/05/2020... General... 28/05/2020... General

Previous Product: <u>Amloperin 5mg/5mg</u>		Batch No.: <u>GR200501</u>				
Sr. No.	Checks	Time	Observation			
			12:50		07:10	
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	✓
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	✓
4	Check and ensure the Correct status board is written.		✓	✓	✓	✓
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	✓
6	Check and ensure the previous batch details are deleted from the inkjet machine.		✓	✓	✓	✓
7	Check and ensure the Alu Alu strips, rejected Carton, Shipper and 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.		✓	✓	✓	✓
12	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	✓

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

Cleaning Satisfactory / Not-satisfactory# (Packing) Sign. /Date: Sy 27/05/2020 Cleaning Satisfactory / Not-satisfactory# (IPQA) Sign. /Date: Sy 27/05/2020

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.

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.
3. Set and operate Overprinting Machine.
4. Overprinting shall be in indelible ink.
5. Overprinting Details shall be checked by Packing and cross-checked by QA before starting the operation.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	PD/LBB/004	PD/BAL/018	NA	PD/STR/001	PD/BAL/020	Secondary Packing Hall
Previous Product:	Amloperin 5mg/5mg					
Batch No.:	GF200501					
Cleaned by:	Sathy					
Checked by Packing:	Sy 27/05/2020					
Verified by IPQA:	Sy 27/05/2020					

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	Sathy	P. H. G. B.	Sathy	
Date	20/04/2020	21/04/2020	22/04/2020	22/04/2020	

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SAI PRIMUS  
LIFE BIOTECH PVT LTD

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

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### BATCH PACKING RECORD

Product Code: 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.

### 21.2 ENVIRONMENTAL CONDITIONS:

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

Shift: (General).....		Date/Time: 27/05/2020 12:30			Date/Time: 27/05/2020 07:30		
		Observation	Checked by Packing	Verified by IPQA	Observation	Checked by Packing	Verified by IPQA
Refer to SOP No.: SOP: QAGN/011	Temperature °C Limit: NMT 25°C	23°C	84	Q	24°C	84	Q

Secondary Packing Started Date/Time: 27/05/2020 13:45... Completed Date/Time: 28/05/2020 14:10

APPROVAL FOR SECONDARY PACKING:

Approved by IPQA Sing/Date: 27/05/2020

### 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.:	GF200502	OK	OK
Mfg. Date:	05/2020	OK	OK
Exp. Date:	04/2023	OK	OK
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	NA
Initiated by Sign. & Date	Mam	Mam	Dhanalakshmi
Checked by Packing Sign. & Date	Ramya 26/05/2020	Ramya 26/05/2020	84 27/05/2020
Verified by IPQA Sign. & Date	Q 26/05/2020	Q 26/05/2020	Q 27/05/2020

#### 22.1 Carton Overprinting Specimen:


S. No.	Date	Carton Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	26/05/2020	01	Ramya 26/05/2020	Q 26/05/2020
02	27/05/2020	01	84 27/05/2020	Q 27/05/2020

Note – Attach specimen copy of over printed carton

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Sankar	P. M. Reddy	J. Muthu
Date	20/04/2020	21/04/2020	22/04/2020	22/04/2020

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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 24
	<b>BATCH PACKING RECORD</b>		Product Code: A08 Batch Size: 6,00,000 Tablets
<b>Product</b>	Amloperin 5mg/5mg	BPR. No.: BPR/T/107-00 Customer:	Batch No.: GFDW0502 Generic Health Care Pvt. Ltd.

### 22.2 Shipper Label Specimen:

S. No.	Date	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	27/05/2020	01	8427/05/2020	8427/05/2020

### 23. CARTON WEIGHT LIMIT SETTING: Date/Shift: 27/05/2020.....Time: 13.50...

Weight of ten individual empty cartons are given below:

1. 5.8	3. 5.7	5. 5.9	7. 5.8	9. 5.7
2. 5.6	4. 5.8	6. 5.8	8. 5.9	10. 5.7

Total weight of ten empty cartons = 57.7

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:

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

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

Weight of ten individual Leaflets are given below:

1. 3.2	3. 3.3	5. 3.2	7. 3.4	9. 3.2
2. 3.3	4. 3.4	6. 3.2	8. 3.3	10. 3.2

Total 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: 55. 57.7	Average weight of one empty Carton (A): 5.77
Weight of ten filled Alu Alu strip: 25.8	Average weight of one filled Alu Alu strip (B): 2.58
Weight of ten Leaflets: 32.7	Average weight of one Leaflet (C): 3.27
Weight of one filled Carton C = (A+3B+C) 16.78	Limit: D = C ± 1 % = (To be established) 16.61 - 16.94
Checked by Packing/Date: 84 27/05/2020	Verified by IPQA/Date: 84 27/05/2020

### 23.2 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	3 x 3 x 10 <sup>5</sup>	84 27/05/2020
2	Control Sample (Middle)	3 x 3 x 10 <sup>5</sup>	84 28/05/2020
3	Control Sample (Final)	1 x 2 x 10 <sup>5</sup>	84 28/05/2020
4	Stability Sample	1 x 10 x 3 x 10 <sup>5</sup>	84 28/05/2020
5	Other Sample	1 x 3 x 10 <sup>5</sup>	84 28/05/2020
6	Analytical sample	1 x 3 x 10 <sup>5</sup>	84 27/05/2020
Total Qty.		65 35 x 10 <sup>5</sup> = 350 Tablets	84 27/05/2020

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	3. 2. 2020	P. K. 2020	84 27/05/2020
Date	20/04/2020	20/04/2020	22/04/2020	22/04/2020

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

### BATCH PACKING RECORD

**Batch Size: 6,00,000 Tablets**

Product

**Amloperin 5mg/5mg**

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

Batch No.: G1F20P503

Customer:

**Generic Health Care Pvt. Ltd.**

Date/ Shift	27/05/2020	(Rem erry)							27/05/2020	/ 28/05/2020						
Parameters	Specification	Packing							IPQA							
		observation														
Time		13:55	14:55	15:45	16:40	17:40	18:45	T	14:10	16:15	18:30	20:45	07:50	12:00	14:00	
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	
No. of cartons in a shrink sleeves	16 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Shrink wrapping temperature*	ND	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
No. of shrink sleeves in a 5 ply shipper	14 shrinks 282-COY-ton	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK		OK	OK	OK	OK	OK	OK	OK	
Checked by		Sy	Sy	Sy	Sy	Sy	Sy		Sy	Sy	Sy	Sy	Sy	Sy	Sy	

\*Temperature to be mentioned.

34 27/05/2020

Date/Shift	23/05/2020	General							observation						
Parameters	Specification	Packing							IPQA						
		07:30	08:30	09:40	10:45	11:50	12:45	13:30							
Time															
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK							
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK							
No. of cartons in a shrink sleeves	16 packed cartons	NA	NA	NA	NA	NA	NA	NA							
Shrink wrapping temperature*	N8	NA	NA	NA	NA	NA	NA	NA							
No. of shrink sleeves in a 5 ply shipper	14 shrinks 282 carton	OK	OK	OK	OK	OK	OK	OK							
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK							
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK							
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK							
Checked by		Sy	Sy	Sy	Sy	Sy	Sy	Sy							

\*Temperature to be mentioned.

Prepared by:

Checked by:

Approved By: \_\_\_\_\_

Dept.

## Production

## Production

## Quality Assurance

## Head Quality Assurance

## Sign

1. Ko-

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24 Feb 1962

01-11-2019

|      |            |
|------|------------|
| Date | 20/04/2020 |
|------|------------|

21/04/2020

22/04/11

8.1.2.2

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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**

Batch No.: G1F dop 5 02

Customer:

**Generic Health Care Pvt. Ltd.**

**24.2 SECONDARY PACKING IN-PROCESS CHECKS:** (Please keep  $\checkmark$  mark if found "Ok")

[illegible]

\*Temperature to be mentioned.

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


[illegible]

\*Temperature to be mentioned.

| Prepared by: |            | Checked by:        |                    | Approved By:           |
|--------------|------------|--------------------|--------------------|------------------------|
| Dept.        | Production | Production         | Quality Assurance  | Head Quality Assurance |
| Sign.        | L. Ko      | <i>[Signature]</i> | <i>[Signature]</i> | <i>[Signature]</i>     |
| Date         | 20/04/2020 | 21/04/2020         | 22/04/2020         | 22/04/2020             |

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|   |   |  |   |
|---|---|--|---|
| <br><b>SAI PRIMUS</b><br>LIFE BIOTECH PVT LTD | <b>SAI PRIMUS LIFE BIOTECH PVT LTD</b><br>Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,<br>Villianur Commune, Puducherry-605009. |  | Page 20 of 24   |
|   | <b>BATCH PACKING RECORD</b>   |  | Product Code: A08<br>Batch Size: 6,00,000 Tablets     |
| Product: Amloperin 5mg/5mg  | BPR. No.: BPR/T/107-00<br>Customer:   |  | Batch No.: 61F200502<br>Generic Health Care Pvt. Ltd. |

25. SHIPPERS WEIGHING: Date/Shift: 27/05/2020..G.. Time: 13:55.. Balance I.D. No.: PD/EA/020

|   |  |
|---|--|
| Weight of ten Shrinks: N/A                      | Average weight of one filled Shrink (E): N/A |
| Weight of ten empty shippers: N/A               | Average weight of one empty shipper (F): N/A |
| Weight of one filled shipper (G) = (14E+F): N/A | Limit: H = G ± 1% = (to be established) N/A  |
| Checked by Packing/Date: Sy 28/05/2020          | Verified by IPQA/Date: Sy 28/05/2020         |

| Shipper No.                       | Gross weight (Kg)                          | Weighed By   | Shipper No.                           | Gross weight (Kg) | Weighed By                             | Shipper No. | Gross weight (Kg)  | Weighed By   | Shipper No. | Gross weight (Kg) | Weighed By |
|-----------------------------------|--|--------------|---------------------------------------|-------------------|--|-------------|--|--------------|-------------|-------------------|------------|
| 1                                 | 5.925                                      | Dhanalakshmi | 26                                    | 5.879             | Dhanalakshmi                           | 51          | 5.869  | Dhanalakshmi | 76          |                   |            |
| 2                                 | 5.888                                      | Dhanalakshmi | 27                                    | 5.872             | Dhanalakshmi                           | 52          | 5.830  | Dhanalakshmi | 77          |                   |            |
| 3                                 | 5.895                                      | Dhanalakshmi | 28                                    | 5.886             | Dhanalakshmi                           | 53          | 5.859  | Dhanalakshmi | 78          |                   |            |
| 4                                 | 5.915                                      | Dhanalakshmi | 29                                    | 5.875             | Dhanalakshmi                           | 54          | 5.867  | Dhanalakshmi | 79          |                   |            |
| 5                                 | 5.927                                      | Dhanalakshmi | 30                                    | 5.873             | Dhanalakshmi                           | 55          | 5.874  | Dhanalakshmi | 80          |                   |            |
| 6                                 | 5.923                                      | Dhanalakshmi | 31                                    | 5.863             | Dhanalakshmi                           | 56          | 5.860  | Dhanalakshmi | 81          |                   |            |
| 7                                 | 5.925                                      | Dhanalakshmi | 32                                    | 5.852             | Dhanalakshmi                           | 57          | 5.834  | Dhanalakshmi | 82          |                   |            |
| 8                                 | 5.923                                      | Dhanalakshmi | 33                                    | 5.849             | Dhanalakshmi                           | 58          | 5.845  | Dhanalakshmi | 83          |                   |            |
| 9                                 | 5.919                                      | Dhanalakshmi | 34                                    | 5.851             | Dhanalakshmi                           | 59          | 5.864  | Dhanalakshmi | 84          |                   |            |
| 10                                | 5.931                                      | Dhanalakshmi | 35                                    | 5.853             | Dhanalakshmi                           | 60          | 5.834  | Dhanalakshmi | 85          |                   |            |
| 11                                | 5.919                                      | Dhanalakshmi | 36                                    | 5.855             | Dhanalakshmi                           | 61          | 5.845  | Dhanalakshmi | 86          |                   |            |
| 12                                | 5.916                                      | Dhanalakshmi | 37                                    | 5.857             | Dhanalakshmi                           | 62          | 5.840  | Dhanalakshmi | 87          |                   |            |
| 13                                | 5.927                                      | Dhanalakshmi | 38                                    | 5.840             | Dhanalakshmi                           | 63          | 5.842  | Dhanalakshmi | 88          |                   |            |
| 14                                | 5.904                                      | Dhanalakshmi | 39                                    | 5.842             | Dhanalakshmi                           | 64          | 5.835  | Dhanalakshmi | 89          |                   |            |
| 15                                | 5.920                                      | Dhanalakshmi | 40                                    | 5.842             | Dhanalakshmi                           | 65          | 5.840  | Dhanalakshmi | 90          |                   |            |
| 16                                | 5.892                                      | Dhanalakshmi | 41                                    | 5.826             | Dhanalakshmi                           | 66          | 5.829  | Dhanalakshmi | 91          |                   |            |
| 17                                | 5.884                                      | Dhanalakshmi | 42                                    | 5.855             | Dhanalakshmi                           | 67          | 5.832  | Dhanalakshmi | 92          |                   |            |
| 18                                | 5.917                                      | Dhanalakshmi | 43                                    | 5.866             | Dhanalakshmi                           | 68          | 5.836  | Dhanalakshmi | 93          |                   |            |
| 19                                | 5.888                                      | Dhanalakshmi | 44                                    | 5.852             | Dhanalakshmi                           | 69          | 5.832  | Dhanalakshmi | 94          |                   |            |
| 20                                | 5.914                                      | Dhanalakshmi | 45                                    | 5.867             | Dhanalakshmi                           | 70          | 5.861  | Dhanalakshmi | 95          |                   |            |
| 21                                | 5.897                                      | Dhanalakshmi | 46                                    | 5.845             | Dhanalakshmi                           | 71          |  |              | 96          |                   |            |
| 22                                | 5.878                                      | Dhanalakshmi | 47                                    | 5.865             | Dhanalakshmi                           | 72          |  |              | 97          |                   |            |
| 23                                | 5.884                                      | Dhanalakshmi | 48                                    | 5.844             | Dhanalakshmi                           | 73          |  |              | 98          |                   |            |
| 24                                | 5.882                                      | Dhanalakshmi | 49                                    | 5.869             | Dhanalakshmi                           | 74          |  |              | 99          |                   |            |
| 25                                | 5.888                                      | Dhanalakshmi | 50                                    | 5.840             | Dhanalakshmi                           | 75          |  |              | 100         |                   |            |
| Total No. of shippers weighed: 70 | De-foiled tablets packed in Shipper No: 70 |              | Checked by Sign / Date: Sy 28/05/2020 |                   | Verified by Sign / Date: Sy 28/05/2020 |             | Loose pack details:<br>Shipper No: .....<br>Quantity: .....<br>Weight: ..... |              |             |                   |            |

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

Weight of filled carton: 169.80  
 Average weight of one filled carton (E): 16.98  
 Weight of ten empty shipper: 11.100  
 Average weight of one empty shipper (F): 1.110  
 Weight of one filled shipper (G) 282E+F = 5.898  
 Limit H = G ± 1% = 5.839 - 5.956  
 No. of carton per shipper has been checked for all 282 shippers

|                    |               |                           |                        |                            |  |
|--------------------|---------------|---------------------------|------------------------|----------------------------|--|
| Prepared by: L. Ko |               | Checked by: P. V. Lakshmi |                        | Approved By: Sy 28/05/2020 |  |
| Dept. Production   | Production    | Quality Assurance         | Head Quality Assurance |                            |  |
| Sign. L. Ko        | P. V. Lakshmi |                           |                        |                            |  |
| Date: 20/04/2020   | 21/04/2020    | 22/04/2020                |                        |                            |  |

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LIFE BIOTECH PVT LTD

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

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### BATCH PACKING RECORD

Product Code: A08

Batch Size: 6,00,000 Tablets

Product

Amloperin 5mg/5mg

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

Batch No.: 61F200502

Customer:

Generic Health Care Pvt. Ltd.

### 26. MAN POWER ALLOCATION:

DATE: 27/05/2020

SHIFT: Amara

| ACTIVITIES   | DONE BY                     |
|--|-----------------------------|
| Alu Alu strip Checking                             | Indra, Sivasankari          |
| Printing Checking in Alu Alu strip                 | Pathya, Naveena             |
| Alu Alu strip weighing                             | Dhanapriya, Maheswari       |
| Insertion of Alu Alu strip and leaflet into carton | Pornu, Saranya, Sivasankari |
| Cartons weighing                                   | Suganthi                    |
| Insertion of carton into shrink sleeve             | NA                          |
| Insertion of shrink wrapped carton into shipper    | NA                          |
| Shipper Label Pasting                              | Dhanalakshmi                |
| Shipper Weighing                                   | Dhanalakshmi                |
| Shipper Strapping                                  | Dhanalakshmi                |
| Shipper packed                                     | From 01 to 36               |
| Signature of Packing                               | 27/05/2020                  |

DATE: 28/05/2020

SHIFT: General

| ACTIVITIES                                      | DONE BY                                   |
|---|---|
| Alu Alu strip Checking                          | Indra, Sivasankari                        |
| Printing Checking in Alu Alu strip              | Pathya, Naveena                           |
| Alu Alu strip weighing                          | Dhanapriya, Maheswari                     |
| Insertion of Alu Alu strip into carton          | Saranya, Sivasankari, Pornu, Deivalakshmi |
| Cartons weighing                                | Suganthi                                  |
| Insertion of carton into shrink sleeve          | NA  |
| Insertion of shrink wrapped carton into shipper | NA  |
| Shipper Label Pasting                           | Dhanalakshmi                              |
| Shipper Weighing                                | Dhanalakshmi                              |
| Shipper Strapping                               | Dhanalakshmi                              |
| Shipper packed                                  | From 37 to 70                             |
| Signature of Packing                            | 28/05/2020                                |

DATE: .....

SHIFT: .....

| ACTIVITIES   | DONE BY          |
|--|------------------|
| Alu Alu strip Checking                             |                  |
| Printing Checking in Alu Alu strip                 |                  |
| Insertion of Alu Alu strip and leaflet into carton |                  |
| Alu Alu strip weighing                             |                  |
| Cartons weighing                                   |                  |
| Insertion of carton into shrink sleeve             |                  |
| Insertion of shrink wrapped carton into shipper    | NA               |
| Shipper Label Pasting                              |                  |
| Shipper Weighing                                   |                  |
| Shipper Strapping                                  |                  |
| Shipper packed                                     | From.....to..... |
| Signature of Packing                               | 28/05/2020       |

DATE: .....

SHIFT: .....

| ACTIVITIES                                      | DONE BY          |
|---|------------------|
| Alu Alu strip Checking                          |                  |
| Printing Checking in Alu Alu strip              |                  |
| Insertion of Alu Alu strip into carton          |                  |
| Alu Alu strip weighing                          |                  |
| Cartons weighing                                |                  |
| Insertion of carton into shrink sleeve          |                  |
| Insertion of shrink wrapped carton into shipper | NA               |
| Shipper Label Pasting                           |                  |
| Shipper Weighing                                |                  |
| Shipper Strapping                               |                  |
| Shipper packed                                  | From.....to..... |
| Signature of Packing                            | 28/05/2020       |

Prepared by:

Checked by:

Approved By:

Dept. Production

Production

Quality Assurance

Head Quality Assurance

Sign.

L. Ka

[Signature]

[Signature]

[Signature]

Date

20/04/2020

21/04/2020

22/04/2020

20/04/2020

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

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### BATCH PACKING RECORD

Product Code: A08

**Batch Size: 6,00,000 Tablets**

## Product

**Amloperin 5mg/5mg**

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

Batch No.: 61F2005D2

Customer:

**Generic Health Care Pvt. Ltd.**

## 27. PACKING MATERIAL RECONCILIATION:

| Sr. No. | Material                                   | Printed Alu. Foil (Kg) | Base Foil (Kg) | Cartons (Nos)      | Leaflets (Nos) | Shrink Sleeves (Nos) | 5 Ply Shipper (Nos) | Strapping Role (Mtrs.) | BOPP Tape (GHPL Printed) (Nos) |
|---------|--|------------------------|----------------|--------------------|----------------|----------------------|---------------------|------------------------|--------------------------------|
| A       | Quantity received for the batch            | 41.500                 | 105.010        | 20400              | 20400          | NA                   | 90                  | 1.008                  | 18                             |
| B       | Additional material received for the batch | NA                     | NA             | NA                 | NA             | NA                   | NA                  | NA                     | NA                             |
| C       | Total material received (A+B)              | 41.500                 | 105.010        | 20400              | 20400          | NA                   | 90                  | 1.008                  | 18                             |
| D       | Quantity packed                            | 15.160                 | 56.673         | 19740              | 19740          | NA                   | 70                  | 0.958                  | 18                             |
| E       | Quantity rejected (Online) & Destroyed     | 8.066                  | 16.016         | 206 <sup>206</sup> | NA             | NA                   | NA                  | 0.018                  | NA                             |
| F       | Quantity Returned                          | 18.128                 | 32.044         | 140                | 647            | NA                   | NA                  | 3.032                  | NA                             |
| G       | Sample affixed on BPR                      | 0.002                  | NA             | 02                 | 02 01          | NA                   | NA                  | NA                     | NA                             |
| H       | QC samples                                 | 0.003                  | 0.011          | 04                 | 04             | NA                   | NA                  | NA                     | NA                             |
| I       | Other samples (If any)                     | 0.005                  | 0.022          | 08                 | 03             | NA                   | NA                  | NA                     | NA                             |
| J       | Total accountable Quantity (D+ E+F+G+H+I)  | 41.364                 | 104.766        | -0-                | -0-            | NA                   | NA                  | NA                     | NA                             |
| K       | Variation (C - J)                          | 0.136                  | 0.244          | -0-                | -0-            | NA                   | NA                  | NA                     | NA                             |
| L       | %Variation (K x 100)/C                     | 0.32%                  | 0.23%          | -0-                | -0-            | NA                   | NA                  | NA                     | NA                             |
| M       | Acceptable limit                           | ±2%                    | ±2%            | ±2%                | ±2%            | ±2%                  |                     |                        |                                |

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

28. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. N/A

| Material                                   | Printed Alu.<br>Foil (Kg) | Base Foil<br>(Kg) | Cartons<br>(Nos) | Leaflets<br>(Nos) | Shrink<br>Sleeves<br>(Nos) | 5 Ply<br>Shipper<br>(Nos) | Strapping<br>Role<br>(Mtrs.) | BOPP Tape<br>(GHPL Printed)<br>(Nos) |
|--|---------------------------|-------------------|------------------|-------------------|----------------------------|---------------------------|------------------------------|--------------------------------------|
| Quantity Returned                          | 18.128                    | 32.244            | 440              | NA                | NA                         | NA                        | 1.008                        | NA                                   |
| Material returned by packing<br>Sign./Date | Sy 23/05/2020             | Sy 23/05/2020     | Sy 23/05/2020    | NA                | NA                         | NA                        | NA                           | NA                                   |
| Verified By IPQA Sign./Date                | Sy 22/05/2020             | Sy 22/05/2020     | Sy 22/05/2020    | NA                | NA                         | NA                        | NA                           | NA                                   |
| Material received by Store<br>Sign./Date   | Khy 1/6/2020              | Khy 1/6/2020      | Khy 1/6/2020     | NA                | NA                         | NA                        | Khy 1/6/2020                 | NA                                   |

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

[illegible]

|              |            |                    |                    |                        |
|--------------|------------|--------------------|--------------------|------------------------|
| Prepared by: |            | Checked by:        |                    | Approved By:           |
| Dept.        | Production | Production         | Quality Assurance  | Head Quality Assurance |
| Sign.        | C. Ka      | <i>[Signature]</i> | <i>[Signature]</i> | <i>[Signature]</i>     |
| Date         | 20/04/2020 | 21/04/2020         | 22/04/2020         |                        |

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AI PRIMUS  
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

Amliperin 5mg/5mg

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

Batch No.: 61Fdo0502

Customer:

Generic Health Care Pvt. Ltd.

## 30. BATCH RECONCILIATION:

|   |  |               |
|---|--|---------------|
| A | Batch Size   | 6,00,000 Nos. |
| B | Quantity received for packing  | 596349        |
| C | Total quantity packed  | 592200        |
| D | Control samples  | 200           |
| E | Analytical Samples   | 120           |
| F | In process samples   | 920           |
| G | Others samples if any (Stability, Regulatory Samples, etc.)                | 30            |
| H | Packing Loss = B - (C + D + E + F + G)                                     | 2679          |
| I | Total Loss = A - (C + D + E + F + G)                                       | 6530          |
| J | Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit %...NL7...95%)* | 99.51%        |
| K | Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit %...NL7...97%)*   | 98.91%        |

\*To be established

Checked by Packing /Date:

Sy 23/05/2020

Verified by IPQA/Date:

R 23/05/2020

## 31. TRANSFER OF FINISHED GOODS:

| Date                   | FGTN No. | Sales | Pack Size | No. of Units in a shipper | No. of Shippers | Transferred Quantity | FGTN Raised by Packing | FGTN Checked by IPQA | FGTN Received by Stores |
|------------------------|----------|-------|-----------|---------------------------|-----------------|----------------------|------------------------|----------------------|-------------------------|
| 23/05/2020             | 0247     | 89103 | 3x10's    | 282x3x10's                | 70              | 70x282x3x10's        | Sy                     | R                    | M. Co                   |
|                        |          |       |           |                           |                 | NA                   | NA                     |                      | NA                      |
| Total Qty. Transferred |          |       |           |                           |                 | 592200<br>Stamps     | Sy                     | R                    | M. Co                   |

## 32. DEVIATION/ EXCEPTION DETAILS:

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

## Deviation / Exception details

| Sr. No. | Stage | Deviation / Exception details | Action taken | Observed By   |
|---------|-------|-------------------------------|--------------|---------------|
|         |       | NA                            |              | Sy 23/05/2020 |

Checked by  
Packing:Verified by  
Packing manager:Approved by  
Head QA:


## 33. BPR REVIEW DETAILS:

| Reviewed by                       | Name              | Sign. /Date                  |
|-----------------------------------|-------------------|------------------------------|
| Packing Executive                 | A. PUVIARASU      | Amg 23/05/2020               |
| QA Executive                      | Ram Kumar         | Ram Kumar 23/05/2020         |
| Production Assistant Manager/ HOD | BALASUBRAMANIAN B | Balasubramanian B 23/05/2020 |
| QA Manager/ HOD                   | Shyler A          | Shyler A 23/05/2020          |

| Prepared by: |            | Checked by:       |                   | Approved By:           |
|--------------|------------|-------------------|-------------------|------------------------|
| Dept.        | Production | Production        | Quality Assurance | Head Quality Assurance |
| Sign.        | L. Ke      | Balasubramanian B | P. V. Sub         | S. Anand               |
| Date         | 20/04/2020 | 22/04/2020        | 22/04/2020        | 23/05/2020             |

UNCONTROLLED



|   |   |                               |   |
|---|---|-------------------------------|---|
| <br><b>SAI PRIMUS</b><br>LIFE BIOTECH PVT LTD | <b>SAI PRIMUS LIFE BIOTECH PVT LTD</b><br>Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate,<br>Villianur Commune, Puducherry-605009. |                               | Page 24 of 24   |
|   | <b>BATCH PACKING RECORD</b>   |                               | <b>Product Code: A08</b>  |
| <b>Product</b>  | <b>Amloperin 5mg/5mg</b>  | <b>BPR. No.: BPR/T/107-00</b> | <b>Batch Size: 6,00,000 Tablets</b>                               |
|   |   | <b>Customer:</b>              | <b>Batch No.: GFD0502</b><br><b>Generic Health Care Pvt. Ltd.</b> |

**34. BATCH RELEASED FOR DESPATCH:**

Total quantity released: 592200 No's

Head QA sign/ Date: [Signature] 28/05/2020

**35. REVISION HISTORY:**

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

|              |                   |                    |                          |                        |
|--------------|-------------------|--------------------|--------------------------|------------------------|
| Prepared by: |                   | Checked by:        |                          | Approved By:           |
| Dept.        | Production        | Production         | Quality Assurance        | Head Quality Assurance |
| Sign.        | <u>L. Ka</u>      | <u>[Signature]</u> | <u>P. H. [Signature]</u> | <u>[Signature]</u>     |
| Date         | <u>20/04/2020</u> | <u>21/04/2020</u>  | <u>22/04/2020</u>        | <u>21/04/2020</u>      |

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