

<b>STABILITY SAMPLE</b> <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD		<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: S, No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		<b>VALIDATION BATCH</b> Page 1 of 26	
<b>BATCH PACKING RECORD</b>		<b>Product Code: L13</b>		<b>Batch Size: 6,00,000 Tablets</b>	
<b>Product</b>		<b>LOLIP 20</b>		<b>BPR. No.: BPR/T/331-00</b>	
		<b>Customer:</b>		<b>Batch No.: 61822161</b>	
				<b>Generic Health Care Pvt. Ltd.</b>	

### BATCH PACKAGING RECORD COVER SHEET


PRODUCT NAME	: LOLIP 20
GENERIC NAME	: Atorvastatin Calcium Tablets 20 mg
LABEL CLAIM	: Each film coated tablet contains: Atorvastatin calcium Trihydrate Equivalent to Atorvastatin ..... 20 mg Colour: Approved colour used.
CODE NO.	: PON/DRUGS/21 14 4376
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/331-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: 61822106 / 07/07/2022
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets
PACKING CONFIGURATION	: 3 x 10 Tablets Pack (Alu Alu Packing)
BPR ISSUED BY/DATE (QA)	: 25/11/2022
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: 28/11/2022
MFG. DATE: 11/2022	EXP. DATE: 10/2025
ALLOTTED BY: QA SIGN/DATE: 25/11/2022	COUNTER CHECKED BY: QA SIGN/DATE: 28/11/2022
QUANTITY RECEIVED FROM PRODUCTION	: 596875 NOS
DATE OF COMMENCEMENT: 05/12/2022	DATE OF COMPLETION: 06/12/2022
QUANTITY	: 6,00,000 NOS
RELEASED QUANTITY OF PACKED TABLETS	: 592200 NOS
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	: 07/12/2022

This BPR contains 26 Pages + 05 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	07/07/2022	07/07/2022	07/07/2022	07/07/2022

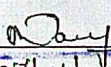

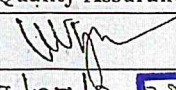
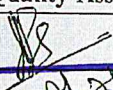
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	<b>BATCH PACKING RECORD</b>	<b>Product Code: L13</b>	<b>Batch Size: 6,00,000 Tablets</b>
<b>Product</b>	<b>LOLIP 20</b>	<b>BPR. No.: BPR/T/331-00</b>	<b>Batch No.: G11822161</b>
		<b>Customer:</b>	<b>Generic Health Care Pvt. Ltd.</b>


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

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	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00 Customer:		Batch No.: G1822161 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, carton 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 Format	Yes
7.	Complete set of BPR Submitted	Yes

Checked By QA/Date: P. 07/07/2022

\*Mention total number of pages.


Remarks (If any) ..... OK .....

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>Nay</u>	<u>M</u>	<u>CAJ</u>	<u>PS</u>
Date	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>

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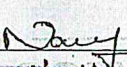
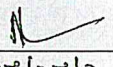


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	<b>BATCH PACKING RECORD</b>	<b>Product Code: L13</b>	<b>Batch Size: 6,00,000 Tablets</b>
<b>Product</b>	<b>LOLIP 20</b>	<b>BPR. No.: BPR/T/331-00</b>	<b>Batch No.: G1822161</b>
		<b>Customer:</b>	<b>Generic Health Care Pvt. Ltd.</b>

### 3. PACKING MATERIAL SPECIFICATION AND INDENT:


Sr. No.	Material	Item Code	Specification	UOM	Standard Qty. for Batch Size 6.0 Lac.
1	252mm Lolip 20 Printed Foil 0.025mm	PPF/SP/L016	Width – 252 ± 1 mm Thickness – 0.025 mm Language – French Color – 2 Colors Item Code – 13/0463	Kg	45.000
2	252 mm Alu Alu base foil	PBF/SP/A004	Width – 252 ± 1 mm Plain non-printed (text matter) aluminum foil.	Kg	150.000
3	3x10's Lolip 20 Printed Carton	PPC/SP/L016	Size – 130 x 60 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 4 colour Language – English/French Item Code – 15/0781	No	20000
4	Lolip Printed Leaflet	PPL/SP/L019	Size – 140 x 175 mm (L x H) Specification – NLT 60 gsm Maplitho Paper. Colour – 2 colours Language – French/ English Item Code: 16/0556	No	20000
5	Shrink Sleeves (PVC)	PPS/SP/P001	Plain PVC Shrink Sleeves	No	2000
6	5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 430 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm <sup>2</sup>	No	75
7	2.5' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	2
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	1
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width - 12 mm Thickness - 0.6 mm	Mtrs	300

<b>Prepared by:</b>		<b>Checked by:</b>		<b>Approved By:</b>
<b>Dept.</b>	<b>Production</b>	<b>Production</b>	<b>Quality Assurance</b>	<b>Head Quality Assurance</b>
<b>Sign.</b>				
<b>Date</b>	07/07/2022	07/07/2022	07/07/2022	07/07/2022

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	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

#### 4. DISPENSING LINE CLEARANCE CHECKS

Date: 03/12/2022 Time: 14:25

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.	8T/LAF/001	8T/BAL/011	- NA -	FOU STORE
Previous Product	FLUGEN 100.			
B. No.	G1822159.			
Cleaned by Sign/Date	Saran 03/12/2022.			
Checked by Store Sign/Date	S4: 03/12/2022.			
Verified by IPQA Sign/Date	G1 03/12/2022			

ENVIRONMENTAL CONDITIONS: Date: 03/12/2022 Time: 14:30	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	S4: 03/12/22	G1 03/12/2022
Differential Pressure across the booth Limit: 5 to 20 mm Water	11mm.	S4: 03/12/22	G1 03/12/2022


APPROVAL FOR DISPENSING BY IPQA: Sign: <u>G1</u> Date: <u>03/12/2022</u>
Dispensing start Time <u>14:35</u> End Time <u>14:55</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>Naray</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>

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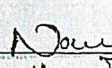
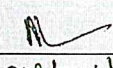
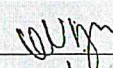
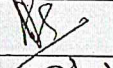
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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 6 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00		Batch No.: 61822161
			Customer:


5. DISPENSING RECORD OF PACKING MATERIALS: Date: 03/12/2022 Shift: G Time: 14:35

Material Name	Item code	UOM	Req. Qty. for Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
252mm Lolip 20 Printed Foil 0.025mm	PPF/SP/L016	Kg	45.000	12.300 36.690	PmG/00334 PmG/00022	01 02	03/12/22	03/12/2022
252 mm Alu Alu base foil	PBF/SP/A004	Kg	150.000	169.660	PmG/00964	07	03/12/22	02/12/2022
3x10's Lolip 20 Printed Carton	PPC/SP/L016	No	20000	21915	PmG/01058	14	03/12/22	03/12/2022
Lolip Printed Leaflet	PPL/SP/L019	No	20000	20000	PmG/01050	03	03/12/22	03/12/2022
Shrink Sleeves (PVC)	PPS/SP/P001	No	2000	2000	PmG/00895	02	03/12/22	03/12/2022
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	75	78	PmG/00864	08	03/12/22	02/12/2022
2.5' GHPL Printed Bopp Tape	PPB/SP/B002	No	2	06	PmG/00870	02	03/12/22	03/12/2022
3' Plain BOPP Tape	PUB/SP/B001	No	1	01	PmG/00505	01	03/12/22	03/12/2022
Strapping role.	PPR/SP/S001	Mtrs	300	01	PmG/00945	01	03/12/22	03/12/2022

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

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 SAI PRIMUS 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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

### 6. LINE CLEARANCE CHECKS:

#### 6.1 PRIMARY PACKING:

Date/ Shift: 05/12/2022 / G1 ..... / 06/12/2022

Previous Product: Ramithiazide 5/12.5		Batch No.: G1822174				
Sr. No.	Checks	Time	Observation			
			10:30 Packing	IPQA	08:04 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 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): 19.04.05/12/2022

Cleaning satisfactory/Not-satisfactory

Verified by IPQA (Sign./Date): G1822174

#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: 05/12/2022 / 10:32

Previous Product: Ram Thiazide 5/12.5				Batch No.: G1822174			
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	Spl. Aff. Alu/Alu	B	PDGN/006	Babu 05/12/22	19.04.05/12/22	G1822174
2.	Alu Alu Packing Machine	PD Alu/001	B	PDOP/020, PDCL/020	Babu 05/12/22	19.04.05/12/22	G1822174

#### 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: 05/12/2022 Time: 10:33			Date: 06/12/2022 Time: 12:30		
	Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	23°	19.04.05/12/22	G1822174	23°C	19.04.05/12/22	G1822174
RH % Limit: NMT 60%	52%	19.04.05/12/22	G1822174	52%	19.04.05/12/22	G1822174
DP Limit: NLT 10 Pascal	11 pascal	19.04.05/12/22	G1822174	11 Pascal	19.04.05/12/22	G1822174

Primary Packing Started Date/Time: 05/12/2022 / 11:20 Completed Date/Time: 06/12/2022 / 12:30

APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: 19.04.05/12/2022

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

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SAI PRIMUS  
LIFE BIOTECH PVT LTD

**SAI PRIMUS LIFE BIOTECH PVT LTD**

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

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**BATCH PACKING RECORD**

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

**LOLIP 20**

BPR. No.: BPR/T/331-00

Batch No.: G1822161

Customer:

Generic Health Care Pvt. Ltd.

**7. VERIFICATION OF DISPENSED PACKING MATERIALS:** Date: 05/12/2022 Shift: G Time: 10:34

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
252mm Lolip 20 Printed Foil 0.025mm	PPF/SP/L016	Kg	pmg/00334	01	M. Koyi	Gf
252 mm Alu Alu base foil	PBF/SP/A004	Kg	pmg/00022	02	M. Koyi	Gf
3x10's Lolip 20 Printed Carton	PPC/SP/L016	No	pmg/00964	07	M. Koyi	Gf
Lolip Printed Leaflet	PPL/SP/L019	No	pmg/01058	14	M. Koyi	Gf
Shrink Sleeves (PVC)	PPS/SP/P001	No	pmg/01050	03	M. Koyi	Gf
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	pmg/00895	02	M. Koyi	Gf
2.5' GHPL Printed Bopp Tape	PPB/SP/B002	No	pmg/00864	08	M. Koyi	Gf
3' Plain BOPP Tape	PUB/SP/B001	No	pmg/00870	02	M. Koyi	Gf
Strapping role.	PPR/SP/S001	Mtrs	pmg/00505	01	M. Koyi	Gf
			pmg/00945	01	M. Koyi	Gf

**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	1					

**9. RECEIPT OF PRODUCT AND MATERIALS:** Date/Shift: 05/12/2022 G Time: 10:35

(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)	28°C	M. Koyi	Gf
2.	Relative Humidity observed on display (Limit: NMT 60%)	50%	M. Koyi	Gf
3.	Bulk product containers are of the required product/Batch number and is approved by QC	yes	M. Koyi	Gf
4.	Status label of machine/ line is for same product	yes	M. Koyi	Gf
5.	Printed foil/Base rolls are of the required product.	yes	M. Koyi	Gf
6.	All secondary packing materials are of the required product	yes	M. Koyi	Gf

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

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	192 mg	M. Koyi	Gf
2.	Colour of Tablet	pale yellow colour	M. Koyi	Gf
3.	Quantity (Net Qty.in Kg)	114.600 kg	M. Koyi	Gf
4.	Number of Containers	04	M. Koyi	Gf

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

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

- Verify the semi-finished Tablets before starting the packing operation.
- 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
Lolip-20	G1822161	11/2022	10/2025	114.600 Kg Equivalent to 596875 Nos.	From Container No. 01 To Container No. 04 Total No. of Containers taken 04
Checked by Packing (Sign. /Date): M. Koyi 05/12/22				Verified By IPQA (Sign. /Date): Gf 05/12/22	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	M. Koyi			
Date	05/12/2022	07/07/2022	07/07/2022	

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 SAI PRIMUS 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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

## 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	28.400	Bala	Gh	6			
2	28.800	Bala	Gh	7			
3	29.000	Bala	Gh	8			
4	26.800	Bala	Gh	9			
5				10			

## 13. CONTAINER CONSUMPTION DETAILS:

S. No	Time From	To	Container No.	Consumed by	S. No	Time From	To	Container No.	Consumed by
1	11:20	14:40	01	Bala	6				
2	14:41	17:50	02	Bala	7				
3	17:51	19:00	03	Bala	8				
4	08:10	10:10	03	Bala	9				
5	10:11	12:30	04	Bala	10				

Checked By Packing (Sign./Date): Day 06/12/22 Verified by IPQA (Sign./Date): Gh 06/12/22

## 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/21 14 4376	06	06
Batch No.:	G1822161	06
Mfg. Date:	11/2022	06
Exp. Date:	10/2025	06
Item Code: 13/0463	06	06
Pack size (3 x 10's)- Carton	310's	06
Other instructions if any	MA	MA
Initiated by	Bala 05/12/2022	Bala 05/12/2022
Checked by Packing (Sign. & Date)	MA 05/12/2022	MA 05/12/2022
Verified by IPQA (Sign. & Date)	Gh 05/12/2022	Gh 05/12/2022

## 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	05/12/2022	01	Bala 05/12/2022	MA 05/12/2022	Gh 05/12/2022
02	06/12/2022	01	Bala	MA 06/12/2022	Gh 06/12/2022

## 16. PACKING INSTRUCTIONS:

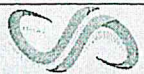
- Verify the status of dispensed primary packaging materials and transfer to the Primary Packing Area.
- Issue the stereos to the concerned Technician and set as per SOP No. QAGN/030 and Record the details in respective table.
- Set and operate Alu Alu Packing Machine as per SOP No. PDOP/020.
- Verify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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>Day</u>	<u>MA</u>	<u>MA</u>	<u>MA</u>
Date	<u>07/12/2022</u>	<u>07/12/2022</u>	<u>07/12/2022</u>	<u>07/12/2022</u>

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	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G18 22161 Generic Health Care Pvt. Ltd.

#### 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	05/12/2022/G	11:20	19:00	11:30	19:10	19/12/2022
02	06/12/2022/L	08:10	12:30	08:20	15:00	19/12/2022
1			NA			

#### 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.

#### 18. ALU ALU PACKING MACHINE PARAMETERS:

Date/Shift: 05/12/2022/G Time: 10:38...

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	18107524	ok	19/12/2022	19/12/2022
Sealing Temperature	(To be established)	190°C	19/12/2022	19/12/2022
Leak test to be performed on 04 Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	ok	19/12/2022	19/12/2022
Machine Speed	(To be established)	35	19/12/2022	19/12/2022

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

Sr. No	Process instructions										
1.	Testing frequency: Startup, End of the activity and after every break										
2.	Acceptance Criteria: Broken Tablet, Empty Packet, Black Particle, Colour variation, Foreign Matter, Dual Tablets / Capsules and all defects should be detected & rejected.										
Date & Time	S. No.	Broken Tablet	Empty Packet	Black Particle	Colour variation	Foreign Matter	Dual Tablets / Capsules	Result	Done By	Checked by Packing	Verified By IPQA
05/12/2022 11:25 14:32 16:50	1	✓	✓	✓	✓	✓	✓	pass	Barb	19/12/2022	G
	2	✓	✓	✓	✓	✓	✓	pass	Barb	19/12/2022	G
	3	✓	✓	✓	✓	✓	✓	pass	Barb	19/12/2022	G
	4	✓	✓	✓	✓	✓	✓	pass	Barb	19/12/2022	G
	5	✓	✓	✓	✓	✓	✓	pass	Barb	19/12/2022	G
06/12/2022 08:18	6	✓	✓	✓	✓	✓	✓	pass	Barb	19/12/2022	G
	7	✓	✓	✓	✓	✓	✓	pass	Barb	19/12/2022	G
	8										
	9										
	10										
	11										
	12										
	13										
	14										
	15										


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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/10/2022	07/10/2022	07/10/2022	07/10/2022

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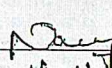

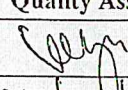
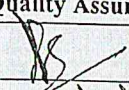


 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00 Customer:		Batch No.: G11822161 Generic Health Care Pvt. Ltd.

20. MACHINE IN-PROCESS CONTROL:

Date/ Shift	05/12/2022/C1								06/12/22/C1							
Machine Operator Name	Baler															
Time of inspection	11:32	11:39	11:47	11:54	11:56	12:18	12:58	13:00	14:09	15:05	16:08	16:15	17:10	18:03	18:20	18:16
Sealing Temperature (To be established)	178°C	178°C	179°C	178°C	190°C	191°C	191°C	190°C	192°C	191°C	190°C	190°C	191°C	190°C	191°C	191°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/ 21 14 4376	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.: G11822161	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date 11/2022	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date 10/2025	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed (To be established)	15	15	40	40	35	35	35	35	35	35	35	35	35	35	35	35
Checked by (Packing)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Checked by (IPQA)	GP	GP	GP	GP	GP	GP	GP	GP	GP	GP	GP	GP	GP	GP	GP	GP


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

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

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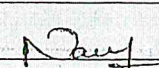
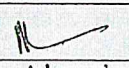
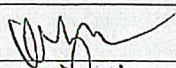



 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G11822161 Generic Health Care Pvt. Ltd.

### 20.1 MACHINE IN-PROCESS CONTROL:

Date/ Shift	06/12/2022									
Machine Operator Name	Bala									
Time of inspection	15:35	19:12	10:10	10:38	11:25					
Sealing Temperature (To be established)	190°C	191°C	190°C	190°C	190°C					
Leak test on Alu Alu strips* (Qty.: 04)	OK	OK	OK	OK	OK					
Knurling /Sealing	OK	OK	OK	OK	OK					
Pocket Formation	OK	OK	OK	OK	OK					
Horizontal cutting	OK	OK	OK	OK	OK					
Vertical cutting	OK	OK	OK	OK	OK					
Quality of Over printing	OK	OK	OK	OK	OK					
Code No.: PON/DRUGS/ 21 14 4376	OK	OK	OK	OK	OK					
B. No.: G11822161	OK	OK	OK	OK	OK					
Mfg. Date 11/2022	OK	OK	OK	OK	OK					
Exp. Date 16/2025	OK	OK	OK	OK	OK					
Machine Speed (To be established)	30	35	30	30	35					
Checked by (Packing)	NA	MA	MA	NA	NA					
Checked by (IPQA)	MA	MA	MA	NA	NA					

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/12/2022	07/12/2022	07/12/2022	07/12/2022

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Product Code: L13

Batch Size: 6,00,000 Tablets

**LOLIP 20**

BPR. No.: BPR/T/331-00

Batch No.: G1822161

Generic Health Care Pvt. Ltd.


## 20.2 MACHINE IN-PROCESS CONTROL:

Date/ Shift
Machine Operator Name
Time of inspection
Sealing Temperature (To be established)
Leak test on Alu Alu strips* (Qty.:_____)
Knurling /Sealing
Pocket Formation
Horizontal cutting
Vertical cutting
Quality of Over printing
Code No.: PON/DRUGS/ 21 14 4376
B. No.:
Mfg. Date
Exp. Date
Machine Speed (To be established)
Checked by (Packing)
Checked by (IPQA)

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign:				
Date:	07/07/2012	07/07/2012	07/07/2012	07/07/2012



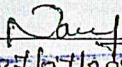
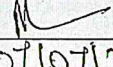


 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BPR. No.: BPR/T/331-00	Batch No.: G1822161
		Customer:	Generic Health Care Pvt. Ltd.

### 20.3 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)
06/12/22	11:40	12:00	0.440	Sudha	Na 06/12/22	Na 06/12/22
				NA		
Total Weight of De-foiled Tablets			0.440	Checked By / Date (Packing): Na 06/12/22	Verified By / Date (IPQA): Na 06/12/22	


### 20.4 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		
06/12/22	12:02	12:10	Sudha	0.400	2083	0.040	208	Na 06/12/22	Na 06/12/22
			NA						
Total				0.400	2083	0.040	208	Na 06/12/22	
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing): Na 06/12/22		Verified By / Date (IPQA): Na 06/12/22			
0.040 Kgs 208..... Nos.									

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/10/2022	07/10/2022	07/10/2022	07/10/2022

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	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

# 21. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift : 05/12/2022 / G ..... / 06/12/22

Previous Product: Remithiazide 5/12.5 Batch No.: G1822174

Sr. No.	Checks	Time	Observation			
			11:00 11:40 Packing	IPQA	11:20 Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	✓
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	✓
4	Check and ensure the Correct status board is written.		✓	✓	✓	✓
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	✓
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓	✓	✓
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	✓	✓
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓	✓	✓
9	Check and ensure the dispensed secondary packing material.		✓	✓	✓	✓
10	Check and ensure the cleanliness of documentation table.		✓	✓	✓	✓
11	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	✓

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

Cleaning Satisfactory / Not satisfactory#  
 (Packing) Sign. /Date: M. Key 05/12/2022  
 Cleaning Satisfactory / Not satisfactory#  
 (IPQA) Sign. /Date: G. Sathish 05/12/2022

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/BAU/015	PD/SWA/002	PD/STA/002	PD/BAU/038	Secondary Packing Hall
Previous Product:	Remithiazide 5/12.5					
Batch No.:	G1822174					
Cleaned by:	K. Nagarajan					
Checked by Packing:	M. Key					
Verified by IPQA:	G. Sathish					

## 21.1 ENVIRONMENTAL CONDITIONS:

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

Shift: ..... G1 .....		Date/Time: 05/12/2022 / 11:42		Date/Time: 06/12/22 / 11:25	
Refer to SOP No.: SOP: QAGN/011		Temperature °C Limit: NMT 25°C	23°C	23°C	23°C
Observation		Checked by Packing	Verified by IPQA	Observation	Checked by Packing
		M. Key	G. Sathish		G. Sathish

Secondary Packing Started Date/Time: 05/12/22 ..... 11:30 ..... Completed Date/Time: 06/12/22 ..... 15:00

APPROVAL FOR SECONDARY PACKING: Approved by IPQA Sing/Date: G. Sathish 06/12/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	M. Key	M. Key	G. Sathish	G. Sathish
Date	07/07/2022	07/07/2022	07/07/2022	07/07/2022

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SAI PRIMUS  
LIFE BIOTECH PVT LTD

**SAI PRIMUS LIFE BIOTECH PVT LTD**

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

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**BATCH PACKING RECORD**

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

BPR. No.: BPR/T/331-00

Batch No.: G11322161

Customer:

Generic Health Care Pvt. Ltd.

**21.2 PACKING DETAILS:**

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

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

Place 10 filled carton in a Shrink Sleeve.

Place 27 Shrink sleeves in each 5 ply shipper.

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

**22. OVER PRINTING DETAILS:**

Overprinting Details (Secondary & Tertiary PM)

Overprinting Details	Overprinted Text	Carton	Insert	5 Ply Shipper Label
Batch No.:	G11322161	06	NA	ok
Mfg. Date:	11/2022	06	NA	ok
Exp. Date:	10/2025	06	NA	ok
Code No.: PON/DRUGS/21 14 4376	06	OK	NA	NA
Pack size:	NA	3 x 10's	NA	27 x 10 x 3 x 10's
Item Code: 15/0781	NA	06	NA	NA
Item Code: 16/0556	NA	NA	06	NA
Initiated by Sign. & Date	NA	NA	NA	Sivakumar
Checked by Packing Sign. & Date	M. K. 05/12/2022	M. K. 05/12/2022	M. K. 05/12/2022	M. K. 05/12/2022
Verified by IPQA Sign. & Date	G. S. 05/12/2022	G. S. 05/12/2022	G. S. 05/12/2022	G. S. 05/12/2022

**22.1 Carton and Shipper Label Specimen:**

S. No.	Date	Carton Specimen No.	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	05/12/2022	01	01	M. K. 05/12/2022	G. S. 05/12/2022

**23. INDIVIDUAL STRIP WEIGHING LIMIT:**

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

1. /	3.	5.	7.	9.
2.	4.	6.	8.	10.

Total weight of ten Empty Alu Alu strips =

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

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

1. 3.7	3. 3.7	5. 3.7	7. 3.7	9. 3.7
2. 3.6	4. 3.7	6. 3.7	8. 3.7	10. 3.7

Total weight of ten Filled Alu Alu strips = 36.9

Avg. Weight of a Filled Alu Alu strip (B): total weight of ten Filled Alu Alu strip/10= 3.69

Limit (C) = NA

(Each missing tablet should be identified)


Strip weighing Done By: Janaki	Checked By: M. K.	Verified By: G. S.
--------------------------------	-------------------	--------------------

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

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	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00 Customer:		Batch No.: G1822161 Generic Health Care Pvt. Ltd.

23.1 CARTON WEIGHT LIMIT SETTING: Date/Shift: 05/12/2022 Time: 11:44..

Weight of ten individual empty cartons are given below:

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

Total weight of ten empty cartons = 87.8

Average weight of an empty carton (D) = Total weight of ten empty carton / 10 = 8.78

Weight of ten individual Leaflets are given below:

1. 1.4	3. 1.4	5. 1.4	7. 1.4	9. 1.4
2. 1.4	4. 1.4	6. 1.4	8. 1.4	10. 1.3

Total weight of ten Leaflets = 13.9

Avg. Weight of a Leaflet (E): total weight of ten Leaflets/10 = 1.39

### 23.2 WEIGHT CHECKS ON CARTON:

Weight of ten empty Carton:	87.8	Average weight of one empty Carton (D):	8.78
Weight of ten filled Alu Alu strip:	36.9	Average weight of one filled Alu Alu strip (B):	3.69
Weight of ten Leaflets:	13.9	Average weight of one Leaflet (E):	1.39
Weight of one filled Carton F = (D+3B+E)	13.86 21.21	Limit: G = F ± 1 % =	13.72 - 13.99 21.0 - 21.4
Checked by Packing/Date:	05/12/2022	Verified by IPQA/Date:	05/12/2022

### 23.3 SAMPLE DRAWN RECORD:


Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7 x 10's	Gjs 05/12/2022
2	Control Sample (Middle)	6 x 10's	Gjs 05/12/2022
3	Control Sample (Final)	4 x 10's	Gjs 05/12/2022
4	Stability Sample	100 x 10's	Gjs 06/12/2022
5	Other Sample	NA	NA
6	Analytical sample	12 x 10's	Gjs 05/12/2022
Total Qty.		139 x 10's	Gjs 06/12/2022

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

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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 18 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G18 22161 Generic Health Care Pvt. Ltd.

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

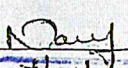
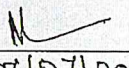

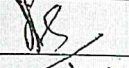
Date/ Shift	05/12/2022 G1	05/12/2022/4											
Parameters	Specification	observation											
		Packing						IPQA					
Time		11:35	12:38	13:40	14:38	15:40	16:42	17:45	18:42	19:33	20:32	21:40	
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	
Carton Overprinting	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	
No. of cartons in a shrink sleeves	10 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
No. of shrink sleeves in a 5 ply shipper	27 shrinks	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Shipper strapping	Proper strapping	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Label appearance and Shipper appearance	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	
Sealing of the shipper with BOPP Tape	H type	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Checked by		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	

\*Temperature to be mentioned.

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

Date/ Shift	06/12/2022												
Parameters	Specification	observation											
		Packing						IPQA					
Time		18:38	19:35	20:40	21:50	22:48	23:40	24:35	25:40				
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				
Carton Overprinting	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok				
No. of cartons in a shrink sleeves	10 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA				
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA				
No. of shrink sleeves in a 5 ply shipper	27 shrinks	NA	NA	NA	NA	NA	NA	NA	NA				
Shipper strapping	Proper strapping	NA	NA	NA	NA	NA	NA	NA	NA				
Label appearance and Shipper appearance	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok				
Sealing of the shipper with BOPP Tape	H type	NA	NA	NA	NA	NA	NA	NA	NA				
Checked by		NA	NA	NA	NA	NA	NA	NA	NA				

\*Temperature to be mentioned.

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

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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: L13

Batch Size: 6,00,000 Tablets

Product **LOLIP 20**

BPR. No.: BPR/T/331-00

Batch No.: G1822161

Customer:

Generic Health Care Pvt. Ltd.

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

Date/ Shift	05/12/2022 G1	05/12/2022 G1 06/12/2022 G1													
Parameters	Specification	observation													
		Packing							IPQA						
Time		12:40	13:42	14:45	15:50	16:48	17:55	18:55	19:57	20:57	21:55	22:35	23:20	24:15	25:25
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	OK	OK
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
No. of cartons in a shrink sleeves	10 packed cartons	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Shrink wrapping temperature*	199°C	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
No. of shrink sleeves in a 5 ply shipper	27 shrinks	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Checked by		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK

\*Temperature to be mentioned.

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

Date/ Shift	06/12/2022 G1	06/12/2022 G1													
Parameters	Specification	observation													
		Packing							IPQA						
Time		09:15	10:18	11:30	12:42	13:50	15:06	16:20	17:24						
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK						
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK						
No. of cartons in a shrink sleeves	10 packed cartons	OK	OK	OK	OK	OK	OK	OK	OK						
Shrink wrapping temperature*	200°C	OK	OK	OK	OK	OK	OK	OK	OK						
No. of shrink sleeves in a 5 ply shipper	27 shrinks	OK	OK	OK	OK	OK	OK	OK	OK						
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK						
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK						
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK						
Checked by		OK	OK	OK	OK	OK	OK	OK	OK						


\*Temperature to be mentioned.

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

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	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
Product <b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:		Batch No.: G1822161 Generic Health Care Pvt. Ltd.

25. SHIPPERS WEIGHING: Date/Shift..05/12/2022/4....Time: ...11:55.. Balance I.D. No.: PD/BAC/038

Weight of ten Shrinks: 2915						Average weight of one filled Shrink (H): 291.5					
Weight of ten empty shippers: 13.7						Average weight of one empty shipper (I): 1.370					
Weight of one filled shipper (J) = (27H+I): 7.350						Limit: K = J ± 1% = 7.276 - 7.423					
Checked by Packing/Date: 19/04/05/12/2022						Verified by IPQA/Date: 05/12/2022					

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	7.335	Guesha	20	7.350	Guesha	39	7.350	Guesha	58	7.346	Guesha
2	7.330	Guesha	21	7.340	Guesha	40	7.346	Guesha	59	7.330	Guesha
3	7.350	Guesha	22	7.360	Guesha	41	7.360	Guesha	60	7.360	Guesha
4	7.340	Guesha	23	7.340	Guesha	42	7.350	Guesha	61	7.360	Guesha
5	7.345	Guesha	24	7.335	Guesha	43	7.360	Guesha	62	7.330	Guesha
6	7.350	Guesha	25	7.350	Guesha	44	7.340	Guesha	63	7.335	Guesha
7	7.335	Guesha	26	7.360	Guesha	45	7.350	Guesha	64	7.350	Guesha
8	7.340	Guesha	27	7.345	Guesha	46	7.360	Guesha	65	7.340	Guesha
9	7.350	Guesha	28	7.335	Guesha	47	7.360	Guesha	66	7.360	Guesha
10	7.350	Guesha	29	7.340	Guesha	48	7.335	Guesha	67	7.350	Guesha
11	7.340	Guesha	30	7.350	Guesha	49	7.340	Guesha	68	7.340	Guesha
12	7.345	Guesha	31	7.360	Guesha	50	7.345	Guesha	69	7.335	Guesha
13	7.340	Guesha	32	7.360	Guesha	51	7.335	Guesha	70	7.350	Guesha
14	7.330	Guesha	33	7.340	Guesha	52	7.350	Guesha	71	7.360	Guesha
15	7.350	Guesha	34	7.350	Guesha	53	7.340	Guesha	72	7.340	Guesha
16	7.345	Guesha	35	7.340	Guesha	54	7.360	Guesha	73	7.335	Guesha
17	7.350	Guesha	36	7.350	Guesha	55	7.350	Guesha	74	2.000	Not
18	7.340	Guesha	37	7.325	Guesha	56	7.340	Guesha	75		
19	7.350	Guesha	38	7.360	Guesha	57	7.345	Guesha	76		

Total No. of shippers weighed: <b>74</b>	De-foiled tablets packed in Shipper No: <b>74</b>	Checked by Sign / Date: Not 07/12/22	Verified by Sign / Date: 07/12/2022	Loose pack details: Shipper No: 74..... Quantity: 23 x 10 x 3 x 10's Weight: 2.000.kg.
---	--	--	--	---


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.				
Date	07/12/2022	07/12/2022	07/12/2022	07/12/2022

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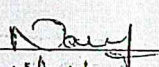
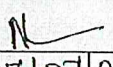
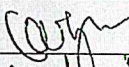



 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 21 of 26
	<b>BATCH PACKING RECORD</b>		<b>Product Code: L13</b>
<b>Product</b>	<b>LOLIP 20</b>	<b>BPR. No.: BPR/T/331-00</b>	<b>Batch Size: 6,00,000 Tablets</b>
		<b>Customer:</b>	<b>Batch No.: G1822461</b>
		<b>Generic Health Care Pvt. Ltd.</b>	


# 26. MAN POWER ALLOCATION:

DATE: 05/12/2022 SHIFT: .....G1.....		DATE: 06/12/2022 SHIFT: .....G1.....	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking	Kamatchi, Sivasubramanian	Alu Alu strip Checking	Kamatchi, Sankari
Printing Checking in Alu Alu strip	Megalai, Citra	Printing Checking in Alu Alu strip	Megalai, Citra
Alu Alu strip weighing	Kanaga, Janaki	Alu Alu strip weighing	Kanaga, Janaki
Insertion of Alu Alu strip and leaflet into carton	Puzhila, Shanthi Priyanka, Vishnu Pragasam	Insertion of Alu Alu strip into carton	Vishnu Pragasam Shanthi, Umairaj
Cartons weighing	Malur	Cartons weighing	Malur
Insertion of carton into shrink sleeve	NA	Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA	Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Geetha	Shipper Label Pasting	Geetha
Shipper Weighing	Geetha	Shipper Weighing	Geetha
Shipper Strapping	NA	Shipper Strapping	NA
Shipper packed	From 01 to 48	Shipper packed	From 49 to 74
Signature of Packing	05/12/22	Signature of Packing	06/12/22

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.				
Date	07/07/2022	07/07/2022	07/07/2022	07/07/2022
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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

27. **PRODUCT COUNTER CHECK LINE CLEARANCE:**  
 Date/ Shift ..05/12/2022.. G1...../.....06/12/22.....

Previous Product: <u>Paracetamol 5/12-5</u>		Batch No.: <u>G1822174</u>				
Sr. No.	Checks	Time	Observation			
			12:30		09:15	
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	✓
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	✓
4	Check and ensure the Correct status board is written.		✓	✓	✓	✓
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	✓
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓	✓	✓
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	✓	✓
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓	✓	✓
9	Check and ensure the dispensed secondary packing material.		✓	✓	✓	✓
10	Check and ensure the cleanliness of documentation table.		✓	✓	✓	✓
11	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	✓

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

Cleaning Satisfactory / Not satisfactory# (Packing) Sign. /Date: <u>M. K. S. 05/12/2022</u>	Cleaning Satisfactory / Not satisfactory# (IPQA) Sign. /Date: <u>G. S. 05/12/2022</u>
--	--

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.:	MA	PD/BAL/037	PD/SL/19/002	PD/STR/1002	PD/BAL/038	FG
Previous Product:	<u>Paracetamol 5/12-5</u>					
Batch No.:	<u>G1822174</u>					
Cleaned by:	<u>Jayaraman</u>					
Checked by Packing:	<u>M. K. S.</u>					
Verified by IPQA:	<u>G. S. 05/12/2022</u>					
Rechecking Started Date/Time: ..05/12/2022..12:40.. Completed Date/Time: <u>06/12/22..17:00..</u>						
<b>APPROVAL FOR COUNTER CHECK:</b>						
			Approved by IPQA Sing/Date: <u>G. S. 05/12/2022</u> .....			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>N. Jay</u>	<u>N.</u>	<u>G. S.</u>	<u>G. S.</u>
Date	<u>05/12/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</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 23 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00 Customer:		Batch No.: G13 221 61 Generic Health Care Pvt. Ltd.

### 27.1 COUNTER CHECK OF PACKED SHIPPERS :

DATE: 05/12/2022 SHIFT: G1		DATE: 05/12/2022 SHIFT: G1	
<b>ACTIVITIES</b>	<b>DONE BY</b>	<b>ACTIVITIES</b>	<b>DONE BY</b>
Alu Alu strip Checking	Vinitha	Alu Alu strip Checking	Vinitha
Printing Checking in Alu Alu strip	Keerthana	Printing Checking in Alu Alu strip	Keerthana
Alu Alu strip weighing	Vinitha	Alu Alu strip weighing	Vinitha
Checking of Alu Alu strip and leaflet in carton	Priya	Checking of Alu Alu strip and leaflet in carton	Priya
Cartons weighing	Jayaram	Cartons weighing	Jayaram
Printing Checking in Shipper Label	Jayaram	Printing Checking in Shipper Label	Jayaram
Shipper Weighing	Jayaram	Shipper Weighing	Jayaram
Shipper Strapping	Keerthana	Shipper Strapping	Jayaram
Shipper Checked	From 01 to 26	Shipper Checked	From 37 to 74
Checked By Packing	05/12/22	Checked By Packing	05/12/22
Verified By IPQA	05/12/22	Verified By IPQA	05/12/22

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

### No. of Defects Identified:

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

Batch Allowed for Despatch: Checked By: 05/12/22


Verified By: 05/12/22

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

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	LOLIP 20	BPR. No.: BPR/T/331-00 Customer:	Batch No.: 61822161 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	48.990	169.660	21915	20000	2000	78	01	06
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	48.990	169.660	21915	20000	2000	78	01	06
D	Quantity packed	28.200	112.600	19740	19740	1974	74	01	06
E	Quantity rejected (Online) & Destroyed	1.263	2.398	2134	219	26	04	NA	NA
F	Quantity Returned	19.500	54.500	NA	NA	NA	NA	NA	NA
G	Sample affixed on BPR	0.0008	0.004	01	01	NA	NA	NA	NA
H	QC samples	0.002	0.014	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.024	0.144	40	40	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	48.990	169.660	21915	20000	2000	78	01	06
K	Variation (C - J)	NA	NA	NA	NA	NA	NA	NA	NA
L	%Variation (K x 100)/C	NA	NA	NA	NA	NA	NA	NA	NA
M	Acceptable limit	± 2 %	± 2 %	± 2 %	± 2 %	± 2 %			

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

NA

### 29. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. 00449

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	19.500	54.500						
Material returned by packing Sign./Date	19/06/2022	19/06/2022						
Verified By IPQA Sign./Date	26/11/2022	26/11/2022						
Material received by Store Sign./Date	07/07/2022	07/07/2022						

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

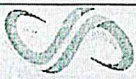
Date	Stereos	Printed Alu. Foil (Kg)	Base Foil (Kg)	Cartons (Nos)	Leaflets (Nos)	Shrink Sleeves (Nos)	5 Ply Shipper (Nos)	Strapping Role (Mtrs.)	BOPP Tape (GHPL Printed) (Nos)
06/12/22	NA	1.263	2.398	2134	219	26	04	NA	NA
Total Qty. Destroyed	NA	1.263	2.398	2134	219	26	04	NA	NA
Destroyed by (Packing)	06/12/22								
Verified by (IPQA)	06/12/22								

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

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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 25 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00 Customer:		Batch No.: G1222161 Generic Health Care Pvt. Ltd.

### 31. BATCH RECONCILIATION:

A	Batch Size	6, 00,000Nos.
B	Quantity received for packing	596875
C	Total quantity packed	592200
D	Control samples	200
E	Analytical Samples	120
F	In process samples	840
G	Others samples if any (Stability, Regulatory Samples, etc.)	1000
H	Packing Loss = B - (C + D + E + F+G)	2515
I	Total Loss = A - (C + D + E + F+G)	5640
J	Packing yield % (C + D + E + F+G) / B X 100 (Yield Limit: .....)*	99.57 %
K	Batch Yield % (C + D + E + F +G) / A X 100 (Yield Limit: .....)*	99.06 %

\* To be established

Checked by Packing /Date: *Nancy 06/12/22*

Verified by IPQA/Date: *G. Senthil Kumar 06/12/22*

### 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
07/12/22	00500	6.0L	2x10's	27x10x2x10's	73	591300	<i>Nancy</i>	<i>Jesha</i>	<i>Rm</i>
				12x10x3x10's	01	900	<i>Nancy</i>	<i>Jesha</i>	<i>Rm</i>
Total Qty. Transferred						592200	<i>Nancy</i>	<i>Jesha</i>	<i>Rm</i>

### 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

Checked by  
Packing:

Verified by  
Packing manager:

Approved by  
Head QA:

### 34. BPR REVIEW DETAILS:


Reviewed by	Name	Sign. /Date
Packing Executive	<i>Cy</i> SUGANYA NANCY DANID	<i>Nancy</i> 07/12/2022
QA Executive	<i>G. Senthil Kumar</i>	<i>G. Senthil Kumar</i> 07/12/2022
Production Assistant Manager/ HOD	<i>S. SWARNAMAR</i>	<i>M</i> 07/12/2022
QA Manager/ HOD	<i>Ram Kumar</i>	<i>R</i> 07/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>Nancy</i>	<i>M</i>	<i>Uthman</i>	<i>R</i>
Date	07/07/2022	07/07/2022	07/07/2022	07/07/2022

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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 26 of 26
	<b>BATCH PACKING RECORD</b>	<b>Product Code: L13</b>	<b>Batch Size: 6,00,000 Tablets</b>
<b>Product</b>	<b>LOLIP 20</b>	<b>BPR. No.: BPR/T/331-00</b>	<b>Batch No.: G18 22161</b>
		<b>Customer:</b>	<b>Generic Health Care Pvt. Ltd.</b>

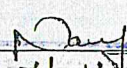
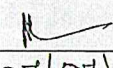
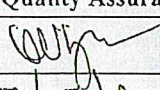
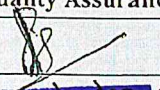
**35. BATCH RELEASED FOR DESPATCH:**

Total quantity released: 592200 No's

Head QA sign/ Date: 15/07/2022

**36. REVISION HISTORY:**

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/331-00	New Document	Nil


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

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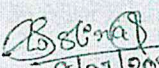
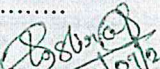
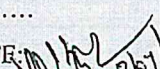



VALIDATION BATCH

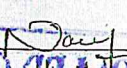
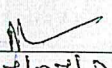
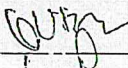

STABILITY BATCH

 <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 26
	<b>BATCH PACKING RECORD</b>	Product Code: L13	Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00	Batch No.: G1822106
		Customer:	Generic Health Care Pvt. Ltd.

**BATCH PACKAGING RECORD COVER SHEET**


PRODUCT NAME	: LOLIP 20
GENERIC NAME	: Atorvastatin Calcium Tablets 20 mg
LABEL CLAIM	Each film coated tablet contains:
	Atorvastatin calcium Trihydrate
	Equivalent to Atorvastatin ..... 20 mg
	Colour: Approved colour used.
CODE NO.	: PON/DRUGS/21 14 4376
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/331-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: G1822106 / 07/07/2022
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets
PACKING CONFIGURATION	: 3 x 10 Tablets Pack (Alu Alu Packing)
BPR ISSUED BY/DATE (QA)	:  08/07/2022
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: L. K. 08/07/2022
MFG. DATE: .....07/2022.....	EXP. DATE: .....06/2025.....
ALLOTTED BY: QA SIGN/DATE:  08/07/2022	COUNTER CHECKED BY: QA SIGN/DATE:  08/07/2022
QUANTITY RECEIVED FROM PRODUCTION	: 595781 NOS
DATE OF COMMENCEMENT: 23/07/2022	DATE OF COMPLETION: 24/07/2022
QUANTITY	: 600000 NOS
RELEASED QUANTITY OF PACKED TABLETS	: 592200 NOS
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	 24/07/2022

This BPR contains 26 Pages + 00 Additional Pages

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

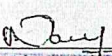

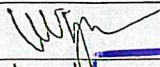
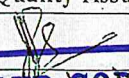
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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 26
	<b>BATCH PACKING RECORD</b>	Product Code: L13	Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00	Batch No.: G1822106
		Customer:	Generic Health Care Pvt. Ltd.


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5	Dispensing record of packing materials	6
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Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
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	<b>BATCH PACKING RECORD</b>	Product Code: L13	Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	<b>BPR. No.:</b> BPR/T/331-00	<b>Batch No.:</b> 618 22106
		<b>Customer:</b>	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) *	26/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	YES NA
b)	Approved specimen of printed foil, carton 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 Format	NA
7.	Complete set of BPR Submitted	YES

Checked By QA/Date:

*[Signature]*  
30/07/2022


\*Mention total number of pages.

Remarks (If any) ..... NA .....

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	07/07/2022	07/07/2022	07/07/2022	07/07/2022

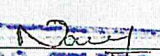

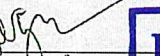

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	<b>BATCH PACKING RECORD</b>	Product Code: L13	Batch Size: 6,00,000 Tablets
	Product: <b>LOLIP 20</b>	BPR. No.: BPR/T/331-00	Batch No.: <b>G1822106</b>
		Customer:	Generic Health Care Pvt. Ltd.


### 3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Item Code	Specification	UOM	Standard Qty. for Batch Size 6.0 Lac.
1	252mm Lolip 20 Printed Foil 0.025mm	PPF/SP/L016	Width – 252 ± 1 mm Thickness – 0.025 mm Language – French Color – 2 Colors Item Code – 13/0463	Kg	45.000
2	252 mm Alu Alu base foil	PBF/SP/A004	Width – 252 ± 1 mm Plain non-printed (text matter) aluminum foil.	Kg	150.000
3	3x10's Lolip 20 Printed Carton	PPC/SP/L016	Size – 130 x 60 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 4 colour Language – English/French Item Code – 15/0781	No	20000
4	Lolip Printed Leaflet	PPL/SP/L019	Size – 140 x 175 mm (L x H) Specification – NLT 60 gsm Maplitho Paper. Colour – 2 colours Language – French/ English Item Code: 16/0556	No	20000
5	Shrink Sleeves (PVC)	PPS/SP/P001	Plain PVC Shrink Sleeves	No	2000
6	5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 430 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm <sup>2</sup>	No	75
7	2.5' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	2
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	1
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width - 12 mm Thickness - 0.6 mm	Mtrs	300

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

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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 26
	<b>BATCH PACKING RECORD</b>	Product Code: L13 BPR. No.: BPR/T/331-00 Customer:	Batch Size: 6,00,000 Tablets Batch No.: 01822106 Generic Health Care Pvt. Ltd.
<b>Product</b>	<b>LOLIP 20</b>		

#### 4. DISPENSING LINE CLEARANCE CHECKS

Date: 22/07/2022 Time: 14:50

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.	BT/LAF/001	STBAL/011	-NA-	FOIL STORE
Previous Product	TRANSNERV-Q10			
B. No.	FT0222039			
Cleaned by Sign/Date	Saran 22/07/2022			
Checked by Store Sign/Date	[Signature] 22/07/2022			
Verified by IPQA Sign/Date	[Signature] 22/07/2022			

ENVIRONMENTAL CONDITIONS: Date: 22/07/2022 Time: 14:55	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	[Signature] 22/07/22	[Signature] 22/07/22
Differential Pressure across the booth Limit: 5 to 20 mm Water	15mm	[Signature] 22/07/22	[Signature] 22/07/22

APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature] Date: 22/07/22
Dispensing start Time: 15:00 End Time: 15:20


Prepared by:	Checked by:		Approved By:
Dept. Production	Production	Quality Assurance	Head Quality Assurance
Sign: [Signature]	[Signature]	[Signature]	[Signature]
Date: 22/07/2022	07/07/2022	07/07/2022	07/07/2022

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07/2022

06/2025

 <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 6 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>		BPR. No.: BPR/T/331-00 Batch No.: 61822106
Customer:			Generic Health Care Pvt. Ltd.


## 5. DISPENSING RECORD OF PACKING MATERIALS: Date: 22/07/2022 Shift: G Time: 14:57

Material Name	Item code	UOM	Req. Qty. for 6.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
252mm Lolip 20 Printed Foil 0.025mm	PPF/SP/L016	Kg	45.000	40.680	PmG/00334	02	[Signature] 22/07/22	[Signature] 22/07/22
252 mm Alu Alu base foil	PBF/SP/A004	Kg	150.000	166.480	PmG/00305	07	[Signature] 22/07/22	[Signature] 22/07/22
3x10's Lolip 20 Printed Carton	PPC/SP/L016	No	20000	20250	PmG/00350	11	[Signature] 22/07/22	[Signature] 22/07/22
Lolip Printed Leaflet	PPL/SP/L019	No	20000	20000	PmG/00351	02	[Signature] 22/07/22	[Signature] 22/07/22
Shrink Sleeves (PVC)	PPS/SP/P001	No	2000	2000	PmG/00895	02	[Signature] 22/07/22	[Signature] 22/07/22
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	75	75	PmG/01453	08	[Signature] 22/07/22	[Signature] 22/07/22
2.5' GHPL Printed Bopp Tape	PPB/SP/B002	No	2	02	PmG/00310	01	[Signature] 22/07/22	[Signature] 22/07/22
3' Plain BOPP Tape	PUB/SP/B001	No	1	01	PmG/241019/ 02	01	[Signature] 22/07/22	[Signature] 22/07/22
Strapping role.	PPR/SP/S001	Mtrs	300	01	PmG/00945	01	[Signature] 22/07/22	[Signature] 22/07/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	[Signature]	[Signature]	[Signature]	[Signature]
Date	07/07/2022	07/07/2022	07/07/2022	07/07/2022

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: 61822106 Generic Health Care Pvt. Ltd.

## 6. LINE CLEARANCE CHECKS:

### 6.1 PRIMARY PACKING:

Date/ Shift 23/07/22 G...08:55/...24/07/22...07:10

Previous Product: Lolip 20		Batch No.: G1822105				
Sr. No.	Checks	Time	Observation			
			08:56 Packing	IPQA	Packing	IPQA
1.	Area status board is updated for "CLEANED" status.		✓	✓	✓	✓
2.	Check and ensure that the area is visually clean and free from previous product		✓	✓	✓	✓
3.	Check and ensure the differential pressure of the area is within specified limit		✓	✓	✓	✓
4.	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
5.	Check the temperature and relative humidity of the area within specified limit		✓	✓	✓	✓
6.	Check the tablets of the previous product/ batch removed.		✓	✓	✓	✓
7.	Check the loose Alu Alu strip cutting, rejected rolls, empty cores of foil of previous product /batch are removed.		✓	✓	✓	✓
8.	Check the surroundings of the machine and free from the previous products and batch		✓	✓	✓	✓
9.	Check the foil printing stereos, Labels of previous product/batch are removed.		✓	✓	✓	✓
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.		✓	✓	✓	✓
11.	Check and ensure the Cleanliness following change part of Alu Alu 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: Not satisfactory Cleaning satisfactory/Not-satisfactory: Not satisfactory  
 Checked by Packing (Sign./Date): 23/07/22 Verified by IPQA (Sign./Date): 23/07/2022

#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: 23/07/22 09:00

Previous Product: Lolip 20				Batch No.: G1822105			
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	SPL/AFF/ALU/001	B	PDGN/006	Gopal	23/07/22	23/07/2022
2.	Alu Alu Packing Machine	PD/ALU/001	B	PDOP/020, PDCL/020	Gopal	23/07/22	23/07/2022

### 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: 23/07/22 Time: 09:00 S....			Date: 24/07/22 Time: 07:14.....		
	Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	23°C	23/07/22	23/07/2022	23°C	24/07/22	23/07/2022
RH % Limit: NMT 60%	59.4 %	23/07/22	23/07/2022	58 %	24/07/22	23/07/2022
DP Limit: NLT 10 Pascal	11 Pascal	23/07/22	23/07/2022	10 Pascal	24/07/22	23/07/2022

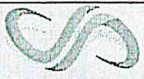
Primary Packing Started Date/Time: 23/07/22 09:55 Completed Date/Time: 24/07/22 1:14.6.....

APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: 23/07/2022

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>23/07/22</u>	<u>23/07/22</u>	<u>23/07/22</u>	<u>23/07/22</u>	
Date	23/07/2022	23/07/2022	23/07/2022	23/07/2022	

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: <u>G11822106</u> Generic Health Care Pvt. Ltd.

**7. VERIFICATION OF DISPENSED PACKING MATERIALS:** Date 23/07/22 Shift G1 Time: 09:07

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
252mm Lolip 20 Printed Foil 0.025mm	PPF/SP/L016	Kg	<u>ProG/00334</u>	<u>02</u>	<u>May</u>	<u>Jesj</u>
252 mm Alu Alu base foil	PBF/SP/A004	Kg	<u>ProG/00205</u>	<u>07</u>	<u>May</u>	<u>Jesj</u>
3x10's Lolip 20 Printed Carton	PPC/SP/L016	No	<u>ProG/00350</u>		<u>May</u>	<u>Jesj</u>
Lolip Printed Leaflet	PPL/SP/L019	No	<u>ProG/00351</u>	<u>02</u>	<u>May</u>	<u>Jesj</u>
Shrink Sleeves (PVC)	PPS/SP/P001	No	<u>ProG/00295</u>	<u>02</u>	<u>May</u>	<u>Jesj</u>
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	<u>ProG/01453</u>	<u>02</u>	<u>May</u>	<u>Jesj</u>
2.5' GHPL Printed Bopp Tape	PPB/SP/B002	No	<u>ProG/00310</u>	<u>01</u>	<u>May</u>	<u>Jesj</u>
3' Plain BOPP Tape	PUB/SP/B001	No	<u>ProB/24109/02</u>	<u>01</u>	<u>May</u>	<u>Jesj</u>
Strapping role.	PPR/SP/S001	Mtrs	<u>ProG/00945</u>	<u>01</u>	<u>May</u>	<u>Jesj</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>NA</u>	<u>NA</u>	<u>NA</u>	<u>NA</u>	<u>NA</u>	<u>NA</u>

**9. RECEIPT OF PRODUCT AND MATERIALS:** Date/Shift 23/07/22 Time: 09:10

(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>28°C</u>	<u>May</u>	<u>Jesj</u>
2.	Relative Humidity observed on display (Limit: NMT 60%)	<u>58%</u>	<u>May</u>	<u>Jesj</u>
3.	Bulk product containers are of the required product/Batch number and is approved by QC	<u>YES</u>	<u>May</u>	<u>Jesj</u>
4.	Status label of machine/ line is for same product	<u>YES</u>	<u>May</u>	<u>Jesj</u>
5.	Printed foil/Base rolls are of the required product.	<u>YES</u>	<u>May</u>	<u>Jesj</u>
6.	All secondary packing materials are of the required product	<u>YES</u>	<u>May</u>	<u>Jesj</u>

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

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	<u>192 mg</u>	<u>May</u>	<u>Jesj</u>
2.	Colour of Tablet	<u>pale yellow</u>	<u>May</u>	<u>Jesj</u>
3.	Quantity (Net Qty.in Kg)	<u>114.390 Kg</u>	<u>May</u>	<u>Jesj</u>
4.	Number of Containers	<u>04</u>	<u>May</u>	<u>Jesj</u>

**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
<u>Lolip 20</u>	<u>G11822106</u>	<u>07/2022</u>	<u>06/2025</u>	<u>114.390 Kg</u> Equivalent to <u>595781</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>May</u> <u>23/07/22</u>				Verified By IPQA (Sign. /Date): <u>Jesj</u> <u>23/07/2022</u>	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>May</u>	<u>May</u>	<u>May</u>	<u>May</u>
Date	<u>23/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</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 9 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
Product <b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:		Batch No.: <b>G1822106</b> Generic Health Care Pvt. Ltd.

### 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	27.580	Jerish	Jes	6			
2	27.110	Jerish	Jes	7			
3	34.180	Jerish	Jes	8			
4	33.750	Jerish	Jes	9			
5				10			

### 13. CONTAINER CONSUMPTION DETAILS:

S. No	Time From	Time To	Container No.	Consumed by	S. No	Time From	Time To	Container No.	Consumed by
1	10:40	11:50	01	Chopal	6				
2	11:51	14:10	02	Chopal	7				
3	14:11	18:00	03	Chopal	8				
4	07:30	11:46	04	Chopal	9				
5			NA		10				

Checked By Packing (Sign. /Date): *Nay* 22/07/22

Verified by IPQA (Sign. /Date): *Jes* 22/07/2022

### 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/21 14 4376	PON/DRUGS /21 14 4376	OK
Batch No.:	G1822106	OK
Mfg. Date:	07/2022	OK
Exp. Date:	06/2025	OK
Item Code: 13/0463	13/0463	OK
Pack size (3 x 10's)- Carton	NA	NA
Other instructions if any	NA	NA
Initiated by	Chopal	Chopal
Checked by Packing (Sign. & Date)	<i>Nay</i> 23/07/22	<i>Nay</i> 23/07/22
Verified by IPQA (Sign. & Date)	<i>Jes</i> 23/07/2022	<i>Jes</i> 23/07/2022

### 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	22/07/22	01	Chopal	<i>Nay</i> 23/07/22	<i>Jes</i> 23/07/2022
02	24/07/22	02	Chopal	<i>S. Jey</i> 24/07/22	<i>Jes</i> 24/07/2022


### 16. PACKING INSTRUCTIONS:

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>Nay</i>	<i>M</i>	<i>Wey</i>	<i>X</i>
Date	22/07/2022	21/07/2022	21/07/2022	22/07/2022

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00		Batch No.: 61822106
	Customer:		Generic Health Care Pvt. Ltd.

**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	23/07/22 G	09:55	12:00	10:45	18:10	Nay 23/07/22
02	24/07/22 G	07:30	11:46	07:38	11:55	S.K. 24/07/22
			N/A			

**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.

**18. ALU ALU PACKING MACHINE PARAMETERS:**

Date/Shift: 23/07/22 G Time: 10:40:00

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	18107529	18107529	Nay 23/07/22	Jes 23/07/2022
Sealing Temperature	(To be established)	195°C	Nay 23/07/22	Jes 23/07/2022
Leak test to be performed on 02 Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	YES	Nay 23/07/22	Jes 23/07/2022
Machine Speed	(To be established)	82	Nay 23/07/22	Jes 23/07/2022

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

Sr. No	Process instructions										
1.	Testing frequency: Startup, End of the activity and after every break										
2.	Acceptance Criteria: Broken Tablet, Empty Packet, Black Particle, Colour variation, Foreign Matter, Dual Tablets / Capsules and all defects should be detected & rejected.										
Date & Time	S. No.	Broken Tablet	Empty Packet	Black Particle	Colour variation	Foreign Matter	Dual Tablets / Capsules	Result	Done By	Checked by Packing	Verified By IPQA
10:42	1	✓	✓	✓	✓	✓	✓	Pass	Gopal	Nay	Jes
11:46	2	✓	✓	✓	✓	✓	✓	Pass	Gopal	Nay	Jes
16:30	3	✓	✓	✓	✓	✓	✓	Pass	Gopal	Nay	Jes
24/07/22	4	✓	✓	✓	✓	✓	✓	PASS	Gopal	S.K.	Jes
07:30	5	✓	✓	✓	✓	✓	✓	Pass	Gopal	S.K.	Jes
09:31	6										
	7										
	8										
	9										
	10										
	11										
	12										
	13										
	14										
	15										


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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	Nay	Nay	Nay	Nay
Date	07/07/2022	07/07/2022	07/07/2022	07/07/2022

\* W.E  
Nay  
23/07/22

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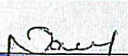

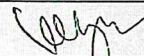



 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>		BPR. No.: BPR/T/331-00 Batch No.: G1822106
	Customer:		Generic Health Care Pvt. Ltd.

20. MACHINE IN-PROCESS CONTROL:

Date/ Shift	23/07/22 G1								24/07/22 / G1							
Machine Operator Name	Chopal															
Time of inspection	10:10	10:21	10:30	10:39	10:40	10:48	11:45	13:10	13:23	14:16	15:12	15:32	16:25	17:30	17:37	17:30
Sealing Temperature (To be established)	120°C	125°C	110°C	110°C	195°C	145°C	195°C	195°C	196°C	196°C	195°C	194°C	194°C	195°C	195°C	194°C
Leak test on Alu Alu strips* (Qty.: 024)	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/21 14 4376	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.:	G1822106	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	07/2022	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	06/2025	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed (To be established)	19	40	19	40	32	30	32	32	32	32	32	32	32	30	30	30
Checked by (Packing)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Checked by (IPQA)	Jesi	Jesi	Jesi	Jesi	NA	Jesi	NA	NA	Jesi	NA	NA	Jesi	NA	NA	NA	NA


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

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

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00 Customer:		Batch No.: G18 22106 Generic Health Care Pvt. Ltd.

### 20.1 MACHINE IN-PROCESS CONTROL:


Date/ Shift	24/07/22 / G																		
Machine Operator Name	GOPAL																		
Time of inspection	01:33 08:36	08:36	09:31	09:45	10:38	11:30	11:40												
Sealing Temperature (To be established)	195°	195°	195°	196°	194°	194°	195°												
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/ 21 14 4376	OK	OK	OK	OK	OK	OK	OK												
B. No.: G18 22106	OK	OK	OK	OK	OK	OK	OK												
Mfg. Date 07/2022	OK	OK	OK	OK	OK	OK	OK												
Exp. Date 06/2025	OK	OK	OK	OK	OK	OK	OK												
Machine Speed (To be established)	30	30	30	30	30	30	30												
Checked by (Packing)	NA	NA	NA	NA	NA	NA	NA												
Checked by (IPQA)	NA	NA	NA	NA	NA	NA	NA												

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

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





 <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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	LOLIP 20	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822106 Generic Health Care Pvt. Ltd.

### 20.2 MACHINE IN-PROCESS CONTROL:

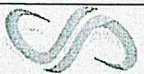
Date/ Shift																			
Machine Operator Name																			
Time of inspection																			
Sealing Temperature (To be established)																			
Leak test on Alu Alu strips* (Qty.:_____)																			
Knurling /Sealing																			
Pocket Formation																			
Horizontal cutting																			
Vertical cutting																			
Quality of Over printing																			
Code No.:	PON/DRUGS/ 21 14 4376																		
B. No.:																			
Mfg. Date																			
Exp. Date																			
Machine Speed (To be established)																			
Checked by (Packing)																			
Checked by (IPQA)																			

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/07/2012	07/07/2012	07/07/2012	07/07/2012

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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 14 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: 61822106 Generic Health Care Pvt. Ltd.

### 20.3 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)
24/07/22	08:48	09:20	0.950	sudha, Jirish	24/07/22	24/07/22
				NA		
Total Weight of De-foiled Tablets			0.950	Checked By / Date (Packing)	24/07/22	Verified By / Date (IPQA):


### 20.4 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		
24/07/22	09:22	09:45	sudha	0.920	4792	0.030	156	24/07/22	24/07/22
			NA						
Total				0.920	4792	0.030	156	24/07/22	
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing):			Verified By / Date (IPQA):		
0.030 Kgs .... 156 Nos.				24/07/22			24/07/22		

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

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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 15 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPRT/331-00 Customer:	Batch No.: <u>61822106</u> Generic Health Care Pvt. Ltd.

21. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift 23/07/22 G1 ..... / 24/07/2022 G1

Previous Product: Lolip 10		Batch No.: G11822105				
Sr. No.	Checks	Time	Observation			
			09:25 Packing	IPQA	07:12 Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		/	/	/	/
2	Check and ensure that waste bin is emptied out and cleaned		/	/	/	/
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		/	/	/	/
4	Check and ensure the Correct status board is written.		/	/	/	/
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		/	/	/	/
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		/	/	/	/
7	Check and ensure the cleanliness of hatch for conveyor belt.		/	/	/	/
8	Check and ensure the cleanliness of conveyer belt with collateral block.		/	/	/	/
9	Check and ensure the dispensed secondary packing material.		/	/	/	/
10	Check and ensure the cleanliness of documentation table.		/	/	/	/
11	Check and ensure the Preventive maintenance records and log book.		/	/	/	/

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

Cleaning Satisfactory / Not satisfactory# Not Cleaning Satisfactory / Not satisfactory# Not  
 (Packing) Sign./Date: 23/07/22 (IPQA) Sign./Date: 23/07/2022  
 Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	<u>PD/COR/004</u>	<u>PD/BAL/015</u>	<u>PD/SWM/001</u>	<u>PD/STM/001</u>	<u>PD/BAL/038</u>	Secondary Packing Hall
Previous Product:	<u>Lolip 10</u>					
Batch No.:	<u>G11822105</u>					
Cleaned by:	<u>Sangari</u>					
Checked by Packing:	<u>Not</u> <u>23/07/22</u>					
Verified by IPQA:	<u>Not</u> <u>23/07/2022</u>					

21.1 ENVIRONMENTAL CONDITIONS:


(Check the environmental conditions of Secondary packing area at the start of process and Record in the below in table)						
Shift: ..... <u>G1</u> .....		Date/Time: <u>23/07/2022</u> <u>09:30</u>		Date/Time: <u>24/07/22</u> <u>07:18</u>		
		Observation	Checked by Packing	Verified by IPQA	Observation	Checked by Packing
Refer to SOP No.: SOP: QAGN/011	Temperature °C Limit: NMT 25°C	<u>23°C</u>	<u>Not</u>	<u>Not</u>	<u>23°C</u>	<u>Not</u>
Secondary Packing Started Date/Time: <u>23/07/2022</u> <u>10:45</u> ..... Completed Date/Time: <u>24/07/22</u> <u>11:55</u>						
APPROVAL FOR SECONDARY PACKING: Approved by IPQA Sing/Date: <u>23/07/2022</u>						

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>Not</u>	<u>Not</u>	<u>Not</u>	<u>Not</u>
Date	<u>23/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>23/07/2022</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 16 of 26
	<b>BATCH PACKING RECORD</b>	Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Batch No.: 121822106
		Customer: Generic Health Care Pvt. Ltd.

## 21.2 PACKING DETAILS:

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

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

Place 10 filled carton in a Shrink Sleeve.

Place 27 Shrink sleeves in each 5 ply shipper.

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

## 22. OVER PRINTING DETAILS:

### Overprinting Details (Secondary & Tertiary PM)

Overprinting Details	Overprinted Text	Carton	Insert	5 Ply Shipper Label
Batch No.:	121822106	ok	NA	ok
Mfg. Date:	07/2022	ok	NA	ok
Exp. Date:	06/2025	ok	NA	ok
Code No.: PON/DRUGS/21 14 4376	PON/DRUGS/21 14 4376	ok	NA	NA
Pack size:	NA	3 x 10's	NA	27 x 10 x 3 x 10's
Item Code: 15/0781	NA	15/0781	NA	NA
Item Code: 16/0556	NA	NA	16/0556	NA
Initiated by Sign. & Date	NA	NA	NA	Kalai
Checked by Packing Sign. & Date	S. L. 23/07/22	S. L. 23/07/22	Nay 23/07/22	S. L. 23/07/22
Verified by IPQA Sign. & Date	(V) 23/07/22	(V) 23/07/22	(V) 23/07/22	(V) 23/07/22

### 22.1 Carton and Shipper Label Specimen:

S. No.	Date	Carton Specimen No.	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01.	23/07/22	01	01	S. L. 23/07/22	J. S. 23/07/22

## 23. INDIVIDUAL STRIP WEIGHING LIMIT:

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

1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
				NA					

Total weight of ten Empty Alu Alu strips =

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

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

1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
3.8	3.7	3.7	3.6	3.6	3.6	3.6	3.6	3.7	3.6

Total weight of ten Filled Alu Alu strips = 36.7

Avg. Weight of a Filled Alu Alu strip (B): total weight of ten Filled Alu Alu strip/10= 3.67

Limit (C) = 3.67


(Each missing tablet should be identified)

Strip weighing Done By: Jangari	Checked By: Nay	Verified By: J. S. 23/07/2022
---------------------------------	-----------------	-------------------------------

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

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: 618 22106 Generic Health Care Pvt. Ltd.

23.1 CARTON WEIGHT LIMIT SETTING: Date/Shift: 23/07/22, 04 Time: 10:50.

Weight of ten individual empty cartons are given below:

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

Total weight of ten empty cartons = 88

Average weight of an empty carton (D) = Total weight of ten empty carton / 10 = 8.8

Weight of ten individual Leaflets are given below:

1. 1.4	3. 1.5	5. 1.5	7. 1.5	9. 1.4
2. 1.4	4. 1.4	6. 1.5	8. 1.4	10. 1.4

Total weight of ten Leaflets = 14.4

Avg. Weight of a Leaflet (E): total weight of ten Leaflets / 10 = 1.44

23.2 WEIGHT CHECKS ON CARTON:

Weight of ten empty Carton:	88	Average weight of one empty Carton (D):	8.8
Weight of ten filled Alu Alu strip:	36.7	Average weight of one filled Alu Alu strip (B):	3.67
Weight of ten Leaflets:	14.4	Average weight of one Leaflet (E):	1.44
Weight of one filled Carton F = (D+3B+E)	21.2	Limit: G = F ± 1 % =	21.0 - 21.4
Checked by Packing/Date:	Nay 23/07/22	Verified by IPQA/Date:	Jes 23/07/2022

23.3 SAMPLE DRAWN RECORD:


Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7 x 10 <sup>s</sup>	Jes 23/07/2022
2	Control Sample (Middle)	6 x 10 <sup>s</sup>	Jes 23/07/2022
3	Control Sample (Final)	7 x 10 <sup>s</sup>	Jes 23/07/2022
4	Stability Sample	100 x 10 <sup>s</sup>	Jes 23/07/2022
5	Other Sample	NA	NA
6	Analytical sample	12 x 10 <sup>s</sup>	Jes 23/07/2022
Total Qty.		132 x 10 <sup>s</sup>	Jes 23/07/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	Nay	H	Jes	Jes
Date	23/07/2022	23/07/2022	23/07/2022	23/07/2022

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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 18 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
Product: <b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:		Batch No.: <b>G1822106</b> Generic Health Care Pvt. Ltd.

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

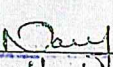
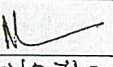
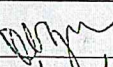
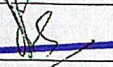
Date/ Shift	23/07/22/G1	G1	24/07/22/G1	28/07/2022 /G1											
Parameters	Specification	observation													
		Packing								IPQA					
Time		10:47	11:50	12:48	13:46	14:51	15:47	16:40	17:56	18:04	19:15	19:30			
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
No. of cartons in a shrink sleeves	10 packed cartons	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		NA	
No. of shrink sleeves in a 5 ply shipper	27 shrinks	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
Shipper strapping	Proper strapping	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK			
Sealing of the shipper with BOPP Tape	H type	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			
Checked by		JS	JS	SJM	SJM	SJM	SJM	SJM	SJM	JS	JS	JS			

\*Temperature to be mentioned.

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


Date/ Shift	23/07/22/G1		24/07/22/G1					24/07/2022 /G1						
Parameters	Specification	observation												
		Packing						IPQA						
Time		17:44	07:38	08:40	09:42	10:35	11:36		07:45	09:49	11:50			
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			
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK		ok	ok	ok			
No. of cartons in a shrink sleeves	10 packed cartons	NA	NA	NA	NA	NA	NA		NA	NA	NA			
Shrink wrapping temperature*		NA	NA	NA	NA	NA	NA		NA	NA	NA			
No. of shrink sleeves in a 5 ply shipper	27 shrinks	NA	NA	NA	NA	NA	NA		NA	NA	NA			NA
Shipper strapping	Proper strapping	NA	NA	NA	NA	NA	NA		NA	NA	NA			
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK		ok	ok	ok			
Sealing of the shipper with BOPP Tape	H type	NA	NA	NA	NA	NA	NA		NA	NA	NA			
Checked by		S.1m	S.1m	S.1m	S.1m	S.1m	S.1m		Jeej	Jeej	Jeej			

\*Temperature to be mentioned.

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

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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 19 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00 Customer:		Batch No.: G1822106 Generic Health Care Pvt. Ltd.

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

Date/ Shift	Parameters	Specification	observation													
			Packing							IPQA						
			9:40	10:38	11:43	12:20	13:50	14:39	15:45	16:48	17:50	18:46	19:52	20:50		
	No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok		
	Carton Overprinting	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok		
	No. of cartons in a shrink sleeves	10 packed cartons	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok		
	Shrink wrapping temperature*	150°C	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok		
	No. of shrink sleeves in a 5 ply shipper	27 shrinks	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok		
	Shipper strapping	Proper strapping	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok		
	Label appearance and Shipper appearance	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok		
	Sealing of the shipper with BOPP Tape	H type	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok	ok		
	Checked by		14	14	14	14	14	14	14	14	14	14	14	14		

\*Temperature to be mentioned.

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

Date/ Shift	Parameters	Specification	observation													
			Packing							IPQA						
			16:23	17:40	19:50	11:01	12:15	13:45	14:02	15:10						
	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						
	Carton Overprinting	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok						
	No. of cartons in a shrink sleeves	10 packed cartons	ok	ok	ok	ok	ok	ok	ok	ok						
	Shrink wrapping temperature*	150°C	ok	ok	ok	ok	ok	ok	ok	ok						
	No. of shrink sleeves in a 5 ply shipper	27 shrinks	ok	ok	ok	ok	ok	ok	ok	ok						
	Shipper strapping	Proper strapping	ok	ok	ok	ok	ok	ok	ok	ok						
	Label appearance and Shipper appearance	Legible and readable	ok	ok	ok	ok	ok	ok	ok	ok						
	Sealing of the shipper with BOPP Tape	H type	ok	ok	ok	ok	ok	ok	ok	ok						
	Checked by		14	14	14	14	14	14	14	14						


\*Temperature to be mentioned.

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

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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 20 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00		Batch No.: 01822106
	Customer:		Generic Health Care Pvt. Ltd.

25. SHIPPERS WEIGHING: Date/Shift: 23/07/22, Ct.... Time: 10.55. Balance I.D. No.: PD/PA/038

Weight of ten Shrinks:	2207	Average weight of one filled Shrink (H):	220.7
Weight of ten empty shippers:	13	Average weight of one empty shipper (I):	1.300
Weight of one filled shipper (J) = (27H+I):	7.258	Limit: K = J ± 1% =	7.186 - 7.330
Checked by Packing/Date: Day 23/07/22		Verified by IPQA/Date: Jesi 23/07/2022	

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	7.260	Aashu	20	7.335	Aashu	39	7.330	Aashu	58	7.305	Aashu
2	7.260	Aashu	21	7.330	Aashu	40	7.325	Aashu	59	7.295	Aashu
3	7.255	Aashu	22	7.335	Aashu	41	7.325	Aashu	60	7.300	Aashu
4	7.250	Aashu	23	7.335	Aashu	42	7.325	Aashu	61	7.315	Aashu
5	7.255	Aashu	24	7.330	Aashu	43	7.315	Aashu	62	7.315	Aashu
6	7.260	Aashu	25	7.330	Aashu	44	7.315	Aashu	63	7.310	Aashu
7	7.325	Aashu	26	7.330	Aashu	45	7.320	Aashu	64	7.300	Aashu
8	7.260	Aashu	27	7.325	Aashu	46	7.330	Aashu	65	7.300	Aashu
9	7.255	Aashu	28	7.320	Aashu	47	7.320	Aashu	66	7.310	Aashu
10	7.265	Aashu	29	7.330	Aashu	48	7.330	Aashu	67	7.300	Aashu
11	7.335	Aashu	30	7.330	Aashu	49	7.320	Aashu	68	7.305	Aashu
12	7.320	Aashu	31	7.330	Aashu	50	7.320	Aashu	69	7.300	Aashu
13	7.325	Aashu	32	7.330	Aashu	51	7.320	Aashu	70	7.305	Aashu
14	7.315	Aashu	33	7.330	Aashu	52	7.310	Aashu	71	7.310	Aashu
15	7.330	Aashu	34	7.325	Aashu	53	7.315	Aashu	72	7.300	Aashu
16	7.325	Aashu	35	7.325	Aashu	54	7.315	Aashu	73	7.305	Aashu
17	7.335	Aashu	36	7.325	Aashu	55	7.310	Aashu	74	2.060	Aashu
18	7.320	Aashu	37	7.330	Aashu	56	7.310	Aashu	75		
19	7.335	Aashu	38	7.330	Aashu	57	7.300	Aashu	76		


Total No. of shippers weighed: <b>74</b>	De-foiled tablets packed in Shipper No: <b>74</b>	Checked by Sign / Date: Day 24/07/2022	Verified by Sign / Date: Jesi 24/07/2022	Loose pack details: Shipper No: 74..... Quantity: 02x10x3x10's Weight: 2.060.....
---	--	---	---	--

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.				
Date	07/07/2022	07/07/2022	07/07/2022	07/07/2022

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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 26
	<b>BATCH PACKING RECORD</b>	Product Code: L13	Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BPR. No.: BPR/T/331-00	Batch No.: 61822106
		Customer:	Generic Health Care Pvt. Ltd.

#### 26. MAN POWER ALLOCATION:

DATE: 23/07/22		DATE: 24/07/22	
SHIFT: G		SHIFT: G	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking	Kamatchi - Sanbasi	Alu Alu strip Checking	SANKARI, KAMATCHI
Printing Checking in Alu Alu strip	Chitra, Naveena	Printing Checking in Alu Alu strip	CHITRA, NAVEENA
Alu Alu strip weighing	manimegalai, Anbu	Alu Alu strip weighing	MANIMEGALAI, ANBU
Insertion of Alu Alu strip and leaflet into carton	Shanthi, Malai	Insertion of Alu Alu strip into carton	SHANTHI, MALAI
Cartons weighing	Rushpa, Raji, Lakshmi	Cartons weighing	PUSHPA, LAKSHMI
Insertion of carton into shrink sleeve	Suganthi	Insertion of carton into shrink sleeve	SGGANTHI
Insertion of shrink wrapped carton into shipper	NA	Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Geetha	Shipper Label Pasting	GEETHA
Shipper Weighing	Geetha	Shipper Weighing	GEETHA
Shipper Strapping	NA	Shipper Strapping	NA
Shipper packed	From 01 to 59	Shipper packed	From 60 to 74
Signature of Packing	Nay 23/07/22	Signature of Packing	S. / 24/07/22


DATE: .....		DATE: .....	
SHIFT: .....		SHIFT: .....	
ACTIVITIES	DONE BY	ACTIVITIES	DONE BY
Alu Alu strip Checking		Alu Alu strip Checking	
Printing Checking in Alu Alu strip		Printing Checking in Alu Alu strip	
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.	Nay	N	Co	X
Date	07/07/2022	07/07/2022	07/07/2022	

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: C1822106 Generic Health Care Pvt. Ltd.

27. **PRODUCT COUNTER CHECK LINE CLEARANCE:**  
 Date/ Shift 26/07/2022 / G ..... 27/07/22 / G.....

Previous Product: Lolip 10		Batch No.: C1822105				
Sr. No.	Checks	Time	Observation.			
			09:40		09:50	
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	✓
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	✓
4	Check and ensure the Correct status board is written.		✓	✓	✓	✓
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	✓
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓	✓	✓
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	✓	✓
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓	✓	✓
9	Check and ensure the dispensed secondary packing material.		✓	✓	✓	✓
10	Check and ensure the cleanliness of documentation table.		✓	✓	✓	✓
11	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	✓

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

Cleaning Satisfactory / Not satisfactory# S. /h Cleaning Satisfactory / Not satisfactory# Jes  
 (Packing) Sign. /Date: 26/07/22 (IPQA) Sign. /Date: 26/07/2022

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


Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	<u>NA</u>	<u>PD/BAL/036</u>	<u>PD/SWM/001</u>	<u>PD/STM/001</u>	<u>PD/BAL/038</u>	<u>FG ROOM</u>
Previous Product:	<u>Lolip 10</u>					
Batch No.:	<u>C1822105</u>					
Cleaned by:	<u>keethi.</u>					
Checked by Packing:	<u>S. /h</u> <u>26/07/22</u>					
Verified by IPQA:	<u>Jes</u> <u>26/07/2022</u>					
Rechecking Started Date/Time:	<u>26/07/2022</u>	<u>09:40</u>	Completed Date/Time:	<u>27/07/22</u>	<u>13:56</u>	
APPROVAL FOR COUNTER CHECK:		Approved by IPQA Sing/Date: <u>Jes</u> <u>26/07/2022</u>				

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>Nany</u>	<u>M</u>	<u>Q</u>	<u>HS</u>
Date	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</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 23 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822106 Generic Health Care Pvt. Ltd.

### 27.1 COUNTER CHECK OF PACKED SHIPPERS :

DATE: 26/07/22		DATE: 27/07/22	
SHIFT: G1		SHIFT: G1	
<b>ACTIVITIES</b>	<b>DONE BY</b>	<b>ACTIVITIES</b>	<b>DONE BY</b>
Alu Alu strip Checking	Shobana, Jayamani.	Alu Alu strip Checking	Shobana, Jayamani.
Printing Checking in Alu Alu strip	Shobana, Jayamani.	Printing Checking in Alu Alu strip	Shobana, Jayamani.
Alu Alu strip weighing	Bharathi.	Alu Alu strip weighing	Bharathi.
Checking of Alu Alu strip and leaflet in carton	Pushpa, Selvi, Malathi.	Checking of Alu Alu strip and leaflet in carton	Pushpa, Selvi, Malathi.
Cartons weighing	Keerthi.	Cartons weighing	Keerthi.
Printing Checking in Shipper Label	Keerthi.	Printing Checking in Shipper Label	Keerthi.
Shipper Weighing	Keerthi.	Shipper Weighing	Keerthi.
Shipper Strapping	Kathavayayan.	Shipper Strapping	Kathavayayan.
Shipper Checked	From 01... to 08.	Shipper Checked	From 09... to 14.
Checked By Packing	Nay 26/07/22	Checked By Packing	Nay 27/07/22
Verified By IPQA	Jeep 26/07/22	Verified By IPQA	Jeep 27/07/22

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

### No. of Defects Identified:

- Minor: - 00 -
- Major: - 00 -
- Critical: - 00 -


Batch Allowed for Despatch: Checked By: Nay 27/07/22

Verified By: Jeep 27/07/22

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

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: 61822106 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	40.680	166.480	20250	20000	2000	75	300	02
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	40.680	166.480	20250	20000	2000	75	300	02
D	Quantity packed	27.750	94.700	19740	19740	1974	74	300	02
E	Quantity rejected (Online) & Destroyed	0.590	1.273	469	219	26	01	NA	NA
F	Quantity Returned	12.300	70.300	NA	NA	NA	NA	NA	NA
G	Sample affixed on BPR	0.001	0.009	01	01	NA	NA	NA	NA
H	QC samples	0.003	0.018	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.036	0.180	40	40	NA	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	40.680	166.480	20250	20000	2000	75	300	02
K	Variation (C - J)	NA	NA	NA	NA	NA	NA	NA	NA
L	%Variation (K x 100)/C	NA	NA	NA	NA	NA	NA	NA	NA
M	Acceptable limit	± 2 %	± 2 %	± 2 %	± 2 %	± 2 %			

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

NA

### 29. 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	12.300	70.300	NA	NA	NA	NA	NA	NA
Material returned by packing Sign./Date	NA	NA						
Verified By IPQA Sign./Date	NA	NA						
Material received by Store Sign./Date	NA	NA						

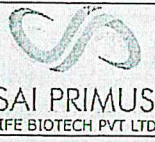
### 30. DESTRUCTION OF REJECTED/UNUSED PRINTED PACKING MATERIALS AND STEREOS:

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)
25/07/22	NA	0.590	1.273	469	219	26	01	NA	NA
Total Qty. Destroyed	NA	0.590	1.273	469	219	26	01	NA	NA
Destroyed by (Packing)	NA								
Verified by (IPQA)	NA								

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	NA	NA	NA	NA
Date	25/07/22	25/07/22	25/07/22	25/07/22

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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 25 of 26
	<b>BATCH PACKING RECORD</b>	Product Code: L13	Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BPR. No.: BPR/T/331-00	Batch No.: 61822106
		Customer:	Generic Health Care Pvt. Ltd.

### 31. BATCH RECONCILIATION:

A	Batch Size	6,00,000Nos.
B	Quantity received for packing	595781
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.)	1000
H	Packing Loss = B - (C + D + E + F + G)	1341
I	Total Loss = A - (C + D + E + F + G)	55604219*
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit: .....)*	99.77%
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit: .....)*	99.07%

\* To be established

Checked by Packing /Date: Nay  
27/07/22

Verified by IPQA/Date: Sej  
27/07/22

### 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
30/07/22	00233	6.0L	3x10's	27x10x3x10	73	59130	S. / W	Sej	R.m
				03x10x3x10	01	90	S. / W	Sej	R.m
Total Qty. Transferred						59220	S. / W	Sej	R.m

### 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
		None		

Checked by  
Packing:

Verified by  
Packing manager:

Approved by  
Head QA:


### 34. BPR REVIEW DETAILS:

Reviewed by	Name	Sign. /Date
Packing Executive	S. KALAI SELVAN	S. / W 30/07/22
QA Executive	JESIMITHA MARY	Sej 30/07/2022
Production Assistant Manager/ HOD	S. SWAKUMAR	N 30/07/2022
QA Manager/ HOD	Stephen N	Sej 30/07/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	Nay			
Date	07/07/2022	07/07/2022	07/07/2022	

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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 26 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00	Batch No.: 61822106
		Customer:	Generic Health Care Pvt. Ltd.

**35. BATCH RELEASED FOR DESPATCH:**

Total quantity released: 592200 No's

Head QA sign/ Date: .

*[Signature]*  
07/07/2022

**36. REVISION HISTORY:**

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/331-00	New Document	Nil

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	07/07/2022	07/07/2022	07/07/2022	07/07/22

**Y. J. S. QUALITY CONTROL**



STABILITY SAMPLE

VALIDATION BATCH

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: L13	Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BPR. No.: BPR/T/331-00	Batch No.: G11822162
		Customer:	Generic Health Care Pvt. Ltd.

## BATCH PACKAGING RECORD COVER SHEET


PRODUCT NAME	: LOLIP 20
GENERIC NAME	: Atorvastatin Calcium Tablets 20 mg
LABEL CLAIM	: Each film coated tablet contains: Atorvastatin calcium Trihydrate Equivalent to Atorvastatin ..... 20 mg Colour: Approved colour used.
CODE NO.	: PON/DRUGS/21 14 4376
DOSAGE FORM	: Tablet
BPR No.	: BPR/T/331-00
REVISION No.	: 00
SUPERSEDE No	: NIL
EFFECTIVE BATCH. No. /DATE	: G11822106 /07/07/2022
MARKET	: Export
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets
PACKING CONFIGURATION	: 3 x 10 Tablets Pack (Alu Alu Packing)
BPR ISSUED BY/DATE (QA)	: <i>JS</i> 25/11/2022
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <i>M</i> 25/11/2022
MFG. DATE: 11/2022	EXP. DATE: 10/2025
ALLOTTED BY: QA SIGN/DATE: <i>JS</i> 25/11/2022	COUNTER CHECKED BY: QA SIGN/DATE: <i>JS</i> 29/11/2022
QUANTITY RECEIVED FROM PRODUCTION	: 594008 NOS
DATE OF COMMENCEMENT: 06/12/2022	DATE OF COMPLETION: 09/12/22
QUANTITY	: 6,00,000 NOS
RELEASED QUANTITY OF PACKED TABLETS	: 592800 NOS
RELEASE OF BATCH BY HEAD QA SIGN/DATE:	: <i>F</i> 07/07/2022

This BPR contains 26 Pages + 02.. 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	07/07/2022	07/07/2022	07/07/2022	07/07/2022

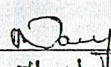
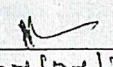


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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 26
	<b>BATCH PACKING RECORD</b>	Product Code: L13	Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00	Batch No.: G11822162
		Customer:	Generic Health Care Pvt. Ltd.

# 1. INDEX


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

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G18 22162 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 / 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	NA
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, carton 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 Format	NA
7.	Complete set of BPR Submitted	YES

Checked By QA/Date: Joseph  
09/07/2022

\*Mention total number of pages.


Remarks (If any) ..... NA - .....

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>

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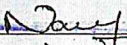


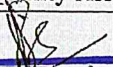
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 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 26
	<b>BATCH PACKING RECORD</b>	<b>Product Code: L13</b>	<b>Batch Size: 6,00,000 Tablets</b>
<b>Product</b>	<b>LOLIP 20</b>	<b>BPR. No.: BPR/T/331-00</b>	<b>Batch No.: G122162</b>
		<b>Customer:</b>	<b>Generic Health Care Pvt. Ltd.</b>


### 3. PACKING MATERIAL SPECIFICATION AND INDENT:

Sr. No.	Material	Item Code	Specification	UOM	Standard Qty. for Batch Size 6.0 Lac.
1	252mm Lolip 20 Printed Foil 0.025mm	PPF/SP/L016	Width – 252 ± 1 mm Thickness – 0.025 mm Language – French Color – 2 Colors Item Code – 13/0463	Kg	45.000
2	252 mm Alu Alu base foil	PBF/SP/A004	Width – 252 ± 1 mm Plain non-printed (text matter) aluminum foil.	Kg	150.000
3	3x10's Lolip 20 Printed Carton	PPC/SP/L016	Size – 130 x 60 x 25 mm (L x W x H) Board – 300 gsm ITC Cyber XL, UV varnished. Colour – 4 colour Language – English/French Item Code – 15/0781	No	20000
4	Lolip Printed Leaflet	PPL/SP/L019	Size – 140 x 175 mm (L x H) Specification – NLT 60 gsm Maplitho Paper. Colour – 2 colours Language – French/ English Item Code: 16/0556	No	20000
5	Shrink Sleeves (PVC)	PPS/SP/P001	Plain PVC Shrink Sleeves	No	2000
6	5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	A 5 Ply flute vertical corrugated inner unprinted in nature. (24 B.F.) Outer Size – 390 x 390 x 430 mm (L x W x H) Bursting Strength – NLT 15.00 Kg/cm <sup>2</sup>	No	75
7	2.5' GHPL Printed Bopp Tape	PPB/SP/B002	Clear Transparent Length of roll – 65m Width – 60 mm Printing – GHPL repeats in Blue	No	2
8	3' Plain BOPP Tape	PUB/SP/B001	Plain BOPP Tape	No.	1
9	Strapping role.	PPR/SP/S001	White or milky white colour. Width - 12 mm Thickness - 0.6 mm	Mtrs	300

<b>Prepared by:</b>		<b>Checked by:</b>		<b>Approved By:</b>
<b>Dept.</b>	<b>Production</b>	<b>Production</b>	<b>Quality Assurance</b>	<b>Head Quality Assurance</b>
<b>Sign.</b>				
<b>Date</b>	07/07/2022	07/07/2022	07/07/2022	07/07/2022

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822162 Generic Health Care Pvt. Ltd.

#### 4. DISPENSING LINE CLEARANCE CHECKS

Date: 06/12/2022 Time: 14:45

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 -	How STORE.
Previous Product	CALCIMAX K2 PLUS.				
B. No.	527 SPL 2205.				
Cleaned by Sign/Date	Saran 06/12/2022.				
Checked by Store Sign/Date	By: 06/12/2022.				
Verified by IPQA Sign/Date	Jes 06/12/2022				


ENVIRONMENTAL CONDITIONS: Date: 06/12/2022 Time: 14:50	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	23°C	By: 06/12/2022	Jes 06/12/2022
Differential Pressure across the booth Limit: 5 to 20 mm Water	10mm.	By: 06/12/2022	Jes 06/12/2022

APPROVAL FOR DISPENSING BY IPQA: Sign: <i>[Signature]</i> Date: 06/12/2022
Dispensing start Time: 14:55 End Time: 15:15

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	07/07/2022	07/07/2022	07/07/2022	07/07/2022

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	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G118 22162 Generic Health Care Pvt. Ltd.


5. DISPENSING RECORD OF PACKING MATERIALS: Date: 06/12/2022 Shift: G Time: 14:55

Material Name	Item code	UOM	Req. Qty. for 6.0 Lac	Issued Qty.	A.R No.	No. of Roll/Box	Issued and Checked by Store	Verified by IPQA
252mm Lolip 20 Printed Foil 0.025mm	PPF/SP/L016	Kg	45.00	19.500 39.930	Pm Q/00334 Pm Q/00022	01 03 02	[Signature] 06/12/22	[Signature] 06/12/2022
252 mm Alu Alu base foil	PBF/SP/A004	Kg	150.000	169.500	Pm Q/00964	07	[Signature] 06/12/22	[Signature] 06/12/2022
3x10's Lolip 20 Printed Carton	PPC/SP/L016	No	20000	22465	Pm Q/01051	14	[Signature] 06/12/22	[Signature] 06/12/2022
Lolip Printed Leaflet	PPL/SP/L019	No	20000	20000	Pm Q/01050	02	[Signature] 06/12/22	[Signature] 06/12/2022
Shrink Sleeves (PVC)	PPS/SP/P001	No	2000	2000	Pm Q/00895	02	[Signature] 06/12/22	[Signature] 06/12/2022
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	75	75	Pm Q/00864	08	[Signature] 06/12/2022	[Signature] 06/12/2022
2.5' GHPL Printed Bopp Tape	PPB/SP/B002	No	2	03	Pm Q/00870	01	[Signature] 06/12/22	[Signature] 06/12/2022
3' Plain BOPP Tape	PUB/SP/B001	No	1	01	Pm Q/00505	01	[Signature] 06/12/22	[Signature] 06/12/2022
Strapping role.	PPR/SP/S001	Mtrs	300	01	Pm Q/00945	01	[Signature] 06/12/22	[Signature] 06/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	[Signature]	[Signature]	[Signature]	[Signature]
Date	07/07/2022	07/07/2022	07/07/2022	07/07/2022

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
Product: <b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:		Batch No.: <b>G18 2262</b> Generic Health Care Pvt. Ltd.

## 6. LINE CLEARANCE CHECKS:

### 6.1 PRIMARY PACKING:

Date/ Shift: 06/12/2022 / G / 07/12/22 / 17/07:00

Previous Product: Lolip-20		Batch No.: G1822162				
Sr. No.	Checks	Time	Observation			
			15:10			
			Packing	IPQA	Packing	IPQA
1.	Area status board is updated for "CLEANED" status.		✓	✓	✓	✓
2.	Check and ensure that the area is visually clean and free from previous product		✓	✓	✓	✓
3.	Check and ensure the differential pressure of the area is within specified limit		✓	✓	✓	✓
4.	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
5.	Check the temperature and relative humidity of the area within specified limit		✓	✓	✓	✓
6.	Check the tablets of the previous product/ batch removed.		✓	✓	✓	✓
7.	Check the loose Alu Alu strip cutting, rejected rolls, empty cores of foil of previous product /batch are removed.		✓	✓	✓	✓
8.	Check the surroundings of the machine and free from the previous products and batch		✓	✓	✓	✓
9.	Check the foil printing stereos, Labels of previous product/batch are removed.		✓	✓	✓	✓
10.	Check that the daily records (log book, balance, temp. & RH) are updated and signed.		✓	✓	✓	✓
11.	Check and ensure the Cleanliness following change part of Alu Alu 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): **19/12/2022**

Cleaning satisfactory/Not satisfactory

Verified by IPQA (Sign./Date): **06/12/2022**

#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: 06/12/2022 / 15:12

Previous Product: <u>Lolip-20</u>				Batch No.: <u>G1822161</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	SPUAPP/Alu/01	A	PDGN/006	Baleph/12/2022	M/19/12/22	Jes/16/12/22
2.	Alu Alu Packing Machine	PD/Alu/01	A	PDOP/020, PDCL/020	Baleph/12/2022	M/19/12/22	Jes/16/12/22

### 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: 06/12/2022 Time: 15:14		Date: 07/12/22 Time: 07:05	
Observation	Packing Sign/Date	Verified by IPQA Sign/Date	Observation	Packing Sign/Date	Verified by IPQA Sign/Date
Temp °C Limit: NMT 25°C	23°C	19/12/2022	23	19/12/2022	19/12/2022
RH % Limit: NMT 60%	52%	19/12/2022	52%	19/12/2022	19/12/2022
DP Limit: NLT 10 Pascal	11 Pascal	19/12/2022	11 Pascal	19/12/2022	19/12/2022


Primary Packing Started Date/Time: 06/12/22 15:12 Completed Date/Time: 07/12/22 07:05

APPROVAL FOR PRIMARY PACKING: IPQA Sign./Date: **19/12/2022**

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<b>19/12/2022</b>	<b>19/12/2022</b>	<b>19/12/2022</b>	<b>19/12/2022</b>	<b>19/12/2022</b>
Date	<b>19/12/2022</b>	<b>19/12/2022</b>	<b>19/12/2022</b>	<b>19/12/2022</b>	<b>19/12/2022</b>

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	LOLIP 20	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G18 22162 Generic Health Care Pvt. Ltd.

**7. VERIFICATION OF DISPENSED PACKING MATERIALS:** Date: 06/12/2022 Shift: G Time: 15:17

Material Name	Item code	UOM	AR No.	Number of Rolls/Packs	Checked by Packing	Verified by QA
252mm Lolip 20 Printed Foil 0.025mm	PPF/SP/L016	Kg	pmg/00334	01	M. Jay	Jesj
252 mm Alu Alu base foil	PBF/SP/A004	Kg	pmg/00062	03	M. Jay	Jesj
3x10's Lolip 20 Printed Carton	PPC/SP/L016	No	pmg/00964	07	M. Jay	Jesj
Lolip Printed Leaflet	PPL/SP/L019	No	pmg/01051	14	M. Jay	Jesj
Shrink Sleeves (PVC)	PPS/SP/P001	No	pmg/01050	02	M. Jay	Jesj
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No	pmg/00895	02	M. Jay	Jesj
2.5' GHPL Printed Bopp Tape	PPB/SP/B002	No	pmg/00864	08	M. Jay	Jesj
3' Plain BOPP Tape	PUB/SP/B001	No	pmg/00870	01	M. Jay	Jesj
Strapping role.	PPR/SP/S001	Mtrs	pmg/00505	01	M. Jay	Jesj
			pmg/00945	01	M. Jay	Jesj

**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	1				M. Jay	

**9. RECEIPT OF PRODUCT AND MATERIALS:** Date/Shift: 06/12/2022 G Time: 15:19

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

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

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

Sr. No.	Description	Observations	Checked By (Packing)	Verified By (IPQA)
1.	Average Weight	193.60	Ka	Jesj
2.	Colour of Tablet	late yellow	Ka	Jesj
3.	Quantity (Net Qty.in Kg)	115.000 kg	Ka	Jesj
4.	Number of Containers	04	Ka	Jesj

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

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


- Verify the semi-finished Tablets before starting the packing operation.
- 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
Lolip-20	G1822162	11/2022	10/2025	115.000 Kg Equivalent to 594008 Nos.	From Container No. 01 To Container No. 04 Total No. of Containers taken 04
Checked by Packing (Sign. /Date): M. Jay / 06/12/22				Verified By IPQA (Sign. /Date): Jesj / 06/12/2022	

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

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	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G118 22162 Generic Health Care Pvt. Ltd.

### 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	28.400	Bala	Jesp	6			
2	28.800	Bala	Jesp	7			
3	29.000	Bala	Jesp	8			
4	36.900	Bala	Jesp	9			
5				10			

### 13. CONTAINER CONSUMPTION DETAILS:

S. No	Time		Container No.	Consumed by	S. No	Time		Container No.	Consumed by
	From	To				From	To		
1	18:00	19:00	01	Bala	6				
2	07:30	10:30	02	Bala	7				
3	10:35	13:40	03	Bala	8				
4	14:20	18:00	04	Bala	9				
5					10				

Checked By Packing (Sign. /Date): *MA* 06/12/2022 Verified by IPQA (Sign. /Date): *Jesp* 06/12/2022

### 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/21 14 4376	06	06
Batch No.:	G11822162	06
Mfg. Date:	11/2022	06
Exp. Date:	10/2025	06
Item Code: 13/0463	06	06
Pack size (3 x 10's)- Carton	3x10's	06
Other instructions if any	MA	MA
Initiated by	Bala 06/12/2022	Bala 06/12/2022
Checked by Packing (Sign. & Date)	<i>MA</i> 06/12/2022	<i>MA</i> 06/12/2022
Verified by IPQA (Sign. & Date)	<i>Jesp</i> 06/12/2022	<i>Jesp</i> 06/12/2022

### 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	06/12/2022	01	Bala 06/12/2022	<i>MA</i> 06/12/2022	<i>Jesp</i> 06/12/2022
02	07/12/2022	01	Bala 07/12/2022	<i>MA</i> 07/12/2022	<i>Jesp</i> 07/12/2022

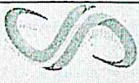
### 16. PACKING INSTRUCTIONS:

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.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign	<i>MA</i>	<i>MA</i>	<i>MA</i>	<i>MA</i>
Date	07/12/2022	07/12/2022	07/12/2022	

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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 26
	<b>BATCH PACKING RECORD</b>		<b>Product Code: L13</b> <b>Batch Size: 6,00,000 Tablets</b>
<b>Product</b>	<b>LOLIP 20</b>	<b>BPR. No.: BPR/T/331-00</b> <b>Customer:</b>	<b>Batch No.: G1822162</b> <b>Generic Health Care Pvt. Ltd.</b>

**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	06/12/2022 (C)	18:00	19:00	18:10	19:05	19/06/12/22
02	07/12/22 (C)	07:30	18:00	07:40	18:15	19/07/12/22
1			NA			

**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.

**18. ALU-ALU PACKING MACHINE PARAMETERS:**

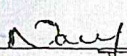
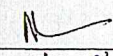
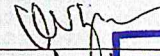
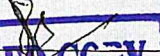
Date/Shift: 06/12/2022 (C) Time: 15:21.....

Parameters	Standard and Limits	Observation	Checked by Packing Sign. / Date	Checked by IPQA Sign. / Date
Change Parts Details	18107529	OK	19/06/12/22	Jesp. 06/12/2022
Sealing Temperature	(To be established)	190°C	19/06/12/22	Jesp. 06/12/2022
Leak test to be performed on 04 Alu Alu strip	Nil (No Alu Alu strip should fail in leak test)	OK	19/06/12/22	Jesp. 06/12/2022
Machine Speed	(To be established)	22	19/06/12/22	Jesp. 11/12/2022

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


Sr. No	Process instructions										
1.	Testing frequency: Startup, End of the activity and after every break										
2.	Acceptance Criteria: Broken Tablet, Empty Packet, Black Particle, Colour variation, Foreign Matter, Dual Tablets / Capsules and all defects should be detected & rejected.										
Date & Time	S. No.	Broken Tablet	Empty Packet	Black Particle	Colour variation	Foreign Matter	Dual Tablets / Capsules	Result	Done By	Checked by Packing	Verified By IPQA
06/12/22 18:08 07/12/22 01:39 17:20	1	✓	✓	✓	✓	✓	✓	pass	Bala	19/06/12/22	Jesp.
	2	✓	✓	✓	✓	✓	✓	pass	Bala	19/06/12/22	Jesp.
	3	✓	✓	✓	✓	✓	✓	pass	Bala	19/06/12/22	Jesp.
	4	✓	✓	✓	✓	✓	✓	pass	Bala	19/06/12/22	Jesp.
	5										
	6										
	7										
	8										
	9										
	10										
	11										
	12										
	13										
	14										
	15										

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

<b>Prepared by:</b>		<b>Checked by:</b>		<b>Approved By:</b>
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/12/2022	07/12/2022	07/12/2022	07/12/2022

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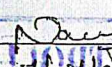
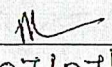
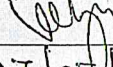



 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G11822162 Generic Health Care Pvt. Ltd.

20. MACHINE IN-PROCESS CONTROL:


Date/ Shift	06/12/2022 G1 07/12/2022 G1															
Machine Operator Name	Bala Bala															
Time of inspection	18:05	18:15	18:21	18:25	18:36	07:35	07:45	08:40	09:43	09:53	10:45	11:50	12:04	12:53	13:59	14:06
Sealing Temperature (To be established)	190°C	115°C	116°C	216°C	210°C	200°C	195°C	200°C	190°C	195°C	195°C	195°C	195°C	196°C	196°C	196°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/ 21 14 4376	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
B. No.:	G11822162	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Mfg. Date	11/2022	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Exp. Date	10/2025	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Machine Speed (To be established)	22	15	40	40	15	26	26	26	26	27	27	27	26	26	26	26
Checked by (Packing)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Checked by (IPQA)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

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

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

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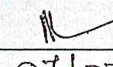
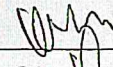



 <b>SAI PRIMUS</b> LIFE BIOTECH PVT LTD	<b>SAI PRIMUS LIFE BIOTECH PVT LTD</b> Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPRT/331-00 Customer:	Batch No.: G1822162 Generic Health Care Pvt. Ltd.

**20.1 MACHINE IN-PROCESS CONTROL:**

Date/ Shift	07/12/2022 / G1															
Machine Operator Name	Bala															
Time of inspection	15:04	16:10	16:32	17:12												
Sealing Temperature (To be established)	197°C	196°C	196°C	196°C												
Leak test on Alu Alu strips* (Qty.: 04 )	OK	OK	OK	OK												
Knurling /Sealing	OK	OK	OK	OK												
Pocket Formation	OK	OK	OK	OK												
Horizontal cutting	OK	OK	OK	OK												
Vertical cutting	OK	OK	OK	OK												
Quality of Over printing	OK	OK	OK	OK												
Code No.: PON/DRUGS/ 21 14 4376	OK	OK	OK	OK												
B. No.: G1822162	OK	OK	OK	OK												
Mfg. Date 11/2022	OK	OK	OK	OK												
Exp. Date 10/2025	OK	OK	OK	OK												
Machine Speed (To be established)	25	27	27	27												
Checked by (Packing)	NA	NA	NA	NA												
Checked by (IPQA)	NA	NA	NA	NA												

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

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

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SAI PRIMUS  
LIFE BIOTECH PVT LTD

**SAI PRIMUS LIFE BIOTECH PVT LTD**

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

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**BATCH PACKING RECORD**

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

BPR. No.: BPR/T/331-00

Batch No.: G1822162

Customer:

Generic Health Care Pvt. Ltd.

**20.2 MACHINE IN-PROCESS CONTROL:**


Date/ Shift	
Machine Operator Name	
Time of inspection	
Sealing Temperature (To be established)	
Leak test on Alu Alu strips* (Qty: _____)	
Knurling /Sealing	
Pocket Formation	
Horizontal cutting	
Vertical cutting	
Quality of Over printing	
Code No.: PON/DRUGS/ 21 14 4376	
B. No.:	
Mfg. Date	
Exp. Date	
Machine Speed (To be established)	
Checked by (Packing)	
Checked by (IPQA)	

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

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/07/2012	07/07/2012	07/07/2012	07/07/2012

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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 14 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822162 Generic Health Care Pvt. Ltd.

### 20.3 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)
07/12/22	16:00	17:15	0.190	Sudha	Not done	Jesp 07/12/22
/						
Total Weight of De-foiled Tablets			0.190 kg	Checked By / Date (Packing): Not done		Verified By / Date (IPQA): Jesp 07/12/22


### 20.4 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		
07/12/22	17:17	17:27	Sudha	0.160	826	0.030	154	Not done	Jesp 07/12/22
/									
Total				0.160	826	0.030	154		
Total Quantity of Rejected Tablets Destroyed				Checked By / Date (Packing): Not done			Verified By / Date (IPQA): Jesp 07/12/22		
0.030 Kgs ... 154 Nos.									

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/12/2022	07/12/2022	07/12/2022	07/12/2022

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 SAI PRIMUS 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 15 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1322162 Generic Health Care Pvt. Ltd.

21. LINE CLEARANCE CHECKS - SECONDARY PACKING:

Date/ Shift ... 06/12/2022 / G ..... / 07/12/22 / 07:10

Previous Product: lolip-20		Batch No.: G1822161				
Sr. No.	Checks	Time	Observation			
			15:38		07:13	
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓	✓	✓
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓	✓	✓
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓	✓	✓
4	Check and ensure the Correct status board is written.		✓	✓	✓	✓
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓	✓	✓
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓	✓	✓
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓	✓	✓
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓	✓	✓
9	Check and ensure the dispensed secondary packing material.		✓	✓	✓	✓
10	Check and ensure the cleanliness of documentation table.		✓	✓	✓	✓
11	Check and ensure the Preventive maintenance records and log book.		✓	✓	✓	✓

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

Cleaning Satisfactory / Not-satisfactory#  
 (Packing) Sign./Date: M. K. S. 06/12/2022  
 Cleaning Satisfactory / Not-satisfactory#  
 (IPQA) Sign./Date: J. S. 06/12/2022

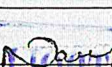

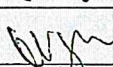
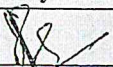
Remarks: # In case the cleaning is not satisfactory / line is not certified then investigate the cause of the failure and take necessary action, re check the area / line and record.

Equipment	Packing Conveyor	Weighing Balance (Carton)	Shrink Sleeve	Strapping	Weighing Balance (shipper)	Area
ID. No.:	PD/WB/004	PD/BAL/015	PD/SWA/009	PD/STA/002	PD/BAL/038	Secondary Packing Hall
Previous Product:	lolip-20					
Batch No.:	G1322161					
Cleaned by:	Greetha					
Checked by Packing:	M. K. S.					
Verified by IPQA:	J. S. 06/12/2022					

21.1 ENVIRONMENTAL CONDITIONS:


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

Shift: .....G.....		Date/Time: 06/12/2022 15:40			Date/Time: 07/12/22 07:15		
		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	28°C	M.K.S	J.S	23°C	✓ J.S	M.P
Secondary Packing Started Date/Time: 06/12/22 15:40..... Completed Date/Time: 07/12/22 07:15							
APPROVAL FOR SECONDARY PACKING:				Approved by IPQA Sing/Date: J.S 06/12/2022			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/12/2022	07/12/2022	07/12/2022	07/12/2022

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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 16 of 26
	<b>BATCH PACKING RECORD</b>	Product Code: L13	Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BPR. No.: BPR/T/331-00	Batch No.: G1822162
		Customer:	Generic Health Care Pvt. Ltd.

### 21.2 PACKING DETAILS:

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

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

Place 10 filled carton in a Shrink Sleeve.

Place 27 Shrink sleeves in each 5 ply shipper.

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

### 22. OVER PRINTING DETAILS:

#### Overprinting Details (Secondary & Tertiary PM)

Overprinting Details	Overprinted Text	Carton	Insert	5 Ply Shipper Label
Batch No.:	G1822162	06	NA	06
Mfg. Date:	11/2022	06	NA	06
Exp. Date:	10/2025	06	NA	06
Code No.: PON/DRUGS/21 14 4376	06	06	NA	NA
Pack size:	NA	3 x 10's	NA	27 x 10 x 3 x 10's
Item Code: 15/0781	NA	06	NA	NA
Item Code: 16/0556	NA	NA	06	NA
Initiated by Sign. & Date	MA	MA	MA	Sivakumar 06/12/22
Checked by Packing Sign. & Date	MA 06/12/2022	MA 06/12/2022	MA 06/12/2022	MA 06/12/2022
Verified by IPQA Sign. & Date	MA 06/12/2022	MA 06/12/2022	MA 06/12/2022	MA 06/12/2022

### 22.1 Carton and Shipper Label Specimen:

S. No.	Date	Carton Specimen No.	Shipper Label Specimen No.	Checked by Packing (Sign & Date)	Verified by IPQA (Sign & Date)
01	06/12/2022	01	01	MA 06/12/2022	MA 06/12/2022

### 23. INDIVIDUAL STRIP WEIGHING LIMIT:

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

1. /	3. /	5. /	7. MA	9. /
2. /	4. /	6. /	8. MA	10. /

Total weight of ten Empty Alu Alu strips = 37.1

Avg. Weight of a Empty Alu Alu strip (A): total weight of ten Empty Alu Alu strip/10 = 3.71

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

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

Total weight of ten Filled Alu Alu strips = 37.1

Avg. Weight of a Filled Alu Alu strip (B): total weight of ten Filled Alu Alu strip/10 = 3.71

Limit (C) = NA


(Each missing tablet should be identified)

Strip weighing Done By: MA	Checked By: MA	Verified By: MA
----------------------------	----------------	-----------------

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	MA	MA	MA	MA
Date	07/07/2022	07/07/2022	07/07/2022	07/07/2022

**UNCONTROLLED CC7Y**



 <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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822162 Generic Health Care Pvt. Ltd.

23.1 CARTON WEIGHT LIMIT SETTING: Date/Shift: 06/12/22 Time: 18:15..

Weight of ten individual empty cartons are given below:

1. 9.0	3. 8.9	5. 9.0	7. 9.1	9. 9.1
2. 8.9	4. 9.0	6. 9.0	8. 9.0	10. 9.0

Total weight of ten empty cartons = 90.0

Average weight of an empty carton (D) = Total weight of ten empty carton / 10 = 9.00

Weight of ten individual Leaflets are given below:

1. 1.4	3. 1.5	5. 1.5	7. 1.4	9. 1.5
2. 1.4	4. 1.4	6. 1.5	8. 1.5	10. 1.4

Total weight of ten Leaflets = 14.5

Avg. Weight of a Leaflet (E): total weight of ten Leaflets/10 = 1.45

23.2 WEIGHT CHECKS ON CARTON:

Weight of ten empty Carton: 90.0	Average weight of one empty Carton (D): 9.0
Weight of ten filled Alu Alu strip: 37.1	Average weight of one filled Alu Alu strip (B): 3.71
Weight of ten Leaflets: 14.5	Average weight of one Leaflet (E): 1.45
Weight of one filled Carton F = (D+3B+E) 21.58	Limit: G = F ± 1% = 21.36 - 21.79
Checked by Packing/Date: 06/12/22	Verified by IPQA/Date: 06/12/22


23.3 SAMPLE DRAWN RECORD:

Sr. No.	Stage of Sample collection	Qty. of Sample	Collected by (Sign. /Date)
1	Control Sample (Initial)	7 x 10's	Jesp 07/12/22
2	Control Sample (Middle)	6 x 10's	Jesp 07/12/22
3	Control Sample (Final)	7 x 10's	Jesp 07/12/22
4	Stability Sample	100 x 10's	Jesp 07/12/22
5	Other Sample	NA	NA
6	Analytical sample	10 x 10's	Jesp 07/12/2022
Total Qty.		132 x 10's.	Jesp 07/12/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/12/2022	07/12/2022	07/12/2022	07/12/2022

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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 18 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822162 Generic Health Care Pvt. Ltd.

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

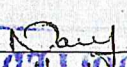
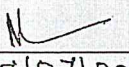


Date/ Shift	06/12/2022 / G1	06/12/2022 / G1													
Parameters	Specification	observation													
		Packing							IPQA						
Time		18:18	17:50	17:00	16:02	15:25	14:03	13:12	12:31	11:50	10:11	09:15	14:17	13:39	
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
No. of cartons in a shrink sleeves	10 packed cartons	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	
No. of shrink sleeves in a 5 ply shipper	27 shrinks	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Shipper strapping	Proper strapping	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Label appearance and Shipper appearance	Legible and readable	NA	NA	NA	NA	NA	NA	NA	OK	OK	OK	OK	OK	OK	
Sealing of the shipper with BOPP Tape	H type	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
Checked by		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	

\*Temperature to be mentioned.

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

Date/ Shift	07/12/2022 / G1	07/12/2022 / G1													
Parameters	Specification	observation													
		Packing							IPQA						
Time		14:03	15:05	16:12	17:09										
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK										
Carton Overprinting	Legible and readable	OK	OK	OK	OK										
No. of cartons in a shrink sleeves	10 packed cartons	NA	NA	NA	NA										
Shrink wrapping temperature*		NA	NA	NA	NA										
No. of shrink sleeves in a 5 ply shipper	27 shrinks	NA	NA	NA	NA										
Shipper strapping	Proper strapping	NA	NA	NA	NA										
Label appearance and Shipper appearance	Legible and readable	NA	NA	NA	NA										
Sealing of the shipper with BOPP Tape	H type	NA	NA	NA	NA										
Checked by		NA	NA	NA	NA										

\*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign				
Date	07/12/2022	07/12/2022	07/12/2022	07/12/2022

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SAI PRIMUS  
LIFE BIOTECH PVT LTD

# SAI PRIMUS LIFE BIOTECH PVT LTD

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

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## BATCH PACKING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

BPR. No.: BPR/T/331-00

Batch No.: G1822162

Customer:

Generic Health Care Pvt. Ltd.

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

Date/ Shift	07/12/22 LG (Ranchodary)														07/12/22 (G)		
Parameters	Specification	observation															
		Packing								IPQA							
Time		09:25	10:30	11:32	12:35	13:42	14:42	15:45	09:38	11:45	13:53	15:50	17:55				
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Carton Overprinting	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
No. of cartons in a shrink sleeves	10 packed cartons	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Shrink wrapping temperature*	152.1 °C	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
No. of shrink sleeves in a 5 ply shipper	27 shrinks	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Shipper strapping	Proper strapping	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Label appearance and Shipper appearance	Legible and readable	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Sealing of the shipper with BOPP Tape	H type	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Checked by		OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				

\*Temperature to be mentioned

\*Temperature to be mentioned.

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


Date/ Shift	07/12/23 LG										(Please keep ✓ mark if found OK)									
Parameters	Specification	observation																		
		Packing					IPQA													
Time		16:48	17:50																	
No. of Alu Alu strip in a carton	3 Alu Alu strip with 10 tabs each and one leaflet.	OK	OK																	
Carton Overprinting	Legible and readable	OK	OK																	
No. of cartons in a shrink sleeves	10 packed cartons	OK	OK																	
Shrink wrapping temperature*	155.2 °C	OK	OK																	
No. of shrink sleeves in a 5 ply shipper	27 shrinks	OK	OK																	
Shipper strapping	Proper strapping	OK	OK																	
Label appearance and Shipper appearance	Legible and readable	OK	OK																	
Sealing of the shipper with BOPP Tape	H type	OK	OK																	
Checked by		NOT	NOT																	

\*Temperature to be mentioned.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/10/2022	07/10/2022	07/10/2022	07/10/2022

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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 20 of 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	<b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G/1822162 Generic Health Care Pvt. Ltd.

25. SHIPPERS WEIGHING: Date/Shift: 06/12/22 G Time: 18:20 Balance I.D. No: PD/BA1/038

Weight of ten Shrinks: 2204		Average weight of one filled Shrink (H): 220.4	
Weight of ten empty shippers: 13.50		Average weight of one empty shipper (I): 1.350	
Weight of one filled shipper (J) = (27H+I): 7.300		Limit: K = J ± 1% = 7.227 - 7.373	
Checked by Packing/Date: 06/12/22		Verified by IPQA/Date: 06/12/2022	

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	7.350	Ganesh	20	7.325	Ganesh	39	7.360	Ganesh	58	7.360	Ganesh
2	7.340	Ganesh	21	7.345	Ganesh	40	7.360	Ganesh	59	7.365	Ganesh
3	7.330	Ganesh	22	7.340	Ganesh	41	7.370	Ganesh	60	7.370	Ganesh
4	7.360	Ganesh	23	7.360	Ganesh	42	7.350	Ganesh	61	7.360	Ganesh
5	7.340	Ganesh	24	7.350	Ganesh	43	7.340	Ganesh	62	7.350	Ganesh
6	7.340	Ganesh	25	7.360	Ganesh	44	7.360	Ganesh	63	7.360	Ganesh
7	7.350	Ganesh	26	7.360	Ganesh	45	7.340	Ganesh	64	7.360	Ganesh
8	7.335	Ganesh	27	7.350	Ganesh	46	7.360	Ganesh	65	7.360	Ganesh
9	7.360	Ganesh	28	7.360	Ganesh	47	7.325	Ganesh	66	7.360	Ganesh
10	7.340	Ganesh	29	7.370	Ganesh	48	7.360	Ganesh	67	7.355	Ganesh
11	7.360	Ganesh	30	7.360	Ganesh	49	7.370	Ganesh	68	7.360	Ganesh
12	7.350	Ganesh	31	7.350	Ganesh	50	7.340	Ganesh	69	7.360	Ganesh
13	7.340	Ganesh	32	7.360	Ganesh	51	7.345	Ganesh	70	7.370	Ganesh
14	7.335	Ganesh	33	7.340	Ganesh	52	7.340	Ganesh	71	7.360	Ganesh
15	7.330	Ganesh	34	7.350	Ganesh	53	7.360	Ganesh	72	7.360	Ganesh
16	7.340	Ganesh	35	7.360	Ganesh	54	7.370	Ganesh	73	7.380	Ganesh
17	7.360	Ganesh	36	7.340	Ganesh	55	7.340	Ganesh	74	2.490	Ganesh
18	7.350	Ganesh	37	7.360	Ganesh	56	7.350	Ganesh	75		
19	7.340	Ganesh	38	7.340	Ganesh	57	7.345	Ganesh	76		


Total No. of shippers weighed: 74	De-foiled tablets packed in Shipper No: 74	Checked by Sign / Date: 07/12/2022	Verified by Sign / Date: 07/12/2022	Loose pack details: Shipper No: ....74.... Quantity: 0.5X10X3X10'S Weight: 2.490.
--------------------------------------	---	---------------------------------------	--	--

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				
Date	07/12/2022	07/12/2022	07/12/2022	07/12/2022

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BPR. No.: BPR/T/331-00 Customer:	Batch No.: 61822162 Generic Health Care Pvt. Ltd.

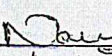

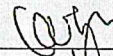

### 26. MAN POWER ALLOCATION:

DATE: 06/12/22	
SHIFT: G1	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Kamatchi, Sivasankari
Printing Checking in Alu Alu strip	Manimegalai, Chitra
Alu Alu strip weighing	Kanaga, Aruljothi
Insertion of Alu Alu strip and leaflet into carton	Santhi, Priyanka, Savitha, Lakshmi
Cartons weighing	Malar
Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Geetha
Shipper Weighing	Geetha
Shipper Strapping	NA
Shipper packed	From 01...to 03..
Signature of Packing	N 706/12/22

DATE: 07/12/22	
SHIFT: G1	
ACTIVITIES	DONE BY
Alu Alu strip Checking	Kamatchi, Sivasankari
Printing Checking in Alu Alu strip	Manimegalai, Chitra
Alu Alu strip weighing	Kanaga, Aruljothi
Insertion of Alu Alu strip into carton	Santhi, Priyanka, Savitha, Lakshmi
Cartons weighing	Malar
Insertion of carton into shrink sleeve	NA
Insertion of shrink wrapped carton into shipper	NA
Shipper Label Pasting	Geetha
Shipper Weighing	Geetha
Shipper Strapping	NA
Shipper packed	From 04...to 74
Signature of Packing	N 707/12/22

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	
Shipper Label Pasting	
Shipper Weighing	
Shipper Strapping	
Shipper packed	From.....to.....
Signature of Packing	


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.				
Date	07/07/2022	07/07/2022	07/07/2022	07/07/2022

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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 26
	<b>BATCH PACKING RECORD</b>		<b>Product Code: L13</b> <b>Batch Size: 6,00,000 Tablets</b>
<b>Product</b>	<b>LOLIP 20</b>	<b>BPR. No.: BPR/T/331-00</b>	<b>Batch No.: G1822162</b>
		<b>Customer:</b>	<b>Generic Health Care Pvt. Ltd.</b>

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

Date/ Shift ... 07/12/22 ... /G1...../

Previous Product: Lolip - 20		Batch No.: 011822161				
Sr. No.	Checks	Time	Observation			
			09105			
			Packing	IPQA	Packing	IPQA
1	Check and ensure that the area is visually clean and free from previous product.		✓	✓		
2	Check and ensure that waste bin is emptied out and cleaned		✓	✓		
3	Check the Pallets area clean and free from any leftovers of previous product /Batch.		✓	✓		
4	Check and ensure the Correct status board is written.		✓	✓		
5	Check and ensure the stereo of the previous product/batch removed and cut into pieces.		✓	✓		
6	Check and ensure the Alu Alu strips, rejected Carton, Shipper and shipper label of previous product/batch are removed.		✓	✓		
7	Check and ensure the cleanliness of hatch for conveyor belt.		✓	✓		
8	Check and ensure the cleanliness of conveyer belt with collateral block.		✓	✓		
9	Check and ensure the dispensed secondary packing material.		✓	✓		
10	Check and ensure the cleanliness of documentation table.		✓	✓		
11	Check and ensure the Preventive maintenance records and log book.		✓	✓		

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

Cleaning Satisfactory / Not-satisfactory# *Not* Cleaning Satisfactory / Not-satisfactory# *Jeep*  
 (Packing) Sign./Date: 07/12/22 (IPQA) Sign./Date: 07/12/22


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.:	NA	PD13AL036	PD1SWM1002	PD1STM1001	PD1BAL041	STF
Previous Product:	Lolip - 20					
Batch No.:	G1822161					
Cleaned by:	Samaran.					
Checked by Packing:	Not 07/12/22					
Verified by IPQA:	Jeep 07/12/22					
Rechecking Started Date/Time:	07/12/22.....09:25. Completed Date/Time: 07/12/22.....18:40					
APPROVAL FOR COUNTER CHECK:		Approved by IPQA Sing/Date: Jeep.....07/12/22.				

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	07/12/22	07/12/22	07/12/22	07/12/22

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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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b> LOLIP 20	BPR. No.: BPR/T/331-00 Customer:		Batch No.: G1822162 Generic Health Care Pvt. Ltd.

### 27.1 COUNTER CHECK OF PACKED SHIPPERS :

DATE: 07.12.22		DATE: .....	
SHIFT: 07		SHIFT: .....	
<b>ACTIVITIES</b>	<b>DONE BY</b>	<b>ACTIVITIES</b>	<b>DONE BY</b>
Alu Alu strip Checking	Kowsalya, Sathya	Alu Alu strip Checking	
Printing Checking in Alu Alu strip	Bharathi	Printing Checking in Alu Alu strip	
Alu Alu strip weighing	NA	Alu Alu strip weighing	
Checking of Alu Alu strip and leaflet in carton	Karthi, Keerthana, prithvika	Checking of Alu Alu strip and leaflet in carton	
Cartons weighing		Cartons weighing	
Printing Checking in Shipper Label	Jayarani	Printing Checking in Shipper Label	
Shipper Weighing	Jayarani	Shipper Weighing	
Shipper Strapping	Murthy	Shipper Strapping	
Shipper Checked	From 01 to 74	Shipper Checked	From: ..... to: .....
Checked By Packing	07/07/23	Checked By Packing	
Verified By IPQA		Verified By IPQA	

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

### No. of Defects Identified:

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

Batch Allowed for Despatch: Checked By: 07/12/22

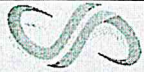
Verified By: 07/12/22

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

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 SAI PRIMUS 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 26
	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
<b>Product</b>	LOLIP 20	BPR. No.: BPR/T/331-00 Customer:	Batch No.: G1822162 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	59.430	169.500	22465	20000	2000	75	01	03
B	Additional material received for the batch	NA	NA	NA	NA	NA	NA	NA	NA
C	Total material received (A+B)	59.430	169.500	22465	20000	2000	75	01	03
D	Quantity packed	27.245	80.850	19760	19760	1976	74	01	03
E	Quantity rejected (Online) & Destroyed	0.710	3.800	2663	NA	13	01	NA	NA
F	Quantity Returned	31.400	84.700	NA	300	NA	NA	NA	NA
G	Sample affixed on BPR	0.010	0.020	01	01	NA	NA	NA	NA
H	QC samples	0.015	0.030	NA	NA	NA	NA	NA	NA
I	Other samples (If any)	0.050	0.100	41	41	11	NA	NA	NA
J	Total accountable Quantity (D+ E+F+G+H+I)	59.430	169.500	22.465	20102	2000	75	01	03
K	Variation (C - J)	NA	NA	NA	102	NA	NA	NA	NA
L	%Variation (K x 100)/C	NA	NA	NA	0.51%	NA	NA	NA	NA
M	Acceptable limit	± 2 %	± 2 %	± 2 %	± 2 %	± 2 %			

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

.....NA.....

### 29. EXCESS PACKING MATERIAL RETURN TO STORE: MRN NO. 00452

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	31.400	84.700	NA	300				
Material returned by packing Sign./Date	NA	NA		NA				
Verified By IPQA Sign./Date	NA	NA		NA				
Material received by Store Sign./Date	NA	NA		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)
08/12/22	NA	0.710	3.800	2663	NA	13	01	NA	NA
Total Qty. Destroyed	NA	0.710	3.800	2663	NA	13	01	NA	NA
Destroyed by (Packing)	NA								
Verified by (IPQA)	NA								

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

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	<b>BATCH PACKING RECORD</b>		Product Code: L13 Batch Size: 6,00,000 Tablets
Product <b>LOLIP 20</b>	BPR. No.: BPR/T/331-00 Customer:		Batch No.: G18 22162 Generic Health Care Pvt. Ltd.

### 31. BATCH RECONCILIATION:

A	Batch Size	6, 00,000Nos.
B	Quantity received for packing	594008
C	Total quantity packed.	592800
D	Control samples	200
E	Analytical Samples	120
F	In process samples	800
G	Others samples if any (Stability, Regulatory Samples, etc.)	1000
H	Packing Loss = B - (C + D + E + F + G)	912
I	Total Loss = A - (C + D + E + F + G)	5080
J	Packing yield % (C + D + E + F + G) / B X 100 (Yield Limit: .....)*	100-15%
K	Batch Yield % (C + D + E + F + G) / A X 100 (Yield Limit: .....)*	99-15%

\* To be established

Checked by Packing /Date: 07/12/22

Verified by IPQA/Date: 07/12/22

### 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
09/12/2022	00503	6.06	3x10's	27x10x3x10's	73	59130	M. Jay	Jesj	R.m
				15x10x3x10's	01	150	M. Jay	Jesj	R.m
Total Qty. Transferred						59280	M. Jay	Jesj	R.m

### 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

Checked by  
Packing:

Verified by  
Packing manager:

Approved by  
Head QA:


### 34. BPR REVIEW DETAILS:

Reviewed by	Name	Sign. /Date
Packing Executive	SUCHANYA NANCY RANI. D	09/12/22
QA Executive	JESINTHA MARY	09/12/2022
Production Assistant Manager/ HOD	SIVA KUMAR	09/12/22
QA Manager/ HOD	RAM KUMAR	09/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	07/12/2022	07/12/2022	07/12/2022	07/12/2022


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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 26 of 26
	<b>BATCH PACKING RECORD</b>	<b>Product Code: L13</b>	<b>Batch Size: 6,00,000 Tablets</b>
<b>Product</b>	<b>LOLIP 20</b>	<b>BPR. No.: BPR/T/331-00</b>	<b>Batch No.: G1822162</b>
		<b>Customer:</b>	<b>Generic Health Care Pvt. Ltd.</b>

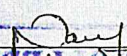
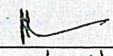
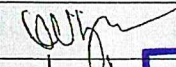
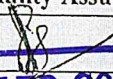
**35. BATCH RELEASED FOR DESPATCH:**

Total quantity released: 592800 No's

Head QA sign/ Date:   
08/12/2022

**36. REVISION HISTORY:**

S. No.	Document No.	Reason for Changes	Supersedes Doc. No.
1	BPR/T/331-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>	<u>07/07/2022</u>

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