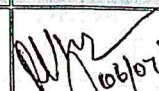
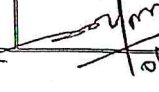


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PROCESS VALIDATION PROTOCOL			Batch Size: 600000
Product name	LOLIP-20	Effective Date	06/07/2022
Protocol No.	PVP: L13	Ref. SOP No.	QAGN/017

PROCESS VALIDATION PROTOCOL

Product Name	LOLIP-10
Label claim	Each film coated tablet contains: Atorvastatin calcium Trihydrate Equivalent to Atorvastatin 20 mg Colour: Approved colour used.
Dosage Form	Tablets
Reference BMR No	BMR/T/331-00
Batch Size	6,00,000
Shelf Life	36 Months
MFG. LIC. NO.	PON/DRUGS/21 14 4376

PROTOCOL APPROVAL

	Department	Name	Designation	Sign & date
Prepared by	Quality Assurance	V. Uthaya Kumar	Asst. Manager	 06/07/2022
Reviewed by	Production	B. VASUBRAMANIAM	JAM	 06/07/2022
	Quality Control	A. VALLARASAN	Asst. N	 06/07/2022
Approved by	Quality Assurance	R. Stephen	Manager	 06/07/2022

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PROCESS VALIDATION PROTOCOL

Batch Size: 600000

Product name	LOLIP-20	Effective Date	06/07/2022
Protocol No.	PVP: L13	Ref. SOP No.	QAGN/017

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2.0 OBJECTIVE

To monitor the process for establishing documented evidence to ensure that the process variables including the critical process parameters are under control and to demonstrate that the process consistently produces a product meeting its predetermined specification and quality attributes.

3.0 SCOPE

The validation activity shall be carried out to ensure that this product, meets predetermined specification and quality attributes when manufactured in stages from Dispensing, Granulation, Compression, Coating and Packing.

4.0 RESPONSIBILITY

Department	Responsibilities
Quality Assurance	To prepare, review, approved and authorized the protocol. Execution these protocol samplings during validation as per sampling plan.
Production	To review and approve the protocol and to co-ordinate and support for process validation.
Quality Control	To review and approve the protocol and responsible to analysis of collected samples.

5.0 IDENTIFICATION OF VALIDATION TEAM AND TRAINING

Personnel shall be identified from QA, QC, PD department and trained for executing this validation activity.

S. No.	Name	Department	Designation	Sign/Date
1.	R. Senthil Kumar	QA Executive	Executive	[Signature] 06/07/2022
2.	Pruthi	QA	Executive	[Signature] 06/07/2022
3.	Chiruvaram	Production	Executive	[Signature] 06/07/2022
4.	R. Chiruvaram	Production	Executive	[Signature] 06/07/2022

Training details

Name of the trainer: R. Senthil Kumar,

Duration: 80 min.

Training details shall be attached in training attendance sheet.

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PROCESS VALIDATION PROTOCOL

Batch Size: 600000

Product name LOLIP-20

Effective Date 06/07/2022

Protocol No. PVP: L13

Ref. SOP No. QAGN/017

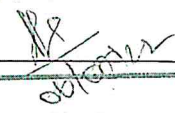
6.0 ABBREVIATIONS

Acronym	Definition	Acronym	Definition
P	Protocol	NMT	Not more than
QA	Quality Assurance	°C	Degree Celsius
QC	Quality Control	%	Percentage
PV	Process validation	mg.	Milligram
BMR	Batch manufacturing record	RPM	Rotation per minute
TABS	Tablets	RSD	Relative standard deviation
IP	Indian pharmacopeia	OOS	Out of Specification
BP	British pharmacopeia	g.	Gram
USP	United states pharmacopeia	Kg.	Kilogram
ICH	International conference on harmonization	lt.	Litre
cGMP	Current Good Manufacturing practices	mm.	Millimetre
IH	In house	ml.	Millilitre
API	Active pharmaceutical ingredient	NLT	Not less than
PD	Production	FG	Finished goods
ID	Identification	RH	Relative humidity
S.	Serial	R-LAF	Reverse laminar Air flow
No.	Number	LOD	Loss on drying
CPP	Critical process parameter	DT	Disintegration time
CQA	Critical quality attributes	Qty.	Quantity
CPC	Critical process control	IPC	In process container
UV	Ultra violet	NA	Not applicable
HPLC	High performance liquid chromatography	MLT	Microbial limit test
Max.	Maximum	HMI	Human Machine Interface
Min.	Minimum		

7.0 TYPE OF VALIDATION

Prospective validation	√
Concurrent validation	-
Re-validation	-

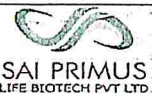
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8.0 REASON FOR VALIDATION

Reasons	Tick in the appropriate row	Reasons	Tick in the appropriate row
New formulation	√	Significant changes in process	-
Change in formulation	-	Change/modification in equipment	-
Change in location	-	Any other reasons (specify)	Concurrent validation
Critical change in some of materials	-		

9.0 PRE REQUISITES OF PROCESS VALIDATION

The batches will be manufactured as per the respective batch manufacturing record.

The equipments utilized for manufacturing as per list of equipments and BMR.

The raw material used for manufacturing will be from approved manufacturer and shall be released by quality control.

The critical process parameters of the process will be evaluated with respect to quality attributes of the products

Sampling of in-process samples will be carried as per established sampling procedure and plan.

Critical in-process will be evaluated with respect to the laid down specification.

Finished drug product of these batches will be analysed as per laid down test procedures and comply with respect to the specifications.

10.0 PRODUCT DETAILS

Product Name	LOLIP-20		
Dosage Form	Oral Tablet		
Label Claim	Each film coated tablet contains: Atorvastatin calcium Trihydrate Equivalent to Atorvastatin 20 mg Colour: Approved colour used.		
Average weight of Coated tablet	195.00 mg		
Batch number	1	2	3
	G1822106	G1822161	G1822162
Batch size	600000	600000	600000
Manufacturing date	07/2022	11/2022	11/2022
Expiry date	06/2025	10/2025	10/2025
Started on	01/07/2022	20/11/22	05/12/2022
Completed on	15/07/2022	05/12/22	06/12/2022

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Product name	LOLIP-20	Effective Date	06/07/2022
Protocol No.	PVP: L13	Ref. SOP No.	QAGN/017

11.0 BILL OF MATERIALS

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

12.0 RAW MATERIAL ANALYTICAL REPORT NUMBERS USED FOR BATCHES

All raw material analytical report numbers refer BMR.

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PROCESS VALIDATION PROTOCOL

Batch Size: 600000

Product name	LOLIP-20	Effective Date	06/07/2022
Protocol No.	PVP: L13	Ref. SOP No.	QAGN/017

13.0 PROCESS EQUIPMENT DESCRIPTION

S. No.	Equipment name	Equipment ID No	Calibration/qualification status
			Next calibration due
1.	Dispensing Booth	ST/DSB/001	Qualified
2.	Vibratory sifter	RD/VBS/001	Qualified
3.	RMG	RD/RMG/001	Qualified
4.	FBD	RD/FBD/001	Qualified
5.	Multi mill	RD/MLM/001	Qualified
6.	Octagonal blender	RD/OCB/001	Qualified
7.	Compression machine	PD/COM/002	Qualified
8.	Packing machine (Alu Alu Packing)	PD/ALU/001	Qualified
9.	Weighing balance (IPQA)	QA/BAL/002	Calibrated
10.	Vernier caliper	QA/VEC/001	Calibrated
11.	Friability apparatus	QA/FRT/001	Calibrated
12.	Hardness tester	QA/HRT/001	Calibrated
13.	Disintegration tester	QA/DTA/002	Calibrated
14.	Moisture balance	QA/MTA/001	Calibrated
15.	Tap density tester	QC/TDA/001	Calibrated
16.	Dissolution test apparatus	QC/DIS/001	Qualified
17.	Sieve Shaker	QC/SSH/001	Qualified
18.	HPLC	QC/HPL/001	Qualified
19.	UV	QC/UVS/001	Qualified

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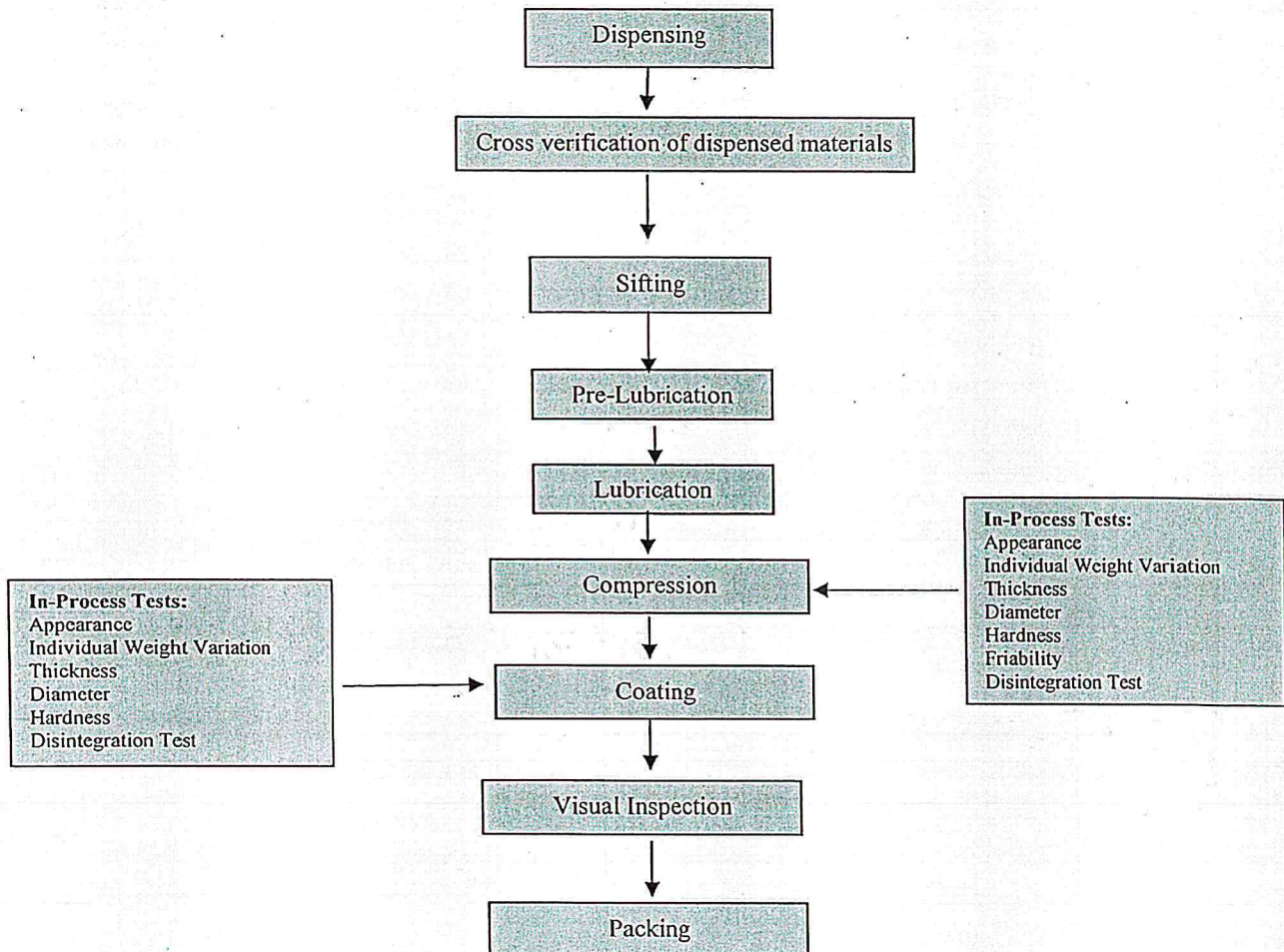
Product name **LOLIP-20**

Effective Date **06/07/2022**

Protocol No. **PVP: L13**

Ref. SOP No. **QAGN/017**

14.0 PROCESS FLOWCHART



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15.0 CRITICAL PROCESS PARAMETERS AND CRITICAL PROCESS ATTRIBUTES

S. No	Process stage	CPP	CQA	CPC	Rational for selection	Process verification
1.	Dispensing	Weighing balance	Weight variation	Manual	Critical process leads to affect product quality	Monthly calibration status and daily verification status will be verified before the use.
2.	Vibratory sifter	Sieve size	Size reduction	Manual	Size of the partial may leads to product quality	Sieve size selection done based on BMR. Sieve integrity shall be verified before and after use.
3.	Granulation	Mixing Time/Speed/Drying Time	Uniformity	HMI	To ensure the mixing proper granulation, To ensure the total drying time and loss on drying.	Through Proper verification
4.	Blending	RPM & Time	Assay and blend uniformity.	Manual	RPM and mixing time will affect the affect product quality.	- Set RPM & time intervals samples shall be collected. - Sampling locations shall be identified based on the occupancy of blender. - Blending/ lubrication time shall be concluded after execution of batches.
5.	Compression	Turret RPM	Physical, chemical properties of tablets.	HMI/ Manual	Turret speed, hardness, hydraulic pressure, penetration, granule level in hopper will affect product quality.	- Sample shall be collect at thickness, various speed, hopper near empty level - Turret RPM & hydraulic pressure shall be verified.
		Compression pressure				
		Hopper level				
6.	Coating	- Pan speed - Temperature - Pressure - Spray rate	Description of tablets, weight gain & spray rate.	manual	Pan RPM, Inlet air temperature, Exhaust temperature, Bed temperature, Spray gun air pressure, Atomizing air pressure, Spray rate.	Check the spray rate, inlet, out let & bed temperature.

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16.0 STAGE WISE SAMPLING LOCATION AND SAMPLE QUANTITY

Stage	Sample Location	Sample size		Test
Lubrication	10Location Sample	Unit dose 1x to 3x, where x = 190 mg (190.0 mg to 570 mg).		Blend uniformity
Lubricated Blend	Composite sample	75 gm		As per in-process specification
Compression	Hardness Challenge	LHS	100 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Dissolution.
		RHS		
Compression	Speed challenge (RPM)	LHS	100 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Assay
		RHS		
Compression	Hopper level challenge	LHS	100 tablets	Description, average weight, Uniformity of weight, thickness, hardness, friability, disintegration time and Assay
		RHS		
Compression	Composite sample	100 tablets		Complete analysis as per in-process compressed tablets specification
		25 g		Microbial tests as per finished product specification
Coating	Composite sample	100 tablets		Complete analysis as per finished product coated tablets specification.
				Microbial tests as per finished product specification

17.0 ACCEPTANCE CRITERIA FOR ALL STAGES

17.1 In process specification for Lubricated blend

S. No.	Test	Specification
1.	Appearance	White colour granular powder
2.	Blend uniformity (Atorvastatin Calcium)	NLT 90%
3.	%RSD	NMT 5 %
4.	Bulk density	For information only
5.	Tap density	For information only
6.	Particle size	For information only
7.	LOD	For information only
8.	Assay (Atorvastatin Calcium)	NLT 90%

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PROCESS VALIDATION PROTOCOL

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Product name	LOLIP-20	Effective Date	06/07/2022
Protocol No.	PVP: L13	Ref. SOP No.	QAGN/017

17.2 In process product specification (Core Tablets Specification)

S. No.	Test	Specification
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side
2.	Average weight(mg)	190.000 mg $\pm$ 3.0 % (184.300 mg – 195.700 mg)
3.	Group Weight	3.800 g $\pm$ 3.0 % (3.686 g to 3.914 g)
4.	Uniformity of weight Tablets	190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)
5.	Hardness	NLT 3.0 Kg (To be established)
6.	Thickness (mm)	3.70 $\pm$ 0.2 mm 3.50 mm – 3.90 mm (To be established)
7.	Friability	NMT 1% w/w
8.	Disintegration Time	NMT 15 Minutes

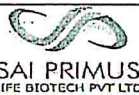
17.3 In process product specification (Coated Tablets Specification)

S.No.	TEST	SPECIFICATIONS
1	Appearance	Pale yellow coloured, circular shaped, film coated tablet with breakline on one side and plain on other side
2	Identification	
	A. By UV	The UV absorption spectrum of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.
	B. By HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.
3	Average weight	195.000 mg $\pm$ 3 % (189.150 mg – 200.850 mg)
4	Uniformity of weight	NMT 2 tablets deviate by more than 7.5% and none deviates by more than 15.0% from the average weight.
5	Thickness	3.80 mm $\pm$ 0.2 mm (3.60 mm to 4.00 mm)
6	Hardness	NLT 3.0 kg
7	Disintegration Time	NMT 30 minutes
8	Dissolution	Not less than 85 % of labeled amount.
9	Uniformity of Dosage Unit	L1: NMT 15
10	Assay by HPLC	
	Each film coated tablet contains:	
	Atorvastatin calcium equivalent to Atorvastatin	18.9 mg to 21.0 mg (94.5 % to 105.0 %)
11	Related Substance By HPLC	1. Atorvastatin Pyrrolidone analog NMT 0.5% 2. Atorvastatin related compound H NMT 1.0%

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Product name	LOLIP-20	Effective Date	06/07/2022
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		3. Atorvastatin epoxy pyrrolooxazin 6-hydroxy analog NMT 0.5% 4. Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog NMT 0.5% 5. Atorvastatin epoxy THF analog NMT 1.0% 6. Atorvastatin related compound D NMT 0.5% 7. Any other unspecified degradation product NMT 0.2% 8. Total degradation products NMT 4.0%
12	Microbiological Limits	1. Total Aerobic Microbial Counts NMT 1000 CFU/g 2. Total combined Yeasts and Mould counts NMT 100CFU/g 3. E.coli should be absent

17.3 Finished product specification (Coated Tablets)

S. No.	Test	Specification
1.	Appearance	Pale yellow coloured, circular shaped, film coated tablet with breakline on one side and plain on other side
2.	Average weight(mg)	195.000 mg $\pm$ 3 % (189.150 mg – 200.850 mg)
3.	Group Weight	3.900 g $\pm$ 3 % (3.783 g – 4.017 g)
4.	Uniformity of weight Tablets	195.000 mg $\pm$ 5 % (185.250 mg – 204.750 mg)
5.	Thickness (mm)	3.80 mm $\pm$ 0.2 mm (3.60 mm to 4.00 mm)
6.	Disintegration Time	NMT 30 mins

18.0 PRODUCT ASSESSMENT CRITERIA

The data will be collected, summarized and a conclusion will be drawn. Any out of specification/Deviation should be investigated. The results should meet limits of acceptance specifications.

19.0 NON COMPLIANCE

Details of deviation (including justification of acceptance if any) done to successfully carryout the validation exercise and any OOS results obtained should be recorded.

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Batch Size: 600000

Product name LOLIP-20

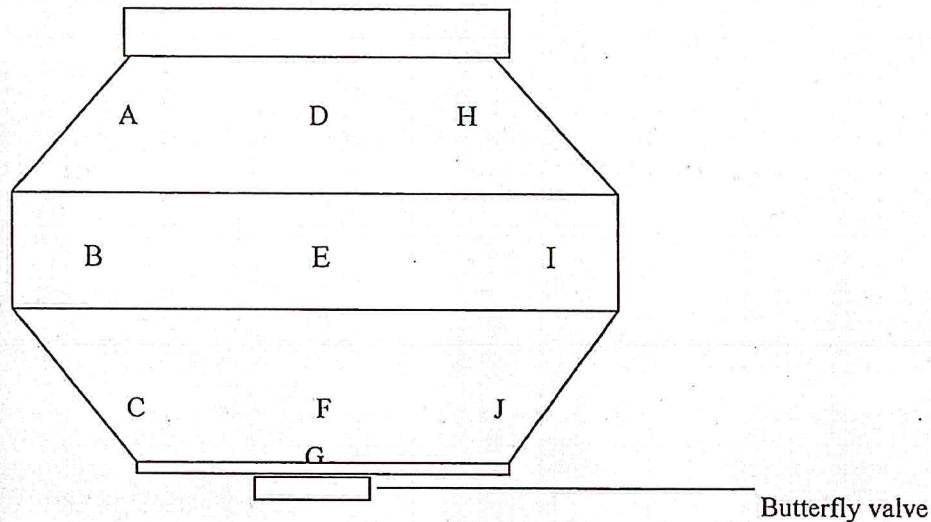
Effective Date 06/07/2022

Protocol No. PVP: L13

Ref. SOP No. QAGN/017

20.0 SAMPLING LOCATIONS DIAGRAMS.

Octagonal blender:



SYMBOL	Location	SAMPLING LOCATION DETAILS
A	Left- Top	From the left side corner near wall side of the blender approx. 2 inch below the top surface of the powder bed.
B	Left- Middle	From the left middle corner near wall side of the blender approx. 5 inch below the top surface of the powder bed.
C	Left- Bottom	From the left side bottom wall side of the blender approx. 2 inch away from the left side of the wall.
D	Center- Top	From the center of the blender approx. 2 inch below the top surface of the powder bed.
E	Center- Middle	From the center of the blender middle surface of the powder bed.
F	Center- Bottom	From the center bottom of the blender bottom layer of the powder bed.
G	Discharge- Port	Approx. center of the discharge port of the blender.
H	Right- Middle	From the right middle corner near side of the blender approx. 2 inch below the top surface of the powder bed.
I	Right- Bottom	From the right-side bottom wall of the blender approx. 2 inch away from the right side of wall.
J	Right-Top	From the right side, corner near wall of the blender approx. 2 inch below the top surface of the powder bed.
Composite Sample		Composite sample from all location.

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21.0 REFERENCE DOCUMENTS

To prepare the validation protocol current version of below mentioned documents are referred, which provide Adequate information of manufacturing & packing process.

SI No	Documents	Ref. No.
1	Batch Manufacturing Record (BMR)	BMR/T/331-00
2	Batch Packing Record (BPR)	BPR/T/331-00
3	Finished Product Specification (FPS)	FPS: L13
4	Process Validation SOP	QAGN/017
5	Master Formula Record (MFR)	MFR/T/186-00

22.0 REVISION HISTORY

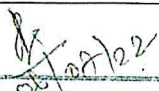
S. No.	Effective date	Version No.	Reason for changes
01		00	New document

23.0 ATTACHMENTS

Analytical reports shall be attached in process validation report.

24.0 REPORT

After execution of protocol, report will be prepared and final conclusion will be drawn.

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PROCESS VALIDATION REPORT		Batch Size: 6,00,000
Product name	LOLIP 20	
Protocol No.	PVR – L13	

PROCESS VALIDATION REPORT

Product name	LOLIP 20
Label claim	Each film coated tablet contains: Atorvastatin calcium Trihydrate Equivalent to Atorvastatin 20 mg Colour: Approved colour used.
Dosage Form	Oral Dosage
BMR No	BMR/T/331-00
Batch Size	6,00,000
Shelf Life	36 Month
MFG. LIC. NO.	PON/DRUGS/21 14 4376
Product Code	L13

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		Revision No: 00
PROCESS VALIDATION REPORT		Batch Size: 6,00,000
Product name	LOLIP 20	
Protocol No.	PVR – L13	

1.0 TABLE OF CONTENT

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Product name	LOLIP 20	
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2.0 OBJECTIVE

To ensure that the critical process variables are checked during validation and to demonstrate the process capability on equipment and utility ensuring that the product meets its predetermined specifications and quality attributes.

The Process validation is being taken for generation of sufficient data and establishing of standard manufacturing process. Three consecutive batches of **LOLIP 20** have taken up for Process Validation. If any problem is observed during manufacturing, the Process Validation shall be extended to other three consecutive batches.

3.0 SCOPE

The scope of this report is limited to the Process Validation of **LOLIP 20**, which defines the procedural aspects to be followed while carrying out process validation activity that includes prerequisites before commencing the actual work.

This report is applicable for the process validation of **LOLIP 20** to be manufactured at Sai Primus Life Biotech Pvt Ltd. Based on the Validation data and summary report, if required BMR will be revised.

4.0 RESPONSIBILITY

The validation group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this report:

Functional Area	Responsibility
Production	- Execution of Process Validation Batch. - Review of Process Validation Report.
Quality Assurance	- Co-ordination with Production and QC to carryout process validation batch. - Monitoring and sampling at the different stages. - Checking and approval of Process Validation Report.
Quality Control	- Analysis of validation batch samples. - Preparation of analytical report and submit to Quality Assurance Department. - Review of Process Validation Report.
Maintenance	To provide necessary utility and environmental condition in process equipment and area





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PROCESS VALIDATION REPORT

Batch Size: 6,00,000

Product name LOLIP 20

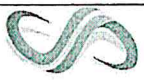
Protocol No. PVR – L13

5.0 ABBREVIATIONS

Acronym	Definition	Acronym	Definition
PVR	Process Validation Report	NMT	Not more than
QA	Quality Assurance	°C	Degree Celsius
QC	Quality Control	%	Percentage
PV	Process validation	mg.	Milligram
BMR	Batch manufacturing record	RPM	Rotation per minute
TABS	Tablets	RSD	Relative standard deviation
IP	Indian pharmacopeia	OOS	Out of Specification
BP	British pharmacopeia	g.	Gram
USP	United states pharmacopeia	Kg.	Kilogram
ICH	International conference on harmonization	lt.	Litre
cGMP	Current Good Manufacturing practices	mm.	Millimetre
IH	In house	ml.	Millilitre
API	Active pharmaceutical ingredient	NLT	Not less than
PD	Production	FG	Finished goods
ID	Identification	RH	Relative humidity
S.	Serial	R-LAF	Reverse laminar Air flow
No.	Number	LOD	Loss on drying
CPP	Critical process parameter	DT	Disintegration time
CQA	Critical quality attributes	Qty.	Quantity
CPC	Critical process control	IPC	In process container
UV	Ultra violet	NA	Not applicable
HPLC	High performance liquid chromatography	MLT	Microbial limit test
Max.	Maximum	HMI	Human Machine Interface
Min.	Minimum		

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Product name	LOLIP 20	
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6.0 PRODUCT DETAILS

Product Name	LOLIP 20		
Dosage Form	Oral Dosage		
Label Claim	Each film coated tablet contains: Atorvastatin calcium Trihydrate Equivalent to Atorvastatin 20 mg Colour: Approved colour used.		
Average weight of coated tablet	195.000 mg		
Batch number	G1822106	G1822161	G1822162
Batch size	6,00,000	6,00,000	6,00,000
Manufacturing date	07/2022	11/2022	11/2022
Expiry date	06/2025	10/2025	01/2026
Started on	07/07/2022	20/11/2022	05/12/2022
Completed on	24/07/2022	07/12/2022	09/12/2022

7.0 PROCESS EQUIPMENT DESCRIPTION

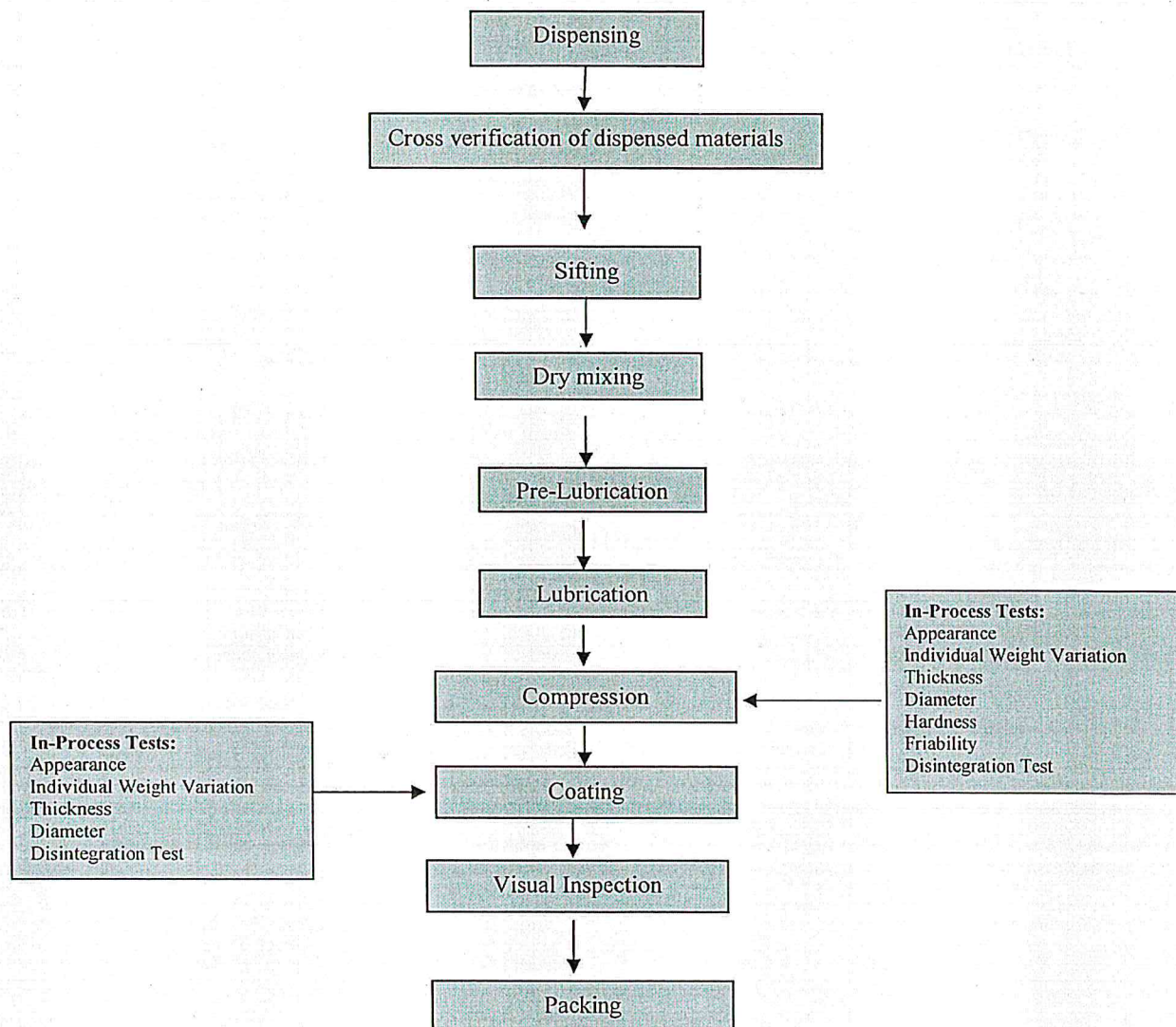
S. No.	Equipment name	Equipment ID No	Calibration/qualification status
1.	Dispensing Booth	ST/DSB/001	Qualified
2.	Vibratory sifter	PD/VBS/002	Qualified
3.	Octagonal blender	PD/OCB/002	Qualified
4.	Compression machine	PD/COM/002	Qualified
5.	Packing machine (Alu Alu Packing)	PD/ALU/001	Qualified
6.	Weighing balance (IPQA)	QA/BAL/002	Calibrated
7.	Vernier caliper	QA/VEC/001	Calibrated
8.	Friability apparatus	QA/FRT/001	Calibrated
9.	Hardness tester	QA/HRT/001	Calibrated
10.	Disintegration tester	QA/DTA/002	Calibrated
11.	Moisture balance	QA/MTA/001	Calibrated
12.	Tap density tester	QC/TDA/001	Calibrated
13.	Dissolution test apparatus	QC/DIS/001	Qualified
14.	Sieve Shaker	QC/SSH/001	Qualified
15.	HPLC	QC/HPL/001	Qualified
16.	UV	QC/UVS/001	Qualified

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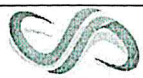
 SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 6 of 22
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Product name	LOLIP 20	
Protocol No.	PVR – L13	

8.0 PROCESS FLOWCHART



WASTE FOR DISPOSAL

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PROCESS VALIDATION REPORT

Batch Size: 6,00,000

Product name LOLIP 20

Protocol No. PVR – L13

9.0 BILL OF MATERIALS :

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

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Product name	LOLIP 20	
Protocol No.	PVR – L13	
		Batch Size: 6,00,000

10.0 MANUFACTURING PROCESS DETAILS:

10.1 SIFTING:

Step No.	Name of Ingredient	Specified in Approved BMR	Observation		
			Batch No.:		
			G1822106	G1822161	G1822162
1.	Sift Atorvastatin Calcium through 80#	Mesh size of sieve (80 #)	80#		
		Sieve Integrity Check before use	OK		
		Sieve Integrity Check after use	OK		
2.	Sift Microcrystalline Cellulose PH 102 through 40#	Mesh size of sieve (40 #)	40#		
		Sieve Integrity Check before use	OK		
		Sieve Integrity Check after use	OK		
3.	Sift Calcium Carbonate, Lactose DCL11, Croscarmellose sodium through 60#	Mesh size of sieve (60 #)	60#		
		Sieve Integrity Check before use	OK		
		Sieve Integrity Check after use	OK		
4.	Sift Colloidal Silicon Dioxide through 30#	Mesh size of sieve (30 #)	30#		
		Sieve Integrity Check before use	OK		
		Sieve Integrity Check after use	OK		
5.	Sift Purified Talc and Magnesium Stearate through 80#	Mesh size of sieve (80 #)	80#		
		Sieve Integrity Check before use	OK		
		Sieve Integrity Check after use	OK		

10.2 BLENDING & LUBRICATION:

Specified in approved BMR	Setting Time	Observations		
		Batch No.:		
		G1822106	G1822161	G1822162
Blending				
Load the sifted materials in to the blender and mix at 10 RPM for 15 minutes.	10 RPM for 15	Load the sifted materials in to the blender and mix at 10 RPM for 15 minutes.		
Lubrication				
Load the Sifted Purified Talc and Magnesium Stearate into the above Pre-lubricated blend and mix for further at 10 RPM for 5 minutes.	10 RPM for 5 Mins	Load the Sifted Purified Talc and Magnesium Stearate into the above Pre-lubricated blend and mix for further at 10 RPM for 5 minutes.		

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Product name	LOLIP 20	
Protocol No.	PVR – L13	
		Batch Size: 6,00,000

10.2.1 Analytical Result of Lubricated Blend (For 01 Min)

Test	Limit	Observation			
UNIFORMITY OF BLEND	NLT 94.5% to NMT 105.0% of the label claim. RSD NMT 5.0%	Sample No.	Batch No.:		
			G1822106	G1822161	G1822162
			Atorvastatin Calcium		
		1	101.88%	98.21%	102.64%
		2	98.39%	97.22%	98.51%
		3	92.23%	98.47%	97.62%
		4	99.87%	96.34%	98.44%
		5	98.07%	100.22%	95.81%
		6	102.96%	96.74%	99.30%
		7	99.77%	100.89%	99.62%
		8	102.55%	97.72%	98.74%
		9	92.93%	98.38%	97.23%
		10	93.84%	100.41%	95.01%
		Min.	92.23%	96.34%	95.01%
		Max.	102.96%	100.89%	102.64%
		Mean	99.08%	98.30%	98.48%
		% RSD	4.05	1.60	2.15
Comments/Remarks	Complies/does not comply with respected to standards of		Complies		

10.6.3 Analytical Result of Lubricated Blend (For 03 Min)

Test	Limit	Observation			
UNIFORMITY OF BLEND	NLT 94.5% to NMT 105.0% of the label claim. RSD NMT 5.0%	Sample No.	Batch No.:		
			G1822106	G1822161	G1822162
			Atorvastatin Calcium		
		1	96.84%	99.06%	100.13%
		2	100.70%	98.45%	99.62%
		3	99.69%	99.54%	98.52%
		4	98.15%	101.79%	98.10%
		5	97.16%	98.65%	100.54%
		6	100.01%	99.54%	100.07%
		7	98.18%	96.75%	99.88%
		8	94.79%	96.20%	98.15%
		9	100.79%	100.09%	99.67%
		10	95.34%	102.16%	96.71%
		Min.	94.79%	96.20%	96.71%
		Max.	100.79%	102.16%	100.54%
		Mean	98.17%	99.30%	99.65%
		% RSD	2.17	2.07	1.22
Comments/Remarks	Complies/does not comply with respected to standards of specification		Complies		

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10.6.4 Analytical Result of Lubricated Blend (For 05 Min)

Test	Limit	Observation			
UNIFORMITY OF BLEND	NLT 94.5% to NMT 105.0% of the label claim. RSD NMT 5.0%	Sample No.	Batch No.:		
			G1822106	G1822161	G1822162
			Atorvastatin Calcium		
		1	97.23%	95.95%	101.38%
		2	98.19%	97.67%	101.15%
		3	95.72%	96.22%	98.89%
		4	100.37%	95.60%	101.23%
		5	99.20%	97.90%	97.87%
		6	102.40%	103.10%	98.01%
		7	96.42%	102.96%	100.02%
		8	99.86%	94.09%	99.15%
		9	99.69%	100.97%	102.81%
		10	98.57%	96.20%	95.05%
		Min.	95.72%	94.09%	95.05%
		Max.	102.40%	103.10%	102.81%
		Mean	98.89%	96.95%	99.59%
		% RSD	2.01	3.24	2.26
Comments/ Remarks	Complies/does not comply with respected to standards of specification		Complies		

11.0 COMPRESSION: (Machine Setting)

Machine Description		Setting as per Approved BMR	Batch No.:		
			G1822106	G1822161	G1822162
Compression machine type		27 Station Double Rotary	27 Station Double Rotary		
Punch Description	Upper punch	8.00 mm circular shaped standard concave breakline punch.	8.00 mm circular shaped standard concave breakline punch.		
	Lower punch	8.00 mm circular shaped standard concave plain punch.	8.00 mm circular shaped standard concave plain punch.		
	Dies	8.00 mm circular shaped standard concave plain punch.	8.00 mm circular shaped standard concave plain punch.		
Tooling Type		D-Tooling	D-Tooling		

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	PROCESS VALIDATION REPORT	
Product name	LOLIP 20	
Protocol No.	PVR – L13	
		Batch Size: 6,00,000

11.1 PRE-COMPRESSION:

Sr. No.	Parameters	Parameters as per approved BMR	Observation			
			B. No.: G1822106			
			LHS		RHS	
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK		OK	
2.	Group Weight	3.800 g ± 3.0 % (3.686 g to 3.914 g)	3.795 g		3.792 g	
3.	Average weight (mg)	190.000 mg ± 3.0 % (184.300 mg – 195.700 mg)	189.30 mg		188.95 mg	
4.	Uniformity of weight Tablets	190.000 mg ± 5.0 % (180.500 mg – 199.500 mg)	187.000 mg	191.000 mg	187.000 mg	191.000 mg
5.	Hardness	NLT 3.0 Kg/ cm ²	8.0 Kg	8.0 Kg	8.0 Kg	8.0 Kg
6.	Thickness (mm)	3.70 ± 0.2 mm 3.50 mm – 3.90 mm	3.47 mm	3.46 mm	3.48 mm	3.47 mm
7.	Friability	NMT 1% w/w	0.11%		0.12%	
8.	Disintegration Time	NMT 15 Minutes	40 sec		44 sec	
9.	Assay of Atorvastatin Calcium %	NLT 94.5% to NMT 105.0%	98.96%			
10.	Comments /Remarks	Complies/ does not comply with respect to standards of specification	Complies			

Note: As per the protocol Pre-compressed tablets analyzed 1st batch only.

11.2 COMPRESSION (Speed Challenge Test):Low Speed (RPM: 12)

Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			G1822106		G1822161		G1822162			
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK	OK	OK	OK	OK
2.	Group Weight	3.800 g ± 3.0 % (3.686 g to 3.914 g)	3.779 g	3.785 g	3.792 g	3.793 g	3.816g	3.809 g		
3.	Average weight (mg)	190.000 mg ± 3.0 % (184.30 mg – 195.70 mg)	188.95 mg	189.25 mg	189.60 mg	189.55 mg	190.08 mg	190.45 mg		
4.	Uniformity of weight Tablets	190.000 mg ± 5.0 % (180.500 mg – 199.500 mg)	187.00 191.00	187.00 191.00	187.00 193.00	186.00 192.00	188.00 194.00	187.00 193.00		
5.	Hardness	NLT 3.0 Kg/ cm ²	8.0 Kg	7.0 Kg	6.5 Kg	7.0 Kg	4.0 Kg	4.0 Kg		
6.	Thickness (mm)	3.70 ± 0.2 mm 3.50 mm – 3.90 mm	3.44 mm	3.42 mm	3.50 mm	3.52 mm	3.74 mm	3.77 mm		
7.	Friability	NMT 1% w/w	0.10%	0.12%	0.01%	0.01%	0.14%	0.10%		
8.	Disintegration Time	NMT 15 Minutes	48 Sec	50 Sec	01 min 30 sec	01 min 25 sec	01 min 47 sec	01 min 37 sec		
9.	Assay of Atorvastatin Calcium %	NLT 94.5% to NMT 105.0%	98.06%		100.24%		99..87%			
10.	Comments /Remarks	Complies/ does not comply with respect to standards of specification	Complies		Complies		Complies			

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Product name	LOLIP 20	
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11.3 COMPRESSION (Speed Challenge Test):High Speed (RPM: 30):

Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			G1822106		G1822161		G1822162			
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK	OK	OK	OK	OK
2.	Group Weight	3.800 g ± 3.0 % (3.686 g to 3.914 g)	3.781 g	3.784 g	3.801 g	3.802 g	3.802 g	3.819 g		
3.	Average weight (mg)	190.000 mg ± 3.0 % (184.30 mg – 195.70 mg)	189.05 mg	189.20 mg	190.05 mg	190.10 mg	190.01 mg	190.95 mg		
4.	Uniformity of weight Tablets	190.000 mg ± 5.0 % (180.500 mg – 199.500 mg)	187.00 191.00	187.00 191.00	188.00 192.00	187.00 194.00	187.00 193.00	188.00 194.00		
5.	Hardness	NLT 3.0 Kg/ cm ²	8.0 Kg	7.0 Kg	6.5 Kg	7.0 Kg	7.0 Kg	7.5 Kg		
6.	Thickness (mm)	3.70 ± 0.2 mm 3.50 mm – 3.90 mm	3.44 mm	3.46 mm	3.52 mm	3.55 mm	3.41 mm	3.44 mm		
7.	Friability	NMT 1% w/w	0.13%	0.12%	0.02%	0.02%	0.11%	0.09%		
8.	Disintegration Time	NMT 15 Minutes	50 sec	52 Sec	01 min 10 sec	01 min 30sec	01 min 37 sec	01 min 46 sec		
9.	Assay of Atorvastatin Calcium %	NLT 94.5% to NMT 105.0%	98.68%		97.74%		99.08%			
10.	Comments /Remarks	Complies/ does not comply with respect to standards of specification	Complies		Complies		Complies			

11.4 COMPRESSION: Low Hardness at Optimum Speed (20 RPM)

Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			G1822106		G1822161		G1822162			
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK	OK	OK		
2.	Group Weight	3.800 g ± 3.0 % (3.686 g to 3.914 g)	3.784 g	3.780 g	3.785 g	3.820 g	3.802 g	3.814 g		
3.	Average weight (mg)	190.000 mg ± 3.0 % (184.30 mg – 195.70 mg)	189.20 mg	189.00 mg	189.25 mg	191.00 mg	190.10 mg	190.70 mg		
4.	Uniformity of weight Tablets	190.000 mg ± 5.0 % (180.500 mg – 199.500 mg)	187.00 191.00	187.00 191.00	186.00 193.00	188.00 195.00	187.00 193.00	188.00 194.00		
5.	Hardness	NLT 3.0 Kg/ cm ²	5.0 Kg	4.0 Kg	5.0 Kg	4.5 Kg	4.0 Kg	4.0 Kg		
6.	Thickness (mm)	3.70 ± 0.2 mm 3.50 mm – 3.90 mm	3.43 mm	3.44 mm	3.58 mm	3.60 mm	3.74 mm	3.81 mm		
7.	Friability	NMT 1% w/w	0.10%	0.09%	0.02%	0.01%	0.44%	0.40%		
8.	Disintegration Time	NMT 15 Minutes	48 Sec	45 Sec	00 min 50 sec	01 min 05 sec	01min 07 sec	01 min 12sec		

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9.	Assay of Atorvastatin Calcium %	NLT 94.5% to NMT 105.0%	100.58%	98.74%	98.87%
10.	Comments /Remarks	Complies/ does not comply with respect to standards of specification	Complies	Complies	Complies

11.5 COMPRESSION: High Hardness at Optimum Speed (20 RPM)

Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			G1822106		G1822161		G1822162			
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK	OK	OK	OK	OK
2.	Group Weight	3.800 g $\pm$ 3.0 % (3.686 g to 3.914 g)	3.784 g	3.782 g	3.796 g	3.803 g	3.809 g	3.801 g		
3.	Average weight (mg)	190.000 mg $\pm$ 3.0 % (184.30 mg – 195.70 mg)	189.20 mg	189.10 mg	189.80 mg	190.15 mg	190.45 mg	190.05 mg		
4.	Uniformity of weight Tablets	190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)	187.00 191.00	187.00 191.00	187.00 194.00	185.00 192.00	188.00 194.00	187.00 193.00		
5.	Hardness	NLT 3.0 Kg/ cm ²	8.0 Kg	7.0 Kg	8.0 Kg	7.5 Kg	6.0 Kg	6.5 Kg		
6.	Thickness (mm)	3.70 $\pm$ 0.2 mm 3.50 mm – 3.90 mm	3.42 mm	3.44 mm	3.45 mm	3.43 mm	3.41 mm	3.44 mm		
7.	Friability	NMT 1% w/w	0.10%	0.11%	0.01%	0.01%	0.03%	0.06%		
8.	Disintegration Time	NMT 15 Minutes	45 Sec	51 Sec	01 min 52 sec	01 min 55 sec	02 min 08 sec	02 min 16 sec		
9.	Assay of Atorvastatin Calcium %	NLT 94.5% to NMT 105.0%	99.58%		100.84%		98.87%			
10.	Comments /Remarks	Complies/ does not comply with respect to standards of specification	Complies		Complies		Complies			

11.6 COMPRESSION (Hopper Challenge Test): (Full Hopper at optimum speed)

Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			G1822106		G1822161		G1822162			
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK	OK	OK	OK	OK
2.	Group Weight	3.800 g $\pm$ 3.0 % (3.686 g to 3.914 g)	3.784 g	3.781 g	3.802 g	3.808 g	3.812g	3.803 g		
3.	Average weight (mg)	190.000 mg $\pm$ 3.0 % (184.30 mg – 195.70 mg)	189.20 mg	189.05 mg	190.10 mg	190.40 mg	190.60 mg	190.15 mg		
4.	Uniformity of weight Tablets	190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)	187.00 191.00	187.00 191.00	188.00 193.00	185.00 195.00	187.00 195.00	188.00 193.00		
5.	Hardness	NLT 3.0 Kg/ cm ²	8.0 Kg	7.0 Kg	7.0 Kg	6.5 Kg	6.0 Kg	6.5 Kg		

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6.	Thickness (mm)	3.70 ± 0.2 mm 3.50 mm – 3.90 mm	3.42 mm	3.41 mm	3.65 mm	3.49 mm	3.53 mm	3.49 mm
7.	Friability	NMT 1% w/w	0.11%	0.12%	0.01%	0.02%	0.10%	0.09%
8.	Disintegration Time	NMT 15 Minutes	50 Sec	52 Sec	01 min 20 sec	01 min 30 sec	01 min 36 sec	01 min 47 sec
9.	Assay of Atorvastatin Calcium %	NLT 94.5% to NMT 105.0%	98.68%		99.74%		99.87%	
10.	Comments /Remarks	Complies/ does not comply with respect to standards of specification	Complies		Complies		Complies	

11.7 COMPRESSION (Hopper Challenge Test): (Middle Hopper at optimum speed)

Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			G1822106		G1822161		G1822162			
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK	OK	OK	OK	OK
2.	Group Weight	3.800 g ± 3.0 % (3.686 g to 3.914 g)	3.785 g	3.782 g	3.811 g	3.808 g	3.812 g	3.799 g		
3.	Average weight (mg)	190.000 mg ± 3.0 % (184.30 mg – 195.70 mg)	189.25 mg	189.10 mg	190.55 mg	190.40 mg	190.60 mg	189.95 mg		
4.	Uniformity of weight Tablets	190.000 mg ± 5.0 % (180.500 mg – 199.500 mg)	187.00 191.00	187.00 191.00	187.00 194.00	186.00 195.00	187.00 195.00	187.00 193.00		
5.	Hardness	NLT 3.0 Kg/ cm ²	7.5 Kg	7.0 Kg	6.0 Kg	6.5 Kg	6.0 Kg	6.5 Kg		
6.	Thickness (mm)	3.70 ± 0.2 mm 3.50 mm – 3.90 mm	3.46 mm	3.48 mm	3.65 mm	3.49 mm	3.50 mm	3.50 mm		
7.	Friability	NMT 1% w/w	0.12%	0.11%	0.01%	0.01%	0.07%	0.08%		
8.	Disintegration Time	NMT 15 Minutes	50 Sec	42 Sec	01 min 57 sec	01 min 44 sec	01 min 47 sec	01 min 38 sec		
9.	Assay of Atorvastatin Calcium %	NLT 94.5% to NMT 105.0%	99.78%		97.74%		99.87%			
10.	Comments /Remarks	Complies/ does not comply with respect to standards of specification	Complies		Complies		Complies			

11.8 COMPRESSION (Hopper Challenge Test): (Low Hopper at optimum speed)

Sr. No.	Parameters	Parameters as per approved BMR	Observation							
			G1822106		G1822161		G1822162			
			LHS	RHS	LHS	RHS	LHS	RHS	LHS	RHS
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK	OK	OK	OK	OK
2.	Group Weight	3.800 g ± 3.0 % (3.686 g to 3.914 g)	3.784 g	3.779 g	3.802 g	3.813 g	3.774 g	3.805 g		

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3.	Average weight (mg)	190.000 mg $\pm$ 3.0 % (184.30 mg – 195.70 mg)	189.20 mg	188.95 mg	190.55 mg	190.40 mg	188.70 mg	190.25 mg
4.	Uniformity of weight Tablets	190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)	187.00 191.00	187.00 191.00	187.00 194.00	186.00 195.00	186.00 192.00	187.00 194.00
5.	Hardness	NLT 3.0 Kg/ cm ²	7.0 Kg	8.5 Kg	6.0 Kg	6.5 Kg	6.0 Kg	6.5 Kg
6.	Thickness (mm)	3.70 $\pm$ 0.2 mm 3.50 mm – 3.90 mm	3.44 mm	3.43 mm	3.65 mm	3.50 mm	3.51 mm	3.50 mm
7.	Friability	NMT 1% w/w	0.11%	0.13%	0.01%	0.0%	0.09%	0.07%
8.	Disintegration Time	NMT 15 Minutes	50 Sec	49 Sec	01 min 57sec	01 min 40 sec	01 min 45 sec	01min 39 sec
9.	Assay of Atorvastatin Calcium %	NLT 94.5% to NMT 105.0%	100.68%		96.74%		99..87%	
10.	Comments /Remarks	Complies/ does not comply with respect to standards of specification	Complies		Complies		Complies	

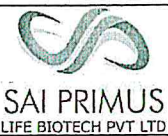
11.9 COMPRESSION (Composite):

Sr. No.	Parameters	Parameters as per approved BMR	Observation					
			G1822106		G1822161		G1822162	
			LHS	RHS	LHS	RHS	LHS	RHS
1.	Appearance	White coloured, circular shaped, uncoated tablet with breakline on one side and plain on other side	OK	OK	OK	OK	OK	OK
2.	Group Weight	3.800 g $\pm$ 3.0 % (3.686 g to 3.914 g)	3.783 g	3.782 g	3.766 g	3.796 g	3.815 g	3.798 g
3.	Average weight (mg)	190.000 mg $\pm$ 3.0 % (184.30 mg – 195.70 mg)	189.15 mg	189.10 mg	188.30 mg	189.80mg	190.75 mg	189.9mg
4.	Uniformity of weight Tablets	190.000 mg $\pm$ 5.0 % (180.500 mg – 199.500 mg)	187.00 191.00	187.00 191.00	186.00 191.00	187.00 194.00	188.00 195.00	187.00 193.00
5.	Hardness	NLT 3.0 Kg/ cm ²	7.0 Kg	7.0 Kg	3.0 Kg	3.0 Kg	6.0 Kg	6.5 Kg
6.	Thickness (mm)	3.70 $\pm$ 0.2 mm 3.50 mm – 3.90 mm	3.42 mm	3.45 mm	6.0 mm	6.5 mm	3.51 mm	3.54 mm
7.	Friability	NMT 1% w/w	0.15%	0.12%	0.01%	0.01%	0.04%	0.07%
8.	Disintegration Time	NMT 15 Minutes	47 Sec	48 Sec	01 min 27 sec	01 min 33 sec	01 min 30 sec	01 min 37 sec
9.	Assay of Atorvastatin Calcium %	NLT 94.5% to NMT 105.0%	100.98%		98.74%		97.87%	
10.	Comments /Remarks	Complies/ does not comply with respect to standards of specification	Complies		Complies		Complies	

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Product name	LOLIP 20	
Protocol No.	PVR – L13	

12.0 COATING

Coating Solution Preparation:

Specified in approved BMR	Observations		
	Batch No.:		
	G1822106	G1822161	G1822162
Take Isopropyl Alcohol in a SS Vessel. Slowly disperse Wincoat WT White 02022 and Yellow oxide of Iron and stir well to disperse completely. Take Purified Water in a SS Vessel. Slowly disperse Tween 80 and stir well to disperse completely. 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	Take Isopropyl Alcohol in a SS Vessel. Slowly disperse Wincoat WT White 02022 and Yellow oxide of Iron and stir well to disperse completely. Take Purified Water in a SS Vessel. Slowly disperse Tween 80 and stir well to disperse completely. 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		

12.1 Procedure for Film Coating:

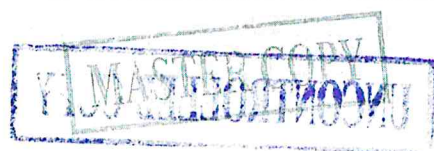
Specified in Approved BMR				
Charge dedusted cores about 114.000 Kg to coating pan. Transfer the coating solution into SS tank. Set and monitor the parameters like PAN RPM, DOSING RATE, INLET AIR TEMP, EXHAUST AIR TEMP, BED TEMP, as per the specification. Start spraying and continue till solution is getting over.				
Parameter	Limits	Observation		
		G1822106	G1822161	G1822162
Avg Weight Gained	2.0 ± 0.5 % w/w	2.04%	1.29%	2.15%

12.2 FINAL COATING PARAMETERS

Parameters	Limits	Observed		
		G1822106	G1822161	G1822162
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)	195.015 mg	193.000 mg	194.600 mg
Weight of 20 tablets	3.900 g ± 3 % (3.783 g – 4.017 g)	3.860 g	3.849 g	3.884 g
Uniformity of weight	195.000 mg ± 5 % (185.250 mg – 204.750 mg)	190 mg	188 mg	188 mg
Thickness	3.80 mm ± 0.2 mm (3.60 mm to 4.00 mm) (To be established)	3.58 mm	3.58 mm	3.55 mm
Disintegration test	NMT 30 min	1 min 48 sec	1 min 57 sec	3 min 10 sec

13.0 INSPECTION

Parameter	Specified	Observation		
		Batch No.:		
		G1822106	G1822161	G1822162
Equipment Name	Inspection Machine	Inspection Machine		
Equipment ID No.	PD/INB/002	PD/INB/002		
No. of Rejected Tablets	To be recorded	52 Nos	260 Nos	1033 Nos



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Product name	LOLIP 20	
Protocol No.	PVR – L13	

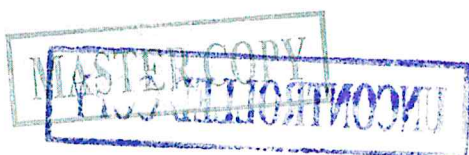
14.0 PACKING PROCESS:

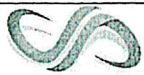
BILL OF PACKING MATERIALS:

Material Name	Item code	UOM	Req. Qty. for 5.0 Lac	Issued Qty.
252mm Lolip 20 Printed Foil 0.025mm	PPF/SP/L016	Kg	45.000	45.000
252 mm Alu Alu base foil	PBF/SP/A004	Kg	150.000	150.000
3x10's Lolip 20 Printed Carton	PPC/SP/L016	No.	20000	20000
Lolip Printed Leaflet	PPL/SP/L019	No.	20000	20000
Shrink Sleeves (PVC)	PPS/SP/P001	No.	2000	2000
5 Ply 390x390x430 mm GHPL Printed Shipper	PPS/SP/G002	No.	75	75
2.5' GHPL Printed Bopp Tape	PPB/SP/B002	No.	2	2
3' Plain BOPP Tape	PUB/SP/B001	No.	1	1

PACKING VALIDATION:

Parameters	Specified	Observation			
		Batch No.:			
		G1822106	G1822161	G1822162	
		Low speed/ Low temp.	Low speed/ High temp.	High speed/ High temp.	High speed/ Low temp.
Machine Speed	To be established	19	19	40	40
Forming / Sealing Temperature	To be established	120°C	210°C	210°C	120°C
Pack Quality	Should be proper	It is Proper	It is Proper	It is Proper	It is Proper
Leak Test	Should be absent	Absent	Absent	Absent	Absent
Printing Details	Should be legible and clear	Legible and Clear	Legible and Clear	Legible and Clear	Legible and Clear
Proper Sealing	Should be proper	It is Proper	It is Proper	It is Proper	It is Proper
Horizontal cutting	Should be OK	Ok	Ok	Ok	Ok
Vertical cutting	Should be OK	Ok	Ok	Ok	Ok
Comments/ Remarks	Complies/does not comply with respected to standards of specification	Complies	Complies	Complies	Complies



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	PROCESS VALIDATION REPORT	
Product name	LOLIP 20	
Protocol No.	PVR – L13	
		Batch Size: 6,00,000

15.0 FINISHED PRODUCT REPORT:

Parameter	Specified	Observation
		Batch No: G1822106
		Composite Sample
Appearance	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	OK
Identification		
A. By HPLC	The retention time of one of the major Peak in the chromatogram of the sample preparation corresponds to the peak due to Atorvastatin calcium in standard preparation as obtained in Assay.	Complies
B. By UV	The UV absorption spectrum of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay.	Complies
Average weight	195.00 mg $\pm$ 5.0 % (185.25 mg to 204.75mg)	193.400 mg
Disintegration Time	NMT 30 minutes	52 seconds
Hardness	NLT 3.0 Kg/cm ²	7.95 Kg/cm ²
Thickness	3.40 mm – 3.80 mm	3.51 mm
Dissolution	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.	Min: 94.63% Max: 96.43% Avg.: 95.57%
Uniformity of content	L1=15	3.242
Assay		
Atorvastatin calcium USP Equivalent to Atorvastatin-10 mg	Not less than 94.50 % and Not more than 105.00 %	100.16%
Related substances:(BY HPLC)		
Atorvastatin pyrrolidone Analog	Not more than 0.5 %	Not Detected
Atorvastatin related compound H	Not more than 1.0 %	0.08%
Atorvastatin epoxy pyrrolooxazin 6- hydroxy analog	Not more than 0.5 %	Not Detected
Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	Not more than 0.5 %	Not Detected
Atorvastatin epoxy THF analog	Not more than 1.0 %	Not Detected
Atorvastatin related compound D	Not more than 0.5 %	0.02%
Any other unspecified degradation product	Not more than 0.2 %	0.04%
Total degradation products	Not more than 4.0 %	0.23%
Microbiological Limits	Total Aerobic Microbial count	NMT 1000 cfu/g
	Total Yeasts and mould counts	NMT 100 cfu/g
	E.Coli	Should be Absent
	Salmonella	Should be Absent
	S.aureus	Should be Absent
	P.aeruginosa	Should be Absent
		20 cfu /g
		<10 cfu/g
		Absent
		Absent
		Absent
		Absent

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	PROCESS VALIDATION REPORT	
Product name	LOLIP 20	
Protocol No.	PVR – L13	
		Batch Size: 6,00,000

Parameter	Specified	Observation
		Batch No: G1822161
		Composite Sample
Appearance	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	OK
Identification		
C. By HPLC	The retention time of one of the major Peak in the chromatogram of the sample preparation corresponds to the peak due to Atorvastatin calcium in standard preparation as obtained in Assay.	Complies
D. By UV	The UV absorption spectrum of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay.	Complies
Average weight	195.00 mg $\pm$ 5.0 % (185.25 mg to 204.75mg)	193.200 mg
Disintegration Time	NMT 30 minutes	01 min 20 sec
Hardness	NLT 3.0 Kg/cm ²	7.53 Kg/cm ²
Thickness	3.40 mm – 3.80 mm	3.64 mm
Dissolution	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.	Min: 97.93% Max: 100.48% Avg.: 98.98%
Uniformity of content	L1=15	5.287
Assay		
Atorvastatin calcium USP Equivalent to Atorvastatin-10 mg	Not less than 94.50 % and Not more than 105.00 %	103.53%
Related substances:(BY HPLC)		
Atorvastatin pyrrolidone Analog	Not more than 0.5 %	Not Detected
Atorvastatin related compound H	Not more than 1.0 %	0.057%
Atorvastatin epoxy pyrrolooxazin 6- hydroxy analog	Not more than 0.5 %	Not Detected
Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	Not more than 0.5 %	Not Detected
Atorvastatin epoxy THF analog	Not more than 1.0 %	Not Detected
Atorvastatin related compound D	Not more than 0.5 %	0.038%
Any other unspecified degradation product	Not more than 0.2 %	0.074%
Total degradation products	Not more than 4.0 %	0.368%
Microbiological Limits	Total Aerobic Microbial count	NMT 1000 cfu/g
	Total Yeasts and mould counts	NMT 100 cfu/g
	E.Coli	Should be Absent
	Salmonella	Should be Absent
	S.aureus	Should be Absent
	P.aeruginosa	Should be Absent
		<10 cfu /g
		<10 cfu/g
		Absent
		Absent
		Absent
		Absent

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PROCESS VALIDATION REPORT

Batch Size: 6,00,000

Product name **LOLIP 20**

Protocol No. **PVR – L13**

Parameter	Specified	Observation
		Batch No: G1822162
		Composite Sample
Appearance	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	OK
Identification		
E. By HPLC	The retention time of one of the major Peak in the chromatogram of the sample preparation corresponds to the peak due to Atorvastatin calcium in standard preparation as obtained in Assay.	Complies
F. By UV	The UV absorption spectrum of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay.	Complies
Average weight	195.00 mg $\pm$ 5.0 % (185.25 mg to 204.75mg)	193.300 mg
Disintegration Time	NMT 30 minutes	01 min 49 sec
Hardness	NLT 3.0 Kg/cm ²	7.5 Kg/cm ²
Thickness	3.40 mm – 3.80 mm	3.59 mm
Dissolution	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.	Min: 97.70% Max: 103.95% Avg.: 101.25%
Uniformity of content	L1=15	8.421
Assay		
Atorvastatin calcium USP Equivalent to Atorvastatin-10 mg	Not less than 94.50 % and Not more than 105.00 %	102.50%
Related substances:(BY HPLC)		
Atorvastatin pyrrolidone Analog	Not more than 0.5 %	Not Detected
Atorvastatin related compound H	Not more than 1.0 %	0.051%
Atorvastatin epoxy pyrrolooxazin 6- hydroxy analog	Not more than 0.5 %	Not Detected
Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	Not more than 0.5 %	Not Detected
Atorvastatin epoxy THF analog	Not more than 1.0 %	Not Detected
Atorvastatin related compound D	Not more than 0.5 %	0.019%
Any other unspecified degradation product	Not more than 0.2 %	0.047%
Total degradation products	Not more than 4.0 %	0.217%
Microbiological Limits	Total Aerobic Microbial count	NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g
	E.Coli	Absent
	Salmonella	Absent
	S.aureus	Absent
	P.aeruginosa	Absent



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Product name	LOLIP 20	
Protocol No.	PVR – L13	

16.0 Deviation and Justification/Corrective Action:

Sr. No.	Deviation details	Justification(s) / Corrective Action(s)	Remarks Acceptable / Not acceptable
1.			
2.			
3.			

17.0 SUMMARY:

The process validation of lolip 20 has been carried out and the results found satisfactory.

18.0 CONCLUSION:

The process validation of lolip 20 batch no: G 1822106, G 1822161, G 1822162 has been carried out to establish the consistency of the process of all the results obtained at blending, compression, coating and packing stage are found within the limit. Hence the process stands validated and document in follow the same process for manufacturing of future batches.

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Revision No: 00

PROCESS VALIDATION REPORT

Batch Size: 6,00,000

Product name	LOLIP 20
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Protocol No. PVR-L13

19.0 REPORT APPROVAL:

The process Validation Report of batch “**LOLIP 20** ” having batch size of 4,00,000 Tablets has been reviewed and complies with requirements.

Prepared By:

Name: Ram Kumar

Sign / Date: 28/02/2023
Quality Assurance

~~Quality Assurance~~

Checked and Reviewed By:

Name: LAUREN BRONKHORST, B

Sign/Date: Barbara L. [Signature]
Production 28/02/2022

Production

Name: A. VA LARACAN

Sign/Date: hr 22/12/2023
Quality Control

Quality Control

Comments: We certify that the process Validation report for “**LOLIP 20**” having batch size of 6,00,000 Tablets has been accepted.

Report Approved By:

Name: R. Stephen

Sign / Date: [Signature] 08/02/23
Head QA

Head-QA

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