

 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 : 591875 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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Prepared by:		Checked by:		Approved By:
Dept.	Production	Production	Quality Assurance	Head Quality Assurance
Sign.	<i>L. K.</i>	<i>S. K.</i>	<i>[Signature]</i>	<i>[Signature]</i>
Date	02/06/2022	02/06/2022	02/06/2022	02/06/22

UNCONTROLLED CCPY

 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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