

 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 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G11822161 Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING 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.
MFR No. / Reference Document No.	: MFR/T/186-00
BMR No.	: BMR/T/331-00
REVISION No.	: 00
SUPERSEDES No.	: NIL
BMR EFFECTIVE BATCH NUMBER/DATE	: G11822106 / 02/06/2022
MFG.LIC No.	: PON/DRUGS/21 14 4376
STORAGE	: Store in cool and dry place. Protect from light and moisture.
BMR ISSUED BY/DATE (QA)	: V. G. 26/11/22
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: L. K. 29/11/2022
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets (117.000 Kg)
MFG. DATE: 01/12/2022	: EXP. DATE: 10/12/2025

RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
		N.A		

ALLOTTED BY: V. G. 26/11/22 QA SIGN/DATE:	COUNTER CHECKED BY: 29/11/2022 QA SIGN/DATE:
DATE OF COMMENCEMENT: 20/11/22	DATE OF COMPLETION: 05/12/22
RELEASED QUANTITY OF TABLETS FOR PACKING : 59875 nos	
RELEASE FOR PACKING STAGE HEAD OF QA SIGN/DATE:	15/12/22

This BMR contains 35 Pages + NA Additional Pages

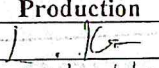
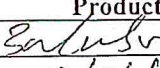
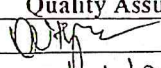
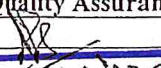
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	29/11/22	29/11/22	29/11/22
Date	02/06/2022	02/06/2022	02/06/2022	02/06/22

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 2 of 35
	BATCH MANUFACTURING RECORD	Product Code: L13 Batch Size: 6,00,000 Tablets BMR. No.: BMRT/331-00 Batch No.: 61822161 Customer: Generic Health Care Pvt. Ltd.
Product	LOLIP 20	

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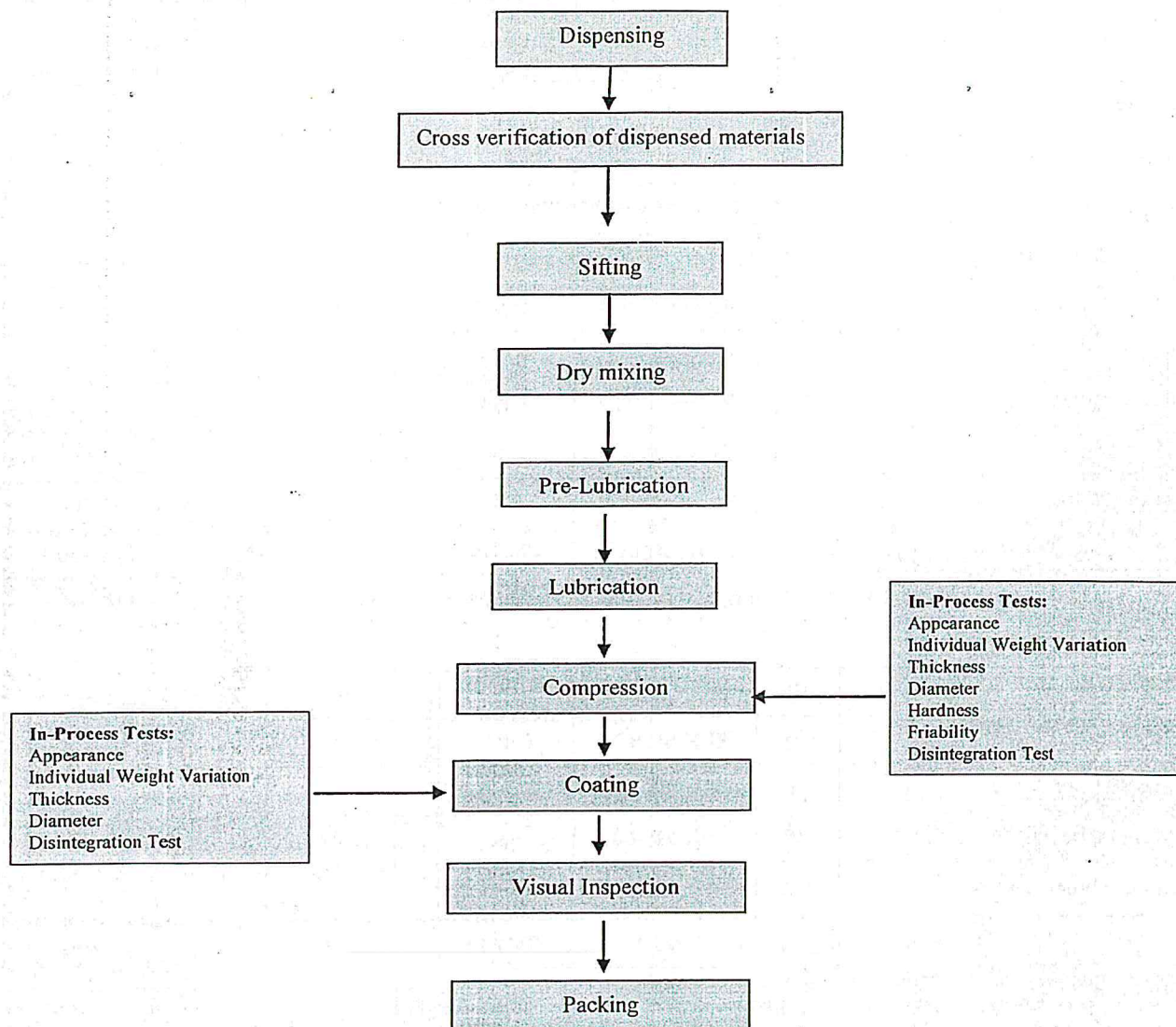
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Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 35
	BATCH MANUFACTURING RECORD	Product Code: L13	Batch Size: 6,00,000 Tablets
	Product	LOLIP 20	Batch No.: 61822161
		Customer:	Generic Health Care Pvt. Ltd.

2.0 PROCESS FLOW CHART



Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>3alubur...</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	02/06/2022	02/06/2022	02/06/2022	02/06/22

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 61222161 Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 6,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 6,00,000 tablets (kg)
Lubrication material:							
1	Atorvastatin Calcium (Micronized)	USP	RAI/SP/A016	22.000 [#]	13.200 [#]	6.15	13.200 [#]
2	Microcrystalline cellulose PH102	BP	REX/SP/M010	49.110	29.466	-	29.466
3	Calcium Carbonate	BP	RAI/SP/C005	0.950	0.570	-	0.570
4	Lactose DCL 11	BP	REX/SP/L004	105.950	63.570	-	63.570
5	Croscarmellose Sodium	BP	REX/SP/C008	6.300	3.780	-	3.780
6	Colloidal Silicon Dioxide	BP	REX/SP/C022	2.850	1.710	-	1.710
7	Purified Talc	BP	REX/SP/P017	1.900	1.140	-	1.140
8	Magnesium Stearate	BP	REX/SP/M011	0.950	0.570	-	0.570
Theoretical Weight of the Lubricated granules				190.000	114.000	-	114.000
Theoretical weight of Compressed tablet				190.000	114.000	-	114.000
Coating Material:							
9	Wincoat WT White 02022	IHS	REX/SP/W001	4.750	2.850	25	3.563 [#]
10	Yellow oxide of Iron	IHS	REX/SP/I004	0.050	0.030	25	0.038 [#]
11	Tween 80	BP	REX/SP/P014	0.200	0.120	25	0.150 [#]
12	Isopropyl Alcohol	BP	REX/SP/I005	q.s.	21.000	-	21.000
13	Purified Water	BP	NA	q.s.	30.000	-	30.000
Theoretical weight of Coated tablet				195.000	117.000	-	117.000

NOTE: *API quantity shall be calculated based on potency.

**Excess Quantity shall be compensating from Microcrystalline cellulose PH 102.

Inclusive of overages

OA: Overages, PL: Process loss

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	30/06/2022	02/06/2022	02/06/2022
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 5 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 61822161 Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR ATORVASTATIN CALCIUM:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Atorvastatin Calcium: 13.200 Kg (A)

Standard quantity of Microcrystalline cellulose PH 102 (B): 29.466 Kg

Calculation for Atorvastatin Calcium:

1) Calculation for Single A. R. No. _____, Assay on dried basis: _____ w/w, LOD: _____ w/w
 Exp. Date: _____

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \text{Kg}$$

2) Calculation for Microcrystalline cellulose PH 102 (B):

Actual Quantity (Kg) (D) = Standard quantity of Microcrystalline cellulose PH 102 - Excess Calculated quantity of Atorvastatin Calcium

$$= 29.466 \text{ Kg} - \text{Kg}$$

$$= \text{Kg}$$

3) Calculation for Atorvastatin Calcium Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (E)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
01	RMG/00009	7.018	99.69	5.07	6.642
Total Actual Quantity (F)					6.642

Calculation for Remaining Quantity Required (G):

$$\text{Theoretical Qty.} - \text{Actual Quantity (F)} = 6.558 \text{ Kg}$$

AR. No.: RMG/00911, Assay on dried basis: 99.770 w/w, LOD: 4.530 %w/w, Exp. Date: 09/2027

$$\text{Actual Quantity (Kg) (H)} = \frac{\text{Remaining qty. required (G)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{6.558 \times 100 \times 100}{99.770 \times (100 - 4.530)} = 6.885 \text{ Kg}$$

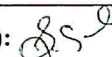
$$\text{Total Qty. of Atorvastatin Calcium to be dispensed (I)} = (E) + (H) = 13.903 \text{ Kg}$$

4) Calculation for Microcrystalline cellulose PH 102 (B):

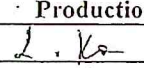
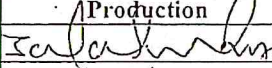
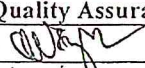
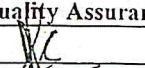
Actual Quantity (Kg) (J) = Standard quantity of Microcrystalline cellulose PH 102 - Excess Calculated quantity of Atorvastatin Calcium

$$= 29.466 \text{ Kg} - 0.703 \text{ Kg}$$

$$= 28.763 \text{ Kg}$$

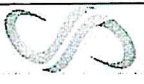
Done By/On (QA):  29/11/2022

Checked By/On (Production):  29/11/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 6 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 30/11/22 Time: 10:10

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 scoop, SS spatula and 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 dispensing booth is clean	✓	✓
7	Check all the gauges of dispensing booth 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	Dispensing Booth	Weighing Balance			Area
ID No.	ST 1DP3 1001	ST 1BA 1004	ST 1BA 1005	ST 1BA 1006	Dispensing Booth
Previous Product	Glenget				
B. No.	G1822142				
Cleaned by Sign/Date	Nishu 30/11/22				
Checked by Store Sign/Date	Rashu 30/11/22				
Verified by IPQA Sign/Date	S. 30/11/22				

ENVIRONMENTAL CONDITIONS: Date: 30/11/22 Time: 10:15		Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)				
Temperature (Limit: NMT 25°C)		22°C	Nishu 30/11/22	S. 30/11/22
Relative Humidity % (Limit: NMT 60%)		58%	Nishu 30/11/22	S. 30/11/22
Differential Pressure (NLT 10 Pascal)		11 Pascal	Nishu 30/11/22	S. 30/11/22
Differential Pressure across the booth Limit: 5 to 20 mm Water		12 mm	Nishu 30/11/22	S. 30/11/22

APPROVAL FOR DISPENSING BY IPQA: Sign: [Signature] Date: 30/11/2022

Dispensing start Time: 10:30 End Time: 12:30

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	[Signature]	[Signature]	[Signature]	[Signature]
Date	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Pudukcherry-605009.	Product LOLIP 20		Batch Size: 6,00,000 Tablets Batch No.: G1222161 Customer: Generic Health Care Pvt. Ltd.
	BATCH MANUFACTURING RECORD		Product Code: L13 BMR. No.: BMR/T/331-00 Customer:
	Product Code: L13		Batch Size: 6,00,000 Tablets Batch No.: G1222161 Customer: Generic Health Care Pvt. Ltd.

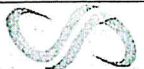
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5.1 Dispensing Weighing Sheet: Balance ID: Q132100410051006 Date: 22/11/22 Shift: 5 Time: 10:30

Sl. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R. No.	Issued Qty.			Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Tare Wt.	Net Wt.			Checked Production (Sign & Date)	Verified IPQA (Sign & Date)
Lubrication material:														
1	Atorvastatin Calcium (Micronized)	USP	RAI/SP/A016	Kg	13.200	13.903	Rm/100911	7.045	0.160	6.885	Rm/100911	Rm/100911	Rm/100911	Rm/100911
2	Microcrystalline cellulose PH102	BP	REX/SP/M010	Kg	29.466	28.763	Rm/100572	28.963	0.200	28.763	Rm/100572	Rm/100572	Rm/100572	Rm/100572
3	Calcium Carbonate	BP	RAI/SP/C005	Kg	0.570	0.570	Rm/100818	610.000	410.000	570.000	Rm/100818	Rm/100818	Rm/100818	Rm/100818
4	Lactose DCL 11	BP	REX/SP/L004	Kg	63.570	63.570	Rm/100816	330.000	0.200	30.000	Rm/100816	Rm/100816	Rm/100816	Rm/100816
5	Croscarmellose Sodium	BP	REX/SP/C008	Kg	3.780	3.780	Rm/100815	3.850	0.070	3.780	Rm/100815	Rm/100815	Rm/100815	Rm/100815
6	Colloidal Silicon Dioxide	BP	REX/SP/C022	Kg	1.710	1.710	Rm/100645	1.910	0.200	1.710	Rm/100645	Rm/100645	Rm/100645	Rm/100645
7	Purified Talc	BP	REX/SP/P017	Kg	1.140	1.140	Rm/100803	1180.000	40.000	1140.000	Rm/100803	Rm/100803	Rm/100803	Rm/100803
8	Magnesium Stearate	BP	REX/SP/M011	Kg	0.570	0.570	Rm/100825	610.000	40.000	570.000	Rm/100825	Rm/100825	Rm/100825	Rm/100825
Coating Material:														
9	Wincoat WT White 02022	IHS	REX/SP/W001	Kg	3.563	3.563	Rm/100964	3.593	0.060	3.533	Rm/100964	Rm/100964	Rm/100964	Rm/100964
10	Yellow oxide of Iron	IHS	REX/SP/I004	Kg	0.038	0.038	Rm/100619	45.000	7.000	38.000	Rm/100619	Rm/100619	Rm/100619	Rm/100619
11	Tween 80	BP	REX/SP/P014	Kg	0.150	0.150	Rm/101173	160.000	40.000	120.000	Rm/101173	Rm/101173	Rm/101173	Rm/101173
12	Isopropyl Alcohol	BP	REX/SP/I005	Kg	21.000	21.000	Rm/101033	23.000	2.000	21.000	Rm/101033	Rm/101033	Rm/101033	Rm/101033
13	Purified Water	BP	NA	Kg	30.000	30.000	Rm/2210672	32.000	2.000	30.000	Rm/2210672	Rm/2210672	Rm/2210672	Rm/2210672

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	Production	Quality Assurance		
Date	02/06/2022	02/06/2022	02/06/2022		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 8 of 35	
	BATCH MANUFACTURING RECORD		Product Code: L13	Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMRT/331-00	Batch No.: 41822161	Customer:

6.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 30/11/22 / 15:30/4 01/12/22 / 4

Sr. No.	Checks	Time	*Observations					
			15:30		09:28			
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.		✓	✓	✓	✓		
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓	✓	✓		
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓	✓	✓		
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓	✓	✓		
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓	✓	✓		
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓	✓	✓		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓	✓	✓		
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓	✓	✓		
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓	✓	✓		
10	Check and ensure that environment condition and record on BMR		✓	✓	✓	✓		
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		✓	✓	NA	NA		
12	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	Shifter	Blender	Area
EQP: ID No.	PP1VBS1001	PP1OCB1001	Granulation - I
Previous Product	Dried maize starch.		
Batch No.	FM012260K		
Cleaned by	praveen		
Checked by	me		
Verified by	me		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: <u>30/11/22</u> Time: <u>15:32</u>			Date: <u>01/12/22</u> Time: <u>09:30</u>			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	22°C	me	me	23°C	me	me			
RH % (NMT 60%)	50%	me	me	52%	me	me			
DP (NLT 10 Pascal)	11	me	me	10	me	me			

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	<u>me</u> <u>30/11/22</u>	<u>me</u> <u>01/12/22</u>	
IPQA Sign/Date:	<u>me</u> <u>30/11/2022</u>	<u>me</u> <u>01/12/2022</u>	
Start and End Time:	<u>15:55</u> <u>17:39</u>	<u>09:40</u> <u>15:40</u>	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>Sulabha</u>	<u>me</u>	<u>me</u>
Date	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G13 22161 Generic Health Care Pvt. Ltd.

6.1 LUBRICATION MATERIAL SIFTING RECORD: Date: 02/06/2022 Shift: 1st

S. No	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by	Vfd by
						From	To				
Dry mixing:											
1	Atorvastatin Calcium	13.903	80#	PP/30-80-80/04	OK/ Not OK	15:55 16:40	17:39 17:40	OK/ Not OK	Regn	MB	SA
2	Microcrystalline cellulose PH102	28.763	40#	PP/30-80-40/09	OK/ Not OK	17:41 17:41	18:35	OK/ Not OK	Regn	M	SA
3	Calcium Carbonate	0.570	60#	PP/30-80-60/05	OK/ Not OK	12:37	12:38	OK/ Not OK	Regn	M	SA
4	Lactose DCL 11	63.570	60#			12:39	14:25		Regn	M	SA
5	Croscarmellose Sodium	3.780	60#			14:26	14:42		Regn	M	SA
6	Colloidal Silicon Dioxide	1.710	30#	PP/30-80-30/08	OK/ Not OK	14:44	14:46	OK/ Not OK	Regn	M	SA
7	Purified Talc	1.140	80#	PP/30-80-80/04	OK/ Not OK	14:47	14:49	OK/ Not OK	Regn	M	SA
8	Magnesium stearate	0.570				14:52	14:54		Regn	M	SA

6.2 BLENDING AND LUBRICATION PROCESS:

Date: 01/06/2022 Shift: 1st

Step No.	Process Instructions	Time		Done by	Ckd by	Verified by IPQA
		Started	Completed			
1	Use hand gloves and goggles while handling the materials.					
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.					
Pre-Lubrication:						
1	Load the sifted materials from step 6.1 (1,6) into the blender and mix for 15 minutes at 10 RPM.	15:04	15:19	Regn	MB	SA
Lubrication:						
2	Load the Sifted Purified Talc and Magnesium Stearate into the above Pre-lubricated blend and mix for further 5 minutes at 10 RPM.	15:21 15:26 15:29	15:27 15:30	Regn	M	SA
3	Unload the lubricated blend in HDPE container having double lined polybag.	15:34	15:40	Regn	M	SA

6.3 WEIGHING OF FINAL BLEND:

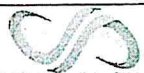
Balance I.D. No.: P.2.1.1.002

Date: 01/06/2022 Shift: 1st Time: 15:45

Sr. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	28.360	1.900	26.460	Regn	M	SA
2	31.180	1.780	29.400	Regn	M	SA
3	30.800	2.100	28.700	Regn	M	SA
4	31.200	2.100	29.100	Regn	M	SA
5						
6						
7						
Total:			113.660			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	S. K.	OK	KS
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 41822161 Generic Health Care Pvt. Ltd.

6.4 RECONCILIATION:

1.0	Theoretical weight of blend	:	114.000 Kg
2.0	Actual Weight of blend	:	113.660 Kg
3.0	Manufacturing Loss (Blending stage) @	:	0.210 Kg
4.0	In-process samples		
	A IPQC Samples	:	NA Kg.
	B QC Samples	:	0.130 Kg.
	C Validation Samples	:	0.030 Kg.
5.0	Total samples: (A + B + C)	:	0.130 Kg
6.0	Total: (2.0 + 5.0)	:	113.790 Kg
7.0	Yield {6.0 / 1.0 x100}*	:	99.81 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 0.210 Kg. (Rejected materials shall be destroyed as per SOP: QAGN/048).

Recovery Addition Quantity in Kg: NA (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: [Signature] / 01/12/22 Checked By IPQA sign/Date: [Signature] / 01/12/22

Test request form raised by Prod Sign/Date: [Signature] / 01/12/22

Test request form received by IPQA Sign/Date: [Signature] / 01/12/22

6.5 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: [Signature] Date: 01/12/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	[Signature]	[Signature]	[Signature]	[Signature]
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

UNCONTROLLED COPY

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMRT/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

7.0 COMPRESSION LINE CLEARANCE CHECKS:

Date: 02/12/22

Sr. No.	Checks	Time:	*Observations					
			09:15		09:23			
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		/	/	/	/		
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		/	/	/	/		
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		/	/	/	/		
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		/	/	/	/		
5	Check and ensure that working desk, analytical balance and other accessories are clean.		/	/	/	/		
6	Check and ensure that Deduster and hosepipe are clean.		/	/	/	/		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		/	/	/	/		
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		/	/	/	/		
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		/	/	/	/		
10	Check and ensure that environmental conditions are recorded in the BMR.		/	/	/	/		
11	Area, equipment and preventive maintenance status board is updated.		/	/	/	/		
12	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR		/	/	NA	NA		
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		/	/	/	/		

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

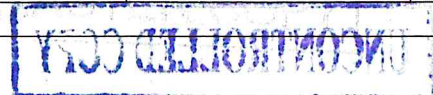
Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD/COM/001	PD/DED/001, PD/DED/002	compression-01
Previous Product	Esomeval 40mg		
Batch No.	G1822157		
Cleaned by	Kusavan		
Checked by	R-ell		
Verified by	P.S		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 02/12/22	Time: 09:18	Date: 03/12/22	Time: 09:26	Date:	Time:
	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	R-ell	P.S	23°C	R-ell	G.P
RH % (NMT 60%)	52%	R-ell	P.S	52%	R-ell	G.P
DP (NLT 10 Pascal)	11 pascal	R-ell	P.S	10 pascal	R-ell	G.P

APPROVAL FOR COMPRESSION:

Production Sign/Date:	R-ell 02/12/2022	R-ell 03/12/2022	
IPQA Sign/Date:	P.S 02/12/2022	G.P 03/12/2022	
Start and End Time:	10:00	18:13	09:30 12:35

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Sakubhary	W.K.P	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/22



 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

8.0 COMPRESSION

8.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 8.00 mm Circular shaped standard concave with breakline on punches. b. Lower punches: 8.00 mm Circular shaped standard concave plain punches. c. Dies: 8.00 mm suitable for above punches. d. Type of tooling - D. <i>R. ell</i> 02/12/2022 Punch Issued by: sign./Date: <i>Kesavan</i> 02/12/2022 Checked and Received by Sign./Date: <i>02/12/22</i> Verified by Sign./ Date:
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

8.2 GRANULES RECEIPT RECORD: Balance ID. No.: PD/BA/015 Date: 02/12/22 Shift: G Time: 09:45

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	28.360	<i>W</i>	<i>R. ell</i>
2	31.180	<i>W</i>	<i>R. ell</i>
3	30.800	<i>W</i>	<i>R. ell</i>
4	31.200	<i>W</i>	<i>R. ell</i>
5			
6			
7			
8			

8.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	20	Every 30 min.	Every 2 Hr.
2.	Average weight (mg)	190.000 mg $\pm$ 3.0 % (184.300 mg – 195.700 mg)	20		
3.	Group Weight	3.800 g $\pm$ 3.0 % (3.686 g to 3.914 g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)	20	Every 2 Hr.	Every 4 Hr.
5.	Hardness	NLT 3.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
6	Thickness (mm)	3.70 $\pm$ 0.2 mm 3.50 mm – 3.90 mm (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Diameter (mm)	(7.80 mm – 8.2 mm) (To be established)	30	Initial	
8.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
9.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ke</i>	<i>Srinivasan</i>	<i>02/06/2022</i>	<i>02/06/2022</i>
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product: LOLIP 20

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

Batch No.: 41322161

Customer:

Generic Health Care Pvt. Ltd.

8.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	Total Hour	M/C Speed	Tablets Output	Done By	Checked By
02/12/22	G	10:00	18:13	08:00	16	410000	Kosareon	22
03/12/2022	G	09:30	12:35	03:30	16	186842	Kosareon	22

8.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness & Diameter):

Balance I.D. No.: PD/BAL/D15

Date: 02/12/22 Shift: G Time: 09:30

LHS					RHS				
Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)	Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)
1	OK	190	3.52	8.00	1	OK	189	3.55	8.00
2	OK	190	3.55	7.99	2	OK	189	3.56	7.99
3	OK	188	3.56	7.98	3	OK	190	3.58	7.98
4	OK	186	3.55	8.01	4	OK	190	3.59	8.00
5	OK	188	3.58	8.02	5	OK	187	3.60	7.98
6	OK	189	3.52	8.01	6	OK	189	3.54	7.99
7	OK	188	3.52	8.02	7	OK	189	3.55	8.01
8	OK	188	3.54	8.01	8	OK	189	3.56	8.02
9	OK	188	3.54	8.00	9	OK	189	3.55	8.01
10	OK	187	3.55	7.98	10	OK	187	3.58	8.00
11	OK	190	3.56	7.99	11	OK	188	3.59	7.99
12	OK	188	3.53	8.02	12	OK	188	3.55	8.01
13	OK	188	3.54	8.01	13	OK	187	3.54	8.00
14	OK	187	3.56	8.05	14	OK	189	3.55	7.98
15	OK	188	3.58	8.00	15	OK	188	3.56	8.01
16	OK	187	3.52	7.98	16	OK	189	3.52	8.02
17	OK	190	3.54	7.99	17	OK	188	3.55	8.03
18	OK	189	3.56	8.01	18	OK	188	3.56	8.02
19	OK	187	3.55	8.00	19	OK	189	3.55	8.05
20	OK	186	3.54	8.02	20	OK	189	3.54	8.01
21	OK	190	3.56	7.98	21	OK	189	3.53	8.00
22	OK	189	3.55	7.98	22	OK	187	3.52	7.98
23	OK	189	3.54	8.01	23	OK	186	3.55	8.01
24	OK	189	3.52	8.00	24	OK	186	3.54	8.02
25	OK	189	3.51	7.98	25	OK	189	3.56	8.04
26	OK	187	3.52	7.99	26	OK	187	3.58	8.02
27	OK	190	3.55	8.02	27	OK	189	3.59	8.03
28	OK	189	3.56	8.01	28	OK	189	3.60	7.99
29	OK	186	3.55	8.00	29	OK	189	3.58	8.01
30	OK	186	3.56	7.99	30	OK	190	3.57	8.00

Note: * Write OK if complies and (X) if does not comply.

Done by Production Sign/Date... R. S. 02/12/2022

Checked by IPQA Sign/Date... M. 02/12/2022

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	J. K.	S. S.	M. S.	S. S.	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022	



 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: <u>G1822161</u> Generic Health Care Pvt. Ltd.

8.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 02/12/22 Shift: 1 Time: 09:46

Parameters	Instrument used	Equip ID No.	Observations of LHS		Observations of RHS		Limits				
			Min	Max	Min	Max					
Appearance	Visual	NA	ok		ok		White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side				
Group Weight	Electronic Balance	PD/BAL/007	3.762 g		3.771 g		3.800 g ± 3.0 % (3.686 g to 3.914 g)				
Average weight	Electronic Balance		188.10 mg		188.55 mg		190.000 mg ± 3.0 % (184.300 mg – 195.700 mg)				
Individual weight	Electronic Balance		186 mg	190 mg	186 mg	190 mg	190.000 mg ± 5.0 % (180.500 mg – 199.500 mg)				
Uniformity of weight	Electronic Balance		-1.11 %	1.01 %	-1.35 %	0.76 %					
Thickness	Vernier Caliper	QAL/VEL/001	3.52 mm	3.58 mm	3.54 mm	3.60 mm	3.70 ± 0.2 mm 3.50 mm – 3.90 mm (To be established)				
Hardness	Hardness Tester	QAL/HRT/001	6.0	6.5	7.0	6.5	7.0	6.5	7.0	6.5	NLT 3.0 Kg (To be established)
Friability	Friabilator	QAL/FRT/002	0.01 %		0.02 %		NMT 1.0% w/w				
DT	DT Apparatus	QAL/DTA/002	01 min 20 sec		01 min 15 sec		NMT 15 minutes				
M/C set done by Operator Name: <u>L. K. V.</u> M/C set up Checked by (Prod. Sign/Date): <u>R. ell</u> <u>02/12/2022</u> M/C Speed: <u>10</u> RPM (To be Established)											
Initial Setting Tablets Destroyed by: Sign: <u>R. ell</u> Date: <u>02/12/22</u> Quantity in Kg.: <u>0.02</u> Quantity in No.: <u>120</u>											
Approval for Batch Compression by IPQA: Sign: <u>R. ell</u> Date: <u>02/12/22</u> Time: <u>09:52</u>											

Thickness: 3.40 mm to 3.60 mm

M
02/12/2022.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K. V.</u>	<u>R. ell</u>	<u>R. ell</u>	<u>R. ell</u>
Date	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 1222161 Generic Health Care Pvt. Ltd.

8.9 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 02/12/2022		Time: 10:10		Shift: G							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	190	8	191	15	187	1	190	8	191	15	191
2	187	9	190	16	189	2	189	9	189	16	189
3	189	10	189	17	188	3	188	10	191	17	191
4	191	11	187	18	191	4	190	11	189	18	189
5	190	12	188	19	190	5	186	12	192	19	191
6	189	13	188	20	189	6	190	13	188	20	190
7	190	14	190			7	189	14	189		
Balance ID No.: PD/BAL/007						M/C Speed: 16 RPM					
Group weight of 20 Tablets: 378.3 g. Avg. wt: 189.15 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 191 mg						Group weight of 20 Tablets: 379.2 g. Avg. wt: 189.60 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 186 mg Max. weight: 192 mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.01%		0.01%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 18 sec		01 min 21 sec		Equipment ID No.: QA/DTA/002	
Done by: R. S. (Production)											
Date: 02/12/2022		Time: 12:17		Shift: G							
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	189	8	189	15	191	1	189	8	190	15	194
2	191	9	191	16	189	2	191	9	189	16	190
3	189	10	190	17	191	3	187	10	194	17	189
4	188	11	189	18	188	4	191	11	189	18	188
5	192	12	191	19	191	5	190	12	194	19	191
6	190	13	190	20	189	6	189	13	190	20	190
7	188	14	189			7	194	14	189		
Balance ID No.: PD/BAL/007						M/C Speed: 16 RPM					
Group weight of 20 Tablets: 379.5 g. Avg. wt: 189.75 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 188 mg Max. weight: 192 mg						Group weight of 20 Tablets: 380.8 g. Avg. wt: 190.40 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 194 mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.02%		0.01%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 20 sec		01 min 21 sec		Equipment ID No.: QA/DTA/002	
Done by: R. S. (Production)											

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	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

8.10 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 02/12/2022		Time: 14:19		Shift: G							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	190	8	188	15	191	1	188	8	192	15	189
2	188	9	191	16	188	2	193	9	191	16	190
3	191	10	190	17	191	3	191	10	188	17	192
4	187	11	188	18	190	4	186	11	190	18	191
5	190	12	192	19	189	5	188	12	193	19	188
6	192	13	190	20	192	6	187	13	190	20	187
7	191	14	190			7	190	14	186		
Balance ID No.: PD1801007						M/C Speed: 16 RPM					
Group weight of 20 Tablets: 3.799 g. Avg. wt: 189.95 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 192 mg						Group weight of 20 Tablets: 3.790 g. Avg. wt: 189.50 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 186 mg Max. weight: 193 mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.03%		0.02%		Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 24 sec		01 min 22 sec		Equipment ID No.: QA/DTA/ 002	
Done by: (Signature) (Production)											
Date: 02/12/2022		Time: 16:21		Shift: G							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	188	8	192	15	190	1	190	8	194	15	191
2	191	9	190	16	187	2	194	9	191	16	190
3	186	10	187	17	185	3	187	10	188	17	194
4	193	11	192	18	189	4	189	11	192	18	187
5	187	12	190	19	193	5	191	12	190	19	191
6	185	13	186	20	191	6	193	13	189	20	193
7	189	14	188			7	189	14	187		
Balance ID No.: PD1801007						M/C Speed: 16 RPM					
Group weight of 20 Tablets: 3.779 g. Avg. wt: 188.95 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 185 mg Max. weight: 193 mg						Group weight of 20 Tablets: 3.810 g. Avg. wt: 190.50 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 194 mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.01%		0.04%		Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 30 sec		01 min 26 sec		Equipment ID No.: QA/DTA/ 002	
Done by: (Signature) (Production)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	(Signature)	(Signature)	(Signature)	(Signature)	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 19 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13
	Product: LOLIP 20		Batch Size: 6,00,000 Tablets
		BMR. No.: BMR/T/331-00	Batch No.: 1822161
		Customer:	Generic Health Care Pvt. Ltd.

8.11 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 02/12/2022		Time: 09:45		Shift: C ₂	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	190	8	187	15	192
2	187	9	193	16	190
3	191	10	192	17	187
4	193	11	188	18	190
5	190	12	186	19	188
6	186	13	189	20	190
7	189	14	191		
Balance ID No.: PD/BA1007			M/C Speed: 16 RPM		
Group weight of 20 Tablets: 3789 g. Avg. wt: 189.45 mg			Group weight of 20 Tablets: 3801 g. Avg. wt: 190.05 mg		
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)		
Min weight: 186 mg Max. weight: 193 mg			Min weight: 187 mg Max. weight: 193 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.01%	0.02%	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 34 sec	01 min 29 sec	Equipment ID No.: QA/DTA/ 002	
Done by: <u>By</u> (Production)					
Date: 03/12/2022		Time: 11:39		Shift: G ₁	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	189	8	189	15	189
2	190	9	188	16	192
3	187	10	189	17	189
4	191	11	187	18	191
5	191	12	191	19	190
6	190	13	190	20	189
7	192	14	190		
Balance ID No.: PD/BA11007			M/C Speed: 16 RPM		
Group weight of 20 Tablets: 3795 g. Avg. wt: 189.75 mg			Group weight of 20 Tablets: 3800 g. Avg. wt: 190.00 mg		
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)		
Min weight: 187 mg Max. weight: 193 mg			Min weight: 186 mg Max. weight: 192 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.02%	0.01%	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 20 sec	01 min 25 sec	Equipment ID No.: QA/DTA/ 002	
Done by: <u>P. V. L.</u> (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. G.</u>	<u>32/11/2022</u>	<u>02/12/2022</u>	<u>02/12/2022</u>
Date	02/12/2022	02/12/2022	02/12/2022	02/12/2022

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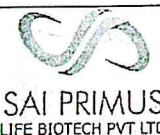
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 20 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 61822161 Generic Health Care Pvt. Ltd.

8.12 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:				Time :				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15		1		8		15					
2		9		16		2		9		16					
3		10		17		3		10		17					
4		11		18		4		11		18					
5		12		19		5		12		19					
6		13		20		6		13		20					
7		14				7		14							
Balance ID No.:						M/C Speed: RPM									
Group weight of 20 Tablets:.....g. Avg. wt:.....mg						Group weight of 20 Tablets:.....g. Avg. wt:.....mg									
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)						Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)									
Min weight. :..... mg Max. weight:..... mg						Min weight. :..... mg Max. weight:..... mg									
						LHS		RHS							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):										Equipment ID No.: QA/FRT/					
Disintegration Time (Limit - NMT 15 minutes)										Equipment ID No.: QA/DTA/					
Done by:(Production)															
Date:				Time :				Shift:							
LHS: Individual weight of 20 tablets (in mg).								RHS: Individual weight of 20 tablets (in mg).							
1		8		15		1		8		15					
2		9		16		2		9		16					
3		10		17		3		10		17					
4		11		18		4		11		18					
5		12		19		5		12		19					
6		13		20		6		13		20					
7		14				7		14							
Balance ID No.:						M/C Speed: RPM									
Group weight of 20 Tablets:.....g. Avg. wt:.....mg						Group weight of 20 Tablets:.....g. Avg. wt:.....mg									
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)						Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)									
Min weight. :..... mg Max. weight:..... mg						Min weight. :..... mg Max. weight:..... mg									
						LHS		RHS							
Friability (Limit: NMT 1% after 4 minutes/100 rotations):										Equipment ID No.: QA/FRT/					
Disintegration Time (Limit - NMT 15 minutes)										Equipment ID No.: QA/DTA/					
Done by:(Production)															

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<i>L. K.</i>	<i>Salubh...</i>	<i>W. H.</i>	<i>R.</i>	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022	

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 21 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

8.13 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. :.....mg Max. weight.:mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. :.....mg Max. weight.:mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. :.....mg Max. weight.:mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. :.....mg Max. weight.:mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>Salabur</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 22 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

8.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): Full Hoppers

Date: 02/12/2022						Time: 10:15						Shift: D																																					
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																																					
1	187	8	182	15	182	1	190	8	185	15	193	2	190	9	189	16	195	3	192	10	188	17	187	4	189	11	190	18	190	19	192	5	189	12	190	20	192	6	192	13	188	20	190	7	192	14	193		
Balance ID No.: QA1341002												M/C Speed: 16 RPM																																					
Group weight of 20 Tablets: 3.802.....g. Avg. wt.: 190.10.....mg												Group weight of 20 Tablets: 3.808.....g. Avg. wt.: 190.40.....mg																																					
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)												Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)																																					
Min weight: 182.....mg Max. weight: 193.....mg												Min weight: 185.....mg Max. weight: 195.....mg																																					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												LHS				RHS				Equipment ID No.: QA/FRT/002																													
Disintegration Time (Limit - NMT 15 minutes)												01 min 20 sec				01 min 30 sec				Equipment ID No.: QA/DTA/002																													
Done by: 02.12.2022 (IPQA)																																																	
Date: 02/12/2022						Time: 10:25						Shift: D						LOW 12PM																															
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																																					
1	190	8	191	15	193	1	189	8	192	15	190	2	189	9	187	16	190	3	190	10	189	17	190	4	189	11	188	18	189	19	188	5	191	12	190	20	188	6	187	13	192	20	188	7	189	14	190		
Balance ID No.: QA1RAL1002												M/C Speed: 8 RPM																																					
Group weight of 20 Tablets: 3.792.....g. Avg. wt.: 189.60.....mg												Group weight of 20 Tablets: 3.793.....g. Avg. wt.: 189.65.....mg																																					
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)												Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)																																					
Min weight: 187.....mg Max. weight: 193.....mg												Min weight: 186.....mg Max. weight: 192.....mg																																					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												LHS				RHS				Equipment ID No.: QA/FRT/002																													
Disintegration Time (Limit - NMT 15 minutes)												01 min 30 sec				01 min 25 sec				Equipment ID No.: QA/DTA/002																													
Done by: 02.12.2022 (IPQA)																																																	

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.				
Date	02/06/2022	02/06/2022	02/06/2022		

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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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1222161

Customer:

Generic Health Care Pvt. Ltd.

8.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 02/12/2022

Time: 10:35

Shift: A

High RPM

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	192	8	191	15	188	1	190	8	189	15	187
2	190	9	192	16	190	2	191	9	188	16	191
3	190	10	186	17	189	3	190	10	188	17	190
4	189	11	192	18	191	4	191	11	194	18	191
5	191	12	190	19	191	5	192	12	192	19	193
6	190	13	190	20	190	6	190	13	188	20	190
7	189	14	191			7	191	14	190		

Balance ID No.: QA/BAL/002

M/C Speed: 18 RPM

Group weight of 20 Tablets: 3.801 g. Avg.
wt: 190.05 mg

Group weight of 20 Tablets: 3.802 g. Avg.
wt: 190.10 mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 188 mg Max. weight: 192 mg

Min weight: 187 mg Max. weight: 194 mg

LHS

RHS

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.02%

0.02%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

01 min 10 sec

01 min 30 sec

Equipment ID No.: QA/DTA/002

Done by: 02/12/2022 (IPQA)

Date: 02/12/2022

Time: 10:45

Shift: A

Low Hardness

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	191	8	190	15	186	1	191	8	195	15	192
2	193	9	187	16	186	2	190	9	194	16	190
3	190	10	182	17	191	3	191	10	190	17	188
4	189	11	189	18	191	4	192	11	190	18	190
5	189	12	186	19	191	5	190	12	190	19	192
6	189	13	182	20	190	6	188	13	192	20	191
7	191	14	189			7	192	14	192		

Balance ID No.: QA/BAL/002

M/C Speed: 18 RPM

Group weight of 20 Tablets: 3.785 g. Avg.
wt: 189.25 mg

Group weight of 20 Tablets: 3.820 g. Avg.
wt: 191 mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: mg Max. weight: mg

Min weight: mg Max. weight: mg

LHS

RHS

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.02%

0.01%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

00 min 50 sec

01 min 05 sec

Equipment ID No.: QA/DTA/002

Done by: 02/12/2022 (IPQA)

Prepared by:

Checked by:

Approved By:

Dept.

Production

Production

Quality Assurance

Head Quality Assurance

Sign.

L. R.

S. S. S.

Q. A.

H. Q. A.

Date

02/06/2022

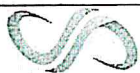
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SAI PRIMUS
LIFE BIOTECH PVT LTD

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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: 61822161

Customer:

Generic Health Care Pvt. Ltd.

8.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 02/12/2022 Time: 10:55 Shift: A High Hardness

LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	190	8	129	15	191	1	191	8	186	15	190
2	190	9	191	16	191	2	189	9	191	16	190
3	194	10	187	17	189	3	189	10	192	17	189
4	192	11	189	18	188	4	190	11	192	18	189
5	192	12	187	19	191	5	192	12	190	19	192
6	188	13	187	20	190	6	191	13	185	20	192
7	189	14	191			7	191	14	192		

Balance ID No.: QA/BAL/002

M/C Speed: 16 RPM

Group weight of 20 Tablets: 3.796 g. Avg.
wt: 189.82 mg

Group weight of 20 Tablets: 3.803 g. Avg.
wt: 190.15 mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 187 mg Max. weight: 194 mg

Min weight: 185 mg Max. weight: 192 mg

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.21%

0.21%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

01 min 52 sec

01 min 55 sec

Equipment ID No.: QA/DTA/002

Done by: 02/12/22 (IPQA)

Date: 02/12/2022 Time: 12:55 Shift: A

LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	189	8	191	15	190	1	189	8	190	15	190
2	193	9	190	16	192	2	194	9	192	16	191
3	190	10	194	17	190	3	190	10	195	17	193
4	191	11	193	18	188	4	186	11	191	18	189
5	187	12	191	19	190	5	191	12	190	19	190
6	189	13	190	20	191	6	190	13	189	20	191
7	190	14	192			7	189	14	188		

Balance ID No.: QA/BAL/002

M/C Speed: 16 RPM

Group weight of 20 Tablets: 3.811 g. Avg.
wt: 190.55 mg

Group weight of 20 Tablets: 3.803 g. Avg.
wt: 190.15 mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 187 mg Max. weight: 194 mg

Min weight: 186 mg Max. weight: 195 mg

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.01%

0.01%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

01 min 57 sec

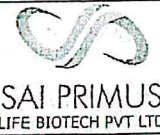
01 min 44 sec

Equipment ID No.: QA/DTA/002

Done by: 02/12/22 (IPQA)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	30/12/22	02/12/22	
Date	02/12/2022	02/12/2022	02/12/2022	

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 25 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 61822161 Generic Health Care Pvt. Ltd.

8.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 02/12/2022		Time: 16:55		Shift: A							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	190	8	190	15	189	1	191	8	189	15	193
2	190	9	189	16	195	2	191	9	191	16	191
3	191	10	192	17	190	3	190	10	191	17	189
4	192	11	190	18	192	4	189	11	190	18	190
5	188	12	191	19	191	5	192	12	192	19	193
6	189	13	189	20	191	6	190	13	190	20	190
7	191	14	193			7	191	14	189		
Balance ID No.: QA/BAI/002						M/C Speed: 16 RPM					
Group weight of 20 Tablets: 3.822 g. Avg. wt: 191.1 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 188 mg Max. weight: 195 mg						Group weight of 20 Tablets: 3.812 g. Avg. wt: 190.6 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 189 mg Max. weight: 193 mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.02%		0.01%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 50 sec		01 min 35 sec		Equipment ID No.: QA/DTA/002	
Done by: ASV (IPQA)											
Date: 03/12/2022		Time: 09:50		Shift: G							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	187	8	188	15	188	1	190	8	187	15	188
2	188	9	189	16	190	2	191	9	187	16	192
3	190	10	191	17	190	3	188	10	189	17	192
4	187	11	187	18	189	4	189	11	187	18	191
5	188	12	187	19	186	5	191	12	191	19	190
6	188	13	188	20	187	6	191	13	189	20	190
7	190	14	188			7	191	14	189		
Balance ID No.: QA/BAI/002						M/C Speed: 16 RPM					
Group weight of 20 Tablets: 3.766 g. Avg. wt: 188.3 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 186 mg Max. weight: 191 mg						Group weight of 20 Tablets: 3.776 g. Avg. wt: 189.8 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 194 mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.01%		0.01%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 24 sec		01 min 25 sec		Equipment ID No.: QA/DTA/002	
Done by: ASV (IPQA)											

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	30/12/2022	02/06/2022	02/06/2022
Date:	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 26 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 61822161 Generic Health Care Pvt. Ltd.

8.18 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	29.990	2.200	27.790	Kaswan	23	AKV
2	30.010	2.100	27.910	Kaswan	23	AKV
3	30.430	2.020	28.350	Kaswan	23	AKV
4	31.200	1.850	29.350	Kaswan	23	AKV
5						
6						
7						
8						
9						
10						

8.19 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: 1.90...mg

1.0	Standard Batch size	:	114.000 Kg.	6,00,000 No.
2.0	Actual weight of Lubricated granules	:	113.660 Kg.	598210 Nos.
3.0	Weight of compressed tablets	:	113.400 Kg.	596842 Nos.
4.0	Rejection during Compression @	:	0.020 Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	: 0.100 Kg.	
	B	QC Samples	: 0.020 Kg.	
	C	Validation Samples	: 0.050 Kg.	
6.0	Total in process samples: (A + B + C)	:	0.170 Kg.	
7.0	Total: (3.0 + 6.0)	:	113.570 Kg.	597726 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		99.62 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.070 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: 03/12/2022 Checked by IPQA Sign/Date: 03/12/2022

Test request form raised by Prod Sign/Date: 02/12/2022

Test request form received by IPQA Sign/Date: 02/12/2022

8.20 RELEASED FOR COATING:

Reconciliation checked and compressed tablets released for coating:

IPQA Sign: AKV Date: 03/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	[Signature]	[Signature]	[Signature]
Date	02/12/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 61822161 Generic Health Care Pvt. Ltd.

9.0 LINE CLEARANCE FOR COATING SOLUTION PREPARATION:

Date/Shift/Time: **03/12/2022** B / 19:22/

Sr. No.	Checks	*Observation			
		Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Derain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	✓	✓		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

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

Equipment	Solution preparation vessel and stirrer	Colloidal Mill	Area
Equipment ID No.	PD/SST/001	PD/CIM/001	Neo coating-01
Previous product	Esomexal 40mg		
Batch No.	61822157		
Cleaned by	Sibin		
Checked by Production Sign/Date:	R.ell 02/12/2022		
Verified by IPQA Sign/Date:	Atk 03/12/2022		

ENVIRONMENTAL CONDITIONS:

(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	23°C	Prod. Sign.	Verified by IPQA	Atk	Date:	Time:
	Relative Humidity % Limit: NMT 60%	52%	R-ell	Atk			

APPROVAL FOR COATING SOLUTION PREPARATION:

Production Sign/Date: R.ell 02/12/2022
Line Clearance IPQA Sign. / Date: Atk 03/12/2022
Start Time/Date: 19:35 / 03/12/2022
End Time/Date: 19:49 / 03/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. V. K.	S. Subramanian	R.ell	
Date	02/12/2022	02/12/2022	02/12/2022	03/12/2022

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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.		Page 28 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G18 22151 Generic Health Care Pvt. Ltd.

10.0 Coating Procedure:

10.1 General Instructions:

1. Prepare the coating solution lot wise.
2. Do not use synthetic containers for storage/ transfer of coating solution
3. Do not use high speed stirrer for preparing coating solution. Avoid direct contact of body with Solvent & coating solution. Solvent based coating should be done in spark proof area.

10.2 TABLETS RECEIPT RECORD OF UNCOATED TABLETS FOR COATING:

Balance ID. No.: PD/BAL/015

Date/Shift/Time: 02/12/2022/P.19:29

Sr. No.	Description	Observations	Checked By (Production)	Verified By (IPQA)
1.	Total Quantity (Net Qty.in Kg)	113.400	R.ell	Atk
2.	Number of Containers	04	R.ell	Atk

10.3 COATING SOLUTION PREPARATION

Sr. No.	General Instructions					
1.	Check the cleanliness of the Solution Preparation area and operation as per current version of SOP.					
2.	Use hand gloves while handling the materials					
3.	Transfer the verified coating materials to Coating solution preparation area.					
Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
1	Take Isopropyl Alcohol in a SS Vessel. Slowly disperse Wincoat WT White 02022 and Yellow oxide of Iron and stir well to disperse completely.	19:35	19:39	subu	R.ell	Atk
2	Take Purified Water in a SS Vessel. Slowly disperse Tween 80 and stir well to disperse completely.	19:40	19:45	subu	R.ell	Atk
3	Add Step 2 solution into the Step 1 solution and stir well with remaining quantity of Purified Water. If required mill the solution with Colloidal mill for 2 minutes	19:46	19:49	subu	R.ell	Atk

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>30/10/2022</u>	<u>02/12/2022</u>	<u>02/12/2022</u>
Date	<u>02/10/2022</u>	<u>02/10/2022</u>	<u>02/10/2022</u>	<u>02/10/2022</u>

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product: LOLIP 20

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

Batch No.: G1822161

Customer:

Generic Health Care Pvt. Ltd.

11.0 COATING AREA:

LINE CLEARANCE CHECKS:

Date/Shift/Time: 03/12/2022/19:30

Sr. No.	Checks	*Observation					
		Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓				
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓				
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓				
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓				
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓				
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓				
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓				
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓				
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓				
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF)	✓	✓				
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓				

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

Equipment	Coating Machine	Area
Equipment ID No.	PD/LCM/00 PD/NEC/001	Coating area
Previous product	Esomeral 40 mg	
Batch No.	G1822157	
Cleaned by	Subu	
Checked by Production Sign/Date:	R.ell 03/12/2022	
Verified by IPQA Sign/Date:	Alk 03/12/2022	

ENVIRONMENTAL CONDITIONS:		Date: 03/12/2022	Time: 19:30	Date:	Time:	Date:	Time:
		Observation	Checked by	Verified by	Observation	Checked by	Verified by
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	23°C	R.ell	Alk			
	Relative Humidity % Limit: NMT 60%	52%	R.ell	Alk			
	Differential Pressure (NLT 10 Pascal)	11 pascal	R.ell	Alk			

APPROVAL FOR COATING:

Production Sign/Date: R.ell
03/12/2022

Line Clearance IPQA Sign. / Date: Alk
03/12/2022

Start Time/Date: 19:52 / 03/12/2022

End Time/Date: 01:31 / 03/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.ell	Subu	Alk	R.ell
Date	02/06/2022	02/06/2022	02/06/2022	04/06/22

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 30 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

11.1 COATING PROCESS:

Process Steps					
Step No.	Name of Ingredient & Operation	Time		Done by	Ckd by Prod.
		Start	Finish		
1	Transfer the compressed tablets in to the coating Area	19:52	19:57	Subu	R.ell
2	Pre-warm the tablet with inlet temp. 35°C to 45°C.	19:58	20:02	Subu	R.ell
3	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: 1.29 % (2.0 - 2.2%)	20:03	09:20	Subu	R.ell
4	When the spraying is complete, dry the tablets perfectly, in the pan by keeping inlet temp. 40°C-50 °C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	09:21	09:26	Subu	R.ell
5	Monitor DT: Limit: NMT 30 minutes. Found Disintegration Time: 02 min 01 sec	09:27	09:31	Subu	R.ell
6	Unload the film coated tablets in a HDPE container lined with double polybag.			Subu	R.ell

11.2 INITIAL CHECKS OF COATING PARAMETERS:

S. No	Parameter	Set	Observed
1	Inlet air Temp.	35°C to 45°C (To be established)	55°C
2	Exhaust air Temp.	50 ± 5 °C (To be established)	49°C
3	Tablet Bed temp.	40°C-50 °C (To be established)	40°C
4	Atomization air pressure	2.0 - 3.0 Kg/cm ² (To be established)	2.5 kg/cm ²
5	Pan speed	2.0 - 4.0 RPM (To be established)	3.0 rpm
6	Spray rate	30 to 70 ml/min (To be established)	70 ml/min
Checked by Production/ Date			R.ell 03/12/2022
Verified by IPQA/ Date			Subu 03/12/2022

11.3 INDIVIDUAL WEIGHT CHECKING OF PRE-WARMED TABLETS:

Sr. No.	Weight (mg)	Sr. No.	Weight (mg)
1	188	11	188
2	190	12	189
3	189	13	190
4	188	14	190
5	187	15	188
6	189	16	189
7	190	17	189
8	190	18	188
9	189	19	187
10	190	20	189
Total		3771	
Avg. Weight		188.55	

11.4 FINAL COATING PARAMETERS CHECKS: (PRODUCTION)

Parameters	Limits	Observed
Description	Pale yellow coloured, circular shaped, film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	195.000 mg ± 3 % (189.150 mg – 200.850 mg)	192 mg
Weight of 20 tablets	3.900 g ± 3 % (3.783 g – 4.017 g)	3842 g
Uniformity of weight	195.000 mg ± 5 % (185.250 mg – 204.750 mg)	-1.25 / 1.35
Thickness	3.80 mm ± 0.2 mm (3.60 mm to 4.00 mm) (To be established)	3.49 to 3.60
Disintegration test	NMT 30 min	02 min 01 sec
Checked by Production/ Date		R.ell 03/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	Subu	R.ell	
Date	02/06/2022	02/06/2022	02/06/2022	

Thickness 3.8mm to 3.8mm
 02/12/2022

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

BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1822161

Customer:

Generic Health Care Pvt. Ltd.

11.5 FINAL COATING PARAMETERS CHECKS: (IPQA)

Parameters	Limits	Observed
Description	Pale yellow coloured, circular shaped, film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	195.000 mg $\pm$ 3 % (189.150 mg – 200.850 mg)	193 mg
Weight of 20 tablets	3.900 g $\pm$ 3 % (3.783 g – 4.017 g)	3849 g
Uniformity of weight	195.000 mg $\pm$ 5 % (185.250 mg – 204.750 mg)	-1.57 / 2.07
Thickness	3.80 mm $\pm$ 0.2 mm (3.60 mm to 4.00 mm) (To be established)	3.50mm – 3.65mm
Disintegration test	NMT 30 min	01 min 54 sec.
Checked by IPQA/ Date		APK 03/12/2022.

11.6 FILM COATING WEIGHT GAIN PARAMETER CHECKS:

[illegible]

11.7 WEIGHT CHECK FOR 20 TABLETS:

BY PRODUCTION			BY IPQA		
S. NO.	INITIAL WEIGHT	FINAL WEIGHT	S. NO.	INITIAL WEIGHT	FINAL WEIGHT
1	190	192	1	187	192
2	189	193	2	188	196
3	191	192	3	190	191
4	190	192	4	187	195
5	189	191	5	188	193
6	190	193	6	188	191
7	189	195	7	190	192
8	190	191	8	188	192
9	190	196	9	189	193
10	191	192	10	191	192
11	190	190	11	187	195
12	189	190	12	187	192
13	191	192	13	188	191
14	189	190	14	188	191
15	190	191	15	188	190
16	189	193	16	190	193
17	190	194	17	190	192
18	191	192	18	189	191
19	189	192	19	196	197
20	190	195	20	187	196
TOTAL	3797	3846	TOTAL	3770	3858
Checked by Production:		R-ell	Checked by IPQA:		ABZ

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	02/06/2022	02/06/2022	02/06/2022	

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7 W. E.
A. B.

 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 32 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G11222161 Generic Health Care Pvt. Ltd.

11.8 PERCENTAGE OF COATING WEIGHT BUILDS UP:

$$\% \text{ of Weight buildup} = \frac{\text{Avg. wt. of coated tablets} - \text{Avg. wt. of core tablet (Pre-warmed)} \times 100}{\text{Avg. wt. of core tablets (Pre-warmed)}}$$

$$= 1.25$$

11.9 ACTUAL AVERAGE WEIGHT OF COATED TABLETS:

$$\frac{\text{Weight of 100 coated tablet}}{100} = 192 \text{ mg}$$

11.10 WEIGHT OF FILM COATED TABLETS:

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	31.730	2.000	29.730	karthi	R-st	APK
2	30.800	1.800	29.000	karthi	R-st	APK
3	31.300	2.200	29.100	karthi	R-st	APK
4	29.120	2.300	26.820	karthi	R-st	APK
5						
TOTAL			114.650			

11.11 RECONCILIATION (COATING STAGE):

Average weight of coated Tablet: ...192...mg

1.0	Batch size	:	117.000 Kg.	6,00,000 Nos.
2.0	Weight of coated tablets	:	114.650 Kg.	597135596354 Nos.
3.0	Coating loss@	:	0.010 Kg.	
4.0	In-process samples of all stages			
	A	IPQC Samples	: 0.020 Kg.	
	B	QC Samples	: 0.020 Kg.	
	C	Validation Samples	: NA..Kg.	
5.0	Total in process samples: (A + B + C)		: 0.040 Kg.	
6.0	Total: (2.0 + 5.0)		: 114.690 Kg.	597343 Nos.
7.0	Yield {6.0 x 100 / 1.0}*		:	99.55 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: ...0.010... Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: R-st 03/12/2022 Checked by IPQA Sign/Date: APK 03/12/2022

Test request form raised by Prod Sign/Date: R-st 03/12/2022

Test request form received by IPQA Sign/Date: APK 03/12/2022

11.12 RELEASE FOR INSPECTION:

Reconciliation checked and coated tablets released for inspection

IPQA Sign: G1F Date: 05/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.Ka	3a/...	...	...
Date	02/06/2022	02/06/2022	02/06/2022	...

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 33 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:		Batch No.: 61822161 Generic Health Care Pvt. Ltd.

12.0 INSPECTION LINE CLEARANCE: Date/Shift/Time: 05/12/2022 1st

Sr. No.	Checks	*Observation			
		Prod	IPQA	Prod	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	✓	✓		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

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

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PD11A3/002	PD1MED1002	Inspection -02
Previous product	Pregnacare		
Batch No.	113 SpL2210F		
Cleaned by	Manju G		
Checked by Production Sign/Date:	05/12/2022		
Verified by IPQA Sign/Date:	05/12/2022		

ENVIRONMENTAL CONDITIONS:		Date: 05/12/22 Time:		Date:		Time:	
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	28°C	h	G.D			
	Relative Humidity % Limit: NMT 60%	52%	h	G.D			

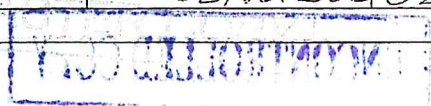
APPROVAL FOR INSPECTION:

Production Sign/Date: 05/12/22

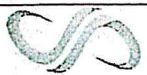
Line Clearance IPQA Sign. / Date: 05/12/22

Start Time/Date: 10:25/05/12/2022 End Time/Date: 12:05/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	2022/06/02	2022/06/02	2022/06/02
Date	02/06/2022	02/06/2022	02/06/2022	02/06/22



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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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G11322161

Customer:

Generic Health Care Pvt. Ltd.

13.0 INSPECTION PROCESS

13.1 INSTRUCTIONS

S. No.	Process Instructions
1	Carry out visual inspection of tablets on inspection belt area as per the SOP No. PDOP/019.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

13.2 PERFORMANCE CHECKS RECORD FOR METAL DETECTOR:

Sr. No	Process instructions
1.	At the start of the activity, after each break and at the end of operation/shift) as per SOP No. PDGN/022.
2.	Testing frequency: Startup, End of the activity and after every break time.
3.	Acceptance Criteria: 1. Ferrous, Stainless steel & Non-Ferrous shall be detected & rejected. 2. Nonmetallic shall not be detected.

Date & Time	Trial No.	Metal Detector ID No.: PD/MED/0022 & PD/MED/.....					Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.4 mm)	Non-metallic	Result		
10:40	1	✓	✓	✓	+	Pass	M	G.D
	2	✓	✓	✓	x	Pass	M	G.D
	3	✓	✓	✓	x	Pass	M	G.D
11:55	1	✓	✓	✓	x	Pass	M	G.D
	2	✓	✓	✓	x	Pass	M	G.D
	3	✓	✓	✓	x	Pass	M	G.D
	1							
	2							
	3							
	1							
	2							
	3							
	1							
	2							
	3							

Note: Put ✓ mark for detection and x mark for non-detection
If during the test Metal Detector fails to reject any of the Standard chips then mention the corrective action taken.
..... (To be filled by Production)
Note: Take QA Approval before proceeding to next stage

13.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
05/12/22	1	4	10:35	12:00	260 nos	Stavula ostim	M 05/12/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. R.	3. R.	W. R.	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 35 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822161 Generic Health Care Pvt. Ltd.

13.4 WEIGHING RECORD OF INSPECTED TABLETS:

Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	28.400	2.000	26.400	6			
2	28.800	2.000	26.800	7			
3	29.000	2.200	26.800	8			
4	26.800	2.200	24.600	9			
5				10			
Total			Kg	Total			Kg
				Grand Total			114.600 Kg

Weighing Done By: Manjula Checked By Prod./ Date: 05/12/2022 Verified by IPQA Sign./Date: 05/12/2022

13.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	117.000 kg	6,00,000 No's
2.0	Tablets transferred for Inspection	:	114.650 kg	597130 No's
3.0	Total weight of good Tablets	:	114.600 kg	596878 No's
4.0	Rejected Tablets	:	0.050 kg	260 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:		99.479 %

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed: 0.050 Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign/Date: 05/12/2022

Checked by IPQA sign/Date: 05/12/2022

13.6 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date : 05/12/2022

BMR Released for packing by QA Head Sign/Date: 05/12/2022

14.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	Surendhar . R	R.ell 05/12/2022
QA Executive	PRASANTH	G.P. 05/12/2022
Production Assistant Manager/ HOD	BAVASUBRAMANIAN. B	Balasubramanian 05/12/2022
QA Manager/ HOD	Ram Kumar	Ram Kumar 05/12/2022

15.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMR/T/331-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Suresh Kumar	W. S. S.	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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VALIDATION BATCH STABILITY BATCH	
SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 43, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	
Page 1 of 35	
BATCH MANUFACTURING RECORD Product	Product Code: L13 BMR. No.: BMRT/331-00 Customer:
LOLIP 20	Batch Size: 6,00,000 Tablets Batch No.: 41822106 Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING 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.
MFR No. / Reference Document No.	: MFR/T/186-00
BMR No.	: BMRT/331-00
REVISION No.	: 00
SUPERSEDES No.	: NIL
BMR EFFECTIVE BATCH NUMBER/DATE	: 61822106 / 02/06/2022
MFG.LIC No.	: PON/DRUGS/21 14 4376
STORAGE	: Store in cool and dry place. Protect from light and moisture.
BMR ISSUED BY/DATE (QA)	: <i>[Signature]</i> 06/07/2022
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	: <i>[Signature]</i> 06/07/2022
SHELF LIFE	: 36 Months
BATCH SIZE	: 6,00,000 Tablets (117.000 Kg)
MFG. DATE: 07/2022	EXP. DATE: 06/2025

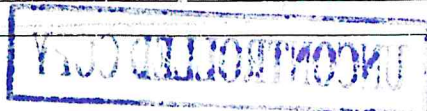
RECOVERY ADDITION RECORD

BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE

ALLOTTED BY: QA SIGN/DATE: <i>[Signature]</i> 06/07/2022	COUNTER CHECKED BY: QA SIGN/DATE: <i>[Signature]</i> 06/07/2022
DATE OF COMMENCEMENT: 07/07/2022	DATE OF COMPLETION: 15/07/2022
RELEASED QUANTITY OF TABLETS FOR PACKING : 595781 Nos	
RELEASE FOR PACKING STAGE HEAD OF QA SIGN/DATE: <i>[Signature]</i> 02/06/2022	

This BMR contains 35 Pages + 03 Additional Pages

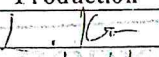
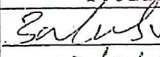
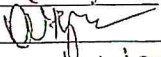
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022



 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 35
	BATCH MANUFACTURING RECORD	Product Code: L13	Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00	Batch No.: G1822106
		Customer:	Generic Health Care Pvt. Ltd.

1.0 INDEX

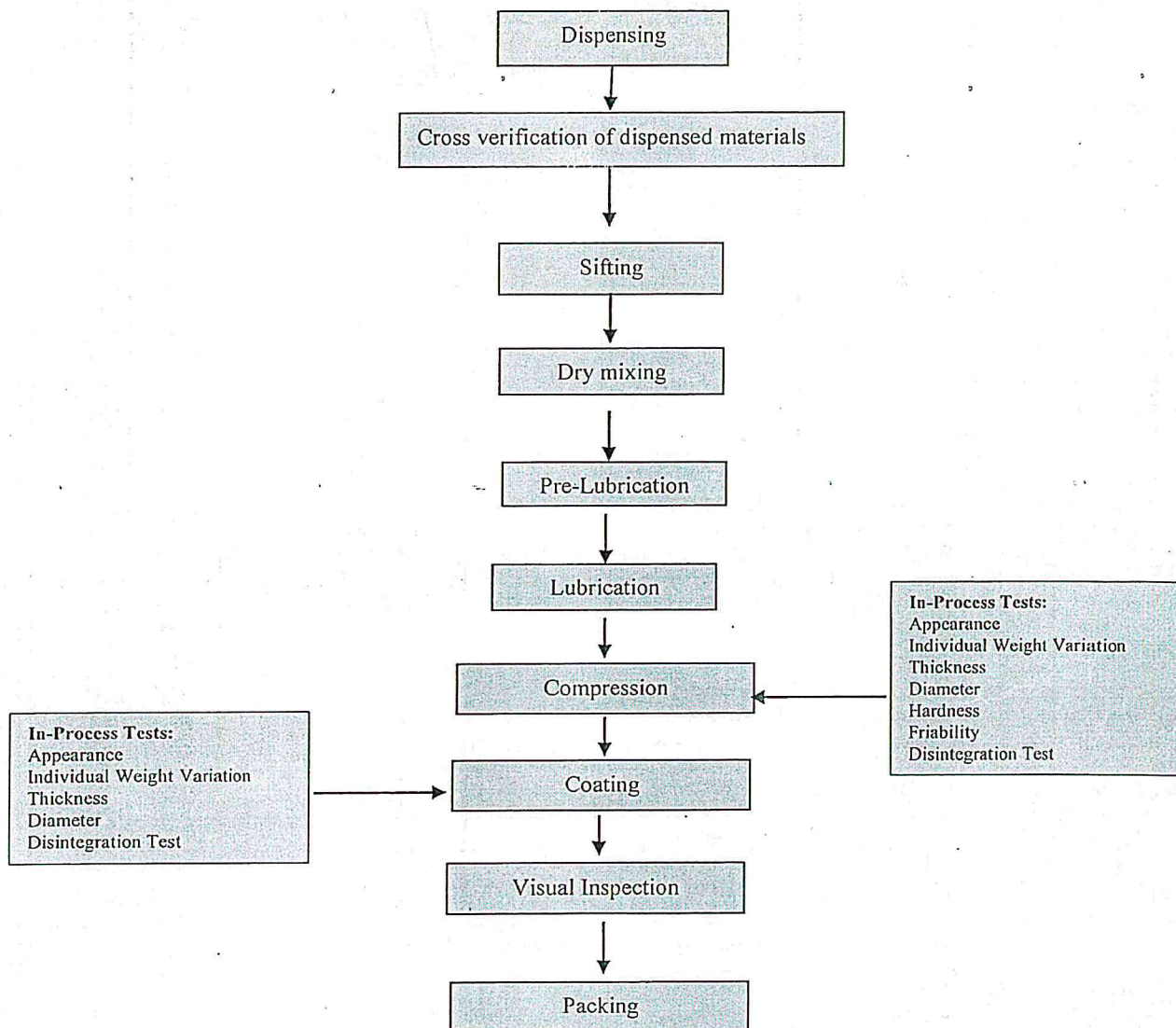
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 35
	BATCH MANUFACTURING RECORD	Product Code: L13	Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00	Batch No.: 31822106
		Customer:	Generic Health Care Pvt. Ltd.

2.0 PROCESS FLOW CHART



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	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 35
	BATCH MANUFACTURING RECORD	Product Code: L13	Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: <u>41822106</u> Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 6,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 6,00,000 tablets (kg)
Lubrication material:							
1	Atorvastatin Calcium (Micronized)	USP	RAI/SP/A016	22.000 [#]	13.200 [#]	6.15	13.200 [#]
2	Microcrystalline cellulose PH102	BP	REX/SP/M010	49.110	29.466	-	29.466
3	Calcium Carbonate	BP	RAI/SP/C005	0.950	0.570	-	0.570
4	Lactose DCL 11	BP	REX/SP/L004	105.950	63.570	-	63.570
5	Croscarmellose Sodium	BP	REX/SP/C008	6.300	3.780	-	3.780
6	Colloidal Silicon Dioxide	BP	REX/SP/C022	2.850	1.710	-	1.710
7	Purified Talc	BP	REX/SP/P017	1.900	1.140	-	1.140
8	Magnesium Stearate	BP	REX/SP/M011	0.950	0.570	-	0.570
Theoretical Weight of the Lubricated granules				190.000	114.000	-	114.000
Theoretical weight of Compressed tablet				190.000	114.000	-	114.000
Coating Material:							
9	Wincoat WT White 02022	IHS	REX/SP/W001	4.750	2.850	25	3.563 [#]
10	Yellow oxide of Iron	IHS	REX/SP/I004	0.050	0.030	25	0.038 [#]
11	Tween 80	BP	REX/SP/P014	0.200	0.120	25	0.150 [#]
12	Isopropyl Alcohol	BP	REX/SP/I005	q.s.	21.000	-	21.000
13	Purified Water	BP	NA	q.s.	30.000	-	30.000
Theoretical weight of Coated tablet				195.000	117.000	-	117.000

NOTE: *API quantity shall be calculated based on potency.

**Excess Quantity shall be compensating from Microcrystalline cellulose PH 102.

Inclusive of overages

OA: Overages, PL: Process loss

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. Ke</i>	<i>30/06/2022</i>	<i>02/06/2022</i>	<i>02/06/2022</i>
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 5 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 01822106 Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR ATORVASTATIN CALCIUM:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Atorvastatin Calcium: 13.200 Kg (A)

Standard quantity of Microcrystalline cellulose PH 102 (B): 29.466 Kg

Calculation for Atorvastatin Calcium:

1) Calculation for Single A. R. No. 2167/00009, Assay on dried basis: 99.69 w/w, LOD: 5.07 w/w
 Exp. Date.....07/07/2022

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{13.200 \times 100 \times 100}{99.69 \times (100 - 5.07)} = 13.948 \text{ Kg}$$

2) Calculation for Microcrystalline cellulose PH 102 (B):

Actual Quantity (Kg) (D) = Standard quantity of Microcrystalline cellulose PH 102 - Excess Calculated quantity of Atorvastatin Calcium

$$= 29.466 \text{ Kg} - 0.748 \text{ Kg}$$

$$= 28.718 \text{ Kg}$$

3) Calculation for Atorvastatin Calcium Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (E)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
Total Actual Quantity (F)					

Calculation for Remaining Quantity Required (G):

Theoretical Qty. - Actual Quantity (F) = _____ Kg

AR. No.: _____, Assay on dried basis: _____ w/w, LOD: _____ %w/w, Exp. Date-----

$$\text{Actual Quantity (Kg) (H)} = \frac{\text{Remaining qty. required (G)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{X \times 100 \times 100}{X(100 -)} = \text{_____ Kg}$$

Total Qty. of Atorvastatin Calcium to be dispensed (I) = (E) + (H) = _____ Kg

4) Calculation for Microcrystalline cellulose PH 102 (B):

Actual Quantity (Kg) (J) = Standard quantity of Microcrystalline cellulose PH 102 - Excess Calculated quantity of Atorvastatin Calcium

$$= 29.466 \text{ Kg} - \text{_____ Kg}$$

$$= \text{_____ Kg}$$

Done By/On (QA):

Checked By/On (Production):

Prepared by:		Checked by:		Approved By:
Dept:	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>Scalathur</u>	<u>W. K.</u>	<u>W. K.</u>
Date	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 6 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: C1822106 Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 07/07/2022 Time: 10:30

Sr. No.	Checks	Observation*	
		Store	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags, documents and scrap from waste bin of previous batch/product are removed from the area.	/	✓
2	Check and ensure that display stand and weighing balance are clean.	/	✓
3	Check and ensure that SS scoop, SS spatula and 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 dispensing booth is clean	/	✓
7	Check all the gauges of dispensing booth 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	Dispensing Booth	Weighing Balance			Area
ID No.	ST1 DPB105	ST1 BAL1004	ST1 BAL1005	ST1 BAL1006	Dispensing Booth-IP
Previous Product	Lolip 10				
B. No.	C1822105				
Cleaned by Sign/Date	Sandra / 07/07/2022				
Checked by Store Sign/Date	J. Dhand / 07/07/2022				
Verified by IPQA Sign/Date	P. G. G. / 07/07/2022				

ENVIRONMENTAL CONDITIONS: Date: 07/07/2022 Time: 10:30	Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)			
Temperature (Limit: NMT 25°C)	24°C	J.A. 07/07/2022	P.G.G. 07/07/2022
Relative Humidity % (Limit: NMT 60%)	57.1	J.A. 07/07/2022	P.G.G. 07/07/2022
Differential Pressure (NLT 10 Pascal)	12	J.A. 07/07/2022	P.G.G. 07/07/2022
Differential Pressure across the booth Limit: 5 to 20 mm Water	14mm	J.A. 07/07/2022	P.G.G. 07/07/2022

APPROVAL FOR DISPENSING BY IPQA: Sign: P. G. G. Date: 07/07/2022

Dispensing start Time 10:45 End Time 11:30

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K.</u>	<u>S. K.</u>	<u>V. K.</u>	<u>V. K.</u>
Date	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 7 of 35	
	BATCH MANUFACTURING RECORD		Product Code: L13	Batch Size: 6,00,000 Tablets
Product LOLIP 20	BMR. No.: BMR/T/331-00		Batch No.: 511822106	Generic Health Care Pvt. Ltd.

5.1 Dispensing Weighing Sheet:

Balance ID: ST 1000, Shift: Night, Date: 02/06/2022, Time: 10:45

Sl. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R. No.	Issued Qty.		Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Tare Wt.			Net Wt.	Checked Production (Sign & Date)
Lubrication material:													
1	Atorvastatin Calcium (Micronized)	USP	RAI/SP/A016	Kg	13.200	13.948	Rm/1000009	14.208	0.264	13.948	J.A.1 07/07/2022	08/07/22	08/07/22
2	Microcrystalline cellulose PH102	BP	REX/SP/M010	Kg	29.466	29.718	Rm/10002450	29.918	0.200	28.718	J.A.1 07/07/2022	08/07/22	08/07/22
3	Calcium Carbonate	BP	RAI/SP/C005	Kg	0.570	0.570	Rm/100189	610.00	40.00	570.00	J.A.1 07/07/2022	08/07/22	08/07/22
4	Lactose DCL 11	BP	REX/SP/L004	Kg	63.570	63.570	Rm/100243	63.780	0.210	63.570	J.A.1 07/07/2022	08/07/22	08/07/22
5	Croscarmellose Sodium	BP	REX/SP/C008	Kg	3.780	3.780	Rm/100220	3.860	0.080	3.780	J.A.1 07/07/2022	08/07/22	08/07/22
6	Colloidal Silicon Dioxide	BP	REX/SP/C022	Kg	1.710	1.710	Rm/100032	1.880	0.170	1.710	J.A.1 07/07/2022	08/07/22	08/07/22
7	Purified Talc	BP	REX/SP/P017	Kg	1.140	1.140	Rm/100140	1180.00	40.00	1140.00	J.A.1 07/07/2022	08/07/22	08/07/22
8	Magnesium Stearate	BP	REX/SP/M011	Kg	0.570	0.570	Rm/100224	610.00	40.00	570.00	J.A.1 07/07/2022	08/07/22	08/07/22
Coating Material:													
9	Wincoat WT White 02022	IHS	REX/SP/W001	Kg	3.563	3.563	Rm/1000084	3.643	0.080	3.563	J.A.1 07/07/2022	08/07/22	08/07/22
10	Yellow oxide of Iron	IHS	REX/SP/I004	Kg	0.038	0.038	Rm/100051	46.00	8.00	38.00	J.A.1 07/07/2022	08/07/22	08/07/22
11	Tween 80	BP	REX/SP/P014	Kg	0.150	0.150	Rm/100113	162.00	12.00	150.00	J.A.1 07/07/2022	08/07/22	08/07/22
12	Isopropyl Alcohol	BP	REX/SP/I005	Kg	21.000	21.000	Rm/100072	23.000	2.000	21.000	J.A.1 07/07/2022	08/07/22	08/07/22
13	Purified Water	BP	NA	Kg	30.000	30.000	P/27/04/19	2.500	2.000	0.500	N/A	08/07/22	08/07/22

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L.K.	Production	Quality Assurance		
Date	02/06/2022	02/06/2022	02/06/2022		

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: 41822106

Customer:

Generic Health Care Pvt. Ltd.

6.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 08/07/22 - G1 / 09/07/22 / G1 /

Sr. No.	Checks	Time	*Observations					
			18:55		09:35			
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.		✓	✓	✓	✓		
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓	✓	✓		
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓	✓	✓		
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓	✓	✓		
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓	✓	✓		
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓	✓	✓		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓	✓	✓		
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓	✓	✓		
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓	✓	✓		
10	Check and ensure that environment condition and record on BMR		✓	✓	✓	✓		
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		✓	✓	NA	NA		
12	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	Shifter	Blender	Area
EQP. ID No.	PD/VBE/001	PD/OCB/001	Granulation-I
Previous Product	Vofel - Myo		
Batch No.	FV0122046		
Cleaned by	Rajan		
Checked by	G.P.		
Verified by	G.P.		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 08/07/22 Time: 19:00			Date: 09/07/22 Time: 09:35			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	G.P.	G.P.	22°C	G.P.	G.P.			
RH % (NMT 60%)	52%	G.P.	G.P.	50%	G.P.	G.P.			
DP (NLT 10 Pascal)	10	G.P.	G.P.	11	G.P.	G.P.			

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	G.P. 08/07/22	G.P. 09/07/22	
IPQA Sign/Date:	G.P. 08/07/22	G.P. 09/07/22	
Start and End Time:	19:02	19:29	09:36 16:10

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	Sulabhy	100%	
Date	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G11829106 Generic Health Care Pvt. Ltd.

6.1 LUBRICATION MATERIAL SIFTING RECORD: Date: 08/07/22 Shift: 07/07/22 / 09/07/22 / 09

S. No	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by	Vfd by
						From	To				
Dry mixing:											
1	Atorvastatin Calcium	13.948	80#	PD/30-SE-80/05	OK/ Not OK	09:36	14:50	OK/ Not OK	Praveen	MP	G.P
2	Microcrystalline cellulose PH102	28.718	40#	PD/20-SE-40/06	OK/ Not OK	14:52	18:30	OK/ Not OK	Praveen	MP	G.P
3	Calcium Carbonate	0.570	60#	PD/30-SE-60/05	OK/ Not OK	19:02	19:03	OK/ Not OK	Vickey	MP	G.P
4	Lactose DCL 11	63.570	60#			19:03	19:19		Vickey	MP	G.P
5	Croscarmellose Sodium	3.780	60#			19:20	19:23		Vickey	MP	G.P
6	Colloidal Silicon Dioxide	1.710	30#	PD/30-SE-30/09	OK/ Not OK	19:23	19:25	OK/ Not OK	Vickey	MP	G.P
7	Purified Talc	1.140	80#	PD/30-SE-80/05	OK/ Not OK	19:25	19:26	OK/ Not OK	Vickey	MP	G.P
8	Magnesium stearate	0.570				19:27	19:29		Vickey	MP	G.P

6.2 BLENDING AND LUBRICATION PROCESS:

Date: 09/07/22 Shift: 07/07/22 / 09/07/22 / 09

Step No.	Process Instructions	Time		Done by	Ckd by	Verified by IPQA
		Started	Completed			
1	Use hand gloves and goggles while handling the materials.					
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.					
Pre-Lubrication:						
1	Load the sifted materials from step 6.1 (1,6) into the blender and mix for 15 minutes at 10 RPM.	15:35	15:50	Praveen	MP	G.P
Lubrication:						
2	Load the Sifted Purified Talc and Magnesium Stearate into the above Pre-lubricated blend and mix for further 5 minutes at 10 RPM.	15:52 15:55	15:53 15:56	Praveen	MP	G.P
3	Unload the lubricated blend in HDPE container having double lined polybag.	15:59 16:05	16:00 16:10	Praveen	MP	G.P

6.3 WEIGHING OF FINAL BLEND:

Balance I.D. No.: PD/1.BAS.1002

Date: 09/07/22 Shift: 07/07/22 / 09/07/22 / 09 Time: 16:15

Sr. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	29.010	1.900	27.110	Praveen	MP	G.P
2	29.140	1.900	27.240	Praveen	MP	G.P
3	29.600	1.880	27.720	Praveen	MP	G.P
4	33.940	2.580	31.360	Praveen	MP	G.P
5						
6						
7						
Total:			113.430			

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. B.</u>	<u>Praveen</u>	<u>Praveen</u>	<u>Praveen</u>	
Date	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	

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	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 10 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product LOLIP 20	BMR. No.: BMRT/331-00 Customer:		Batch No.: 61822106 Generic Health Care Pvt. Ltd.

6.4 RECONCILIATION:

1.0	Theoretical weight of blend	:	114.000 Kg
2.0	Actual Weight of blend	:	113.430 Kg
3.0	Manufacturing Loss (Blending stage) @	:	0.390 Kg
4.0	In-process samples		
	A IPQC Samples	:	0.04 Kg.
	B QC Samples	:	0.150 Kg.
	C Validation Samples	:	0.030 Kg.
5.0	Total samples: (A + B + C)	:	0.180 Kg
6.0	Total: (2.0 + 5.0)	:	113.610 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.65 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 0.390 Kg. (Rejected materials shall be destroyed as per SOP: QAGN/048).

Recovery Addition Quantity in Kg: 0.00 (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: [Signature] / 09/07/22 Checked By IPQA sign/Date: [Signature] / 09/07/22

Test request form raised by Prod Sign/Date: [Signature] / 09/07/22

Test request form received by IPQA Sign/Date: [Signature] / 09/07/22

6.5 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: [Signature] Date: 09/07/22

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	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 11 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822106 Generic Health Care Pvt. Ltd.

7.0 COMPRESSION LINE CLEARANCE CHECKS:

Date: 12/07/2022 / 13/07/2022

Sr. No.	Checks	Time:	*Observations					
			09:35		09:15			
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		/	/	/	/		
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		/	/	/	/		
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		/	/	/	/		
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		/	/	/	/		
5	Check and ensure that working desk, analytical balance and other accessories are clean.		/	/	/	/		
6	Check and ensure that Deduster and hosepipe are clean.		/	/	/	/		
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		/	/	/	/		
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		/	/	/	/		
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		/	/	/	/		
10	Check and ensure that environmental conditions are recorded in the BMR.		/	/	/	/		
11	Area, equipment and preventive maintenance status board is updated.		/	/	/	/		
12	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR		/	/	NA	NA		
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		/	/	/	/		

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

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD1 Com/003	PD1 Deb/005	Compression -03
Previous Product	lolip-10		
Batch No.	G1822105		
Cleaned by	Pxm		
Checked by	DK 12/07/2022		
Verified by	Qs 12/07/2022		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 12/07/22 Time: 09:40			Date: 13/07/22 Time: 09:20			Date: Time:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	DK	Qs	22°C	R-ell	P			
RH % (NMT 60%)	52%	DK	Qs	50%	R-ell	P			
DP (NLT 10 Pascal)	10 pascal	DK	Qs	11 pascal	R-ell	P			

APPROVAL FOR COMPRESSION:

Production Sign/Date:	DK 12/07/2022	R-ell 13/07/2022	
IPQA Sign/Date:	Qs 12/07/2022	P 13/07/2022	
Start and End Time:	10:10	17:51	09:26 16:45

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Salub...	DDK...	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 12 of 35
	BATCH MANUFACTURING RECORD	Product Code: L13	Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00	Batch No.: 71822106
		Customer:	Generic Health Care Pvt. Ltd.

8.0 COMPRESSION

8.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 8.00 mm Circular shaped standard concave with breakline on punches. b. Lower punches: 8.00 mm Circular shaped standard concave plain punches. c. Dies: 8.00 mm suitable for above punches. d. Type of tooling - D. DY 12/07/2022 Punch Issued by: sign./Date: _____ Checked and Received by Sign./Date: _____ Verified by Sign./Date: _____
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

8.2 GRANULES RECEIPT RECORD: Balance ID. No.: P01BAL015 Date: 12/07/2022 Shift: G Time: 09:45

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	29.010	AK	DK
2	29.140	AK	DK
3	29.600	AK	DK
4	32.940	AK	DK
5			
6			
7			
8			

8.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	20	Every 30 min.	Every 2 Hr.
2.	Average weight (mg)	190.000 mg $\pm$ 3.0 % (184.300 mg – 195.700 mg)	20		
3.	Group Weight	3.800 g $\pm$ 3.0 % (3.686 g to 3.914 g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)	20	Every 2 Hr.	Every 4 Hr.
5.	Hardness	NLT 3.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
6.	Thickness (mm)	3.70 $\pm$ 0.2 mm 3.50 mm – 3.90 mm (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Diameter (mm)	(7.80 mm – 8.2 mm) (To be established)	30	Initial	
8.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
9.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	32/06/2022	02/06/2022	
Date	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 13 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20		BMR. No.: BMR/T/331-00 Batch No.: 61822106 Customer: Generic Health Care Pvt. Ltd.

8.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	Total Hour	M/C Speed	Tablets Output	Done By	Checked By
12/07/22	G1	12:50	17:51	5 hours 39 min	15	285000	Praan	DM
13/07/2022	G1	09:26	16:45	8 hours 11 min	15	310736	Kesavan	R. S. S.
					NA			

Two
OK

8.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness & Diameter):

Balance I.D. No.: PD/BAL/009

Date: 12/07/2022 Shift: G1 Time: 11:39

LHS					RHS				
Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)	Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)
1	OK	187	3.46	8.05	1	OK	191	3.48	8.05
2	OK	187	3.45	8.04	2	OK	193	3.49	8.06
3	OK	187	3.48	8.06	3	OK	186	3.50	8.04
4	OK	187	3.49	8.04	4	OK	192	3.45	8.03
5	OK	187	3.46	8.03	5	OK	191	3.45	8.04
6	OK	186	3.49	8.02	6	OK	190	3.46	8.05
7	OK	186	3.48	8.05	7	OK	190	3.47	8.06
8	OK	188	3.47	8.04	8	OK	189	3.48	8.05
9	OK	188	3.45	8.06	9	OK	191	3.47	8.04
10	OK	187	3.49	8.05	10	OK	190	3.46	8.06
11	OK	186	3.48	8.05	11	OK	192	3.47	8.07
12	OK	188	3.45	8.06	12	OK	188	3.46	8.05
13	OK	189	3.46	8.05	13	OK	188	3.45	8.04
14	OK	187	3.45	8.04	14	OK	186	3.46	8.03
15	OK	186	3.47	8.06	15	OK	190	3.48	8.02
16	OK	186	3.45	8.05	16	OK	189	3.47	8.03
17	OK	188	3.46	8.07	17	OK	190	3.46	8.05
18	OK	189	3.47	8.05	18	OK	189	3.45	8.07
19	OK	187	3.48	8.06	19	OK	194	3.48	8.06
20	OK	188	3.47	8.05	20	OK	190	3.49	8.05
21	OK	186	3.46	8.04	21	OK	188	3.50	8.06
22	OK	187	3.45	8.03	22	OK	189	3.48	8.05
23	OK	186	3.48	8.06	23	OK	191	3.47	8.03
24	OK	189	3.47	8.05	24	OK	188	3.46	8.02
25	OK	189	3.46	8.04	25	OK	192	3.45	8.01
26	OK	189	3.48	8.06	26	OK	189	3.44	8.05
27	OK	186	3.47	8.07	27	OK	190	3.47	8.04
28	OK	189	3.48	8.06	28	OK	190	3.48	8.04
29	OK	188	3.46	8.03	29	OK	190	3.41	8.06
30	OK	188	3.45	8.04	30	OK	191	3.47	8.07

Note: * Write OK if complies and (X) if does not comply.

Done by Production Sign/Date... R. S. S. 12/07/2022

Checked by IPQA Sign/Date... G. S. S. 12/07/2022

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	J. K.	G. S. S.	G. S. S.	G. S. S.	
Date	02/06/2022	02/06/2022	02/06/2022		

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 14 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:		Batch No.: G1822106 Generic Health Care Pvt. Ltd.

8.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 12/07/2022 Shift: G1 Time: 11:57

Parameters	Instrument used	Equip ID No.	Observations of LHS				Observations of RHS				Limits
			Min		Max		Min		Max		
Appearance	Visual	NA	ok				ok				White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side
Group Weight	Electronic Balance	PD/BAL/009	3.744 g				3.799 g				3.800 g $\pm$ 3.0 % (3.686 g to 3.914 g)
Average weight	Electronic Balance		187.20 mg				189.95 mg				190.000 mg $\pm$ 3.0 % (184.300 mg – 195.700 mg)
Individual weight	Electronic Balance		186 mg	189 mg	186 mg	194 mg	190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)				
Uniformity of weight	Electronic Balance		-0.64 %	0.96 %	-2.07 %	2.13 %					
Thickness	Vernier Caliper	QA/VE/002	3.45 mm	3.49 mm	3.44 mm	3.50 mm	3.70 $\pm$ 0.2 mm 3.50 mm – 3.90 mm (To be established)				
Hardness	Hardness Tester	QA/HRT/002	8.5	8.0	8.5	8.0	8.5	8.0	8.5	8.0	NLT 3.0 Kg (To be established)
Friability	Friabilator	QA/FRT/002	0.14 %				0.18 %				NMT 1.0% w/w 002
DT	DT Apparatus	QA/DTA/001	00 mins 30 sec				00 min 35 sec				NMT 15 minutes
M/C set done by Operator Name: <u>Prasanna</u> M/C set up Checked by (Prod. Sign/Date): <u>R. S. S.</u> <u>12/07/2022</u>											
M/C Speed: <u>15</u> RPM (To be Established)											
Initial Setting Tablets Destroyed by: Sign: <u>R. S. S.</u> Date: <u>12/07/2022</u> Quantity in Kg.: <u>0.030</u> Quantity in No.: <u>130</u>											
Approval for Batch Compression by IPQA: Sign: <u>[Signature]</u> Date: <u>12/07/2022</u> Time: <u>12:03</u>											

* Thickness : 3.40 to 3.50 mm

12/07/2022

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>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>

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

Generic Health Care Pvt. Ltd.

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UNCONTROLLED CCFY



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

Generic Health Care Pvt. Ltd.

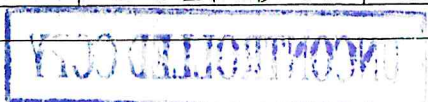
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 17 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMRT/331-00 Customer:	Batch No.: <u>G11B22106</u> Generic Health Care Pvt. Ltd.

8.9 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: <u>12/07/2022</u>		Time: <u>10:27</u>		Shift: <u>G1</u>																
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).																
1	190	8	190	15	191	1	189	8	191	15	188									
2	189	9	191	16	190	2	187	9	191	16	191									
3	191	10	189	17	188	3	190	10	193	17	190									
4	188	11	190	18	191	4	192	11	190	18	192									
5	189	12	192	19	190	5	191	12	188	19	190									
6	188	13	191	20	192	6	190	13	190	20	191									
7	192	14	188			7	189	14	189											
Balance ID No.: <u>PD1BAL1009</u>						M/C Speed: <u>10</u> RPM														
Group weight of 20 Tablets: <u>3.800</u>g. Avg. wt.: <u>190.00</u> ..mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. : <u>188</u> mg Max. weight: <u>192</u> mg						Group weight of 20 Tablets: <u>3.802</u>g. Avg. wt.: <u>190.10</u>mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. : <u>187</u> mg Max. weight: <u>193</u> mg														
						<table border="1"> <tr> <td>LHS</td> <td>RHS</td> <td></td> </tr> <tr> <td>Friability (Limit: NMT 1% after 4 minutes/100 rotations):</td> <td><u>0.16/.</u></td> <td><u>0.12/.</u></td> </tr> <tr> <td>Disintegration Time (Limit - NMT 15 minutes)</td> <td><u>00 min 40 sec</u></td> <td><u>00 min 44 sec</u></td> </tr> </table>						LHS	RHS		Friability (Limit: NMT 1% after 4 minutes/100 rotations):	<u>0.16/.</u>	<u>0.12/.</u>	Disintegration Time (Limit - NMT 15 minutes)	<u>00 min 40 sec</u>	<u>00 min 44 sec</u>
LHS	RHS																			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	<u>0.16/.</u>	<u>0.12/.</u>																		
Disintegration Time (Limit - NMT 15 minutes)	<u>00 min 40 sec</u>	<u>00 min 44 sec</u>																		
Done by: <u>R.sll</u>(Production)																				
Date: <u>12/07/2022</u>		Time: <u>12:15</u>		Shift: <u>G1</u>																
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).																
1	189	8	190	15	189	1	191	8	192	15	192									
2	187	9	189	16	191	2	190	9	190	16	191									
3	186	10	188	17	188	3	189	10	189	17	190									
4	189	11	190	18	190	4	192	11	192	18	190									
5	191	12	191	19	189	5	190	12	190	19	191									
6	190	13	189	20	190	6	190	13	191	20	192									
7	189	14	187			7	189	14	188											
Balance ID No.: <u>PD1BAL1009</u>						M/C Speed: <u>15</u> RPM														
Group weight of 20 Tablets: <u>3.781</u>g. Avg. wt.: <u>189.05</u> ..mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. : <u>186</u> mg Max. weight: <u>191</u> mg						Group weight of 20 Tablets: <u>3.809</u>g. Avg. wt.: <u>190.45</u>mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. : <u>189</u> mg Max. weight: <u>192</u> mg														
						<table border="1"> <tr> <td>LHS</td> <td>RHS</td> <td></td> </tr> <tr> <td>Friability (Limit: NMT 1% after 4 minutes/100 rotations):</td> <td><u>0.15/.</u></td> <td><u>0.12/.</u></td> </tr> <tr> <td>Disintegration Time (Limit - NMT 15 minutes)</td> <td><u>00 min 30 sec</u></td> <td><u>00 min 32 sec</u></td> </tr> </table>						LHS	RHS		Friability (Limit: NMT 1% after 4 minutes/100 rotations):	<u>0.15/.</u>	<u>0.12/.</u>	Disintegration Time (Limit - NMT 15 minutes)	<u>00 min 30 sec</u>	<u>00 min 32 sec</u>
LHS	RHS																			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	<u>0.15/.</u>	<u>0.12/.</u>																		
Disintegration Time (Limit - NMT 15 minutes)	<u>00 min 30 sec</u>	<u>00 min 32 sec</u>																		
Done by: <u>R.sll</u>(Production)																				

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. L.</u>	<u>B. S. S.</u>	<u>A. S.</u>	<u>R. S.</u>	
Date	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	



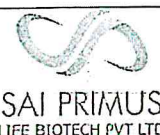
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13
	Product		Batch Size: 6,00,000 Tablets
LOLIP 20		BMR. No.: BMRT/331-00	Batch No.: 41822106
		Customer:	Generic Health Care Pvt. Ltd.

8.10 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 12/07/2022		Time: 14:20		Shift: G1							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	190	8	189	15	189	1	192	8	189	15	192
2	188	9	188	16	190	2	190	9	191	16	189
3	192	10	192	17	188	3	189	10	191	17	190
4	190	11	190	18	192	4	191	11	190	18	191
5	189	12	189	19	192	5	192	12	190	19	189
6	191	13	190	20	190	6	190	13	189	20	192
7	190	14	190			7	189	14	191		
Balance ID No.: PD/BAL/009						M/C Speed: 15 RPM					
Group weight of 20 Tablets: 3799g. Avg. wt: 189.95mg						Group weight of 20 Tablets: 3807g. Avg. wt: 190.35mg					
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)						Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)					
Min weight: 188mg Max. weight: 192mg						Min weight: 189mg Max. weight: 192mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.18%		0.17%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						00min 50sec		00min 46sec		Equipment ID No.: QA/DTA/001	
Done by: R.ull (Production)											
Date: 12/07/2022		Time: 16:22		Shift: G1							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	192	8	188	15	192	1	190	8	189	15	192
2	190	9	189	16	190	2	192	9	188	16	188
3	188	10	190	17	188	3	188	10	190	17	189
4	191	11	192	18	189	4	189	11	192	18	190
5	190	12	188	19	191	5	191	12	188	19	191
6	189	13	189	20	190	6	190	13	190	20	192
7	192	14	191			7	192	14	191		
Balance ID No.: PD/BAL/009						M/C Speed: 15 RPM					
Group weight of 20 Tablets: 3799g. Avg. wt: 189.95mg						Group weight of 20 Tablets: 3802g. Avg. wt: 190.10mg					
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)						Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)					
Min weight: 188mg Max. weight: 192mg						Min weight: 188mg Max. weight: 192mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.17%		0.18%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						00min 53sec		00min 47sec		Equipment ID No.: QA/DTA/001	
Done by: DK (Production)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	30/06/2022	02/06/2022		
Date	02/06/2022	02/06/2022	02/06/2022		

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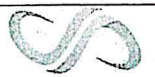
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 19 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13
	Product: LOLIP 20		Batch Size: 6,00,000 Tablets
		BMR. No.: BMRT/331-00	Batch No.: G1822106
		Customer:	Generic Health Care Pvt. Ltd.

8.11 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 12/07/2022		Time: 09:33		Shift: 67							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	188	8	191	15	190	1	187	8	191	15	191
2	190	9	190	16	188	2	191	9	189	16	190
3	189	10	189	17	192	3	188	10	190	17	191
4	191	11	190	18	190	4	192	11	189	18	189
5	190	12	189	19	190	5	190	12	188	19	190
6	189	13	190	20	189	6	190	13	190	20	191
7	190	14	191			7	189	14	189		
Balance ID No.: PD/BAL/009						M/C Speed: 15 RPM					
Group weight of 20 Tablets: 3796 g. Avg. wt: 189.8 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 188 mg Max. weight: 192 mg						Group weight of 20 Tablets: 3795 g. Avg. wt: 189.75 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 192 mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.12%		0.14%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						0 min 47 sec		0 min 45 sec		Equipment ID No.: QA/DTA/001	
Done by: R. S. (Production)											
Date: 13/07/2022		Time: 11:35		Shift: 67							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	189	8	190	15	188	1	190	8	188	15	191
2	192	9	192	16	189	2	192	9	190	16	192
3	188	10	190	17	190	3	188	10	192	17	187
4	190	11	189	18	192	4	190	11	190	18	189
5	191	12	191	19	188	5	192	12	191	19	190
6	188	13	192	20	190	6	189	13	188	20	188
7	187	14	190			7	187	14	189		
Balance ID No.: PD/BAL/009						M/C Speed: 15 RPM					
Group weight of 20 Tablets: 3796 g. Avg. wt: 189.8 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 192 mg						Group weight of 20 Tablets: 3793 g. Avg. wt: 189.65 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 192 mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.18%		0.17%		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						0 min 40 sec		0 min 53 sec		Equipment ID No.: QA/DTA/001	
Done by: D. K. (Production)											

Prepared by:		Checked by:		Approved By:	
Dept:	Production	Production	Quality Assurance	Head Quality Assurance	
Sign:	L. K.	S. A. S.	M. S.	R. S.	
Date:	02/06/2022	02/06/2022	02/06/2022	02/06/2022	

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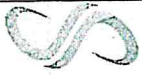
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 20 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product LOLIP 20	BMR. No.: BMR/T/331-00 Customer:		Batch No.: G1822106 Generic Health Care Pvt. Ltd.

8.12 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 13/07/2022		Time: 13:30		Shift: G1							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	189	8	188	15	190	1	188	8	192	15	191
2	191	9	192	16	189	2	187	9	190	16	189
3	192	10	190	17	188	3	192	10	193	17	192
4	190	11	189	18	192	4	191	11	187	18	190
5	188	12	192	19	190	5	192	12	192	19	189
6	192	13	190	20	190	6	190	13	190	20	191
7	190	14	189			7	187	14	189		
Balance ID No.: PD/RAL/007						M/C Speed: 15 RPM					
Group weight of 20 Tablets: 380.1 g. Avg. wt: 19.005 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 188 mg Max. weight: 192 mg						Group weight of 20 Tablets: 380.4 g. Avg. wt: 19.020 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 193 mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.21%		0.20%		Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)						00 min 48 sec		00 min 45 sec		Equipment ID No.: QA/DTA/ 001	
Done by: R. S. L. (Production)											
Date: 13/07/2022		Time: 15:31		Shift: G1							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	188	8	187	15	189	1	189	8	189	15	187
2	190	9	189	16	191	2	191	9	191	16	190
3	187	10	191	17	190	3	192	10	192	17	192
4	192	11	192	18	188	4	190	11	188	18	190
5	190	12	190	19	189	5	188	12	190	19	191
6	188	13	188	20	190	6	190	13	189	20	189
7	190	14	187			7	187	14	188		
Balance ID No.: PD/RAL/1009						M/C Speed: 15 RPM					
Group weight of 20 Tablets: 378.6 g. Avg. wt: 18.930 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 192 mg						Group weight of 20 Tablets: 379.3 g. Avg. wt: 18.965 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 192 mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.18%		0.19%		Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)						00 min 50 sec		00 min 43 sec		Equipment ID No.: QA/DTA/ 001	
Done by: DK. 13.07.2022 (Production)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	S. S. S.	M. H.	K. S.	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 21 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMRT/331-00 Customer:	Batch No.: G1822106 Generic Health Care Pvt. Ltd.

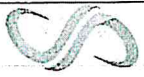
8.13 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: mg Max. weight: mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: mg Max. weight: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: mg Max. weight: mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: mg Max. weight: mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>Rajashree</i>	<i>Q.A.</i>	<i>Q.A.</i>
Date	02/06/2022	02/06/2022	02/06/2022	

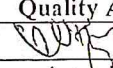
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 22 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822106 Generic Health Care Pvt. Ltd.

8.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 12/07/2022		Time: 10.55		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	189	8	191	15	188
2	190	9	189	16	189
3	188	10	188	17	190
4	191	11	190	18	189
5	187	12	191	19	191
6	189	13	187	20	190
7	190	14	189		
Balance ID No.: QA/RA/102			M/C Speed: 10 RPM		
Group weight of 20 Tablets: 3.786.....g. Avg. wt.: 189.30.....mg			Group weight of 20 Tablets: 3.779.....g. Avg. wt.: 188.95.....mg		
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)		
Min weight: 187.....mg Max. weight: 191.....mg			Min weight: 187.....mg Max. weight: 191.....mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.11%	0.10%	Equipment ID No.: QA/FRT/ 002
Disintegration Time (Limit - NMT 15 minutes)			00 min 40 sec	00 min 40 sec	Equipment ID No.: QA/DTA/ 001
Done by: (IPQA)					
Date: 12/07/2022		Time: 12.24		Shift: G	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	188	8	190	15	190
2	190	9	188	16	189
3	191	10	187	17	188
4	190	11	189	18	191
5	189	12	190	19	189
6	188	13	188	20	188
7	189	14	187		
Balance ID No.: QA/RA/102			M/C Speed: 10 RPM		
Group weight of 20 Tablets: 3.779.....g. Avg. wt.: 188.95.....mg			Group weight of 20 Tablets: 3.785.....g. Avg. wt.: 189.25.....mg		
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)		
Min weight: 187.....mg Max. weight: 191.....mg			Min weight: 187.....mg Max. weight: 191.....mg		
			LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			0.10%	0.12%	Equipment ID No.: QA/FRT/ 002
Disintegration Time (Limit - NMT 15 minutes)			00 min 48 sec	00 min 57 sec	Equipment ID No.: QA/DTA/ 001
Done by: (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822106 Generic Health Care Pvt. Ltd.

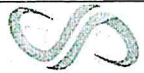
8.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: <u>12/04/2022</u>		Time: <u>12.28</u>		Shift: <u>'G' 'H' Rm</u>							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	190	8	189	15	187	1	188	8	190	15	191
2	191	9	188	16	189	2	189	9	189	16	187
3	189	10	190	17	188	3	190	10	190	17	189
4	191	11	191	18	190	4	191	11	191	18	190
5	188	12	189	19	189	5	190	12	188	19	189
6	187	13	188	20	187	6	187	13	189	20	188
7	190	14	190			7	188	14	190		
Balance ID No.: <u>QA/BAL/002</u>						M/C Speed: <u>20</u> RPM					
Group weight of 20 Tablets: <u>3781</u>g. Avg. wt: <u>189.05</u>mg						Group weight of 20 Tablets: <u>3784</u>g. Avg. wt: <u>189.2</u>mg					
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)						Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)					
Min weight: <u>187</u>mg Max. weight: <u>191</u>mg						Min weight: <u>187</u>mg Max. weight: <u>191</u>mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						LHS		RHS		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						Down 50 sec		Down 52 sec		Equipment ID No.: QA/DTA/001	
Done by: <u>GS</u>(IPQA)											
Date: <u>12/04/2022</u>		Time: <u>12.39</u>		Shift: <u>'G' 'H' HARDNESS</u>							
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	190	8	189	15	189	1	190	8	187	15	190
2	188	9	190	16	188	2	189	9	189	16	189
3	189	10	191	17	190	3	187	10	190	17	190
4	187	11	188	18	191	4	191	11	188	18	191
5	191	12	187	19	187	5	189	12	187	19	189
6	190	13	190	20	190	6	188	13	189	20	190
7	188	14	191			7	189	14	188		
Balance ID No.: <u>QA/BAL/002</u>						M/C Speed: <u>10</u> RPM					
Group weight of 20 Tablets: <u>3784</u>g. Avg. wt: <u>189.20</u>mg						Group weight of 20 Tablets: <u>3780</u>g. Avg. wt: <u>189.00</u>mg					
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)						Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)					
Min weight: <u>187</u>mg Max. weight: <u>191</u>mg						Min weight: <u>187</u>mg Max. weight: <u>191</u>mg					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						LHS		RHS		Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)						Down 48 sec		Down 45 sec		Equipment ID No.: QA/DTA/001	
Done by: <u>GS</u>(IPQA)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L. P.</u>	<u>S. S. S.</u>	<u>Q. A. S.</u>	<u>H. Q. S.</u>	
Date	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	

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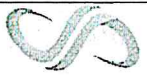
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 24 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 41822106 Generic Health Care Pvt. Ltd.

8.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 12/07/2022		Time: 12.41		Shift: G1 1st HARBNESS			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	189	8	188	15	189	1	188
2	190	9	190	16	196	2	190
3	191	10	191	17	191	3	191
4	188	11	187	18	188	4	187
5	187	12	189	19	189	5	189
6	190	13	190	20	190	6	190
7	189	14	188			7	191
Balance ID No.: QA/BAL/002				M/C Speed: 60 RPM			
Group weight of 20 Tablets: 3787.....g. Avg. wt: 189.35...mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187.....mg Max. weight: 191.....mg				Group weight of 20 Tablets: 3782.....g. Avg. wt: 189.10...mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187.....mg Max. weight: 191.....mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.10%		0.11%	
Disintegration Time (Limit - NMT 15 minutes)				00min 45sec		00min 52sec	
Equipment ID No.: QA/FRT/002				Equipment ID No.: QA/DTA/001			
Done by: G13.....(IPQA)							
Date: 12/07/22		Time: 13.10		Shift: G1 1st HARBNESS			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	188	8	191	15	188	1	189
2	189	9	187	16	189	2	188
3	190	10	188	17	190	3	187
4	191	11	189	18	191	4	189
5	189	12	190	19	189	5	187
6	188	13	191	20	187	6	190
7	190	14	189			7	189
Balance ID No.: QA/BAL/002				M/C Speed: RPM			
Group weight of 20 Tablets: 3787.....g. Avg. wt: 189.35...mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187.....mg Max. weight: 191.....mg				Group weight of 20 Tablets: 3781.....g. Avg. wt: 189.05...mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187.....mg Max. weight: 191.....mg			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				0.11%		0.12%	
Disintegration Time (Limit - NMT 15 minutes)				00min 45sec		00min 52sec	
Equipment ID No.: QA/FRT/002				Equipment ID No.: QA/DTA/001			
Done by: G13.....(IPQA)							

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. K.	30/07/2022	02/06/2022		
Date	02/06/2022	02/06/2022	02/06/2022		

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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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

BMR. No.: BMRT/331-00

Batch No.: 611822106 (A)

Customer:

Generic Health Care Pvt. Ltd.

8.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): MAIDLE HOPPER

Date: 13/07/2022

Time: 11:53

Shift: 9

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	189	8	188	15	191
2	190	9	189	16	187
3	191	10	190	17	189
4	188	11	191	18	190
5	187	12	189	19	188
6	190	13	188	20	189
7	191	14	190		

1	190	8	189	15	189
2	188	9	190	16	188
3	189	10	191	17	187
4	190	11	188	18	190
5	191	12	187	19	189
6	189	13	190	20	188
7	188	14	191		

Balance ID No.: QA/BAL/02

M/C Speed: 15 RPM

Group weight of 20 Tablets: 3.785.....g. Avg.
wt: 189.25...mg

Group weight of 20 Tablets: 3.782.....g. Avg.
wt: 189.10...mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 187..... mg Max. weight: 191..... mg

Min weight: 187..... mg Max. weight: 191..... mg

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

LHS: 0.12 % RHS: 0.11 %

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

LHS: 00 min 50 sec RHS: 00 min 47 sec

Equipment ID No.: QA/DTA/001

Done by: G.S. Bhatnagar.....(IPQA)

Composite Hopper

Date: 13/07/2022

Time: 15:55:15

Shift: 9

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	188	8	189	15	190
2	190	9	188	16	191
3	191	10	190	17	189
4	189	11	191	18	188
5	188	12	189	19	187
6	190	13	187	20	190
7	191	14	189		

1	189	8	190	15	189
2	188	9	189	16	188
3	190	10	187	17	190
4	191	11	189	18	189
5	187	12	188	19	188
6	189	13	189	20	191
7	188	14	190		

Balance ID No.: QA/BAL/02

M/C Speed: 15 RPM

Group weight of 20 Tablets: 3.784.....g. Avg.
wt: 189.20...mg

Group weight of 20 Tablets: 3.779.....g. Avg.
wt: 188.95...mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 187..... mg Max. weight: 191..... mg

Min weight: 187..... mg Max. weight: 191..... mg

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

LHS: 0.11 % RHS: 0.13 %

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

LHS: 00 min 50 sec RHS: 00 min 49 sec

Equipment ID No.: QA/DTA/001

Done by: G.S. Bhatnagar.....(IPQA)

Prepared by:

Checked by:

Approved By:

Dept. Production

Production

Quality Assurance

Head Quality Assurance

Sign. L. K.

G.S. Bhatnagar

[Signature]

[Signature]

Date 02/06/2022

02/06/2022

02/06/2022

02/06/22

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 25 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product LOLIP 20	BMR. No.: BMR/T/331-00 Customer:		Batch No.: 618 22 106(B) Generic Health Care Pvt. Ltd.

8.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours): Composite

Date: 12/07/2022		Time: 16:45		Shift: 6	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	190	8	187	15	188
2	189	9	189	16	189
3	187	10	188	17	190
4	188	11	190	18	191
5	190	12	191	19	189
6	189	13	190	20	188
7	191	14	189		
Balance ID No.: QA/BAL/002			M/C Speed: 15 RPM		
Group weight of 20 Tablets: 3783 g. Avg. wt: 189.15 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 191 mg			Group weight of 20 Tablets: 3782 g. Avg. wt: 189.10 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 191 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS: 0.154	RHS: 0.124	Equipment ID No.: QA/FRT/ 002
Disintegration Time (Limit - NMT 15 minutes)			comin 47Sec	comin 48Sec	Equipment ID No.: QA/DTA/ 001
Done by: [Signature] (IPQA)					
Date:		Time:		Shift:	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1		8		15	
2		9		16	
3		10		17	
4		11		18	
5		12		19	
6		13		20	
7		14			
Balance ID No.:			M/C Speed: RPM		
Group weight of 20 Tablets: g. Avg. wt: mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: mg Max. weight: mg			Group weight of 20 Tablets: g. Avg. wt: mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: mg Max. weight: mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/
Disintegration Time (Limit - NMT 15 minutes)					Equipment ID No.: QA/DTA/
Done by: (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	[Signature]	[Signature]	[Signature]	[Signature]
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022



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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 25 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMRT/331-00 Customer:	Batch No.: <u>61822106</u> Generic Health Care Pvt. Ltd.

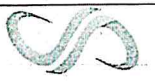
8.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: <u>12/07/2022</u>						Time: <u>17:10</u>						Shift: <u>9</u>																					
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																					
1	190	8	191	15	189	1	189	8	190	15	191	2	189	9	189	2	188	9	189	16	189	3	188	10	187	3	190	10	188	3	188	17	188
2	189	9	189	16	190	4	191	11	191	18	189	4	191	11	191	4	187	11	190	18	189	5	189	12	188	5	189	12	189	5	189	19	190
3	188	10	187	17	188	6	187	13	189	20	191	6	188	13	188	6	188	13	188	20	188	7	190	14	190	7	189	14	190	7	189	14	190
Balance ID No.: <u>QA/RAL/002</u>												M/C Speed: <u>15</u> RPM																					
Group weight of 20 Tablets: <u>3782</u> g. Avg. wt: <u>189.10</u> mg												Group weight of 20 Tablets: <u>3784</u> g. Avg. wt: <u>189.20</u> mg																					
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)												Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)																					
Min weight: <u>187</u> mg Max. weight: <u>191</u> mg												Min weight: <u>188</u> mg Max. weight: <u>191</u> mg																					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												Equipment ID No.: QA/FRT/002																					
Disintegration Time (Limit - NMT 15 minutes)												Equipment ID No.: QA/DTA/001																					
Done by: <u>[Signature]</u> (IPQA)																																	
Date: <u>13/07/2022</u>						Time: <u>09:48</u>						Shift: <u>9</u>																					
LHS: Individual weight of 20 tablets (in mg).												RHS: Individual weight of 20 tablets (in mg).																					
1	189	8	187	15	190	1	189	8	187	15	191	2	190	9	189	2	190	9	189	16	192	3	188	10	188	3	188	10	188	3	188	17	190
2	188	9	188	16	187	4	187	11	190	18	189	4	187	11	190	4	187	11	190	18	189	5	189	12	191	5	189	12	191	5	189	19	191
3	190	10	190	17	188	6	187	13	188	20	187	6	190	13	190	6	190	13	190	20	188	7	189	14	189	7	188	14	189	7	188	14	189
Balance ID No.: <u>QA/RAL/002</u>												M/C Speed: <u>15</u> RPM																					
Group weight of 20 Tablets: <u>3774</u> g. Avg. wt: <u>188.70</u> mg												Group weight of 20 Tablets: <u>3784</u> g. Avg. wt: <u>189.20</u> mg																					
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)												Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)																					
Min weight: <u>187</u> mg Max. weight: <u>191</u> mg												Min weight: <u>187</u> mg Max. weight: <u>192</u> mg																					
Friability (Limit: NMT 1% after 4 minutes/100 rotations):												Equipment ID No.: QA/FRT/002																					
Disintegration Time (Limit - NMT 15 minutes)												Equipment ID No.: QA/DTA/001																					
Done by: <u>[Signature]</u> (IPQA)																																	

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>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 26 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 61822106 Generic Health Care Pvt. Ltd.

8.18 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	30.530	1.900	28.630	Kesavan	R.sll	Q/s
2	30.290	1.830	28.460	Kesavan	R.sll	Q/s
3	30.230	1.900	28.330	Kesavan	R.sll	Q/s
4	30.460	2.690	27.770	Kesavan	R.sll	Q/s
5						
6						
7						
8						
9						
10						

8.19 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: ...190.mg

1.0	Standard Batch size	:	114.000 Kg.	6,00,000 No.
2.0	Actual weight of Lubricated granules	:	113.430 Kg.	597000 Nos.
3.0	Weight of compressed tablets	:	113.190 Kg.	595736 Nos.
4.0	Rejection during Compression @	:	0.030 Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	: 0.140 Kg.	
	B	QC Samples	: 0.020 Kg.	
	C	Validation Samples	: 0.070 Kg.	
6.0	Total in process samples: (A + B + C)	:	0.160 Kg.	
7.0	Total: (3.0 + 6.0)	:	113.350 Kg.	596578 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		99.42 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: ...0.050... Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: ...R.sll/13/06/2022... Checked by IPQA Sign/Date: ...Q/s/13/06/2022...

Test request form raised by Prod Sign/Date: ...R.sll/13/06/2022...

Test request form received by IPQA Sign/Date: ...Q/s/13/06/2022...

8.20 RELEASED FOR COATING:

Reconciliation checked and compressed tablets released for coating:

IPQA Sign: ...Q/s... Date: 14/06/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L.K.	[Signature]	[Signature]	[Signature]
Date	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 27 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:		Batch No.: G1822106 Generic Health Care Pvt. Ltd.

9.0 LINE CLEARANCE FOR COATING SOLUTION PREPARATION:

Date/Shift/Time: 14/07/2022 / 6.1.09.55

Sr. No.	Checks	*Observation			
		Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	/	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	/	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	/	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	/	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	/	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	/	✓		
7	Check and ensure that instruments to be used are within calibration due date.	/	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	/	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	/	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	/	✓		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	/	✓		

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

Equipment	Solution preparation vessel and stirrer	Colloidal Mill	Area
Equipment ID No.	NA	PD/C/M/001	Solution prep Area - 01
Previous product	End cal. Ke strong		
Batch No.	F E 0122026		
Cleaned by	Abi		
Checked by Production Sign/Date:	L 14/07/2022		
Verified by IPQA Sign/Date:	G 14/07/2022		

ENVIRONMENTAL CONDITIONS:		Date: 14/07/2022 Time: 10.00		Date: Time:	
		Observation	Prod. Sign.	Verified by IPQA	Prod. Sign.
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	23 °C	L	G	
	Relative Humidity % Limit: NMT 60%	52 %	L	G	

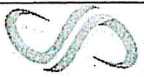
APPROVAL FOR COATING SOLUTION PREPARATION:

Production Sign/Date: <u>L 14/07/2022</u>
Line Clearance IPQA Sign. / Date: <u>G 14/07/2022</u>
Start Time/Date: <u>10:20</u> / <u>14/07/2022</u> End Time/Date: <u>10:40</u> / <u>14/07/2022</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L	Abi	G	
Date	02/06/2022	02/06/2022	02/06/2022	

Y100 CHLOROTHALOM

UNCONTROLLED CC7Y

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 28 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00	Batch No.: G1R22106
		Customer:	Generic Health Care Pvt. Ltd.

10.0 Coating Procedure:

10.1 General Instructions:

1. Prepare the coating solution lot wise.
2. Do not use synthetic containers for storage/ transfer of coating solution
3. Do not use high speed stirrer for preparing coating solution. Avoid direct contact of body with Solvent & coating solution. Solvent based coating should be done in spark proof area.

10.2 TABLETS RECEIPT RECORD OF UNCOATED TABLETS FOR COATING:

Balance ID. No.: PD/12AL/015

Date/Shift/Time: 14/07/2022/5/10-15

Sr. No.	Description	Observations	Checked By (Production)	Verified By (IPQA)
1.	Total Quantity (Net Qty.in Kg)	112.190	L	Gps
2.	Number of Containers	04	L	Gps

10.3 COATING SOLUTION PREPARATION

Sr. No.	General Instructions					
1.	Check the cleanliness of the Solution Preparation area and operation as per current version of SOP.					
2.	Use hand gloves while handling the materials					
3.	Transfer the verified coating materials to Coating solution preparation area.					
Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
1	Take Isopropyl Alcohol in a SS Vessel. Slowly disperse Wincoat WT White 02022 and Yellow oxide of Iron and stir well to disperse completely.	10.20	10.30	Karthi	L	Gps
2	Take Purified Water in a SS Vessel. Slowly disperse Tween 80 and stir well to disperse completely.	10.31	10.35	Karthi	L	Gps
3	Add Step 2 solution into the Step 1 solution and stir well with remaining quantity of Purified Water. If required mill the solution with Colloidal mill for 2 minutes	10.36	10.40	Karthi	L	Gps

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	3a/06/2022	10/06/2022	Rs
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

UNCONTROLLED CC7Y

 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 29 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:		Batch No.: 41822106 Generic Health Care Pvt. Ltd.

11.0 COATING AREA:

LINE CLEARANCE CHECKS: Date/Shift/Time: 14/07/2022 19:10:10...../...../.....

Sr. No.	Checks	*Observation					
		Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	/	/				
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	/	/				
3	Check and ensure that machine body, machine parts and control panel are clean.	/	/				
4	Check and ensure that absence of previous batch/product below container weighing balance.	/	/				
5	Check and ensure that working desk, analytical balance and other accessories are clean.	/	/				
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Derain point are clean.	/	/				
7	Check and ensure that instruments to be used are within calibration due date.	/	/				
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	/	/				
9	Check and ensure that environmental conditions are recorded in the BMR.	/	/				
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF)	/	/				
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	/	/				

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

Equipment	Coating Machine	Area
Equipment ID No.	<u>PO/NEC/001</u>	Coating area <u>01</u>
Previous product	<u>Erndcal kistron g</u>	
Batch No.	<u>EE012025</u>	
Cleaned by	<u>Abi</u>	
Checked by Production Sign/Date:	<u>R 14/07/2022</u>	
Verified by IPQA Sign/Date:	<u>G S 14/07/2022</u>	

ENVIRONMENTAL CONDITIONS:		Date: <u>14/07/2022</u> Time: <u>19:10</u>		Date: <u>14/07/2022</u> Time: <u>19:10</u>		Date: <u>14/07/2022</u> Time: <u>19:10</u>		Date: <u>14/07/2022</u> Time: <u>19:10</u>	
		Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	<u>23°C</u>	<u>L</u>	<u>G S</u>					
	Relative Humidity % Limit: NMT 60%	<u>52%</u>	<u>L</u>	<u>G S</u>					
	Differential Pressure (NLT 10 Pascal)	<u>12 pascal</u>	<u>L</u>	<u>G S</u>					

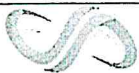
APPROVAL FOR COATING:

Production Sign/Date: <u>R 14/07/2022</u>
Line Clearance IPQA Sign. / Date: <u>G S 14/07/2022</u>
Start Time/Date: <u>12:20</u> / <u>14/07/2022</u> End Time/Date: <u>17:05</u> / <u>14/07/2022</u>

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<u>L S</u>	<u>G S</u>	<u>W S</u>	<u>R</u>	
Date	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>04/06/2022</u>	

Y100 CONTROL ROOM

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 30 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 41822106 Generic Health Care Pvt. Ltd.

11.1 COATING PROCESS:

Process Steps						
Step No.	Name of Ingredient & Operation	Time		Done by	Ckd by Prod.	Vfd by IPQA
		Start	Finish			
1	Transfer the compressed tablets in to the coating Area	12.20	12.25	magadh	L	P
2	Pre-warm the tablet with inlet temp. 35°C to 45°C.	12.26	12.31	magadh	L	P
3	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: 2.04 % (2.0 - 2.2%)	12.34	16.30	Magadh	L	P
4	When the spraying is complete, dry the tablets perfectly, in the pan by keeping inlet temp. 40°C-50 °C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	16.31	16.45	magadh	L	P
5	Monitor DT: Limit: NMT 30 minutes. Found Disintegration Time: 1 min 50 sec.	16.47	17.05	magadh	L	P
6	Unload the film coated tablets in a HDPE container lined with double polybag.			magadh	L	P

11.2 INITIAL CHECKS OF COATING PARAMETERS:

S. No	Parameter	Set	Observed
1	Inlet air Temp.	35°C to 45°C (To be established)	60°C
2	Exhaust air Temp.	50 ± 5 °C (To be established)	51 °C
3	Tablet Bed temp.	40°C-50 °C (To be established)	32 °C
4	Atomization air pressure	2.0 - 3.0 Kg/cm ² (To be established)	2.5 kg/cm ²
5	Pan speed	2.0 - 4.0 RPM (To be established)	3.5 rpm
6	Spray rate	30 to 70 ml/min (To be established)	50 ml/min
Checked by Production/ Date			L/14/07/2022
Inlet Air temp. 60°C 14/07/2022 Verified by IPQA/ Date			P/14/07/2022

11.3 INDIVIDUAL WEIGHT CHECKING OF PRE-WARMED TABLETS:

Sr. No.	Weight (mg)	Sr. No.	Weight (mg)
1	189	11	190
2	187	12	191
3	190	13	189
4	191	14	187
5	189	15	188
6	188	16	190
7	190	17	190
8	189	18	187
9	187	19	190
10	189	20	191
Total		3.782 gm	
Avg. Weight		189.1 mg	

11.4 FINAL COATING PARAMETERS CHECKS: (PRODUCTION)

Parameters	Limits	Observed
Description	Pale yellow coloured, circular shaped, film coated tablet with breakline on one side and plain on other side	ok
Theoretical weight per tablet	195.000 mg ± 3 % (189.150 mg – 200.850 mg)	192 mg
Weight of 20 tablets	3.900 g ± 3 % (3.783 g – 4.017 g)	3.840 gm
Uniformity of weight	195.000 mg ± 5 % (185.250 mg – 204.750 mg)	-1.56 %
Thickness	3.80 mm ± 0.2 mm (3.60 mm to 4.00 mm) (To be established)	3.45 - 3.59 mm
Disintegration test	NMT 30 min	1 min 50 sec
Checked by Production/ Date		L/14/07/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

Thickness: 3.40 - 3.80 mm

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 31 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product LOLIP 20	BMR. No.: BMR/T/331-00 Customer:		Batch No.: <u>G1822106</u> Generic Health Care Pvt. Ltd.

11.5 FINAL COATING PARAMETERS CHECKS: (IPQA)

Parameters	Limits	Observed
Description	Pale yellow coloured, circular shaped, film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	195.000 mg $\pm$ 3 % (189.150 mg – 200.850 mg)	193.015 mg
Weight of 20 tablets	3.900 g $\pm$ 3 % (3.783 g – 4.017 g)	3.860 g
Uniformity of weight	195.000 mg $\pm$ 5 % (185.250 mg – 204.750 mg)	-1.5% / +0.50
Thickness	3.80 mm $\pm$ 0.2 mm (3.60 mm to 4.00 mm) (To be established)	3.58 mm
Disintegration test	NMT 30 min	OK min 18 Sec
Checked by IPQA/ Date		12/07/2022

11.6 FILM COATING WEIGHT GAIN PARAMETER CHECKS:

S. No.	Start time	End time	Inlet temp.	Outlet temp.	Bed temp.	Pan RPM	Atomizing air pressure	Initial weight gain (A)	Final weight gain (B)	Difference C = B-A	Percentage weight gain	Ckd by	Verified by
1	12.40	13.40	60°C	51°C	32°C	25rpm	3.0kg/cm ²	190	191	1	0.52%	L	
1	13.45	13.45	60°C	51°C	32°C	25rpm	3.0kg/cm ²	191	192	1	0.52%	L	
2	13.41	14.45	60°C	51°C	32°C	3rpm	3.5kg/cm ²	191	192	1	0.52%	L	
2	13.46	15.15	60°C	51°C	32°C	3rpm	3.5kg/cm ²	191	192	1	0.52%	L	
3	14.50	15.55	60°C	52°C	34°C	3rpm	3.5kg/cm ²	192	193	1	0.52%	L	
3	15.20	16.20	60°C	52°C	34°C	3rpm	3.5kg/cm ²	191	193	2	1.04%	L	
4	16.00	16.30	60°C	52°C	35°C	3rpm	3.5kg/cm ²	193	194	1	0.52%	L	

11.7 WEIGHT CHECK FOR 20 TABLETS:

BY PRODUCTION			BY IPQA		
S. NO.	INITIAL WEIGHT	FINAL WEIGHT	S. NO.	INITIAL WEIGHT	FINAL WEIGHT
1	189	193	1	190	192
2	190	190	2	188	192
3	191	194	3	189	192
4	188	192	4	190	194
5	187	190	5	191	192
6	189	194	6	189	192
7	191	191	7	188	194
8	190	193	8	190	192
9	190	190	9	191	193
10	189	194	10	188	194
11	187	192	11	187	190
12	188	192	12	189	192
13	190	194	13	190	194
14	189	191	14	189	193
15	190	193	15	188	194
16	187	193	16	187	192
17	188	190	17	189	193
18	190	194	18	190	192
19	189	192	19	189	194
20	190	191	20	190	193
TOTAL	3.782 (gm)	3.843 (g)	TOTAL	3.782	3.856
Checked by Production: L			Checked by IPQA: D		

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	30/06/2022	02/07/2022	
Date	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 32 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13
	Product: LOLIP 20		Batch Size: 6,00,000 Tablets
			Batch No.: 61822106
		Customer:	Generic Health Care Pvt. Ltd.

11.8 PERCENTAGE OF COATING WEIGHT BUILDS UP:

$$\% \text{ of Weight buildup} = \frac{\text{Avg. wt. of coated tablets} - \text{Avg. wt. of core tablet (Pre-warmed)} \times 100}{\text{Avg. wt. of core tablets (Pre-warmed)}}$$

$$= 2.04\%$$

11.9 ACTUAL AVERAGE WEIGHT OF COATED TABLETS:

$$\frac{\text{Weight of 100 coated tablet}}{100} = 192 \text{ mg}$$

11.10 WEIGHT OF FILM COATED TABLETS:

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	27.580	2.080	25.500	Magesh	L	Ch
2	27.530	1.870	25.660	Magesh	L	Ch
3	32.670	1.910	30.760	Magesh	L	Ch
4	34.960	2.480	32.480	Magesh	L	Ch
5						
TOTAL			114.400			

11.11 RECONCILIATION (COATING STAGE):

Average weight of coated Tablet: 1.92 mg

1.0	Batch size	:	117.000 Kg.	6,00,000 Nos.
2.0	Weight of coated tablets	:	114.400 Kg.	595833 Nos.
3.0	Coating loss@	:	0.010 Kg.	
4.0	In-process samples of all stages			
	A	IPQC Samples	: 0.010 Kg.	
	B	QC Samples	: 0.010 Kg.	
	C	Validation Samples	: NA Kg.	
5.0	Total in process samples: (A + B + C)	:	0.040 Kg.	
6.0	Total: (2.0 + 5.0)	:	114.440 Kg.	596041 Nos.
7.0	Yield {6.0 x 100 / 1.0}*	:		99.34 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.010 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: L. K. 14/07/2022 Checked by IPQA Sign/Date: Ch. 14/07/2022

Test request form raised by Prod Sign/Date: L. K. 15/07/2022

Test request form received by IPQA Sign/Date: Ch. 15/07/2022

11.12 RELEASE FOR INSPECTION:

Reconciliation checked and coated tablets released for inspection

IPQA Sign: Ch. Date: 15/07/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	3a/abun	W. K.	
Date	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 33 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822106 Generic Health Care Pvt. Ltd.

12.0 INSPECTION LINE CLEARANCE: Date/Shift/Time: 15/07/2022 / 67 / 09:05/

Sr. No.	Checks	*Observation			
		Prod	IPQA	Prod	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	✓	✓		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

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

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PD/INB/001	PD/MED/001	Inspection - D
Previous product	Fruiteal K2 Strong		
Batch No.	FF01220264		
Cleaned by	Jenny 19/07/22		
Checked by Production Sign/Date:	15/07/2022		
Verified by IPQA Sign/Date:	G/S 15/07/2022		

ENVIRONMENTAL CONDITIONS:		Date: 15/07/2022 Time: 09:05		Date:		Time:	
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	23°C	19/07/22	G/S			
	Relative Humidity % Limit: NMT 60%	52%	19/07/22	G/S			

APPROVAL FOR INSPECTION:	
Production Sign/Date: <u>19/07/2022</u>	
Line Clearance IPQA Sign. / Date: <u>15/07/2022</u>	
Start Time/Date: <u>09:13</u> / <u>15/07/2022</u>	End Time/Date: <u>16:33</u> / <u>15/07/2022</u>

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. Ka</u>	<u>[Signature]</u>	<u>[Signature]</u>	<u>[Signature]</u>
Date	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/22</u>

Y-100 CILLOXATAMOL

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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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1822106

Customer:

Generic Health Care Pvt. Ltd.

13.0 INSPECTION PROCESS

13.1 INSTRUCTIONS

S. No.	Process Instructions
1	Carry out visual inspection of tablets on inspection belt area as per the SOP No. PDOP/019.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

13.2 PERFORMANCE CHECKS RECORD FOR METAL DETECTOR:

Sr. No	Process instructions
1.	At the start of the activity, after each break and at the end of operation/shift) as per SOP No. PDGN/022.
2.	Testing frequency: Startup, End of the activity and after every break time.
3.	Acceptance Criteria: 1. Ferrous, Stainless steel & Non-Ferrous shall be detected & rejected. 2. Nonmetallic shall not be detected.

Date & Time	Trial No.	Metal Detector ID No.: PD/MED/001 & PD/MED/002...					Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.4 mm)	Non-metallic	Result		
15/07/2022 09:19	1	✓	✓	✓	X	pass	M. Kari	CLB
	2	✓	✓	✓	X	pass	M. Kari	CLB
	3	✓	✓	✓	X	pass	M. Kari	CLB
15/07/2022 11:09	1	✓	✓	✓	X	pass	M. Kari	CLB
	2	✓	✓	✓	X	pass	M. Kari	CLB
	3	✓	✓	✓	X	pass	M. Kari	CLB
15/07/2022 12:03	1	✓	✓	✓	X	pass	M. Kari	CLB
	2	✓	✓	✓	X	pass	M. Kari	CLB
	3	✓	✓	✓	X	pass	M. Kari	CLB
15/07/2022 16:28	1	✓	✓	✓	X	pass	M. Kari	CLB
	2	✓	✓	✓	X	pass	M. Kari	CLB
	3	✓	✓	✓	X	pass	M. Kari	CLB
/	1				na			
	2							
	3							

Note: Put ✓ mark for detection and x mark for non-detection
If during the test Metal Detector fails to reject any of the Standard chips then mention the corrective action taken.
.....
..... (To be filled by Production)
Note: Take QA Approval before proceeding to next stage

13.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
15/07/2022	01	04	09:13	16:33	0.010	Tranzy 15/07/2022	M. Kari 15/07/2022
/							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Kari	30/07/2022	UNK	
Date	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 35 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: <u>G1822106</u> Generic Health Care Pvt. Ltd.

13.4 WEIGHING RECORD OF INSPECTED TABLETS:

Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	97.580	7.240	25.340	6			
2	97.110	2.690	25.020	7			
3	34.180	1.900	32.280	8			
4	33.750	2.000	31.750	9			
5				10			
Total			114.390Kg	Total			Kg
Grand Total						114.390 Kg	

Weighing Done By: Jony Checked By Prod./ Date: M. Kalyan 15/07/2022 Verified by IPQA Sign./Date: G. Senthil Kumar 15/07/2022

13.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	117.000 kg	6,00,000 No's
2.0	Tablets transferred for Inspection	:	114.400 kg	595833 No's
3.0	Total weight of good Tablets	:	114.390 kg	595781 No's
4.0	Rejected Tablets	:	0.010 kg	52 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:		99.30 %

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed: 0.010 Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign/Date: M. Kalyan 15/07/2022

Checked by IPQA sign/Date: G. Senthil Kumar 15/07/2022

13.6 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign/Date: G. Senthil Kumar 15/07/2022

BMR Released for packing by QA Head Sign/Date: R. Stephen 15/07/2022

14.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	K. Viswanath	<u>K. Viswanath</u> 15/07/2022
QA Executive	G. Senthil Kumar	<u>G. Senthil Kumar</u> 15/07/2022
Production Assistant Manager/ HOD	M. M. Mohamed	<u>M. M. Mohamed</u> 15/07/2022
QA Manager/ HOD	R. Stephen	<u>R. Stephen</u> 15/07/2022

15.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMR/T/331-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K</u>	<u>Senthil Kumar</u>	<u>W. K</u>	<u>R. Stephen</u>
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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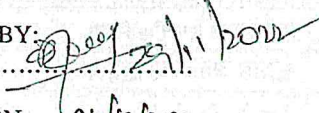
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		VALIDATION BATCH Page 1 of 35
	BATCH MANUFACTURING RECORD	Product Code: L13	Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMRT/331-00	Batch No.: G1822162
		Customer:	Generic Health Care Pvt. Ltd.

BATCH MANUFACTURING RECORD COVER SHEET

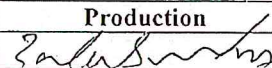
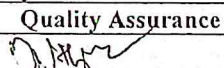
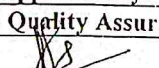
PRODUCT NAME : LOLIP 20
GENERIC NAME : Atorvastatin Calcium Tablets 20 mg
LABEL CLAIM : Each film coated tablet contains:
 Atorvastatin calcium Trihydrate
 Equivalent to Atorvastatin 20 mg
 Colour: Approved colour used.
MFR No. / Reference Document No. : MFR/T/186-00
BMR No. : BMR/T/331-00
REVISION No. : 00
SUPERSEDES No. : NIL
BMR EFFECTIVE BATCH NUMBER/DATE : G1822106 / 02/06/2022
MFG.LIC No. : PON/DRUGS/21 14 4376
STORAGE : Store in cool and dry place. Protect from light and moisture.
BMR ISSUED BY/DATE (QA) : N. K. 26/11/22
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION) : L. K. 29/11/2022
SHELF LIFE : 36 Months
BATCH SIZE : 6,00,000 Tablets (117.000 Kg)
MFG. DATE: 11/2022 : **EXP. DATE: 10/2025**

RECOVERY ADDITION RECORD

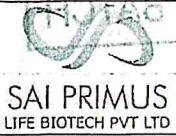
BATCH NO	MFG	EXP	QUANTITY	REVISED BATCH SIZE
		N.A		

ALLOTTED BY: N. K. 26/11/22
QA SIGN/DATE:
DATE OF COMMENCEMENT: 05/12/2022
RELEASED QUANTITY OF TABLETS FOR PACKING : 594008
RELEASE FOR PACKING STAGE : 
HEAD OF QA SIGN/DATE:
COUNTER CHECKED BY: 
QA SIGN/DATE:
DATE OF COMPLETION: 06/12/2022

This BMR contains 35 Pages + NA Additional Pages

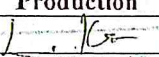
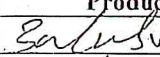
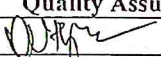
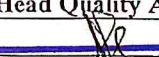
Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
	L. K.			
	02/06/2022	02/06/2022	02/06/2022	02/06/22

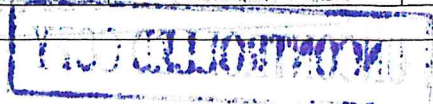
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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 2 of 35
	BATCH-MANUFACTURING RECORD	Product Code: L13 BMR. No.: BMR/T/331-00 Customer:	Batch Size: 6,00,000 Tablets Batch No.: G1822162 Generic Health Care Pvt. Ltd.
Product	LOLIP 20		

1.0 INDEX

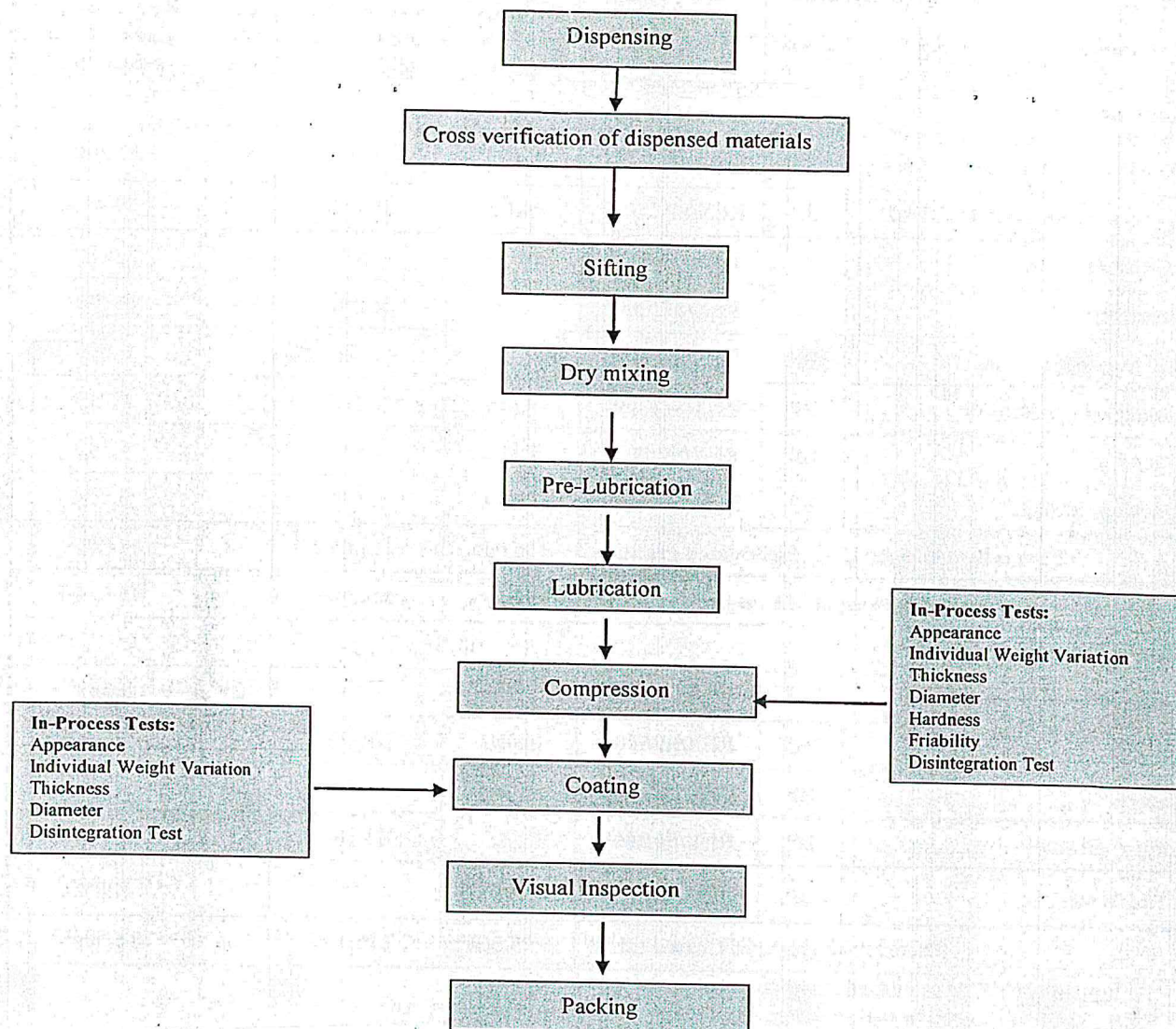
Sr. No.	Content	Page No.
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2.0	Flow Chart	3
3.0	Indent of active pharmaceutical ingredients & excipients	4
4.0	Calculation	5
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6.0	Line clearance for Sifting and granulation.	8
7.0	Granulation instruction, sieve integrity checks, sifting instruction, wet granulation, drying record, sifting and milling record	9-11
8.0	Blending Line clearance, Blending and Lubrication process, Lubrication material sifting record, Blending and Lubrication records, Weight record, Reconciliation, Release for Compression	12-13
9.0	Compression Line Clearance	14
10.0	Compression instruction, Granules receipt record, compression specification, compression machine running status, initial In-process checks, Compression specification/ Parameters, In-process checks (Production and IPQA), uniformity of weight checks (Production and IPQA), weight record of compressed tablets, Reconciliation	15-30
11.0	Release for Coating	
12.0	Line clearance for Coating solution preparation	
13.0	General instruction, tablets receipt record for coating, coating solution preparation procedure	
14.0	Line Clearance for Coating	
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16.0	Release for Inspection	30
17.0	Inspection Line clearance	31
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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	02/06/2022	02/06/2022	02/06/2022	



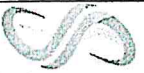
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 3 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 BMR. No.: BMR/T/331-00 Customer:
Product LOLIP 20			Batch Size: 6,00,000 Tablets Batch No.: 611222162 Generic Health Care Pvt. Ltd.

2.0 PROCESS FLOW CHART



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	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 4 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13
	Product		Batch Size: 6,00,000 Tablets
	LOLIP 20		Batch No.: G122162
	Customer:		Generic Health Care Pvt. Ltd.

3.0 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS & EXCIPIENTS:

Sr. No.	Name of the Ingredient	Spec.	Item Code	Quantity/ Tablets (mg)	Std. quantity per 6,00,000 tablets (kg)	OA/ PL (%)	Req. quantity per 6,00,000 tablets (kg)
Lubrication material:							
1	Atorvastatin Calcium (Micronized)	USP	RAI/SP/A016	22.000 [#]	13.200 [#]	6.15	13.200 [#]
2	Microcrystalline cellulose PH102	BP	REX/SP/M010	49.110	29.466	-	29.466
3	Calcium Carbonate	BP	RAI/SP/C005	0.950	0.570	-	0.570
4	Lactose DCL 11	BP	REX/SP/L004	105.950	63.570	-	63.570
5	Croscarmellose Sodium	BP	REX/SP/C008	6.300	3.780	-	3.780
6	Colloidal Silicon Dioxide	BP	REX/SP/C022	2.850	1.710	-	1.710
7	Purified Talc	BP	REX/SP/P017	1.900	1.140	-	1.140
8	Magnesium Stearate	BP	REX/SP/M011	0.950	0.570	-	0.570
Theoretical Weight of the Lubricated granules				190.000	114.000	-	114.000
Theoretical weight of Compressed tablet				190.000	114.000	-	114.000
Coating Material:							
9	Wincoat WT White 02022	IHS	REX/SP/W001	4.750	2.850	25	3.563 [#]
10	Yellow oxide of Iron	IHS	REX/SP/I004	0.050	0.030	25	0.038 [#]
11	Tween 80	BP	REX/SP/P014	0.200	0.120	25	0.150 [#]
12	Isopropyl Alcohol	BP	REX/SP/I005	q.s.	21.000	-	21.000
13	Purified Water	BP	NA	q.s.	30.000	-	30.000
Theoretical weight of Coated tablet				195.000	117.000	-	117.000

NOTE: *API quantity shall be calculated based on potency.

**Excess Quantity shall be compensating from Microcrystalline cellulose PH 102.

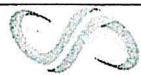
Inclusive of overages

OA: Overages, PL: Process loss

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ke	3a	Q	
Date	02/06/2022	02/06/2022	02/06/2022	

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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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: 61822162

Customer:

Generic Health Care Pvt. Ltd.

4.0 ASSAY AND LOD CALCULATIONS FOR ATORVASTATIN CALCIUM:

Note: If assay of API is more than 100%, consider 100% at the time of calculation.

Standard quantity of Atorvastatin Calcium: 13.200 Kg (A)

Standard quantity of Microcrystalline cellulose PH 102 (B): 29.466 Kg

Calculation for Atorvastatin Calcium:

1) Calculation for Single A. R. No. RM61/00911, Assay on dried basis: 99.770 w/w, LOD: 4.530 w/w
Exp. Date: 09/2024

$$\text{Actual Quantity (Kg) (C)} = \frac{\text{Standard qty. required} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{13.200 \times 100 \times 100}{99.770 \times (100 - 4.530)} = 13.858 \text{ Kg}$$

2) Calculation for Microcrystalline cellulose PH 102 (B):

Actual Quantity (Kg) (D) = Standard quantity of Microcrystalline cellulose PH 102 - Excess Calculated quantity of Atorvastatin Calcium

$$= 29.466 \text{ Kg} - 0.658 \text{ Kg}$$

$$= 28.808 \text{ Kg.}$$

3) Calculation for Atorvastatin Calcium Multiple A. R. No.:

Sr. No.	A. R. No.	Available Qty. (Kg) (E)	Assay % w/w	LOD % w/w	Actual Qty. = $\frac{\text{Available Qty.} \times \text{Assay} \times (100 - \text{LOD})}{100 \times 100}$
Total Actual Quantity (F)					

Calculation for Remaining Quantity Required (G):

Theoretical Qty. - Actual Quantity (F) = _____ Kg

AR. No.: _____, Assay on dried basis: _____ w/w, LOD: _____ %w/w, Exp. Date: _____

$$\text{Actual Quantity (Kg) (H)} = \frac{\text{Remaining qty. required (G)} \times 100 \times 100}{\text{Assay} \times (100 - \text{LOD})} = \frac{X \times 100 \times 100}{X(100 -)} = \text{_____ Kg.}$$

Total Qty. of Atorvastatin Calcium to be dispensed (I) = (E) + (H) = _____ Kg

4) Calculation for Microcrystalline cellulose PH 102 (B):

Actual Quantity (Kg) (J) = Standard quantity of Microcrystalline cellulose PH 102 - Excess Calculated quantity of Atorvastatin Calcium

$$= 29.466 \text{ Kg} - \text{_____ Kg}$$

$$= \text{_____ Kg.}$$

Done By/On (QA): AS 29/11/2022

Checked By/On (Production): L. K 29/11/2022

Prepared by:

Checked by:

Approved By:

Dept. Production Production Quality Assurance Head Quality Assurance

Sign. L. K. S. K. S. K. S. K.

Date 02/06/2022 02/06/2022 02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 6 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 61822162 Generic Health Care Pvt. Ltd.

5.0 DISPENSING LINE CLEARANCE CHECKS

Date: 30/11/22 Time: 10:10

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 scoop, SS spatula and 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 dispensing booth is clean	✓	✓
7	Check all the gauges of dispensing booth 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	Dispensing Booth	Weighing Balance			Area
ID No.	ST 1DPB1004	ST 1BAC1004	ST 1BAC1005	ST 1BAC1006	Dispensing Booth
Previous Product	Genset				
B. No.	651822142				
Cleaned by Sign/Date	Vignesh 30/11/22				
Checked by Store Sign/Date	P. S. S. 30/11/22				
Verified by IPQA Sign/Date	P. S. S. 30/11/22				

ENVIRONMENTAL CONDITIONS: Date: 30/11/22 Time: 10:15		Observation	Checked by Store Sign/Date	Verified by IPQA Sign/Date
(For Reference SOP No.: QAGN/011)				
Temperature (Limit: NMT 25°C)		23°C	P.S.S. 30/11/22	P.S.S. 30/11/2022
Relative Humidity % (Limit: NMT 60%)		58%	P.S.S. 30/11/22	P.S.S. 30/11/2022
Differential Pressure (NLT 10 Pascal)		11 pascals	P.S.S. 30/11/22	P.S.S. 30/11/2022
Differential Pressure across the booth Limit: 5 to 20 mm Water		12mm	P.S.S. 30/11/22	P.S.S. 30/11/2022

APPROVAL FOR DISPENSING BY IPQA: Sign: P. S. S. Date: 30/11/22

Dispensing start Time: 10:30 End Time: 12:30

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	P. S. S.	P. S. S.	P. S. S.
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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SAI PRIMUS
LIFE BIOTECH PVT LTD

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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Product
LOLIP 20

BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

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

Batch No.: G 18 22 162

Customer:
Generic Health Care Pvt. Ltd.

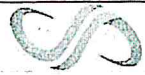
5.1 Dispensing Weighing Sheet:

Balance ID: 301302 Date: 02/06/2022 Shift: 1 Time: 09:30

Sr. No.	Ingredients	Spec.	Item code	UOM	Std. Qty.	Req. Qty.	A.R No.	Issued Qty.		Weighed By Store (Sign & Date)	Checked By (IPQA) (Sign & Date)	Cross Checked by	
								Gross Wt.	Tare Wt.			Net Wt.	Checked Production (Sign & Date)
Lubrication material:													
1	Atorvastatin Calcium (Micronized)	USP	RAI/SP/A016	Kg	13.200	13.558	Rm4/00911	14.018	0.160	13.858	30/11/22	30/11/22	30/11/22
2	Microcrystalline cellulose PH102	BP	REX/SP/M010	Kg	29.466	28.808	Rm4/00572	29.008	0.200	28.808	30/11/22	30/11/22	30/11/22
3	Calcium Carbonate	BP	RAI/SP/C005	Kg	0.570	0.570	Rm4/00818	610.05	40.05	570.05	30/11/22	30/11/22	30/11/22
4	Lactose DCL 11	BP	REX/SP/L004	Kg	63.570	63.570	Rm4/00876	30.000	0.200	30.000	30/11/22	30/11/22	30/11/22
5	Croscarmellose Sodium	BP	REX/SP/C008	Kg	3.780	3.780	Rm4/00875	3.850	0.070	3.780	30/11/22	30/11/22	30/11/22
6	Colloidal Silicon Dioxide	BP	REX/SP/C022	Kg	1.710	1.710	Rm4/00605	1.910	0.200	1.710	30/11/22	30/11/22	30/11/22
7	Purified Talc	BP	REX/SP/P017	Kg	1.140	1.140	Rm4/00802	1180.05	40.05	1140.05	30/11/22	30/11/22	30/11/22
8	Magnesium Stearate	BP	REX/SP/M011	Kg	0.570	0.570	Rm4/00825	610.05	40.05	570.05	30/11/22	30/11/22	30/11/22
Coating Material:													
9	Wincoat WT White 02022	IHS	REX/SP/W001	Kg	3.563	3.563	Rm4/00964	3.579	0.260	3.319	30/11/22	30/11/22	30/11/22
10	Yellow oxide of Iron	IHS	REX/SP/I004	Kg	0.038	0.038	Rm4/00679	15.05	70.5	38.05	30/11/22	30/11/22	30/11/22
11	Tween 80	BP	REX/SP/P014	Kg	0.150	0.150	Rm4/00173	16.05	10.05	6.05	30/11/22	30/11/22	30/11/22
12	Isopropyl Alcohol	BP	REX/SP/I005	Kg	21.000	21.000	Rm4/00123	23.000	2.000	21.000	30/11/22	30/11/22	30/11/22
13	Purified Water	BP	NA	Kg	30.000	30.000	Rm4/00112	32.00	2.00	30.00	30/11/22	30/11/22	30/11/22

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	L. Ka	30/11/2022	30/11/2022		
Date	02/06/2022	02/06/2022	02/06/2022		

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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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1822162

Customer:

Generic Health Care Pvt. Ltd.

6.0 BLENDING LINE CLEARANCE CHECKS: Date/Shift: 02/12/22 / 17 /

Sr. No.	Checks	Time	*Observations					
			Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers, polythene bags, Tags and documents of previous batch/product are removed.	09:35	✓	✓				
2	Check and ensure that Scrap from waste bin is removed and new polythene bag is put into it.		✓	✓				
3	Check and ensure that display, display stand, weighing balance are clean.		✓	✓				
4	Check and ensure that SS storage Cabinet and Drain point are clean.		✓	✓				
5	Check and ensure that absence of previous batch/product from area below machine		✓	✓				
6	Check and ensure that all equipment body and inside the vessel are clean		✓	✓				
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean		✓	✓				
8	Check and ensure that instruments to be used are within calibration due date and earthing connection.		✓	✓				
9	Check and ensure that daily records (Logbook, Balance, Temp. & RH) are updated and signed.		✓	✓				
10	Check and ensure that environment condition and record on BMR		✓	✓				
11	Check and ensure that rinse water is released from QC and attached the test request from (TRF)		NA	NA				
12	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	Shifter	Blender	Area
EQP. ID No.	PP/VBS/001	PP/OCB/001	Granulation - I
Previous Product	Lolip-20		
Batch No.	G1822161		
Cleaned by	praveen		
Checked by	ME		
Verified by	ME		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 02/12/22 Time: 09:37			Date:			Date:		
	Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	ME	ME						
RH % (NMT 60%)	52%	ME	ME						
DP (NLT 10 Pascal)	16	ME	ME						

APPROVAL FOR SIFTING AND BLENDING:

Production Sign/Date:	ME 02/12/22		
IPQA Sign/Date:	ME 02/12/2022		
Start and End Time:	09:45	16:50	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	Sulabharthy	MOH	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 9 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13
	Batch Size: 6,00,000 Tablets		Batch No.: 618 22162
Product	LOLIP 20	BMR. No.: BMR/T/331-00	Customer:
		Generic Health Care Pvt. Ltd.	

6.1 LUBRICATION MATERIAL SIFTING RECORD: Date: 02/12/22 Shift: 67

S. No	Name of Ingredient	Weight before sifting in Kg	Sieve size	ID No.	Sieve Integrity before use	Time		Sieve Integrity after use	Done by	Ckd by	Vfd by
						From	To				
Dry mixing:											
1	Atorvastatin Calcium	13.858	80#	PO/30-80-80/07	OK Not OK	09:45	12:40	OK Not OK	pram	M	F
2	Microcrystalline cellulose PH102	28.808	40#	PO/30-80-40/11	OK Not OK	12:42	13:30	OK Not OK	pram	M	F
3	Calcium Carbonate	0.570	60#	PO/30-80-60/08	OK Not OK	13:32	13:33	OK Not OK	pram	M	F
4	Lactose DCL 11	63.570	60#			14:05	15:42		pram	M	F
5	Croscarmellose Sodium	3.780	60#			15:43	15:46		pram	M	F
6	Colloidal Silicon Dioxide	1.710	30#	PO/30-80-30/08	OK Not OK	15:48	15:52	OK Not OK	pram	M	F
7	Purified Talc	1.140	80#	PO/30-80-80/07	OK Not OK	15:53	15:58	OK Not OK	pram	M	F
8	Magnesium stearate	0.570				15:57	15:58		pram	M	F

6.2 BLENDING AND LUBRICATION PROCESS:

Date: 02/12/22 Shift: 67

Step No.	Process Instructions	Time		Done by	Ckd by	Verified by IPQA
		Started	Completed			
1	Use hand gloves and goggles while handling the materials.					
2	Operate the Octagonal Blender as per the current version of the SOP No. PDOP/009.					
Pre-Lubrication:						
1	Load the sifted materials from step 6.1 (1,6) into the blender and mix for 15 minutes at 10 RPM.	16:10	16:25	pram	M	F
Lubrication:						
2	Load the Sifted Purified Talc and Magnesium Stearate into the above Pre-lubricated blend and mix for further 5 minutes at 10 RPM.	16:27 16:32 16:35	16:30 16:33 16:36	pram	M	F
3	Unload the lubricated blend in HDPE container having double lined polybag.	16:40	16:50	pram	M	F

6.3 WEIGHING OF FINAL BLEND:

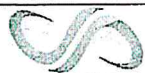
Balance I.D. No.: PO/30-80-80/07

Date: 02/12/22 Shift: 67 Time: 16:52

Sr. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Prod.	Verified by IPQA
1	37.000	2.360	34.640	pram	M	F
2	33.080	2.200	30.880	pram	M	F
3	34.040	2.480	31.560	pram	M	F
4	18.520	1.960	16.560	pram	M	F
5						
6						
7						
Total:			113.760			

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. P.	Sulabharthi	OK	
Date	02/06/2022	02/06/2022	02/06/2022	

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: 61322162

Customer:

Generic Health Care Pvt. Ltd.

6.4 RECONCILIATION:

1.0	Theoretical weight of blend	:	114.000 Kg
2.0	Actual Weight of blend	:	113.700 Kg
3.0	Manufacturing Loss (Blending stage) @	:	0.170 Kg
4.0	In-process samples		
	A IPQC Samples	:	0.04 Kg.
	B QC Samples	:	0.100 Kg.
	C Validation Samples	:	0.030 Kg.
5.0	Total samples: (A + B + C)	:	0.130 Kg
6.0	Total: (2.0 + 5.0)	:	113.830 Kg
7.0	Yield {6.0 / 1.0 x 100}*	:	99.85 %

* Actually yield will be calculated after 3 validation batches.

@Total rejects destroyed: 0.170 Kg. (Rejected materials shall be destroyed as per SOP: QAGN/048).

Recovery Addition Quantity in Kg: 0.170 (Recovery addition materials shall be as per SOP: QAGN/047).

Done by Production sign/Date: 02/06/2022 Checked By IPQA sign/Date: 02/06/2022

Test request form raised by Prod Sign/Date: 02/06/2022

Test request form received by IPQA Sign/Date: 02/06/2022

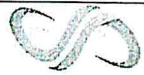
6.5 RELEASED FOR COMPRESSION:

Reconciliation checked and blend is released for compression

IPQA Sign: 02/06/2022 Date: 02/06/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	J. K.	30/06/2022	02/06/2022	02/06/2022
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur
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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1822162

Customer:

Generic Health Care Pvt. Ltd.

7.0 COMPRESSION LINE CLEARANCE CHECKS:

Date: 03/12/2022

Sr. No.	Checks	Time:	*Observations					
			12:45	06:22	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty SS containers/ containers polythene bags, Tags, and documents of previous batch/product are removed.		/	/	/	/	/	/
2	Check and ensure that absence of tablets of previous batch/product from area below machine and inside machine by opening the guard of machine.		/	/	/	/	/	/
3	Check and ensure that the machine body and machine parts like hoppers, feed frame, dust collection chute, hosepipe and ejection chute and control panel are clean.		/	/	/	/	/	/
4	Check and ensure that absence of tablet of previous batch/product below the weighing balance, check the cleanliness of area and equipment.		/	/	/	/	/	/
5	Check and ensure that working desk, analytical balance and other accessories are clean.		/	/	/	/	/	/
6	Check and ensure that Deduster and hosepipe are clean.		/	/	/	/	/	/
7	Check and ensure that Tube light fixture, supply grills, riser grills and filters and electrical fixtures are clean.		/	/	/	/	/	/
8	Check and ensure that instruments to be used are within calibration due date, and Punch inspection record		/	/	/	/	/	/
9	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.		/	/	/	/	/	/
10	Check and ensure that environmental conditions are recorded in the BMR.		/	/	/	/	/	/
11	Area, equipment and preventive maintenance status board is updated.		/	/	/	/	/	/
12	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR		NA	NA	NA	NA	NA	NA
13	Equipment status is updated for Cleaned and Preventive Maintenance label.		/	/	/	/	/	/

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

Equipment	Compression Machine	Deduster	Area
EQP ID No.	PD/COM/001/001	PD/DED/001, PD/DED/002	Compression-01
Previous Product	Lolip-20		
Batch No.	G1822162		
Cleaned by	Kesavan		
Checked by	R-ell		
Verified by	G.P		

ENVIRONMENTAL CONDITIONS: (SOP No.: QAGN/011)	Date: 03/12/22	Time: 13:40	Date: 05/12/22	Time: 06:25	Date:	Time:
	Observation	Checked by	Verified by	Observation	Checked by	Verified by
Temperature °C (NMT 25°C)	23°C	R-ell	G.P	23°C	R-ell	G.P
RH % (NMT 60%)	52%	R-ell	G.P	52%	R-ell	G.P
DP (NLT 10 Pascal)	11 pascal	R-ell	G.P	11 pascal	R-ell	G.P

APPROVAL FOR COMPRESSION:

Production Sign/Date:	R-ell 02/12/2022	R-ell 05/12/2022	
IPQA Sign/Date:	G.P 03/12/2022	G.P 05/12/2022	
Start and End Time:	14:46 20:35	06:37 11:48	

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ko	Salubh	W.H.K	
Date	02/06/2022	02/06/2022	02/06/2022	

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

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: 71822162

Customer:

Generic Health Care Pvt. Ltd.

8.0 COMPRESSION

8.1 PROCESS INSTRUCTIONS:

Sr. No.	Process Instructions
1	Check the cleanliness of area and equipment.
2	Ensure that the correct punch set are issued as per the Punch issue record.
3	Set the Double Rotary Compression Machine with a. Upper punches: 8.00 mm Circular shaped standard concave with breakline on punches. b. Lower punches: 8.00 mm Circular shaped standard concave plain punches. c. Dies: 8.00 mm suitable for above punches. d. Type of tooling - D.
	Punch Issued by: sign./Date: 03/12/2022 Checked and Received by Sign./Date: 03/12/2022 Verified by Sign./Date: 03/12/2022
4	Transfer the blend to compression cubicle. Load the blend into hopper manually.
5	Operate the Double Rotary Compression machine as per the current version of SOP: PDOP/010 and reject tablets of the first three round which shall be destroyed as per SOP: QAGN/048.
6	Collect the tablets of one complete rotation and carry out In-process checks for thickness, weight and appearance, record the observations in the BMR. Verify the tablets for uniformity of weight and hardness and record in the BMR.
7	Collect the compressed tablets in double polythene bag lined and labelled cleaned HDPE containers/SS container.
8	Check and record the weight of the compressed tablets.

8.2 GRANULES RECEIPT RECORD: Balance ID. No.: PD/RAC/015 Date: 03/12/2022 Shift: 4 Time: 14:02

Sr. No.	Gross Weight in Kg	Issued By Production	Checked by Production
1	37.000	MA	MA
2	33.080	MA	MA
3	34.040	MA	MA
4	13.520	MA	MA
5			
6			
7			
8			

8.3 COMPRESSION SPECIFICATION / PARAMETERS:

Sr. No.	Parameter	Limits	No. of tablets to be checked from each side	Frequency	
				Production	IPQA
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	20	Every 30 min.	Every 2 Hr.
2.	Average weight (mg)	190.000 mg $\pm$ 3.0 % (184.300 mg – 195.700 mg)	20		
3.	Group Weight	3.800 g $\pm$ 3.0 % (3.686 g to 3.914 g)	20	Every 30 min.	Every 2 Hr.
4.	Uniformity of weight Tablets	190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)	20	Every 2 Hr.	Every 4 Hr.
5.	Hardness	NLT 3.0 Kg (To be established)	4	Every 30 min.	Every 2 Hr.
6.	Thickness (mm)	3.70 $\pm$ 0.2 mm 3.50 mm – 3.90 mm (To be established)	4	Every 30 min.	Every 2 Hr.
7.	Diameter (mm)	(7.80 mm – 8.2 mm) (To be established)	30	Initial	
8.	Friability	NMT 1% w/w	6 g	Every 2 Hr.	Every 4 Hr.
9.	Disintegration Time	NMT 15 Minutes	6	Every 2 Hr.	Every 4 Hr.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.			
Date	02/12/2022	02/12/2022	02/12/2022	

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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.		Page 13 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G11822162 Generic Health Care Pvt. Ltd.

8.4 COMPRESSION MACHINE RUNNING STATUS:

Date	Shift	Start Time	End Time	Total Hour	M/C Speed	Tablets Output	Done By	Checked By
03/12/2022	G	14:46	20:25	5 hour 00 min	16	335000	Kesava	R. S. J
05/12/2022	A	07:37	11:48	5 hour 11 min	16	259263	veluri	R. S. J

8.5 INITIAL INPROCESS CHECKS: (Appearance, Uniformity of Weight, Thickness & Diameter):

Balance I.D. No.: PD/BAL/007

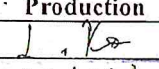
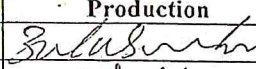
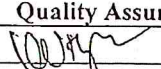
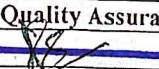
Date: 03/12/22 Shift: G Time: 14:15

LHS					RHS				
Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)	Sr. No.	Appearance *	Weight (in mg)	Thickness (in mm)	Diameter (in mm)
1	OK	191	3.51	8.04	1	OK	189	3.46	8.01
2	OK	190	3.47	8.01	2	OK	192	3.49	8.03
3	OK	187	3.49	8.03	3	OK	190	3.50	8.00
4	OK	190	3.50	8.05	4	OK	193	3.48	8.04
5	OK	189	3.52	8.02	5	OK	190	3.51	8.02
6	OK	190	3.48	8.01	6	OK	188	3.49	8.05
7	OK	188	3.50	8.06	7	OK	191	3.52	8.01
8	OK	192	3.47	8.01	8	OK	190	3.53	8.03
9	OK	190	3.51	8.04	9	OK	193	3.51	8.01
10	OK	187	3.48	8.03	10	OK	191	3.48	8.04
11	OK	189	3.50	8.04	11	OK	189	3.46	8.02
12	OK	191	3.49	8.01	12	OK	192	3.49	8.00
13	OK	190	3.49	8.03	13	OK	190	3.50	8.03
14	OK	192	3.47	8.05	14	OK	193	3.49	8.01
15	OK	189	3.50	8.02	15	OK	191	3.52	8.04
16	OK	191	3.48	8.04	16	OK	190	3.48	8.02
17	OK	187	3.46	8.02	17	OK	192	3.50	8.06
18	OK	190	3.49	8.04	18	OK	190	3.49	8.03
19	OK	191	3.52	8.03	19	OK	193	3.51	8.01
20	OK	188	3.50	8.01	20	OK	191	3.50	8.04
21	OK	190	3.48	8.00	21	OK	188	3.48	8.02
22	OK	189	3.51	8.04	22	OK	190	3.47	8.04
23	OK	191	3.49	8.02	23	OK	191	3.50	8.01
24	OK	187	3.50	8.00	24	OK	189	3.49	8.05
25	OK	190	3.52	8.04	25	OK	193	3.52	8.03
26	OK	190	3.48	8.01	26	OK	190	3.50	8.01
27	OK	187	3.50	8.03	27	OK	189	3.48	8.00
28	OK	189	3.52	8.02	28	OK	191	3.46	8.04
29	OK	190	3.49	8.01	29	OK	190	3.49	8.01
30	OK	190	3.50	8.01	30	OK	191	3.50	8.05

Note: * Write OK if complies and (X) if does not comply.

Done by Production Sign/Date.....²³⁴03/12/2022

Checked by IPQA Sign/Date.....^{G.P}03/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	02/12/2022	02/10/2022	02/10/2022	

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SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1122262

Customer:

Generic Health Care Pvt. Ltd.

8.6 COMPRESSION SPECIFICATION AND PARAMETERS: Date: 03/12/22 Shift: G1 Time: 14:30

Parameters	Instrument used	Equip ID No.	Observations of LHS					Observations of RHS					Limits
			Min		Max			Min		Max			
Appearance	Visual	NA	OK					OK					White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side
Group Weight	Electronic Balance	PD/BA/1007	3.792 g					3.818 g					3.800 g $\pm$ 3.0 % (3.686 g to 3.914 g)
Average weight	Electronic Balance		189.60 mg					190.90 mg					190.000 mg $\pm$ 3.0 % (184.300 mg – 195.700 mg)
Individual weight	Electronic Balance		187 mg	192 mg		188 mg		193 mg		190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			
Uniformity of weight	Electronic Balance		-1.39 %	1.25 %		-1.54 %		1.08 %					
Thickness	Vernier Caliper	GA/EC/1001	3.46 mm		3.52 mm			3.46 mm		3.53 mm		3.70 $\pm$ 0.2 mm 3.50 mm – 3.90 mm (To be established)	
Hardness	Hardness Tester	GA/HAD/1001	6.0	6.5	6.0	6.5	6.0	6.5	6.0	6.5	6.0	NLT 3.0 Kg (To be established)	
Friability	Friabilator	GA/FAR/1002	0.10%					0.12%					NMT 1.0% w/w
DT	DT Apparatus	GA/DT/1002	01 min 39 sec					01 min 43 sec					NMT 15 minutes
M/C set done by Operator Name: K. S. S. M. M. C. set up Checked by (Prod. Sign/Date): 03/12/22													
M/C Speed: 10 RPM (To be Established)													
Initial Setting Tablets Destroyed by: Sign: 22 Date: 03/12/22 Quantity in Kg: 0.20 Quantity in No: 105													
Approval for Batch Compression by IPQA: Sign: G. L. Date: 03/12/2022 Time: 14:47													

Thickness: 3.40mm to 3.50mm

M
03/12/2022

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	02/06/2022	02/06/2022	02/06/2022	

UNCONTROLLED CC7Y



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

Batch Size: 6,00,000 Tablets

Batch No.: G18 22162

Generic Health Care Pvt. Ltd.

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	02/06/2022	02/06/2022	02/06/2022	UNCONTROLLED COPY

~~UNCONTROLLED COPY~~



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

BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLP 20

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

Batch No.: G1222162

Customer:

Generic Health Care Pvt. Ltd.

8.8 IN-PROCESS CHECKS: (For IPQA)

[illegible]

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. B.</i>	<i>E. A. L. L.</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

UNCONTROLLED CC7Y



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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: 41822162

Customer:

Generic Health Care Pvt. Ltd.

8.9 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 03/12/2022		Time: 15:01		Shift: C	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	190	8	188	15	192
2	189	9	192	16	190
3	191	10	190	17	188
4	187	11	193	18	191
5	188	12	191	19	189
6	191	13	187	20	191
7	193	14	189		
Balance ID No.: PD18A002			M/C Speed: 16 RPM		
Group weight of 20 Tablets: 3800.00 g. Avg. wt: 190.00 mg			Group weight of 20 Tablets: 3827.00 g. Avg. wt: 191.35 mg		
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)		
Min weight: 187.00 mg Max. weight: 193.00 mg			Min weight: 188.00 mg Max. weight: 194.00 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 40 sec	01 min 34 sec	Equipment ID No.: QA/DTA/002	
Done by: (Production)					
Date: 03/12/2022		Time: 17:05		Shift: C	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	189	8	190	15	189
2	190	9	189	16	187
3	191	10	190	17	190
4	187	11	189	18	189
5	189	12	190	19	190
6	190	13	191	20	191
7	191	14	190		
Balance ID No.: PD18A002			M/C Speed: 16 RPM		
Group weight of 20 Tablets: 3796.00 g. Avg. wt: 189.80 mg			Group weight of 20 Tablets: 3774.00 g. Avg. wt: 188.70 mg		
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)		
Min weight: 187.00 mg Max. weight: 191.00 mg			Min weight: 187.00 mg Max. weight: 191.00 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		LHS	RHS	Equipment ID No.: QA/FRT/002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 25 sec	01 min 25 sec	Equipment ID No.: QA/DTA/001	
Done by: (Production)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 18 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1822162 Generic Health Care Pvt. Ltd.

8.10 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 03/12/2022		Time: 19:10		Shift: B							
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).							
1	187	8	188	15	188	1	188	8	190	15	189
2	189	9	189	16	189	2	191	9	189	16	191
3	190	10	190	17	191	3	190	10	192	17	190
4	189	11	188	18	190	4	189	11	190	18	189
5	192	12	189	19	189	5	188	12	189	19	186
6	189	13	191	20	190	6	189	13	191	20	189
7	188	14	190			7	191	14	192		
Balance ID No.: PD/BAL/007						M/C Speed: 16 RPM					
Group weight of 20 Tablets: 371.86.....g. Avg. wt: 18.5930.mg						Group weight of 20 Tablets: 379.3.....g. Avg. wt: 18.965.mg					
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)						Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)					
Min weight: 18.7..... mg Max. weight: 19.2..... mg						Min weight: 18.6..... mg Max. weight: 19.2..... mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.10%		0.09%		Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 22 sec		01 min 25 sec		Equipment ID No.: QA/DTA/ 002	
Done by: R. Sll (Production)											
Date: 05/12/2022		Time: 06:45		Shift: A							
LHS: Individual weight of 20 tablets (in mg).						RHS: Individual weight of 20 tablets (in mg).					
1	190	8	186	15	190	1	188	8	193	15	191
2	188	9	191	16	187	2	187	9	191	16	190
3	191	10	190	17	190	3	189	10	190	17	189
4	188	11	189	18	189	4	190	11	189	18	190
5	187	12	190	19	191	5	189	12	191	19	191
6	189	13	189	20	189	6	191	13	190	20	190
7	192	14	191			7	189	14	189		
Balance ID No.: PD/BAL/007						M/C Speed: 16 RPM					
Group weight of 20 Tablets: 379.5.....g. Avg. wt: 18.975.mg						Group weight of 20 Tablets: 379.0.....g. Avg. wt: 18.950.mg					
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)						Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)					
Min weight: 18.6..... mg Max. weight: 19.4..... mg						Min weight: 18.7..... mg Max. weight: 19.3..... mg					
						LHS		RHS			
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						0.09%		0.11%		Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)						01 min 35 sec		01 min 40 sec		Equipment ID No.: QA/DTA/ 002	
Done by: R. Sll (Production)											

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.					
Date	02/10/2022	02/06/2022	02/06/2022	02/06/2022	

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 19 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product LOLIP 20	BMR. No.: BMR/T/331-00 Customer:		Batch No.: 61222162 Generic Health Care Pvt. Ltd.

8.11 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date: 05/12/2022		Time: 08:46		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	190	8	190	15	189
2	189	9	189	16	192
3	188	10	192	17	189
4	189	11	188	18	191
5	191	12	189	19	190
6	192	13	191	20	188
7	189	14	190		
Balance ID No.: PD/R A/1007			M/C Speed: 14 RPM		
Group weight of 20 Tablets: 3796 g. Avg. wt: 189.80 mg			Group weight of 20 Tablets: 3802 g. Avg. wt: 191.00 mg		
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)		
Min weight: 188 mg Max. weight: 192 mg			Min weight: 187 mg Max. weight: 193 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.08%	0.11%	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 40 sec	01 min 25 sec	Equipment ID No.: QA/DTA/ 002	
Done by: R.ell (Production)					
Date: 05/12/2022		Time: 10:47		Shift: A	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	189	8	189	15	191
2	188	9	190	16	190
3	193	10	189	17	188
4	187	11	191	18	189
5	189	12	190	19	192
6	191	13	188	20	187
7	190	14	189		
Balance ID No.: PD/R A/1007			M/C Speed: 16 RPM		
Group weight of 20 Tablets: 3790 g. Avg. wt: 189.50 mg			Group weight of 20 Tablets: 3796 g. Avg. wt: 189.80 mg		
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)		
Min weight: 187 mg Max. weight: 193 mg			Min weight: 187 mg Max. weight: 192 mg		
		LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):		0.12%	0.11%	Equipment ID No.: QA/FRT/ 002	
Disintegration Time (Limit - NMT 15 minutes)		01 min 37 sec	01 min 41 sec	Equipment ID No.: QA/DTA/ 002	
Done by: R.ell (Production)					

Prepared by:		Checked by:		Approved By:
Dept:	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. G.	[Signature]	[Signature]	[Signature]
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022







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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1822162

Customer:

Generic Health Care Pvt. Ltd.

8.12 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)				Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			
Min weight. :..... mg Max. weight:..... mg				Min weight. :..... mg Max. weight:..... mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							
Date:		Time :		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg			
Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)				Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)			
Min weight. :..... mg Max. weight:..... mg				Min weight. :..... mg Max. weight:..... mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):				Equipment ID No.: QA/FRT/			
Disintegration Time (Limit - NMT 15 minutes)				Equipment ID No.: QA/DTA/			
Done by:(Production)							

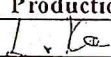
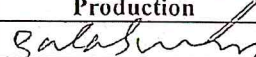
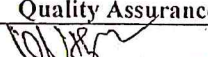
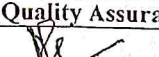
Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022	

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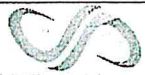
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 21 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 61222162 Generic Health Care Pvt. Ltd.

8.13 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR PRODUCTION (Frequency: Every 2 hours):

Date:		Time:		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. :..... mg Max. weight:..... mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. :..... mg Max. weight:..... mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						Equipment ID No.: QA/FRT/	
Disintegration Time (Limit - NMT 15 minutes)						Equipment ID No.: QA/DTA/	
Done by:(Production)							
Date:		Time:		Shift:			
LHS: Individual weight of 20 tablets (in mg).				RHS: Individual weight of 20 tablets (in mg).			
1	8	15		1	8	15	
2	9	16		2	9	16	
3	10	17		3	10	17	
4	11	18		4	11	18	
5	12	19		5	12	19	
6	13	20		6	13	20	
7	14			7	14		
Balance ID No.:				M/C Speed: RPM			
Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. :..... mg Max. weight:..... mg				Group weight of 20 Tablets:.....g. Avg. wt:.....mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight. :..... mg Max. weight:..... mg			
				LHS	RHS		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):						Equipment ID No.: QA/FRT/	
Disintegration Time (Limit - NMT 15 minutes)						Equipment ID No.: QA/DTA/	
Done by:(Production)							

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.				
Date	02/06/2022	02/06/2022	02/06/2022	

UNCONTROLLED CC7Y



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 MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: 41822162

Customer:

Generic Health Care Pvt. Ltd.

8.14 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 03/12/2022

Time: 15:00

Shift: B

Low RPM

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	191	8	192	15	191	1	192	8	189	15	192
2	188	9	189	16	192	2	190	9	187	16	190
3	192	10	190	17	188	3	191	10	192	17	191
4	190	11	191	18	190	4	190	11	193	18	193
5	193	12	189	19	191	5	189	12	190	19	189
6	189	13	192	20	193	6	191	13	192	20	191
7	191	14	194			7	188	14	189		

Balance ID No.: QA/BAL/002

M/C Speed: 11 RPM

Group weight of 20 Tablets: 3.816 g. Avg.
wt: 190.8 mg

Group weight of 20 Tablets: 3.809 g. Avg.
wt: 190.45 mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 188 mg Max. weight: 194 mg

Min weight: 187 mg Max. weight: 193 mg

LHS

RHS

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.14%

0.10%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

01 mins
47 sec

01 mins
37 sec

Equipment ID No.: QA/DTA/002

Done by: [Signature] 03/12/2022 (IPQA)

Date: 03/12/2022

Time: 15:09

Shift: B

High RPM

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	191	8	190	15	188	1	192	8	188	15	192
2	188	9	187	16	192	2	190	9	193	16	195
3	190	10	189	17	190	3	187	10	192	17	190
4	192	11	192	18	191	4	189	11	194	18	188
5	187	12	190	19	193	5	191	12	191	19	192
6	191	13	189	20	189	6	192	13	192	20	194
7	192	14	191			7	190	14	189		

Balance ID No.: QA/BAL/002

M/C Speed: 18 RPM

Group weight of 20 Tablets: 3.802 g. Avg.
wt: 190.1 mg

Group weight of 20 Tablets: 3.819 g. Avg.
wt: 190.95 mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 187 mg Max. weight: 193 mg

Min weight: 188 mg Max. weight: 194 mg

LHS

RHS

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

0.11%

0.09%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

01 mins
37 sec

01 mins
46 sec

Equipment ID No.: QA/DTA/002

Done by: [Signature] 03/12/2022 (IPQA)

Prepared by:

Checked by:

Approved By:

Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	[Signature]	[Signature]	[Signature]	[Signature]
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

UNCONTROLLED CC7Y

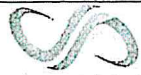
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 23 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:		Batch No.: G1822162 Generic Health Care Pvt. Ltd.

8.15 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 03/12/2022		Time: 15:15		Shift: B. Low Hardness	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	192	8	192	15	190
2	188	9	189	16	190
3	190	10	187	17	192
4	187	11	190	18	191
5	191	12	192	19	193
6	193	13	189	20	188
7	190	14	188		
Balance ID No.: QA/BAL/002			M/C Speed: 16 RPM		
Group weight of 20 Tablets: 3.802 g. Avg. wt: 190.10 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 193 mg			Group weight of 20 Tablets: 3.814 g. Avg. wt: 190.70 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 188 mg Max. weight: 194 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			0.44 min 07.32 sec	0.40 min 12.32 sec	Equipment ID No.: QA/DTA/002
Done by: [Signature] 03/12/2022 (IPQA)					
Date: 03/12/2022		Time: 15:30		Shift: B. High Hardness	
LHS: Individual weight of 20 tablets (in mg).			RHS: Individual weight of 20 tablets (in mg).		
1	190	8	191	15	189
2	188	9	190	16	192
3	192	10	192	17	190
4	190	11	190	18	189
5	189	12	191	19	191
6	194	13	190	20	190
7	191	14	190		
Balance ID No.: QA/BAL/002			M/C Speed: 16 RPM		
Group weight of 20 Tablets: 3.809 g. Avg. wt: 190.45 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 188 mg Max. weight: 194 mg			Group weight of 20 Tablets: 3.801 g. Avg. wt: 190.05 mg Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg) Min weight: 187 mg Max. weight: 193 mg		
Friability (Limit: NMT 1% after 4 minutes/100 rotations):			LHS	RHS	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)			0.03 min 03.32 sec	0.02 min 16.32 sec	Equipment ID No.: QA/DTA/002
Done by: [Signature] 03/12/2022 (IPQA)					

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	[Signature]	[Signature]	[Signature]	[Signature]
Date	02/06/2022	02/06/2022	02/06/2022	

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1822162

Customer:

Generic Health Care Pvt. Ltd.

8.16 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 03/12/2022

Time: 15:45

Shift: B Full Hopper

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	190	8	188	15	188	1	189	8	190	15	193
2	188	9	191	16	190	2	190	9	190	16	189
3	191	10	191	17	195	3	189	10	192	17	190
4	190	11	192	18	191	4	188	11	189	18	189
5	192	12	190	19	193	5	191	12	191	19	191
6	187	13	189	20	189	6	190	13	190	20	192
7	193	14	191			7	189	14	191		

Balance ID No.: QA/BAL/002

M/C Speed: 16 RPM

Group weight of 20 Tablets: 3.812 g. Avg.
wt: 190.60 mg

Group weight of 20 Tablets: 3.803 g. Avg.
wt: 190.15 mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 187 mg Max. weight: 195 mg

Min weight: 188 mg Max. weight: 193 mg

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

LHS 0.10%

RHS 0.09%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

LHS 01 min 36 sec

RHS 01 min 47 sec

Equipment ID No.: QA/DTA/002

Done by: [Signature] (IPQA)

Date: 03/12/2022

Time: 19:50

Shift: C

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	189	8	190	15	191	1	188	8	190	15	189
2	190	9	193	16	195	2	190	9	188	16	191
3	189	10	191	17	192	3	191	10	191	17	190
4	191	11	189	18	189	4	187	11	189	18	188
5	193	12	191	19	190	5	189	12	192	19	192
6	189	13	192	20	191	6	190	13	193	20	188
7	188	14	189			7	192	14	190		

Balance ID No.: QA/BAL/002

M/C Speed: 16 RPM

Group weight of 20 Tablets: 3.815 g. Avg.
wt: 190.75 mg

Group weight of 20 Tablets: 3.798 g. Avg.
wt: 189.9 mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 188 mg Max. weight: 195 mg

Min weight: 187 mg Max. weight: 193 mg

Friability (Limit: NMT 1% after 4 minutes/100 rotations):

LHS 0.04%

RHS 0.07%

Equipment ID No.: QA/FRT/002

Disintegration Time (Limit - NMT 15 minutes)

LHS 01 min 30 sec

RHS 01 min 37 sec

Equipment ID No.: QA/DTA/002

Done by: [Signature] (IPQA)

Prepared by:

Checked by:

Approved By:

Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	[Signature]	[Signature]	[Signature]	[Signature]
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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Product	LOLIP 20	BATCH MANUFACTURING RECORD	Product Code: L13	Batch Size: 6,00,000 Tablets
			BMR. No.: BMR/T/331-00	Batch No.: G1222162
			Customer:	Generic Health Care Pvt. Ltd.

8.17 UNIFORMITY OF WEIGHT INPROCESS CHECKS FOR IPQA (Frequency: Every 4 hours):

Date: 05/12/2022

Time: 07:00

Shift: A

(Middle Hopper)

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	189	8	191	15	190
2	193	9	188	16	188
3	191	10	194	17	191
4	190	11	192	18	190
5	195	12	190	19	192
6	188	13	189	20	187
7	191	14	193		

1	188	8	193	15	189
2	192	9	192	16	190
3	188	10	189	17	189
4	190	11	191	18	187
5	191	12	188	19	191
6	189	13	190	20	190
7	190	14	192		

Balance ID No.: BA/BA/002

M/C Speed: 16 RPM

Group weight of 20 Tablets: 3.212 g. Avg. wt: 190.6 mg

Group weight of 20 Tablets: 3.799 g. Avg. wt: 189.95 mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 187 mg Max. weight: 195 mg

Min weight: 187 mg Max. weight: 193 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.071	0.024	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	01 min 47 sec	01 min 39 sec	Equipment ID No.: QA/DTA/002

Done by: K. S. J. (IPQA)

Date: 05/12/2022

Time: 11:10

Shift: A

(End Hopper)

LHS: Individual weight of 20 tablets (in mg).

RHS: Individual weight of 20 tablets (in mg).

1	187	8	190	15	188
2	188	9	187	16	190
3	186	10	189	17	189
4	187	11	187	18	192
5	189	12	188	19	191
6	190	13	191	20	187
7	188	14	190		

1	189	8	193	15	191
2	187	9	190	16	193
3	190	10	190	17	190
4	182	11	189	18	188
5	189	12	191	19	189
6	190	13	188	20	192
7	191	14	192		

Balance ID No.: BA/BA/002

M/C Speed: 16 RPM

Group weight of 20 Tablets: 3.774 g. Avg. wt: 188.7 mg

Group weight of 20 Tablets: 3.805 g. Avg. wt: 190.25 mg

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Limit: 190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)

Min weight: 186 mg Max. weight: 192 mg

Min weight: 187 mg Max. weight: 194 mg

	LHS	RHS	
Friability (Limit: NMT 1% after 4 minutes/100 rotations):	0.09%	0.02%	Equipment ID No.: QA/FRT/002
Disintegration Time (Limit - NMT 15 minutes)	01 min 45 sec	01 min 39 sec	Equipment ID No.: QA/DTA/002

Done by: A. K. (IPQA)

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>S. A. S.</i>	<i>V. K.</i>	<i>V. K.</i>
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1822162

Customer:

Generic Health Care Pvt. Ltd.

8.18 WEIGHING RECORD OF COMPRESSED TABLETS:

S. No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	30.310	1.900	28.410	vetri	R.ell	9.5
2	30.500	2.100	28.400	vetri	R.ell	9.5
3	26.350	2.200	24.150	vetri	R.ell	9.5
4	34.430	2.480	31.950	vetri	R.ell	9.5
5						
6						
7						
8						
9						
10						

8.19 RECONCILIATION (COMPRESSION STAGE):

Average weight of Uncoated Tablet: 19.0...mg

1.0	Standard Batch size	:	114.000 Kg.	6,00,000 No.
2.0	Actual weight of Lubricated granules	:	113.700 Kg	598421 Nos.
3.0	Weight of compressed tablets	:	112.910 Kg	594263 Nos.
4.0	Rejection during Compression @	:	0.020 Kg.	
5.0	In-process samples of all stages			
	A	IPQC Samples	: 0.100 Kg.	
	B	QC Samples	: 0.010 Kg.	
	C	Validation Samples	: 0.010 Kg.	
6.0	Total in process samples: (A + B + C)	:	0.220 Kg.	
7.0	Total: (3.0 + 6.0)	:	113.120 Kg.	595368 Nos.
8.0	Yield {7.0 / 1.0 x 100}*	:		99.22 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.550 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: R.ell 05/11/2022 Checked by IPQA Sign/Date: G.1805/12/2022

Test request form raised by Prod Sign/Date: R.ell 03/11/2022

Test request form received by IPQA Sign/Date: G.1803/11/2022

8.20 RELEASED FOR COATING:

Reconciliation checked and compressed tablets released for coating:

IPQA Sign: ARB Date: 05/12/2022

Prepared by:		Checked by:		Approved By:
Dept:	Production	Production	Quality Assurance	Head Quality Assurance
Sign:				
Date:	02/10/2022	02/10/2022	02/10/2022	

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	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 413 22162 Generic Health Care Pvt. Ltd.

9.0 LINE CLEARANCE FOR COATING SOLUTION PREPARATION:

Date/Shift/Time: 05/12/2022 / B / 16:25 / NA

Sr. No.	Checks	*Observation			
		Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓		
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓		
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓		
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓		
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	✓	✓		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓		

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

Equipment	Solution preparation vessel and stirrer	Colloidal Mill	Area
Equipment ID No.	NA	PD/CLM1001	Soln-prep-area
Previous product	Taintoco C2+		
Batch No.	716 SPL 2203 F		
Cleaned by	Abi		
Checked by Production Sign/Date:	05/12/2022		
Verified by IPQA Sign/Date:	05/12/2022		

ENVIRONMENTAL CONDITIONS:

		Date: 05/12/2022 Time: 16:08			Date: Time:		
		Observation	Prod. Sign.	Verified by IPQA	Observation	Prod. Sign.	Verified by IPQA
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	23 °C	05	Abi		NA	
	Relative Humidity % Limit: NMT 60%	52 %	05	Abi			

APPROVAL FOR COATING SOLUTION PREPARATION:

Production Sign/Date: 05/12/2022

Line Clearance IPQA Sign. / Date: 05/12/2022

Start Time/Date: 16:15 / 05/12/2022

End Time/Date: 16:29 / 05/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. K.	Subashini	05/12/2022	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 28 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: G1222162 Generic Health Care Pvt. Ltd.

10.0 Coating Procedure:

10.1 General Instructions:

1. Prepare the coating solution lot wise.
2. Do not use synthetic containers for storage/ transfer of coating solution
3. Do not use high speed stirrer for preparing coating solution. Avoid direct contact of body with Solvent & coating solution. Solvent based coating should be done in spark proof area.

10.2 TABLETS RECEIPT RECORD OF UNCOATED TABLETS FOR COATING:

Balance ID. No.: PD/Ra/1015

Date/Shift/Time: 05/12/2022/B/16:13

Sr. No.	Description	Observations	Checked By (Production)	Verified By (IPQA)
1.	Total Quantity (Net Qty.in Kg)	112.910	AB	ASH
2.	Number of Containers	04	AB	ASH

10.3 COATING SOLUTION PREPARATION

Sr. No.	General Instructions					
1.	Check the cleanliness of the Solution Preparation area and operation as per current version of SOP.					
2.	Use hand gloves while handling the materials					
3.	Transfer the verified coating materials to Coating solution preparation area.					
Step No.	Name of Ingredient & Operation	Time		Done by	Checked by Prod.	Verified by IPQA
		Start	Finish			
1	Take Isopropyl Alcohol in a SS Vessel. Slowly disperse Wincoat WT White 02022 and Yellow oxide of Iron and stir well to disperse completely.	16:15	16:20	Abi	AB	ASH
2	Take Purified Water in a SS Vessel. Slowly disperse Tween 80 and stir well to disperse completely.	16:21	16:26	Abi	AB	ASH
3	Add Step 2 solution into the Step 1 solution and stir well with remaining quantity of Purified Water. If required mill the solution with Colloidal mill for 2 minutes	16:27	16:29	Abi	AB	ASH

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	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1822162

Customer:

Generic Health Care Pvt. Ltd.

11.0 COATING AREA:

LINE CLEARANCE CHECKS:

Date/Shift/Time: 05/12/2022 / B /

Sr. No.	Checks	*Observation					
		Prod.	IPQA	Prod.	IPQA	Prod.	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	✓	✓				
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	✓	✓				
3	Check and ensure that machine body, machine parts and control panel are clean.	✓	✓				
4	Check and ensure that absence of previous batch/product below container weighing balance.	✓	✓				
5	Check and ensure that working desk, analytical balance and other accessories are clean.	✓	✓				
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures and Drain point are clean.	✓	✓				
7	Check and ensure that instruments to be used are within calibration due date.	✓	✓				
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	✓	✓				
9	Check and ensure that environmental conditions are recorded in the BMR.	✓	✓				
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF)	✓	✓				
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	✓	✓				

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

Equipment	Coating Machine	Area
Equipment ID No.	PD1 NCC 1001	Coating area - 01
Previous product	Taintance C2+	
Batch No.	7168 PL 2203 F	
Cleaned by	Alo	
Checked by Production	AB	
Sign/Date:	05/12/2022	
Verified by IPQA Sign/Date:	ABK 05/12/2022	

ENVIRONMENTAL CONDITIONS:		Date: 05/12/2022 Time: 10:00			Date: Time:			Date: Time:		
		Observation	Checked by	Verified by	Observation	Checked by	Verified by	Observation	Checked by	Verified by
(Refer to SOP No.: QAGN/011)	Temperature °C Limit: NMT 25 °C	28°C	AB	ABK						
	Relative Humidity % Limit: NMT 60%	52%	AB	ABK						
	Differential Pressure (NLT 10 Pascal)	11 Pa seal	AB	ABK						

APPROVAL FOR COATING:

Production Sign/Date: AB 05/12/2022

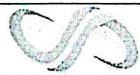
Line Clearance IPQA Sign. / Date: ABK 05/12/2022

Start Time/Date: 16:33 / 05/12/2022

End Time/Date: 18:25 / 05/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	AB	ABK	ABK	ABK
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product: LOLIP 20

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

Batch No.: G1222162

Customer:

Generic Health Care Pvt. Ltd.

11.1 COATING PROCESS:

Process Steps					
Step No.	Name of Ingredient & Operation	Time		Done by	Ckd by Prod.
		Start	Finish		
1	Transfer the compressed tablets in to the coating Area	16:33	16:36	Abi	24
2	Pre-warm the tablet with inlet temp. 35°C to 45°C.	16:37	16:47	Abi	24
3	Arrange the spray gun in such a way that the spray droplets just touch the tablet bed on upper rim. The spray should not fall on the wall of the pan. Weight gain obtained: 2.15 % (2.0 - 2.2%)	16:48	18:13	Abi	24
4	When the spraying is complete, dry the tablets perfectly, in the pan by keeping inlet temp. 40°C-50 °C with intermittently flipping the tablets, until no more solvent odour is observed. Caution: Ensure the tablet bed temperature does not rise excessively.	18:14	18:19	Abi	24
5	Monitor DT: Limit: NMT 30 minutes. Found Disintegration Time: 03min 08 sec	18:20	18:25	Abi	24
6	Unload the film coated tablets in a HDPE container lined with double polybag.			Abi	24

11.2 INITIAL CHECKS OF COATING PARAMETERS:

S. No	Parameter	Set	Observed
1	Inlet air Temp.	35°C to 45°C (To be established)	44°C
2	Exhaust air Temp.	50 ± 5 °C (To be established)	52°C
3	Tablet Bed temp.	40°C-50 °C (To be established)	43°C
4	Atomization air pressure	2.0 - 3.0 Kg/cm ² (To be established)	2.5 Kg/cm ²
5	Pan speed	2.0 - 4.0 RPM (To be established)	3.0 RPM
6	Spray rate	30 to 70 ml/min (To be established)	70 ml/min
Checked by Production/ Date			24/05/2022
Verified by IPQA/ Date			24/05/2022

11.3 INDIVIDUAL WEIGHT CHECKING OF PRE-WARMED TABLETS:

Sr. No.	Weight (mg)	Sr. No.	Weight (mg)
1	187	11	190
2	191	12	188
3	190	13	190
4	188	14	192
5	190	15	187
6	192	16	189
7	190	17	190
8	188	18	190
9	189	19	188
10	190	20	191
Total		3,810 g	
Avg. Weight		190.50 g	

11.4 FINAL COATING PARAMETERS CHECKS: (PRODUCTION)

Parameters	Limits	Observed
Description	Pale yellow coloured, circular shaped, film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	195.000 mg ± 3 % (189.150 mg - 200.850 mg)	193.26 (mg)
Weight of 20 tablets	3.900 g ± 3 % (3.783 g - 4.017 g)	3.865 g
Uniformity of weight	195.000 mg ± 5 % (185.250 mg - 204.750 mg)	-1.71% / 0.89%
Thickness	3.80 mm ± 0.2 mm (3.60 mm to 4.00 mm) (To be established)	3.42 - 3.53 (mm)
Disintegration test	NMT 30 min	03 min 08 sec
Checked by Production/ Date		24/05/2022

Prepared by:		Checked by:		Approved By:	
Dept.	Production	Production	Quality Assurance	Head Quality Assurance	
Sign.					
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022	

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

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1822162

Customer:

Generic Health Care Pvt. Ltd.

11.5 FINAL COATING PARAMETERS CHECKS: (IPOA)

Parameters	Limits	Observed
Description	Pale yellow coloured, circular shaped, film coated tablet with breakline on one side and plain on other side	OK
Theoretical weight per tablet	195.000 mg $\pm$ 3 % (189.150 mg – 200.850 mg)	194.60 mg
Weight of 20 tablets	3.900 g $\pm$ 3 % (3.783 g – 4.017 g)	3.824 g
Uniformity of weight	195.000 mg $\pm$ 5 % (185.250 mg – 204.750 mg)	-1.24 / 0.71
Thickness	3.80 mm $\pm$ 0.2 mm (3.60 mm to 4.00 mm) (To be established)	3.45 - 3.55 mm
Disintegration test	NMT 30 min	03 min 10 sec
Checked by IPQA/ Date		17/05/2022

11.6 FILM COATING WEIGHT GAIN PARAMETER CHECKS:

[illegible]

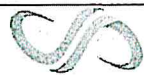
11.7 WEIGHT CHECK FOR 20 TABLETS:

BY PRODUCTION			BY IPQA		
S. NO.	INITIAL WEIGHT	FINAL WEIGHT	S. NO.	INITIAL WEIGHT	FINAL WEIGHT
1	190	192	1	191	195
2	188	191	2	189	193
3	191	190	3	187	194
4	189	193	4	190	194
5	187	191	5	191	195
6	190	192	6	190	193
7	189	190	7	190	191
8	190	193	8	191	194
9	190	191	9	188	194
10	183	192	10	191	192
11	190	190	11	188	193
12	189	195	12	189	191
13	191	194	13	190	193
14	190	192	14	188	192
15	188	193	15	191	193
16	190	191	16	190	193
17	189	190	17	189	191
18	191	194	18	190	191
19	190	193	19	188	192
20	188	191	20	190	196
TOTAL	3788	3838	TOTAL	3790	3860
Checked by Production:		205/12/2022	Checked by IPQA:		205/11/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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LIFE BIOTECH PVT LTD

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

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: 41822162

Customer:

Generic Health Care Pvt. Ltd.

11.8 PERCENTAGE OF COATING WEIGHT BUILDS UP:

$$\% \text{ of Weight buildup} = \frac{\text{Avg. wt. of coated tablets} - \text{Avg. wt. of core tablet (Pre-warmed)}}{\text{Avg. wt. of core tablets (Pre-warmed)}} \times 100$$

$$= 1.62\%$$

11.9 ACTUAL AVERAGE WEIGHT OF COATED TABLETS:

$$\frac{\text{Weight of 100 coated tablet}}{100} = 193.60 \text{ mg}$$

11.10 WEIGHT OF FILM COATED TABLETS:

Container No.	Gross Weight (Kg)	Tare Weight (Kg)	Net weight (Kg)	Weighed by	Checked by Production	Verified by IPQA
1	27.720	2.400	25.320	Karthi	27	18
2	30.910	2.400	28.510	Karthi	27	18
3	29.910	1.900	28.010	Karthi	27	18
4	25.410	2.110	23.300	Karthi	27	18
5				M		1
TOTAL			115.200			

11.11 RECONCILIATION (COATING STAGE):

Average weight of coated Tablet: 193.60 mg

1.0	Batch size	:	117.000 Kg.	6,00,000 Nos.
2.0	Weight of coated tablets	:	115.200 Kg.	595041 Nos.
3.0	Coating loss@	:	0.010 Kg.	
4.0	In-process samples of all stages			
	A	IPQC Samples	: 0.020 Kg.	
	B	QC Samples	: 0.020 Kg.	
	C	Validation Samples	: NA Kg.	
5.0	Total in process samples: (A + B + C)	:	0.040 Kg.	
6.0	Total: (2.0 + 5.0)	:	115.240 Kg.	595247 Nos.
7.0	Yield {6.0 x 100 / 1.0}*	:		99.21 %

* Actually yield will be calculated after 3 validation batches

@Total rejects destroyed: 0.010 Kg. (Rejected materials shall be destroyed as per SOP No.: QAGN/048)

Done by Production Sign/Date: 27/05/2022 Checked by IPQA Sign/Date: 18/05/2022

Test request form raised by Prod Sign/Date: 05/12/2022

Test request form received by IPQA Sign/Date: 18/05/2022

11.12 RELEASE FOR INSPECTION:

Reconciliation checked and coated tablets released for inspection

IPQA Sign: 06/12/2022 Date: 06/12/2022

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign:	L. K.	3/12/2022	11/12/2022	
Date:	02/06/2022	02/06/2022	02/06/2022	

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SAI PRIMUS LIFE BIOTECH PVT LTD

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

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BATCH MANUFACTURING RECORD

Product Code: L13

Batch Size: 6,00,000 Tablets

Product

LOLIP 20

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

Batch No.: G1822/b2

Customer:

Generic Health Care Pvt. Ltd.

12.0 INSPECTION LINE CLEARANCE:

Date/Shift/Time: 06/12/22/A/15:05

Sr. No.	Checks	*Observation			
		Prod	IPQA	Prod	IPQA
1	Check and ensure that empty containers, polythene bags, Tags and documents of previous batch/product are removed.	/	/		
2	Check and ensure that absence of previous batch/product from area below machine and inside machine.	/	/		
3	Check and ensure that machine body, machine parts and control panel are clean.	/	/		
4	Check and ensure that absence of previous batch/product below container weighing balance.	/	/		
5	Check and ensure that working desk, analytical balance and other accessories are clean.	/	/		
6	Check and ensure that Tube light fixture, supply grills, riser grills and filters, electrical fixtures are clean.	/	/		
7	Check and ensure that instruments to be used are within calibration due date.	/	/		
8	Check and ensure that daily records (Logbook, Balance, Temp. and RH) are updated and signed.	/	/		
9	Check and ensure that environmental conditions are recorded in the BMR.	/	/		
10	Check and ensure that rinse water is released from QC and attached the test request from (TRF) in BMR	/	/		
11	Equipment status is updated for Cleaned, Qualification and Preventive maintenance.	/	/		

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

Equipment	Inspection Belt	Metal Detector	Area
Equipment ID No.	PDI MNR 1002	PDI MED/002	Inspection - 02
Previous product	Cela-mox 102 plus		
Batch No.	527 SPL 2205		
Cleaned by	Sai M 06/12/22		
Checked by Production Sign/Date:	M 06/12/22		
Verified by IPQA Sign/Date:	G.P. 06/12/22		

ENVIRONMENTAL CONDITIONS:

Date: 06/12/22 Time: 15:10

Date: Time:

Observation

Prod. Sign.

Verified by IPQA

Observation

Prod. Sign.

Verified by IPQA

(Refer to
SOP No.:
QAGN/011)

Temperature °C Limit: NMT 25 °C

23 °C

M

G.P.

Relative Humidity % Limit: NMT 60%

52 %

M

G.P.

APPROVAL FOR INSPECTION:

Production Sign/Date: M 06/12/22

Line Clearance IPQA Sign. / Date: G.P. 06/12/22

Start Time/Date: 15:15 / 06/12/2022

End Time/Date: 08:18:00 / 06/12/2022

*Wt
R-41

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	Sai M	G.P.	
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
	Product: LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 41222162 Generic Health Care Pvt. Ltd.

13.0 INSPECTION PROCESS

13.1 INSTRUCTIONS

S. No.	Process Instructions
1	Carry out visual inspection of tablets on inspection belt area as per the SOP No. PDOP/019.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

13.2 PERFORMANCE CHECKS RECORD FOR METAL DETECTOR:

Sr. No	Process instructions
1.	At the start of the activity, after each break and at the end of operation/shift) as per SOP No. PDGN/022.
2.	Testing frequency: Startup, End of the activity and after every break time.
3.	Acceptance Criteria: 1. Ferrous, Stainless steel & Non-Ferrous shall be detected & rejected. 2. Nonmetallic shall not be detected.

Date & Time	Trial No.	Metal Detector ID No.: PD/MED/.....&PD/MED/.....					Checked by Production	Verified By IPQA
		Ferrous (0.3 mm)	Stainless steel (0.5 mm)	Non-Ferrous (0.4 mm)	Non-metallic	Result		
15:20	1	✓	✓	✓	X	Pass	R.ell	ABK
	2	✓	✓	✓	X	Pass	R.ell	ABK
	3	✓	✓	✓	X	Pass	R.ell	ABK
18:00	1	✓	✓	✓	X	Pass	R.ell	ABK
	2	✓	✓	✓	X	Pass	R.ell	ABK
	3	✓	✓	✓	X	Pass	R.ell	ABK
	1							
	2							
	3							
	1							
	2							
	3							
	1							
	2							
	3							

Note: Put ✓ mark for detection and X mark for non-detection
 If during the test Metal Detector fails to reject any of the Standard chips then mention the corrective action taken.
 (To be filled by Production)
 Note: Take QA Approval before proceeding to next stage

13.3 TABLETS VISUAL INSPECTION RECORD:

Date	Container No		Time		Total Quantity Rejected	Tablet Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
06/12/2022	15:15	18:00	15:15	18:00	0.200	vitoria	R.ell 06/12/22

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	L. Ka	30/06/2022	02/06/2022	02/06/2022
Date	02/06/2022	02/06/2022	02/06/2022	02/06/2022

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 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		Page 35 of 35
	BATCH MANUFACTURING RECORD		Product Code: L13 Batch Size: 6,00,000 Tablets
Product	LOLIP 20	BMR. No.: BMR/T/331-00 Customer:	Batch No.: 61822162 Generic Health Care Pvt. Ltd.

13.4 WEIGHING RECORD OF INSPECTED TABLETS:

Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg	Container No	Gross weight Kg	Tare weight Kg	Net. weight Kg
1	28.400	2.600	26.400	6			
2	28.800	2.000	26.800	7			
3	29.000	2.200	26.800	8			
4	36.900	1.900	35.000	9			
5				10			
Total			Kg	Total			Kg
				Grand Total			115.000 Kg

Weighing Done By: Nichol Checked By Prod./ Date: R. ell 06/12/2022 Verified by IPQA Sign./Date: Alk 06/12/2022

13.5 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of Tablets	:	117.000 kg	6,00,000 No's
2.0	Tablets transferred for Inspection	:	115.200 kg	595041 No's
3.0	Total weight of good Tablets	:	115.000 kg	594008 No's
4.0	Rejected Tablets	:	0.200 kg	1033 No's
5.0	*Yield = $\frac{3.0}{1.0} \times 100$	:		99.00 %

*Actually yield will be calculated after 3 validation batches.

Total rejects destroyed: 0.200 Kg.

Rejected materials should be destroyed in the presence of QA.

Done by Production sign./Date: R. ell 06/12/2022

Checked by IPQA sign./Date: Alk 06/12/2022

13.6 RELEASE FOR PACKING:

BMR reviewed by IPQA Sign./Date : <u>Alk 06/12/2022</u>
BMR Released for packing by QA Head Sign./Date: <u>Alk 06/12/2022</u>

14.0 BMR REVIEW DETAILS:

Reviewed by	Name	Sign./Date
Production Executive	Surendhar . R	R. ell 06/12/2022
QA Executive	PRASANTH	G.P 06/12/2022
Production Assistant Manager/ HOD	MOOP MOHAMMED	M 06/12/2022
QA Manager/ HOD	RAN KUMAR	(F) (P) 06/12/2022

15.0 REVISION HISTORY:

Sr. No.	Document No.	Reason for Revision	Supersedes No.
1	BMR/T/331-00	New Document	Nil

Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<u>L. K</u>	<u>Alk</u>	<u>Alk</u>	<u>Alk</u>
Date	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>	<u>02/06/2022</u>

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