SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009	Page 1 of 2
QUALITY CONTROL	CERTIFICATE OF ANALYSIS FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	**LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)**			
A.R.No.	:	**BS/140722/02**			
Batch No.	:	**G1822106**	**Batch Size**	:	**6.0 L**
Mfg. Date	:	**Jul-2022**	**Exp. Date**	:	**Jun-2025**
Sampling Date	:	**14.07.2022**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**18.07.2022**	**Release Date**	:	**30.07.2022**

S.No.	TEST	RESULTS	LIMITS
01.	**Description**	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.
02.	**Identification** A) By UV	Complies	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	Complies	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.
03.	**Average weight of tablets**	193.40 mg	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)
04.	**Uniformity of weight**	+2.38 % to -1.76 %	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15.0 %.
05.	**Dimensions:**		
	Thickness	Min 3.46 mm / Max 3.55 mm / Avg. 3.51 mm	3.40 mm to 3.80 mm
	Diameter	Min 8.06 mm / Max 8.09 mm / Avg. 8.08mm	7.80 mm to 8.20 mm
06.	**Hardness**	7.95 kg/cm2	NLT 3.0 kg/cm2
07.	**Disintegration time**	52 seconds	Not more than 30 minutes
08.	**Dissolution by UV**		
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Min 94.63 % / Max 96.43 % / Avg. 95.57 %	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	30/07/2022	30/07/2022	30/07/2022

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009	Page 2 of 2
QUALITY CONTROL	CERTIFICATE OF ANALYSIS FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	**LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)**			
A.R.No.	:	**BS/140722/02**			
Batch No.	:	**G1822106**	**Batch Size**	:	**6.0 L**
Mfg. Date	:	**Jul-2022**	**Exp. Date**	:	**Jun-2025**
Sampling Date	:	**14.07.2022**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**18.07.2022**	**Release Date**	:	**30.07.2022**

09.	**Uniformity of dosage unit by HPLC**		
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	L1=3.242	L1=15
10.	**Related substances:(BY HPLC)**		
	Atorvastatin pyrrolidone Analog	Not Detected	Not more than 0.5 %
	Atorvastatin related compound H	0.08%	Not more than 1.0 %
	Atorvastatin epoxy pyrrolooxazin 6- hydroxy analog	Not Detected	Not more than 0.5 %
	Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	Not Detected	Not more than 0.5 %
	Atorvastatin epoxy THF analog	Not Detected	Not more than 1.0 %
	Atorvastatin related compound D	0.02%	Not more than 0.5 %
	Any other unspecified degradation product	0.04%	Not more than 0.2 %
	Total degradation products	0.23%	Not more than 4.0 %
11.	**Assay: Each Film coated tablet contains:**		
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	100.16 %	Not less than 90.00 % and Not more than 110.00 %
12.	**Microbiological limits:**		
	Total Aerobic Microbial count	20 cfu /g	NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g	NMT 100 cfu/g
	E.Coli	Absent	Should be Absent
	Salmonella	Absent	Should be Absent
	S.aureus	Absent	Should be Absent
	P.aeruginosa	Absent	Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to ~~BP~~/USP ~~and In-house~~ Specification.

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	30/07/2022	30/07/2022	30/07/2022

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S.No. 4/3, Plot No.3, kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 1	Issued by (QA): Date: 29/01/22
		Format No.: F/QCGN/022/04	
	TESTING AND RELEASE OF INTERMEDIATE AND FINISHED PRODUCTS	Revision No.: 01	
TITLE:	CHECK LIST OF FINISHED PRODUCT	Review Period: 02 Years	
		Effective Date: 02/03/2022	

Name of the Product: Lolip-20	
Analytical Report No. BS/140722/02	Batch No. GI822106

Log entry Verification (Put √ mark on verified)	CONTENTS	S.No.	No. of Pages
Balance log entry ✓	Check list- Finished product	1-1	1
WS log entry ✓	Test request form	2-3	2
WS validity entry ✓	Observation during sampling form	NA	NA
HPLC Column entry ✓	Certificate of analysis	4-5	2
HPLC Ins. log entry ✓	Result of analysis (Analytical work record)	6-22	17
Dissolution log entry ✓	Physical parameter sheet Tablet / Capsule / Sachet	NA	NA.
UV-VIS log entry ✓	Graph of UV-VIS spectrophotometer	23-27	5
pH meter log entry ✓	Graph of IR spectrophotometer	NA	NA.
IR log entry NA.	LC chromatogram	28-47	20.
	Tapped density test report	NA	NA
	KF-Autotitra report	NA	NA.
	Microbiological test report	48-54	7
	Outside laboratory testing report	55-71	17.
	Additional test report if any	72-73	2.
	The above product consist of 73 pages	Total pages 73	

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SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.3, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 1	Issued by QA/Date: 25/06/2021
			No.: F/QAGN/026/01
	SAMPLING POLICY		Revision No: 01
TITLE	TEST REQUEST FORM		Review Period: 2 years
			Effective Date: 19/06/2021

Date: 14/07/2022

From (Dept): PRODUCTION		To: Q.C. DEPARTMENT
Name of the Item/: Product/ ~~Previous: Product~~* :	LOLIP 20	Quantity sampled 1. 120 Tabs 2. Coated stage 3. - NA - 4. - NA -
Batch No.* :	G1822206	
Batch Size* :	6.0L	
Mfg. Date* :	07/2022	Sampled on: 14/07/2022
Exp. Date* :	06/2025	Sampled by: G. SENTHIL KUMARAN
Stage* :	Coated stage	Analyzed By: Kajal
		Analytical Reference No. BJ/140722/02

Tests:

1. As per Specification
2. .....
3. .....
4. .....

28/7 14/07/2022	G. Senthilkumar 14/07/2022	14/07/2022
TRF raised by Sign/Date	TRF given to QC by QA Sign/Date	Head of QC Sign/Date

*wherever not applicable write NA

Drug

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.3, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.	Page 1 of 1	Issued by QA/Date: 25/06/22
		No.: F/QAGN/026/01	
	SAMPLING POLICY	Revision No: 01	
TITLE	TEST REQUEST FORM	Review Period: 2 years	
		Effective Date: 19/06/2021	

Date: 23/07/22

From (Dept): PACKING		To: Q.C. DEPARTMENT
Name of the Item/: Product/ ~~Previous~~: ~~Product~~* :	LOLIP-20	Quantity sampled 1. Finished goods 2. 120 tablets 3. NA 4.
Batch No.* :	G1822106	
Batch Size* :	6.0L	
Mfg. Date* :	07/2022	Sampled on: 23/07/2022
Exp. Date* :	06/2025	Sampled by: JESI
Stage* :	FINISHED GOODS	Analyzed By: Kavya
		Analytical Reference No. FP/2307221/01

Tests:

1. AS PER SPECIFICATION
2. NA
3.
4.

S. 23/07/22	Jesi 23/07/2022	23/07/2022
TRF raised by Sign/Date	TRF given to QC by QA Sign/Date	Head of QC Sign/Date

*wherever not applicable write NA

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009	Page 1 of 2
QUALITY CONTROL	CERTIFICATE OF ANALYSIS FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	**LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)**			
A.R.No.	:	**BS/140722/02**			
Batch No.	:	**G1822106**	**Batch Size**	:	**6.0 L**
Mfg. Date	:	**Jul-2022**	**Exp. Date**	:	**Jun-2025**
Sampling Date	:	**14.07.2022**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**18.07.2022**	**Release Date**	:	**30.07.2022**

S.No.	TEST	RESULTS	LIMITS
01.	**Description**	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.
02.	**Identification** A) By UV	Complies	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	Complies	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.
03.	**Average weight of tablets**	193.40 mg	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)
04.	**Uniformity of weight**	+2.38 % to -1.76 %	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15.0 %.
05.	**Dimensions:**		
	Thickness	Min 3.46 mm / Max 3.55 mm / Avg. 3.51 mm	3.40 mm to 3.80 mm
	Diameter	Min 8.06 mm / Max 8.09 mm / Avg. 8.08mm	7.80 mm to 8.20 mm
06.	**Hardness**	7.95 kg/cm2	NLT 3.0 kg/cm2
07.	**Disintegration time**	52 seconds	Not more than 30 minutes
08.	**Dissolution by UV**		
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Min 94.63 % / Max 96.43 % / Avg. 95.57 %	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	30/07/2022	30/07/2022	30/07/2022

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009	Page 2 of 2
QUALITY CONTROL	CERTIFICATE OF ANALYSIS FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)			
A.R.No.	:	BS/140722/02			
Batch No.	:	G1822106	Batch Size	:	6.0 L
Mfg. Date	:	Jul-2022	Exp. Date	:	Jun-2025
Sampling Date	:	14.07.2022	Sample Qty	:	120 Tablets
Analysis Date	:	18.07.2022	Release Date	:	30.07.2022

09.	**Uniformity of dosage unit by HPLC**		
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	L1=3.242	L1=15
10.	**Related substances:(BY HPLC)**		
	Atorvastatin pyrrolidone Analog	Not Detected	Not more than 0.5 %
	Atorvastatin related compound H	0.08%	Not more than 1.0 %
	Atorvastatin epoxy pyrrolooxazin 6- hydroxy analog	Not Detected	Not more than 0.5 %
	Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	Not Detected	Not more than 0.5 %
	Atorvastatin epoxy THF analog	Not Detected	Not more than 1.0 %
	Atorvastatin related compound D	0.02%	Not more than 0.5 %
	Any other unspecified degradation product	0.04%	Not more than 0.2 %
	Total degradation products	0.23%	Not more than 4.0 %
11.	**Assay: Each Film coated tablet contains:**		
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	100.16 %	Not less than 90.00 % and Not more than 110.00 %
12.	**Microbiological limits:**		
	Total Aerobic Microbial count	20 cfu /g	NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g	NMT 100 cfu/g
	E.Coli	Absent	Should be Absent
	Salmonella	Absent	Should be Absent
	S.aureus	Absent	Should be Absent
	P.aeruginosa	Absent	Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to ~~BP~~/USP ~~and In-house~~ Specification.

	Tested By	Checked By	Approved By
Sign			
Name	Kayal	Ramesh	Vallarasan
Date	30/07/2022	30/07/2022	30/07/2022

Issued by: / Date: 14/07/2022			Format No.: F/QCGN/022/01
SAI PRIMUS LIFE BIOTECH PVT LTD	RESULTS OF ANALYSIS		ROA No: ROA/L13-00
QUALITY CONTROL	FINISHED PRODUCT		Page 1 of 2

BRAND NAME	:	LOLIP 20 mg TABLETS			
GENERIC NAME	:	Atorvastatin Calcium Tablets USP 20 mg			
B.No.	:	G1822106	A.R.No.	:	BSIIU0722102
B. SIZE	:	6.0L	MFG. DATE	:	07/2022
SAMPLE QTY	:	120 Tablets.	EXP. DATE	:	06/2025
ANALYSIS STARTED ON	:	18/07/2022	DATE OF COMPLETION	:	30/07/2022

S.No.	TEST	RESULTS	LIMITS
01	DESCRIPTION	Pale yellow Coloured Circular, biconvex film Coated tablet with break line on one side and plain on other side.	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.
02	IDENTIFICATION A. By UV B. By HPLC	Complies. Complies.	The UV absorption spectrum of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay. 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.
03	AVERAGE WEIGHT	193.4 mg	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)
04	UNIFORMITY OF WEIGHT	+2.38% to -1.76%	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15.0 %
05	DIMENSIONS Thickness Diameter	Min. Max. Avg. 3.46mm 3.55mm 3.51mm 8.06mm 8.09mm 8.08mm	 3.40 mm to 3.80 mm 7.80 mm to 8.20 mm
06	HARDNESS	7.95 kg/cm^2	NLT 3.0 kg/cm^2
07	DISINTEGRATION TIME	00 minutes 52 seconds	Not more than 30 minutes
08	DISSOLUTION By UV	Min Max Avg. 94.63% 96.43% 95.57%	Not less than 85.0 % of labeled amount.
09	UNIFORMITY OF DOSAGE UNIT BY HPLC	3.242	L1=15

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Tang		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

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SAI PRIMUS LIFE BIOTECH PVT LTD	RESULTS OF ANALYSIS	ROA No: ROA/L13-00
QUALITY CONTROL	FINISHED PRODUCT (Tablets/Capsule)	Page 2 of 2

BRAND NAME	:	LOLIP 20 mg TABLETS			
GENERIC NAME	:	Atorvastatin Calcium Tablets USP 20 mg			
B.No.	:	9182206	A.R.No.	:	BS/1407221/02
B. SIZE	:	6.0 L	MFG. DATE	:	07/2022
SAMPLE QTY	:	120 Tablets.	EXP. DATE	:	06/2025
ANALYSIS STARTED ON	:	18/07/2022	DATE OF COMPLETION	:	30/07/2022

S.No.	TEST	RESULTS	LIMITS
10	**RELATED SUBSTANCES (By HPLC)**		
	Atorvastatin pyrrolidone Analog	ND	Not more than 0.5 %
	Atorvastatin related compound H	0.08%	Not more than 1.0 %
	Atorvastatin epoxy pyrrolooxazin 6-hydroxy analog	ND	Not more than 0.5 %
	Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	ND	Not more than 0.5 %
	Atorvastatin epoxy THF analog	ND	Not more than 1.0 %
	Atorvastatin related compound D	0.02 %	Not more than 0.5 %
	Any other unspecified degradation product	0.04%	Not more than 0.2 %
	Total degradation products	0.23%	Not more than 4.0 %
11	**ASSAY (By HPLC)** **Each Film coated tablet contains:** Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	100.16%	Not less than 90.0% and not more than 110.0% of labeled claim.
12	**MICROBIOLOGICAL LIMITS**		
	Total Aerobic Microbial count	20 cfu/g	NMT 1000 CFU/g
	Total Yeasts and mould counts	<10 cfu/g	NMT 100 CFU/g
	E.Coli	Absent	Should be Absent
	Salmonella	Absent	Should be Absent
	S.aureus	Absent	Should be Absent
	P.aeruginosa	Absent	Should be Absent

REMARKS: The sample complies/~~not complies~~ as per specification.

ANALYSED BY : J. Kayal	**CHECKED BY :**	**APPROVED BY:**
DATE : 30/07/2022	**DATE :** 30/07/2022	**DATE:** 30/07/2022

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kayal		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		**Date of Issue:** 07/07/2022	

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Issued by : Date: 14/07/2022		Format No.: F/QCGN/022/02
SAI PRIMUS LIFE BIOTECH PVT LTD	ANALYTICAL WORK RECORD	AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT	Page 1 of 15
BRAND NAME	LOLIP 20 mg TABLETS	
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg	
B.No.	: G1822106	A.R. No. : BL1407221102

S.No	Name of the test
1.	**DESCRIPTION:**
	Pale yellow coloured, biconvex film coated tablet with breakline on one side and plain on both side.

✓ Complies/ ~~Does not comply.~~	Analysed by: Sy Date: 21/07/2022	Witnessed by: Date: 26/07/2022

2.	**A. IDENTIFICATION: A.By UV**
	Observation: Complies.

✓ Complies/ ~~Does not comply.~~	Analysed by: J. Kanyal Date: 18/07/2022	Witnessed by: Date: 30/07/2022

	B. IDENTIFICATION: By HPLC
	Observation: Complies.

✓ Complies/ ~~Does not comply.~~	Analysed by: J. Kanyal Date: 18/07/2022	Checked by: Date: 30/07/2022

3.	**AVERAGE WEIGHT:**

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Analytical balance	QC/ABL/1003	12/08/2022

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kanyal		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

BRAND NAME	LOLIP 20 mg TABLETS		
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg		
B.No.	: G1822106	A.R. No.	: BS/140722/02

Weight of 20 tablets 3.868 g

Average weight = $\frac{3.868}{20}$ x 1000 = 193.4 mg

✓ Complies/ Does not comply.	Analysed by: Date: 21/07/2022	Checked by: Date: 30/07/2022

4. UNIFORMITY OF WEIGHT:

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Analytical balance	QC/ABL/003	12/08/2022

Weight of 20 tablets 3.868 g

S. No.	Weight of Tablet	S. No.	Weight of Tablet
1	0.190	11	0.193
2	0.191	12	0.192
3	0.194	13	0.193
4	0.195	14	0.192
5	0.198	15	0.193
6	0.195	16	0.190
7	0.193	17	0.196
8	0.192	18	0.191
9	0.196	19	0.195
10	0.193	20	0.196
Average			0.1934
Minimum			0.190
Maximum			0.198

SAI PRIMUS LIFE BIOTECH PVT LTD	ANALYTICAL WORK RECORD		AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT		Page 3 of 15
BRAND NAME	LOLIP 20 mg TABLETS		
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg		
B.No.	: G1822106	A.R. No.	: BS/140722/02

Calculation:

Lowest % = $\frac{0.190}{0.193.4} \times 100 - 100 = -1.76\%$

Highest % = $\frac{0.198}{0.193.4} \times 100 - 100 = +2.38\%$

✓ Complies/ Does not comply.	Analysed by: [signature] Date: 21/07/2022	Checked by: [signature] Date: 30/07/2022

5. DIMENSION: A) Thickness

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Digital Vernier caliper	QC/DVC/001	27/07/2022

Thickness	Tablet 1	Tablet 2	Tablet 3	Tablet 4	Tablet 5
In mm	3.54	3.49	3.53	3.48	3.52
	Tablet 6	Tablet 7	Tablet 8	Tablet 9	Tablet 10
	3.52	3.53	3.51	3.55	3.46
Minimum: 3.46 mm.		Maximum: 3.55 mm		Average: 3.51 mm	

✓ Complies/ Does not comply.	Analysed by: [signature] Date: 21/07/2022	Checked by: [signature] Date: 30/07/2022

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	[signature]	[signature]	[signature]
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

DIMENSION: B) Diameter

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Digital Vernier caliper	QC/DVC/001	27/07/2022

Length	Tablet 1	Tablet 2	Tablet 3	Tablet 4	Tablet 5
In mm	8.07	8.08	8.06	8.09	8.07
	Tablet 6	Tablet 7	Tablet 8	Tablet 9	Tablet 10
	8.08	8.08	8.08	8.09	8.06
Minimum: 8.06 mm		Maximum: 8.09 mm		Average: 8.08 mm	

Complies/ Does not comply. ✓ | Analysed by: Date: 21/07/2022 | Checked by: Date: 30/07/2022

6. HARDNESS:

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Tablet Hardness Tester	QC/TMT/001	27/07/2022

Hardness	Tablet 1	Tablet 2	Tablet 3	Tablet 4	Tablet 5
In kg	7.0	8.8	8.5	8.8	7.5
	Tablet 6	Tablet 7	Tablet 8	Tablet 9	Tablet 10
	7.8	8.5	8.3	7.5	6.8
Minimum: 6.8 kg/cm²		Maximum: 8.8 kg/cm²		Average: 7.95 kg/cm²	

Complies/ Does not comply. ✓ | Analysed by: Date: 21/07/2022 | Checked by: Date: 30/07/2022

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
Date	07/07/2022	07/07/2022	08/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

SAI PRIMUS LIFE BIOTECH PVT LTD	ANALYTICAL WORK RECORD	AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT	Page 5 of 15
BRAND NAME	LOLIP 20 mg TABLETS	
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg	
B.No.	: 918 22106	A.R. No. : BS/140722/02

7. DISINTEGRATION TIME:

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Disintegration apparatus	QC/DTA/001	18/08/2022

Medium: water

Temperature: 36.8 °C

No of Tablets used: 06

Discs: ~~used~~/~~Not used~~.

Observed time: 00 minutes 52 seconds.

Complies/ ~~Does not comply~~.

Analysed by: [signature]
Date: 21/07/2022

Checked by: [signature]
Date: 21/07/2022

8. DISSOLUTION: (By UV)

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Analytical balance	QC/ABL/002	12/08/2022
2.	Dissolution	QC/DIS/001	30/05/2023
3.	~~HPLC~~ UV-Vis Spectrophotometer	QC/UVS/001	27/09/2022
4.	pH meter	QC/PHM/001	26/07/2022

Details Of Chemical / Reagents:

S. No	Chemicals/Reagents Name	Make	Grade	Batch No.	Valid Up To
1.	Potassium dihydrogen orthophosphate	Rankem	AR	J212F22	24/07/2025
2.	Sodium hydroxide	Rankem	AR	J191B22	28/07/2025
3.	Acetonitrile	Rankem	~~AR~~ HPLC	T050A22	25/07/2024

*Used

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	[signature]	[signature]	[signature]
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

SAI PRIMUS LIFE BIOTECH PVT LTD	ANALYTICAL WORK RECORD	AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT	Page 6 of 15
BRAND NAME	LOLIP 20 mg TABLETS	
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg	
B.No.	: G1822106	A.R. No. : BS/140722/02

Details of standard:

S. No.	Standard	Std. No	valid up to	Vial No	Vial Valid up to	Potency
1.	Atorvastatin Calcium	WS/CAL/064	08/06/2023	01	08/06/2023	94.42%

Dissolution parameters

Apparatus : Paddelle (Paddle)

Medium : PH 6.8 phosphate buffer (PH 6.8 phosphate buffer)

Volume : 900 mL (900 mL)

Time intervals : 15 min (15 min)

Speed : 75 RPM (75 RPM)

Temperature : 37.0 °C (37 °C ± 0.5 °C)

Instrumental Conditions:

Mode : UV-Visible Sepectroscopy (Ultraviolet - visible spectroscopy)

Cell : 0.5 (0.5 cm)

Blank : Medium (Medium)

Wavelength : 244 (244 nm)

Preparation of 0.05 M phosphate Buffer solution:

Dissolved 6.8 g(6.8 g) of monobasic potassium Phosphate in 9000 mL(900 ml) of water, adjust with 6N sodium hydroxide to a 6.8 (pH of 6.8) and dilute with Water to 10000 ml(1000 ml).

Preparation of Diluent:

Mixed of 500 ml(50 ml) of Acetonitrile and 500 ml(50 ml) of water.

Preparation of Standard Stock Solution:

Weigh accurately and dissolved 26.88 mg(26 mg) of Atorvastatin Calcium working standard in a 25 ml(25 ml) of volumetric flask. Add about 15 ml(15 ml) of Diluent to dissolve the substance. Shake mechanically for 10 min(10 mins) or until dissolved. Dilute up to the mark using Diluent. (Concentration: 1 mg/ml of USP Atorvastatin Calcium working standard)

Preparation of Standard Solution:

Dilute 2 ml(2 ml) of above solution to 100 ml(100 ml) using disso medium.

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	T. Kangad		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

SAI PRIMUS LIFE BIOTECH PVT LTD	ANALYTICAL WORK RECORD	AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT	Page 7 of 15
BRAND NAME	LOLIP 20 mg TABLETS	
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg	
B.No.	: 91822106	A.R. No. : BS/140722/02

(Concentration: 0.020 mg/ml of Atorvastatin Calcium working standard)

Preparation of Sample Solution:

Place one tablets in each vessel containing 900 ml(900 ml) of dissolution medium maintained at 37 °C (± 0.5 °C). With draw the aliquot from vessel, at given interval, through a suitable filter or centrifuge. (Concentration: 0.022 mg/ml of Atorvastatin Calcium)

Calculation: Refer to Excel Sheet

Calculated the content of Atorvastatin Calcium equivalent to Atorvastatin by using following formula,

$$= \frac{}{} \times \frac{2}{25} \times \frac{900}{100} \times \frac{}{1} \times \frac{100}{100} \times \frac{}{20} \times 0.967$$

✓ Complies/ ~~Does not comply.~~	Analysed by: Date: 01/07/2022	Checked by: Date: 04/07/2022

10. RELATED SUBSTANCES :(By HPLC) Outside Report.

Details of Instruments:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Analytical balance		
2.	HPLC		
3.	pH meter		

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	T. Bangal		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

BRAND NAME	LOLIP 20 mg TABLETS		
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg		
B.No.	: GIS22106	A.R. No.	: BS/140722/02

Details of chemical /Reagents:

S. No.	Chemicals/Reagents Name	Make	Grade	Batch No.	Valid up to
1.	Monobasic ammonium phosphate				
2.	Acetic acid				
3.	Ammonium hydroxide				
4.	Acetonitrile				
5.	Tetrahydrofuran				
6.	Methanol				
7.	N, N-Dimethylformide				

Details of standard:

S. No.	Standard	Std. No	valid up to	Vial No	Vial Valid up to	Potency
1.	Atorvastatin Calcium					

Chromatographic Conditions:

Column type : _____ (C18 4.6 mm x 150 mm, 3.5 µm or Equivalent)

Detector wavelength : _____ nm (244 nm)

Column temperature : _____ ° C (30°C)

Sample temperature : _____ ° C (10°C)

Injection volume : _____ µL (20 µL)

Mobile phase:

Time	Mobile phase A (%)	Mobile phase B (%)	Flow rate (ml/ min)
0	100	0	1.8
30	100	0	1.8
45	25	75	1.5
50	25	75	1.5
55	20	80	1.5
58	100	0	1.8

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

SAI PRIMUS LIFE BIOTECH PVT LTD	ANALYTICAL WORK RECORD		AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT		Page 9 of 15
BRAND NAME	LOLIP 20 mg TABLETS		
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg		
B.No.	: G1822106	A.R. No.	: BS/140722/02

65	100	0	1.8

For the standard solution, the run time is only 30 min. For the system suitability solution and Sample solution, the run time is 65 min.

Preparation of Buffer:

Dissolved _____g(5.75 g) of monobasic ammonium phosphate in _____ml(1000 ml) of water. Adjust with dilute Acetic acid (10 % v/v) or dilute ammonium hydroxide (10 % v/v) to a pH _____(pH of 4.3 ± 0.05).

Preparation of Solution A:

Prepared the solution of _____ml(925 ml) of acetonitrile and _____ml(75 ml) of stabilizer- free tetrahydrofuran solution.

Preparation of Mobile phase A:

Mixed of _____ml(420 ml) of solution A and _____ml(580 ml) of buffer. Sonicate and Filter through 0.45 micron membrane filter and degas.

Preparation of Mobile phase B:

Mixed of _____ml(600 ml) of methanol and _____ml(200 ml) of solution A and _____ml(200 ml) of buffer. Sonicate and Filter through 0.45 micron membrane filter and degas.

Diluent:

N, N-Dimethylformide.

Preparation of System Suitability solution:

Weigh accurately _____mg(6 mg) of USP Atorvastatin Calcium RS, _____mg(5 mg) of USP Atorvastatin Calcium Compound B RS, _____mg(1 mg) of USP Atorvastatin Related Compound H RS, and _____mg(0.5 mg) of USP Atorvastatin Related Compound D RS in _____ml(100 ml) volumetric flask. Add _____ml(50 ml) of diluent and dissolve the substance. Sonicate to dissolve if necessary. Dilute up to the mark using the same solvent.

Preparation of Standard solution:

Weight accurately and transfer _____mg(50 mg) of Atorvastatin calcium working standard in _____ml(100 ml) volumetric flask. Add _____ml(70 ml) of Diluent and dissolve the substance. Sonicate to dissolve, if Necessary. Dilute up to the mark with Diluent. Further dilute _____ml(1 ml) of this solution with _____ml(100 ml) of diluent.

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Bengal		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

(Concentration: 5 µg/ml of USP Atorvastatin calcium working standard)

Preparation of Placebo solution:

Transfer the _____mg(438 mg) of placebo (equivalent to about 50 mg of atorvastatin), to a _____ml(50 ml) volumetric Flask. Add _____ml(30 ml) of diluent and shake mechanically for _____mins(15 mins). Dilute with diluent to volume and pass the solution through a suitable filter of 0.45-µm pore Size, discarding the first few ml of the Filtrate.

Preparation of Sample powder:

Weigh accurately _____20 tablets and make the powder by using mortar and pestle. Use the same for preparation of sample solution. Calculate the average weight by taking weight of 20 tablets taken above and use the same for calculation.

Preparation of Sample solution:

Transfer the _____mg(488 mg) of powder (equivalent to about 50 mg of atorvastatin), to a _____ml(50 ml) volumetric Flask. Add _____ml(30 ml) of diluent and shake mechanically for _____mins(15 min). Dilute with diluent to volume and pass the solution through a suitable filter of 0.45-µm pore Size, discarding the first few ml of the Filtrate.(Concentration: 1 mg/ml of atorvastatin)

Suitability requirements:

1)The Resolution between the peaks corresponding to Atorvastatin related compound B and Atorvastatin obtained with standard solution should_____(not less than 1.4)

2)The tailing factor for the peak of Atorvastatin with standard solution should _____(not more than 2.0).

3) The % RSD for the peak area response of Atorvastatin obtained with the replicate injections of standard solution should _____(not more than 5.00)

4) The Signal-noise –ratio of Atorvastatin related compound D _____(not less than 10.0)

Calculations:

Calculate the percentage of each impurity in the portion of tables taken.

$$= \frac{1}{100} \times \frac{50}{100} \times \frac{P}{100} \times \frac{100}{20} \times 0.967 \times x$$

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kangal		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

SAI PRIMUS LIFE BIOTECH PVT LTD	ANALYTICAL WORK RECORD	AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT	Page 11 of 15
BRAND NAME	LOLIP 20 mg TABLETS	
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg	
B.No.	: G1822106	A.R. No. : BS/140722/02

	Analysed by:	Checked by:
Complies/ Does not comply	Date:	Date:

11 **ASSAY AND CONTENT UNIFORMITY(By HPLC):**

Details of Instruments:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Analytical balance	QC/ABL/002	12/08/2022
2.	HPLC	QC/HPL/003	05/08/2022
3.	pH meter	QC/PHM/001	18/07/2022

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kanojia		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

SAI PRIMUS LIFE BIOTECH PVT LTD	ANALYTICAL WORK RECORD	AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT	Page 12 of 15
BRAND NAME	LOLIP 20 mg TABLETS	
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg	
B.No.	: G1822106	A.R. No. : BS/140722/02

Details of chemical /Reagents:

S. No.	Chemicals/Reagents Name	Make	Grade	Batch No.	Valid up to
1.	Anhydrous Citric acid	Finar	AR	7964/0321R	16/09/2024
2.	Ammonium hydroxide	Rankem	AR	B002A22	15/07/2024
3.	Acetonitrile	Rankem	HPLC	T050A22	17/07/2024
4.	Tetrahydrofuran	Emplura	AR	SBISF71084	16/07/2024
5.	Methanol	Rankem	HPLC	R291F22	17/07/2024

Details of standard:

S. No.	Standard	Std. No	valid up to	Vial No	Vial Valid up to	Potency
1.	Atorvastatin Calcium	WS/CAL/04	08/06/2023	01	08/06/2023	94.42%

Chromatographic Conditions:

Column type : C18 (4.6mm x 250mm, 5µm) QC-LC-010 (C18 4.6 mm x 250 mm, 5 µm or Equivalent)

Flow rate : 1.5 mL/min (1.5 mL/minute)

Detector wavelength : 244 nm (244 nm)

Column temperature : 30 °C (30°C)

Injection volume : 20 µL (20 µL)

Preparation of 0.05 M ammonium citrate buffer pH 4.0:

Dissolved 19.238g (9.62 g) of anhydrous Citric acid in 1900 ml(950 ml) of water. Adjust with dilute ammonium hydroxide to a pH 4.02 (pH of 4.0) and dilute with water to 2000 ml(1000 ml).

Preparation of Mobile phase:

Mixed 540 ml(270 ml) of acetonitrile and 400 ml(200 ml) of stabilizer-free tetrahydrofuran and 1060 ml(530 ml) of buffer. Sonicate and Filter through 0.45 micron membrane filter and degas.

Preparation of Solution A:

Dissolved 19.278g(9.62 g) of anhydrous citric acid in 1900 ml(950 ml) of water, adjust with ammonium hydroxide to a pH 7.41 (pH of 7.4) and dilute with water to 2000 ml(1000ml)

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kanyal		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

SAI PRIMUS LIFE BIOTECH PVT LTD	ANALYTICAL WORK RECORD	AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT	Page 13 of 15
BRAND NAME	LOLIP 20 mg TABLETS	
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg	
B.No.	: 41822106	A.R. No. : BS/14672 2/02

Preparation of Diluent:

Mixed of 1000 ml(1 ml) of acetonitrile and 1000 ml(1 ml) of Solution A.

System suitability solution: NA

Weigh accurately _____mg(10 mg) of USP Atorvastatin calcium working standard and _____mg(1 mg) of USP Atorvastatin Related Compound H RS in a _____ml(100 ml) volumetric flask. Add _____ml(70 ml) of Diluent and dissolve the substance. Shake mechanically for _____min(30 min) or until dissolved. Dilute up to the mark using the same solvent.(Concentration: 0.1 mg/ml of USP Atorvastatin calcium RS and 0.01 mg/ml of USP Atorvastatin related compound H RS)

Preparation of Standard solution:

Weigh and transfer about 20.74 mg(20.70mg) of Atorvastatin calcium working standard to a 200 ml(200 ml) volumetric flask. Add about 100 ml(100 ml) of diluent. Shake for 15 mins(15 minutes), Dissolve make up with same solvent. (Concentration: 0.1 mg/ml of Atorvastatin calcium working standard)

Preparation of Sample powder:

Weigh accurately 3.875 20 tablets and make the powder by using mortar and pestle. Use the same for preparation of sample solution. Calculate the average weight by taking weight of 20 tablets taken above and use the same for calculation.

Preparation of Sample solution:

Weigh accurately and transfer accurately 1942.10mg 1935.81 mg (10 tablets) (equivalent to 200 mg of Atorvastatin) in a 200 ml(200 ml) volumetric flask. Add about 100 ml(100 ml) of diluent. Shake for 15 min(15 minutes), dilute with same solvent and centrifuge or pass through a suitable 0.45-µm pore Size filter. Further dilute 5 ml(5 ml) of this solution in to 50 ml(50 ml) of volumetric flask with diluent.(Concentration: 0.1 mg/ml of atorvastatin Calcium)

Preparation of content uniformity:

Take 1 1 tablet into 200 ml(200 ml) of volumetric flask, Add about 50 ml(50 ml) of diluent. Shake for 15 min(15 minutes) or until dissolved and make up with diluent centrifuge or Pass through a suitable filter of 0.45 µm pore size.

System suitability requirement:

1)The Resolution between the peaks corresponding to Atorvastatin and Atorvastatin related compound H

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

obtained with standard solution should _____(not less than 5.0)

2) The tailing factor for the peak of Atorvastatin with standard solution should 1.0 (not more than 1.5).

3) The % RSD for the peak area response of Atorvastatin obtained with the replicate injections of standard solution should 0.2 (not more than 1.00)

Calculation:(ASSAY) Refer to Excel sheet.

1)Calculated the content of Atorvastatin tablet by using following formula,

$$= \frac{}{200} \times \frac{200}{200} \times \frac{50}{5} \times \frac{}{} \times \frac{100}{100} \times \frac{}{20} \times 0.967$$

2) Calculate the average content of assay by using following formula,

$$= \frac{+}{2}$$

3)Calculations (Uniformity content): Refer to Excel sheet.

Calculated the content of Atorvastatin tablet by using following formula

$$= \frac{}{200} \times \frac{200}{1} \times \frac{}{100} \times \frac{100}{20} \times 0.967$$

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kanya		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

SAI PRIMUS LIFE BIOTECH PVT LTD	ANALYTICAL WORK RECORD		AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT		Page 15 of 15
BRAND NAME	LOLIP 20 mg TABLETS		
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg		
B.No.	: G1822106	A.R. No.	: BS/140722/02

Complies/ ~~Does not comply.~~	Analysed by: J. Kayal Date: 18/07/2022	Checked by: Date: 30/07/2022

12.	**MICROBIOLOGICAL LIMITS:**
	Observation: Refer MLT Report

Complies/ ~~Does not comply~~.	Analysed by: Date: 28/07/2022	Checked by: Date: 30/07/2022

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kayal		
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: 07/07/2022	

SAI PRIMUS
LIFE BIOTECH PVT LTD

EXCEL SHEET FOR DISSOLUTION CALCULATION

Name of Product	LOLIP 20 MG TABLET_(COATED)		
Date of Analysis	21/07/2022	**Batch No.**	G1822106
Mfg. Date	Jul-22	**Exp. Date**	Jun-25
WS No.	WS-21-032	**% Purity**	94.42
WS Weight (WS)	26.88	**WS Validity**	09/04/2023
Sample Weight (SW)	1	**Label Claim (LC)**	20

Std. Dilution	26.88	2	1	1	1	1
	25	100	1	1	1	1
Sample Dilution	1	1	1	1	1	1
	900	1	1	1	1	1

CF1	0.967
CF2	1
CF3	1
CF4	1

Calculation Formula	Smp. Area/Abs	Std Dilution	94.42	100	CF1	CF3
	Std. Area/Abs	Sample Dilution	100	20	CF2	CF4

Sr. No.	Standard Area/Abs	Standard RT
1	0.393	0
2	0.393	0
3	0.393	0
4	0.393	0
5	0.393	0
6		
Average	0.393	0.000
SD	0	0
%RSD	0.0	#DIV/0!

Tablet	Area/Abs.
Tab1	0.425
Tab2	0.421
Tab3	0.428
Tab4	0.424
Tab5	0.429
Tab6	0.424
Average	
Minimum	
Maximum	

Result %	Result mg
95.53	19.11
94.63	18.93
96.20	19.24
95.30	19.06
96.43	19.29
95.30	19.06
95.57	**19.12**
94.63	**18.93**
96.43	**19.29**

Analysed By Date	21/07/2022	**Checked By Date**	30/07/2022

SAI PRIMUS LIFE BIOTECH PVT LTD
PHOTOMETRIC REPORT

24

21/07/2022 20:02:49

File Name: D:\UV DATA\Data\DATA 2022\JULY 2022\21072022\LOLIP_20_G1822106_DS_STD_.unk

Sample Table

	Sample ID	WL244.0	Comments
1	BLANK	0.000	MEDIUM
2	STANDARD	0.393	ATORVASTATIN CALCIUM
3			

[Wavelengths]
Wavelength Name: WL244.0
Wavelength: 244.00 nm

[Calibration Curve]
Cal. Curve Type: Raw Data

[Measurement Parameters(Standard)]

[Measurement Parameters(Sample)]
Data Acquired by: Instrument
Delay sample read: Disabled
Repeat: Disabled

[Equations]

[Pass Fail]

[Method Summary]
Title:
Date/Time: 21/07/2022 17:49:07
Comments:
Sample Preparations:

[Instrument Properties]
Instrument Type: UV-1900 Series
Measuring Mode: Absorbance
Slit Width: 1.0 nm
Light Source Change Wavelength: 340.8 nm
S/R Exchange: Normal

.....

Software Information
Software Name: UVProbe
Version: 2.70
Mode: Security Mode

Data Information
Filename: D:\UV DATA\Data\DATA 2022\JULY 2022\2107202\LOLIP_20_G1822106_DS_STD_.unk
Title: dissolution
Analyst: BOOBALAN
Date/Time: 21/07/2022 17:51:51
Comments: disso

Instrument Information
Instrument Name: UV1900
Instrument Type: UV-1900 Series
Model (S/N): UV1900 (A12425780886)

Analysed By :
Date : 21/07/2022

Checked By :
Date : 21/07/2022

SAI PRIMUS LIFE BIOTECH PVT LTD
PHOTOMETRIC REPORT

21/07/2022 20:03:10

File Name: D:\UV DATA\Data\DATA 2022\JULY 2022\21072022\LOLIP_20_G1822106_DS_SPL_.unk

Sample Table

	Sample ID	Conc	WL244.0	Comments
1	JAR_1	95.577	0.425	LOLIP_20_G1822106
2	JAR_2	94.578	0.421	COATED
3	JAR_3	96.198	0.428	
4	JAR_4	95.299	0.424	
5	JAR_5	96.458	0.429	
6	JAR_6	95.419	0.424	
7				

[Wavelengths]
Wavelength Name: WL244.0
Wavelength: 244.00 nm

[Calibration Curve]
Column for Cal. Curve: WL244.0
Cal. Curve Type: K Factor
Cal. Curve Unit: mg/l
Selected Wavelength: WL244.0
Calibration Equation: (Conc) = K1(unk abs) + K0
K1: 224.8120
K0: 0.0000

[Measurement Parameters(Standard)]

[Measurement Parameters(Sample)]
Data Acquired by: Instrument
Delay sample read: Disabled
Repeat: Disabled

[Equations]

[Pass Fail]

[Method Summary]
Title:
Date/Time: 21/07/2022 17:52:45
Comments:
Sample Preparations:

.....

Software Information
Software Name: UVProbe
Version: 2.70
Mode: Security Mode

Data Information
Filename: D:\UV DATA\Data\DATA 2022\JULY 2022\2107202\LOLIP_20_G1822106_DS_SPL_.unk
Title: DOSSOLUTION
Analyst: BOOBALAN
Date/Time: 21/07/2022 17:59:21
Comments: DISSO

Instrument Information
Instrument Name: UV1900
Instrument Type: UV-1900 Series
Model (S/N): UV1900 (A12425780886)

Analysed By :
Date : 21/07/2022

Checked By :
Date : 30/07/2022

SAI PRIMUS LIFE BIOTECH PVT LTD
PHOTOMETRIC REPORT

18/07/2022 11:55:02

File Name: D:\UV DATA\Data\DATA 2022\JULY 2022\18072022\LOLIP-20_G1822106_IDENTIFICATION.unk

Sample Table

	Sample ID	WL244.0	Comments
1	BLANK	0.000	DILUENT
2	STD	3.605	ATOVASTATIN
3	SPL	3.839	LOLIP-20
4			

[Wavelengths]
Wavelength Name: WL244.0
Wavelength: 244.00 nm

[Calibration Curve]
Cal. Curve Type: Raw Data

[Measurement Parameters(Standard)]

[Measurement Parameters(Sample)]
Data Acquired by: Instrument
Delay sample read: Disabled
Repeat: Disabled

[Equations]

[Pass Fail]

[Method Summary]
Title:
Date/Time: 18/07/2022 11:48:28
Comments:
Sample Preparations:

[Instrument Properties]
Instrument Type: UV-1900 Series
Measuring Mode: Absorbance
Slit Width: 1.0 nm
Light Source Change Wavelength: 340.8 nm
S/R Exchange: Normal

.....

Software Information
Software Name: UVProbe
Version: 2.70
Mode: Security Mode

Data Information
Filename: D:\UV DATA\Data\DATA 2022\JULY 2022\1807202\LOLIP-20_G1822106_IDENTIFICATION.unk
Title: LOLIP-20
Analyst: KAYAL
Date/Time: 18/07/2022 11:54:41
Comments: IDENTIFICATION

Instrument Information
Instrument Name: UV1900
Instrument Type: UV-1900 Series
Model (S/N): UV1900 (A12425780886)

Analysed By : J. Kayal
Date : 18/07/2022

Checked By :
Date : 18/07/2022

LOLIP-20 mg TABLETS	
Batch	**G1822106**
S.NO	**UNIFORMITY**
1	102.12
2	99.72
3	99.3
4	100.98
5	100.64
6	100.02
7	103.76
8	100.71
9	100.22
10	99.54
AVG	**100.70**
STDEV	**1.351**

FORMULA	**AV=KS**	
	K	2.4
	S	1.351

RESULT	**3.242**

J. Kayal
18/07/2022

30/07/2022

SAI PRIMUS
LIFE BIOTECH PVT LTD

EXCEL SHEET FOR ASSAY CALCULATION FP

Name of Product	LOLIP_20MG TABLETS						
Date of Analysis	18.07.2022			**Batch No.**	G1822106		
Mfg. Date	Jul-22			**Exp. Date**	Jun-25		
WS No.	WS/CAL/064			**% Purity**	94.42		
WS Weight (WS)	20.74			**WS Validity**	8/6/2023		
Sample Weight (SW)	1			**Label Claim (LC)**	20		
CF1	0.967	**CF2**	1	**CF3**	1	**CF4**	1

Std. Dilution	20.74	1	1	1	1
	200	1	1	1	1
Sample Dilution	1	5	1	1	1
	200	50	1	1	1

Calculation Formula	Smp. Area/Abs	Std Dilution	94.42	193	CF1	CF3
	Std. Area/Abs	Sample Dilution	100		CF2	CF4

Avg.WT	193.00
SPL-1 WT(mg)	1942.1
SPL-2 WT(mg)	1935.81

Sr. No.	**Standard Area/Abs**	**Standard RT**
1	3100559	8.709
2	3094531	8.712
3	3091842	8.704
4	3083247	8.695
5	3099405	8.693
Average	3093917	8.703
SD	6942.01	0.01
RSD	0.22	0.10

Sr. No.	**Sample Area/Abs**	
1	3292050	**SPL-1**
2	3283823	**SPL-2**
3		
4		
5		
6		
Average	3287937	

Assay (mg) SPL-1	**20.0236**
Assay (mg) SPL-2	**20.0385**
AVERAGE	**20.0311**

Assay (%) SPL-1	**100.12**
Assay (%) SPL-2	**100.19**
AVERAGE	**100.16**

Analysed By	J. Kang	**Checked By**	
Date	20/07/2022	**Date**	20/07/2022

SAI PRIMUS
LIFE BIOTECH PVT LTD

EXCEL SHEET FOR UNIFORMITY OF CONTENT

Name of Product	LOLIP_20MG				
Date of Analysis	18/07/2022	**Batch No.**	G1822106	**Conversion Factor1**	0.967
Mfg. Date	Jul-22	**Exp. Date**	Jun-25	**Conversion Factor2**	1
WS No.	WS/CAL/064	**% Purity**	94.42	**Conversion Factor3**	1
WS Weight (WS)	20.74	**WS Validity**	08/06/2023	**Conversion Factor4**	1
Sample Weight (SW)	1	**Label Claim (LC)**	20		

Std. Dilution	20.74	1	1	1	1
	200	1	1	1	1
Sample Dilution	1	1	1	1	1
	200	1	1	1	1

Calculation Formula	Smp. Area	Std Dilution	94.42	100	**Conversion Factor1**	**Conversion Factor3**	**% Assay**
	Std. Area	Sample Dilution	100	20	**Conversion Factor2**	**Conversion Factor4**	

Sr. No.	**Standard Area**	**Standard RT**
1	3100559	8.709
2	3094531	8.712
3	3091842	8.704
4	3083247	8.695
5	3099405	8.693
6		
7		
8		
Average	3093917	8.703
SD	6942.006713	0.00838451
RSD	0.2	0.1

Sample

UC	**AREA**	**Smp. Weight**	**%**	**mg**	**Minimum %**
UC1	3336856	1	102.12	20.42	**99.30**
UC2	3258523	1	99.72	19.94	
UC3	3244790	1	99.30	19.86	
UC4	3299625	1	100.98	20.20	
UC5	3288654	1	100.64	20.13	**Maximum %**
UC6	3268251	1	100.02	20.00	**103.76**
UC7	3390388	1	103.76	20.75	
UC8	3290881	1	100.71	20.14	
UC9	3274873	1	100.22	20.04	
UC10	3252574	1	99.54	19.91	
		Avg	**100.70**		

Analysed By Date	J. Kongal 20/07/2022	**Checked By Date**	30/07/2022

Sample Set Method: 18072022_LOLIP_AS_FP_SS

Vial	Inj Vol (uL)	# of Injs	SampleName	Function	Method Set / Report or Export Method	Run Time (Minutes)
49	20.0	1	BLANK_AS	Inject Controls	LOLIP_AS_FP_MSET	20.00
50	20.0	5	STANDARD_AS	Inject Standards	LOLIP_AS_FP_MSET	20.00
49	20.0	1	BLANK_AS	Inject Controls	LOLIP_AS_FP_MSET	20.00
51	20.0	1	LOLIP-20_G1822106_SP_01	Inject Samples	LOLIP_AS_FP_MSET	20.00
52	20.0	1	LOLIP-20_G1822106_SP_02	Inject Samples	LOLIP_AS_FP_MSET	20.00
50	20.0	1	STANDARD_AS_BKT_1	Inject Standards	LOLIP_AS_FP_MSET	20.00
53	20.0	1	LOLIP-20_G1822106_UC_01	Inject Samples	LOLIP_AS_FP_MSET	20.00
54	20.0	1	LOLIP-20_G1822106_UC_02	Inject Samples	LOLIP_AS_FP_MSET	20.00
55	20.0	1	LOLIP-20_G1822106_UC_03	Inject Samples	LOLIP_AS_FP_MSET	20.00
56	20.0	1	LOLIP-20_G1822106_UC_04	Inject Samples	LOLIP_AS_FP_MSET	20.00
57	20.0	1	LOLIP-20_G1822106_UC_05	Inject Samples	LOLIP_AS_FP_MSET	20.00
50	20.0	1	STANDARD_AS_BKT_2	Inject Standards	LOLIP_AS_FP_MSET	20.00
58	20.0	1	LOLIP-20_G1822106_UC_06	Inject Samples	LOLIP_AS_FP_MSET	20.00
59	20.0	1	LOLIP-20_G1822106_UC_07	Inject Samples	LOLIP_AS_FP_MSET	20.00
60	20.0	1	LOLIP-20_G1822106_UC_08	Inject Samples	LOLIP_AS_FP_MSET	20.00
61	20.0	1	LOLIP-20_G1822106_UC_09	Inject Samples	LOLIP_AS_FP_MSET	20.00
62	20.0	1	LOLIP-20_G1822106_UC_10	Inject Samples	LOLIP_AS_FP_MSET	20.00
50	20.0	1	STANDARD_AS_BKT_3	Inject Standards	LOLIP_AS_FP_MSET	20.00
				Condition Column	WASHING SOLUTION_C_MSET	150.00
				Condition Column	WASHING SOLUTION_D_MSET	50.00
				Equilibrate	SHUTDOWN_MSET	0.01

J. Kanal
18/07/2022

18/07/2022

Empower 3 SOFTWARE

INSTRUMENT METHOD

SAI PRIMUS LIFE BIOTECH PVT LTD

Instrument Method: LOLIP_AS_FP_IM

Stored: 30/06/2022 19:09:59 IST

Method Information

Method Comments	INSTRUMENT METHOD CREATED
Method Modified User	KAYAL
Method Locked	No
Method Id	1964
Old Id	
Method Version	1
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

W2489 Instrument Setup

Wavelength Mode	Single Wavelength
Lamp On	On

Channel A

Comment	
Wavelength	244(nm)
Sampling Rate	20(points/sec)
Data Mode	Absorbance
Time Constant	0.1000(sec)
Autozero On Wavelength Change	Maintain Baseline
Autozero On Inject Start	Yes

Analog 1

Sensitivity	2.0000(AUFS)
Chart Polarity	Positive (+)
Voltage Offset	0(mV)
Enable Chart Mark	Yes

Run Events Yes

Pulse Width	1.0(sec)
Rect Wave Period	0.2(sec)

W2690/5 Instrument Setup

Type	W2690/5
Instrument Status	On
Channel Name	2690/5
Description	244
Use Channel Monitor	On
Monitor Parameter	System Pressure

Analysed by : J. kayal
Date : 18/07/2022

Checked by : [illegible]
Date : 18/07/2022

Stroke Volume	100uL (flow rates <= 3.030 mL/min)
Chart Out	%A
Syringe Draw Rate	Normal
Depth Of Needle	0.0
Degas Mode	On
Pump Mode	Isocratic
Flow	1.500
%A	100.0
%B	0.0
%C	0.0
%D	0.0
High Limit	5000.0
Low Limit	0.0
Enable Sample Temp	False
Enable Column Temp	True
Bubble Detect	True
Pre Column Volume	0.0
Sample Temp Target	-1.0
Sample Temp Range	5.0
Sparge A	0.0
Sparge B	0.0
Sparge C	0.0
Sparge D	0.0
Column Temp Target	30.0
Column Temp Range	5.0
Flow Ramp	2.00
Column choice	No Change
Column Equil Minutes	0.00
Needle Wash	Normal
Switch 1	No Change
Switch 2	No Change
Switch 3	No Change
Switch 4	No Change
Use Events	False
Solvent A	
Solvent B	
Solvent C	
Solvent D	

Revision History

Version 1 30/06/2022 19:09:59 IST User Vallarasan Method (\Hplc\2022\QC_HPL_003\JUN-2022 : 1942) copied into project. (from Full Audit Trail project)

Version 1 01/06/2022 16:46:25 IST User Vallarasan Method (\Hplc\2022\QC_HPL_003\MAY-2022 : 2289) copie into project. (from Full Audit Trail project)

Version 1 02/05/2022 09:06:31 IST User Vallarasan Method (\Hplc\2022\QC_HPL_003\APR-2022 : 6916) copied into project. (from Full Audit Trail project)

Analysed by : J. Kayal
Date : 18/07/2022

Checked by :
Date : 18/07/2022

Version 1 20/04/2022 12:33:51 IST User KAYAL Created method 'LOLIP_AS_FP_IM'. INSTRUMENT METHOD CREATED

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User	Method Locked
1	LOLIP_AS_FP_IM	Instrument	INSTRUMENT METHOD CREATED	30/06/2022 19:09:59 IST	KAYAL	No

Method Version Summaries

	Method Id	Old Id	Method Version	Source S/W Info
1	1964		1	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

Analysed by : J. kayal
Date : 18/07/2022

Checked by :
Date : 18/07/2022

Empower 3 SOFTWARE

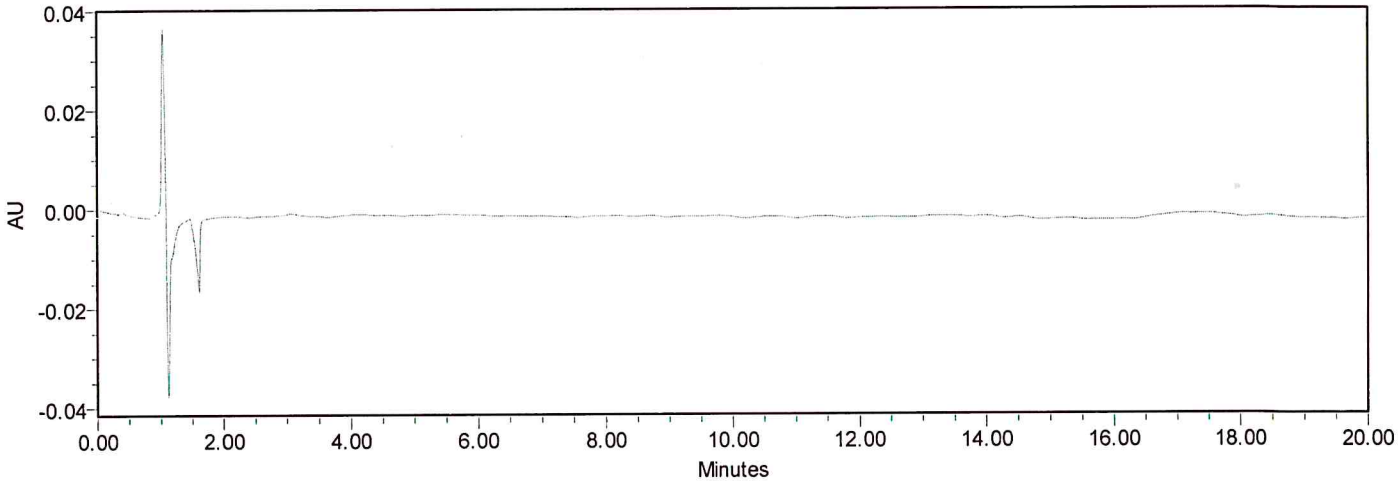
CHROMATOGRAPHIC DATA

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	BLANK_AS	Acquired By:	KAYAL
Sample Type:	Control	Sample Set Name:	18072022_LOLIP_AS_FP_SS
Vial:	49	Acq. Method Set:	LOLIP_AS_FP_MSET
Injection #:	1	Processing Methoc	LOLIP_AS_FP_PM
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 244nm
Date Acquired:	18/07/2022 11:30:06 IST		
Date Processed:	19/07/2022 13:03:27 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	ATORVASTATIN CALCIUM	1	8.700		

Analysed by : J. Kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 2747

Project Name: 2022\QC_HPL_003\JUL-2022
Printed Date: 20/07/2022
Printed Time: 15:36:03 Asia/Calcutta

RSD REPORT

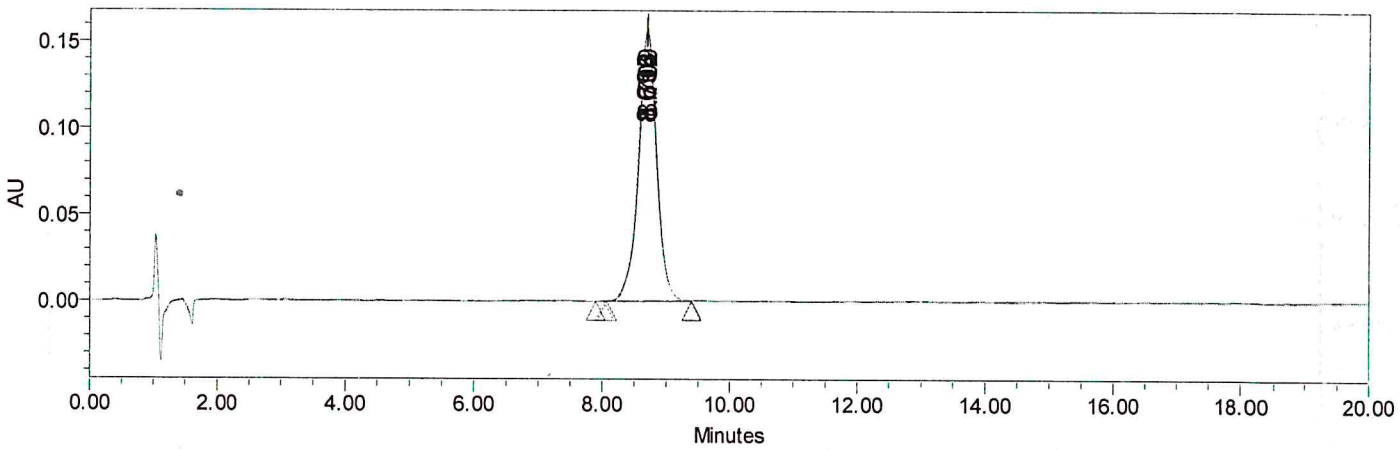
SAMPLE INFORMATION

Sample Name:	STANDARD_AS	Acquired By:	KAYAL
Sample Type:	Standard	Sample Set Name:	18072022_LOLIP_AS_FP_SS
Vial:	50	Acq. Method Set:	LOLIP_AS_FP_MSET
Injection #:	1, 2, 4, 5, 3	Processing Methoc	LOLIP_AS_FP_PM
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 244nm

Date Acquired: 18/07/2022 11:51:15 IST, 18/07/2022 12:12:09 IST, 18/07/2022 12:33:05 IST, 18/07/2022 12:54:00 IST, 18/07/2022 13:14:55 IST

Date Processed: 19/07/2022 13:03:28 IST

Auto-Scaled Chromatogram



Peak Name: ATORVASTATIN CALCIUM

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	ATORVASTATIN CALCIUM	1	8.709	3100559	1.0	4835
2	ATORVASTATIN CALCIUM	2	8.712	3094531	1.0	4796
3	ATORVASTATIN CALCIUM	3	8.704	3091842	1.0	4761
4	ATORVASTATIN CALCIUM	4	8.695	3083247	1.0	4733
5	ATORVASTATIN CALCIUM	5	8.693	3099405	1.0	4748
Mean			8.703	3093917	1.0	4775
Std. Dev.			0.008	6941.913		
% RSD			0.1	0.2		

Analysed by : J. Kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

Reported by User: KAYAL (KAYAL)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3000

Project Name: 2022\QC_HPL_003\JUL-2022
Printed Date: 20/07/2022
Printed Time: 15:36:51 Asia/Calcutta

Empower 3 SOFTWARE

CHROMATOGRAPHIC DATA

SAI PRIMUS LIFE BIOTECH PVT LTD

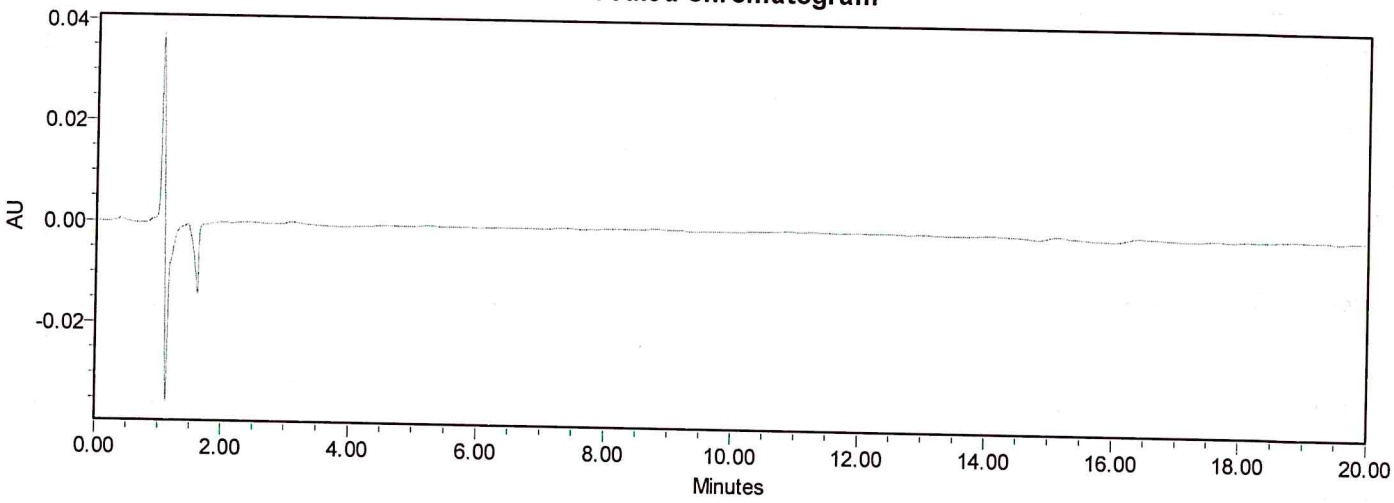
SAMPLE INFORMATION

Sample Name:	BLANK_AS	Acquired By:	KAYAL
Sample Type:	Control	Sample Set Name:	18072022_LOLIP_AS_FP_SS
Vial:	49	Acq. Method Set:	LOLIP_AS_FP_MSET
Injection #:	1	Processing Methoc	LOLIP_AS_FP_PM
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 244nm

Date Acquired: 18/07/2022 13:36:18 IST

Date Processed: 19/07/2022 13:03:28 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	ATORVASTATIN CALCIUM	1	8.700		

Analysed by : J. Kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 2747

Project Name: 2022\QC_HPL_003\JUL-2022
Printed Date: 20/07/2022
Printed Time: 15:37:13 Asia/Calcutta

Empower 3 SOFTWARE

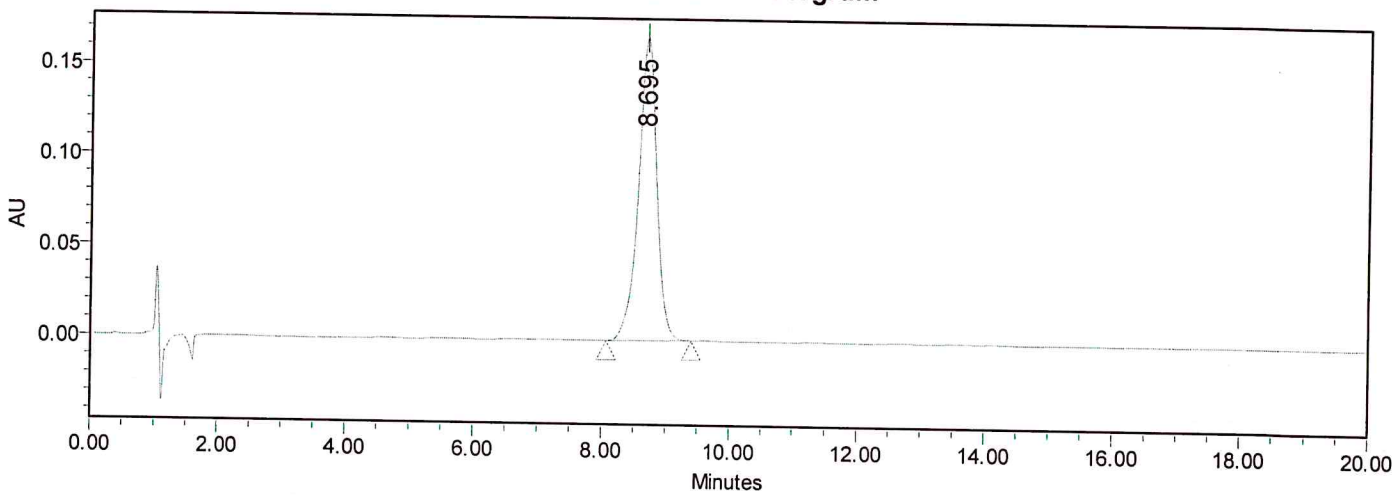
CHROMATOGRAPHIC DATA

SAI PRIMUS LIFE BIOTECH PVT LTD

SAMPLE INFORMATION

Sample Name:	LOLIP-20_G1822106_SP_01	Acquired By:	KAYAL
Sample Type:	Unknown	Sample Set Name:	18072022_LOLIP_AS_FP_SS
Vial:	51	Acq. Method Set:	LOLIP_AS_FP_MSET
Injection #:	1	Processing Methoc	LOLIP_AS_FP_PM
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 244nm
Date Acquired:	18/07/2022 13:57:17 IST		
Date Processed:	19/07/2022 13:03:28 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	ATORVASTATIN CALCIUM	1	8.695	3292050	100.00

Analysed by : J. kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 2747
Page: 1 of 1

Project Name: 2022\QC_HPL_003\JUL-2022
Printed Date: 20/07/2022
Printed Time: 15:37:44 Asia/Calcutta

Empower 3 SOFTWARE

CHROMATOGRAPHIC DATA

SAI PRIMUS LIFE BIOTECH PVT LTD

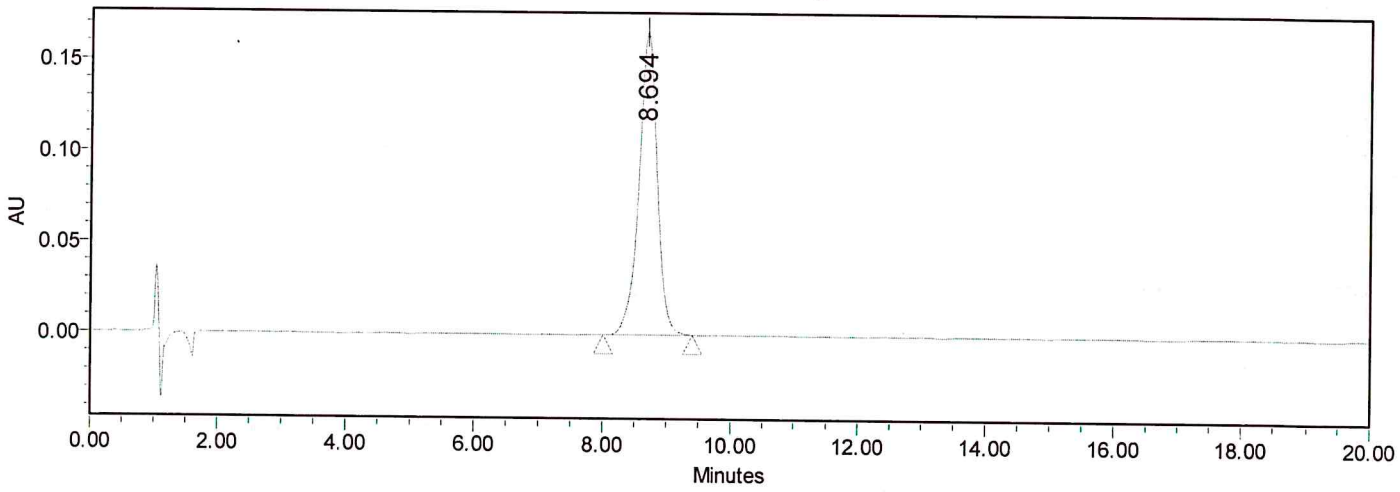
SAMPLE INFORMATION

Sample Name:	LOLIP-20_G1822106_SP_02	Acquired By:	KAYAL
Sample Type:	Unknown	Sample Set Name:	18072022_LOLIP_AS_FP_SS
Vial:	52	Acq. Method Set:	LOLIP_AS_FP_MSET
Injection #:	1	Processing Metho:	LOLIP_AS_FP_PM
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 244nm

Date Acquired: 18/07/2022 14:18:11 IST

Date Processed: 19/07/2022 13:03:28 IST

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	ATORVASTATIN CALCIUM	1	8.694	3283823	100.00

Analysed by : J. kayal
Date : 20/07/2022

Checked by :
Date : 30/07/2022

Reported by User: KAYAL (KAYAL)
Report Method: CHROMATOGRAPHIC DATA
Report Method ID: 2747

Project Name: 2022\QC_HPL_003\JUL-2022
Printed Date: 20/07/2022
Printed Time: 15:39:07 Asia/Calcutta

Empower 3 SOFTWARE

RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

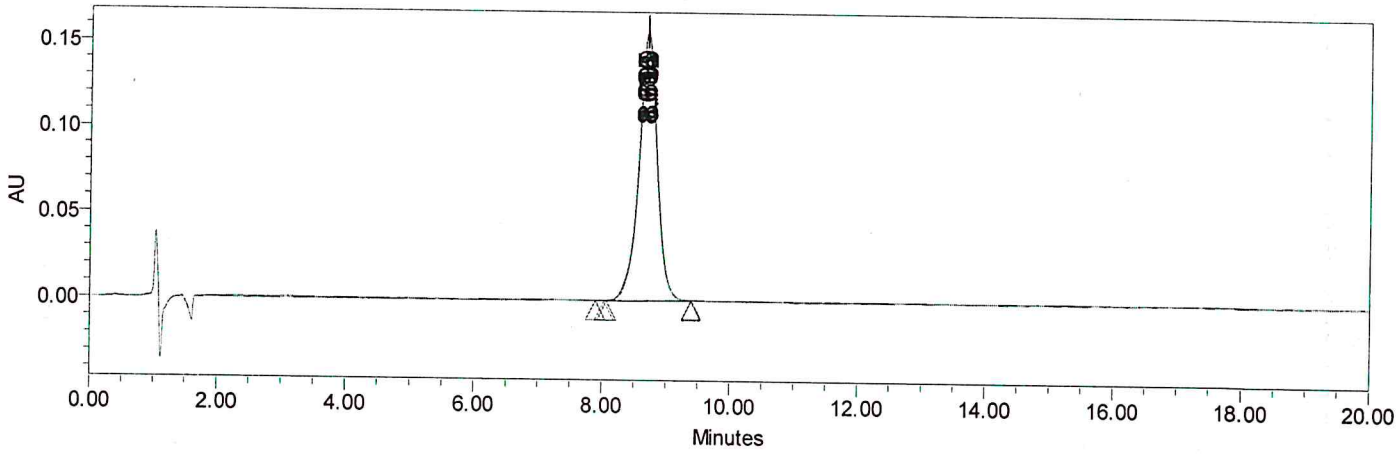
SAMPLE INFORMATION

Sample Name:	STANDARD_AS, STANDARD_AS_BKT_1	Acquired By:	KAYAL
Sample Type:	Standard	Sample Set Name:	18072022_LOLIP_AS_FP_SS
Vial:	50	Acq. Method Set:	LOLIP_AS_FP_MSET
Injection #:	1, 2, 4, 5, 3	Processing Methoc	LOLIP_AS_FP_PM
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 244nm

Date Acquired: 18/07/2022 11:51:15 IST, 18/07/2022 12:12:09 IST, 18/07/2022 12:33:05 IST, 18/07/2022 12:54:00 IST, 18/07/2022 13:14:55 IST, 18/07/2022 14:39:10 IST

Date Processed: 19/07/2022 13:03:28 IST

Auto-Scaled Chromatogram



Peak Name: ATORVASTATIN CALCIUM

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	ATORVASTATIN CALCIUM	1	8.709	3100559	1.0	4835
2	ATORVASTATIN CALCIUM	1	8.695	3128817	1.0	4787
3	ATORVASTATIN CALCIUM	2	8.712	3094531	1.0	4796
4	ATORVASTATIN CALCIUM	3	8.704	3091842	1.0	4761
5	ATORVASTATIN CALCIUM	4	8.695	3083247	1.0	4733
6	ATORVASTATIN CALCIUM	5	8.693	3099405	1.0	4748
Mean			8.701	3099733	1.0	4777
Std. Dev.			0.008	15542.345		
% RSD			0.1	0.5		

Analysed by : J. Kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

Reported by User: KAYAL (KAYAL)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3000
Page: 1 of 1

Project Name: 2022\QC_HPL_003\JUL-2022
Printed Date: 20/07/2022
Printed Time: 15:39:35 Asia/Calcutta

Empower 3 SOFTWARE

RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

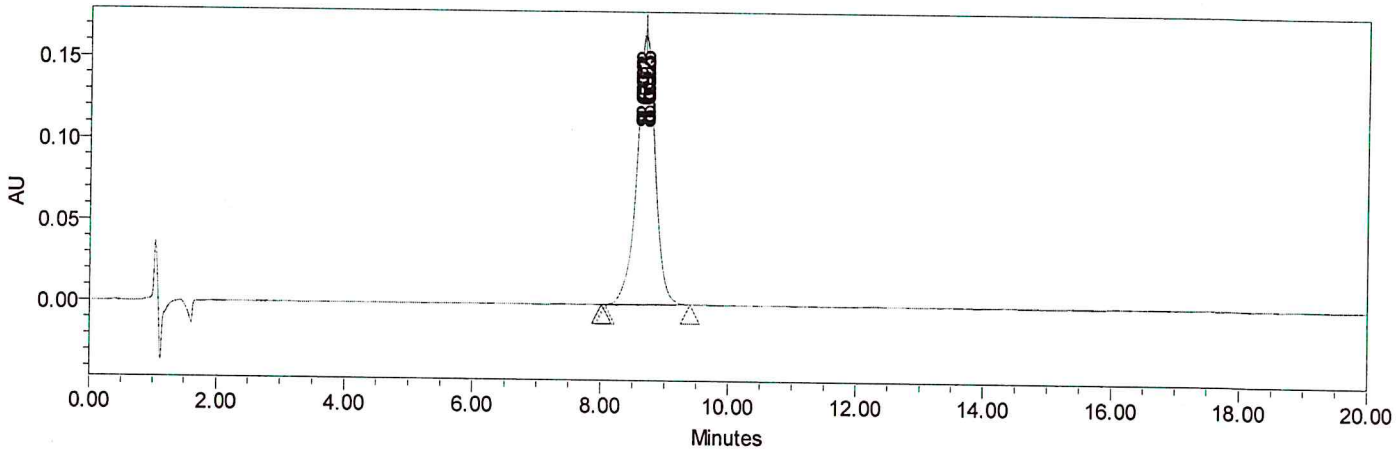
SAMPLE INFORMATION

Sample Name:	LOLIP-20_G1822106_UC_04,	Acquired By:	KAYAL
Sample Type:	Unknown	Sample Set Name:	18072022_LOLIP_AS_FP_SS
Vial:	55, 54, 56, 53, 57	Acq. Method Set:	LOLIP_AS_FP_MSET
Injection #:	1	Processing Methoc	LOLIP_AS_FP_PM
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 244nm

Date Acquired: 18/07/2022 15:00:04 IST, 18/07/2022 15:21:00 IST, 18/07/2022 15:41:56 IST, 18/07/2022 16:02:51 IST, 18/07/2022 16:23:46 IST

Date Processed: 19/07/2022 13:03:28 IST

Auto-Scaled Chromatogram



Peak Name: ATORVASTATIN CALCIUM

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	ATORVASTATIN CALCIUM	1	8.693	3336856	1.0	4778
2	ATORVASTATIN CALCIUM	1	8.692	3258523	1.0	4760
3	ATORVASTATIN CALCIUM	1	8.692	3244790	1.0	4758
4	ATORVASTATIN CALCIUM	1	8.693	3299625	1.0	4767
5	ATORVASTATIN CALCIUM	1	8.693	3288654	1.0	4732
Mean			8.693	3285690	1.0	4759
Std. Dev.			0.000	36165.522		
% RSD			0.0	1.1		

Analysed by: J. kayal
Date : 20/07/2022

Checked by:
Date : 20/07/2022

Reported by User: KAYAL (KAYAL)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3000

Project Name: 2022\QC_HPL_003\JUL-2022
Printed Date: 20/07/2022
Printed Time: 15:40:20 Asia/Calcutta

RSD REPORT

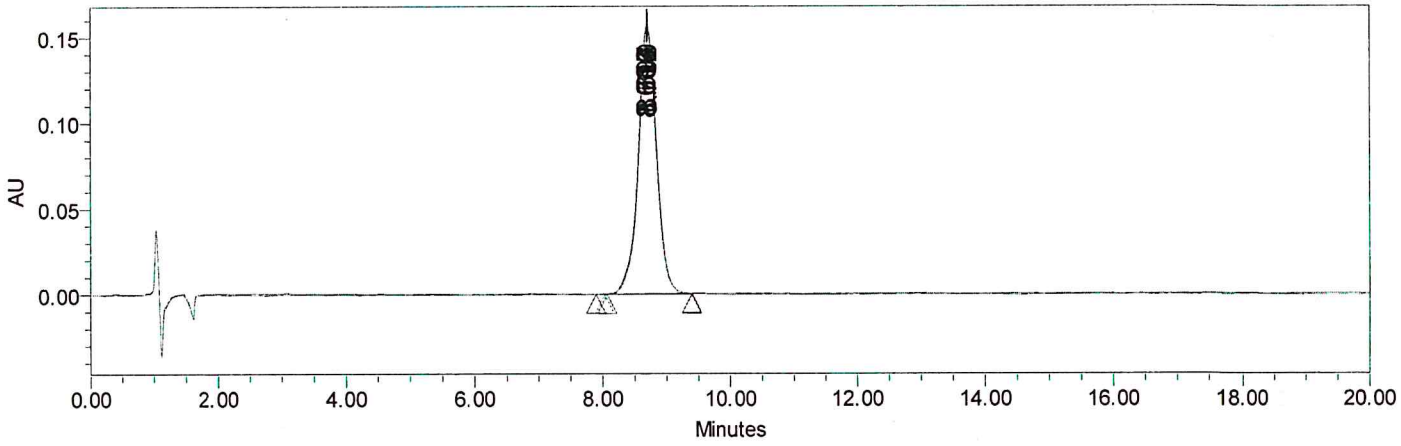
SAMPLE INFORMATION

Sample Name:	STANDARD_AS, STANDARD_AS_BKT_2	Acquired By:	KAYAL
Sample Type:	Standard	Sample Set Name:	18072022_LOLIP_AS_FP_SS
Vial:	50	Acq. Method Set:	LOLIP_AS_FP_MSET
Injection #:	1, 2, 4, 5, 3	Processing Metho	LOLIP_AS_FP_PM
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 244nm

Date Acquired: 18/07/2022 11:51:15 IST, 18/07/2022 12:12:09 IST, 18/07/2022 12:33:05 IST, 18/07/2022 12:54:00 IST, 18/07/2022 13:14:55 IST, 18/07/2022 16:44:45 IST

Date Processed: 19/07/2022 13:03:28 IST

Auto-Scaled Chromatogram



Peak Name: ATORVASTATIN CALCIUM

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	ATORVASTATIN CALCIUM	1	8.709	3100559	1.0	4835
2	ATORVASTATIN CALCIUM	1	8.694	3135173	1.0	4757
3	ATORVASTATIN CALCIUM	2	8.712	3094531	1.0	4796
4	ATORVASTATIN CALCIUM	3	8.704	3091842	1.0	4761
5	ATORVASTATIN CALCIUM	4	8.695	3083247	1.0	4733
6	ATORVASTATIN CALCIUM	5	8.693	3099405	1.0	4748
Mean			8.701	3100793	1.0	4772
Std. Dev.			0.008	17950.898		
% RSD			0.1	0.6		

Analysed by: J. Kayal
Date : 20/07/2022

Checked by:
Date : 20/07/2022

Reported by User: KAYAL (KAYAL)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3000

Project Name: 2022\QC_HPL_003\JUL-2022
Printed Date: 20/07/2022
Printed Time: 15:42:02 Asia/Calcutta

RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

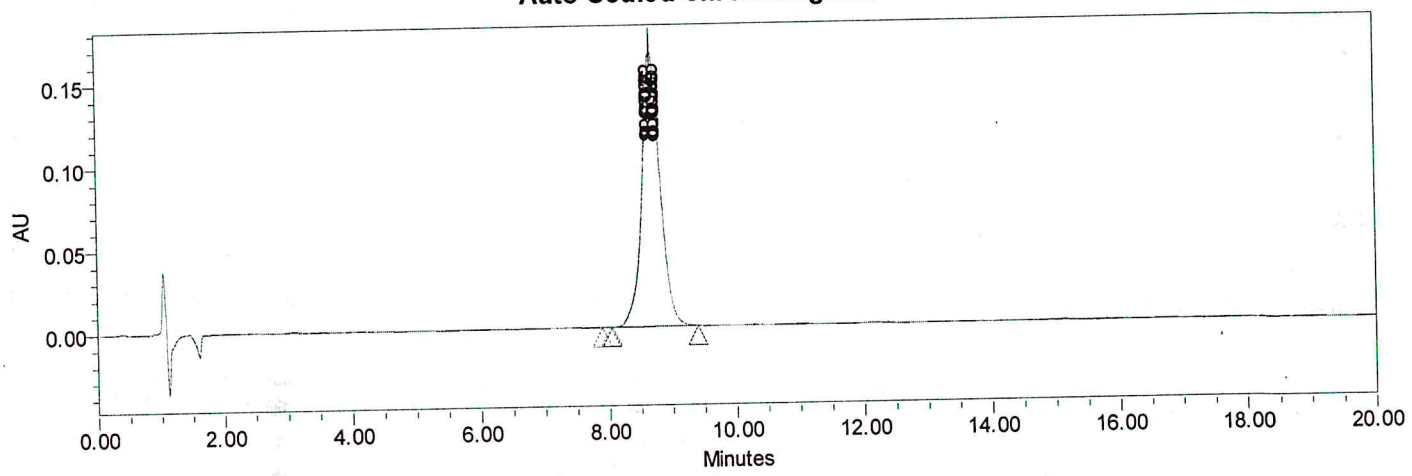
SAMPLE INFORMATION

Sample Name:	LOLIP-20_G1822106_UC_07,	Acquired By:	KAYAL
Sample Type:	Unknown	Sample Set Name:	18072022_LOLIP_AS_FP_SS
Vial:	58, 61, 59, 60, 62	Acq. Method Set:	LOLIP_AS_FP_MSET
Injection #:	1	Processing Methoc	LOLIP_AS_FP_PM
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 244nm

Date Acquired: 18/07/2022 17:05:40 IST, 18/07/2022 17:26:35 IST, 18/07/2022 17:47:31 IST, 18/07/2022 18:08:26 IST, 18/07/2022 18:29:22 IST

Date Processed: 19/07/2022 13:03:28 IST, 19/07/2022 13:03:29 IST

Auto-Scaled Chromatogram



Peak Name: ATORVASTATIN CALCIUM

	Peak Name	Injection	RT	Area
1	ATORVASTATIN CALCIUM	1	8.692	3268251
2	ATORVASTATIN CALCIUM	1	8.693	3390388
3	ATORVASTATIN CALCIUM	1	8.696	3290881
4	ATORVASTATIN CALCIUM	1	8.695	3274873
5	ATORVASTATIN CALCIUM	1	8.694	3252574
Mean			8.694	3295393
Std. Dev.			0.001	54853.576
% RSD			0.0	1.7

Analysed by: J. Kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

Reported by User: KAYAL (KAYAL)
Report Method: RSD REPORT
Report Method ID: 5615
Page: 1 of 1

Project Name: 2022\QC_HPL_003\JUL-2022
Printed Date: 20/07/2022
Printed Time: 15:46:10 Asia/Calcutta

Empower 3 SOFTWARE

RSD REPORT

SAI PRIMUS LIFE BIOTECH PVT LTD

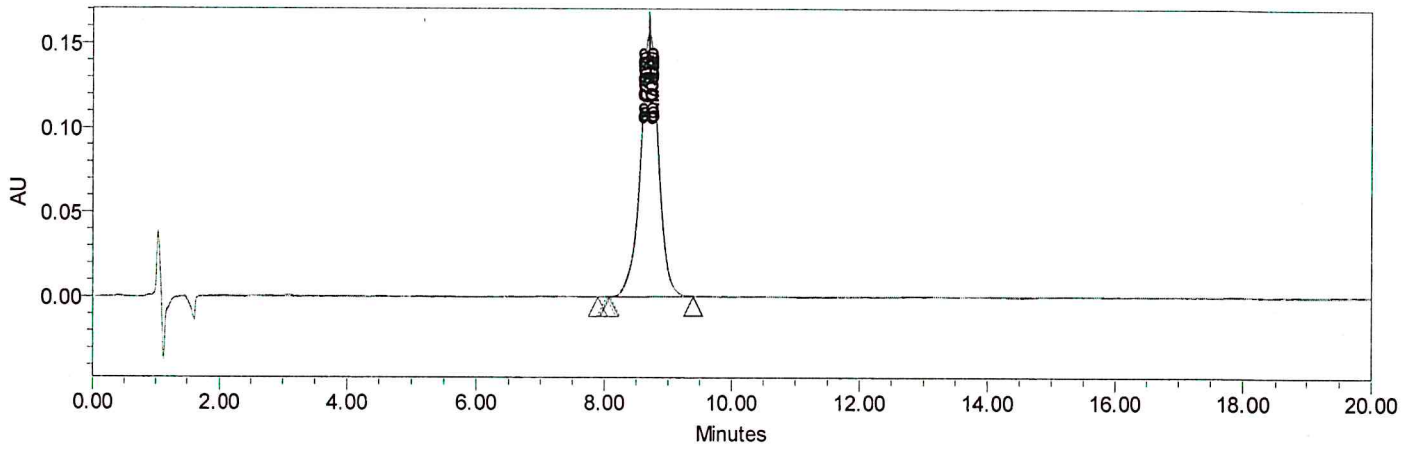
SAMPLE INFORMATION

Sample Name:	STANDARD_AS, STANDARD_AS_BKT_3	Acquired By:	KAYAL
Sample Type:	Standard	Sample Set Name:	18072022_LOLIP_AS_FP_SS
Vial:	50	Acq. Method Set:	LOLIP_AS_FP_MSET
Injection #:	1, 2, 4, 5, 3	Processing Method:	LOLIP_AS_FP_PM
Injection Volume:	20.00 ul	Channel Name:	W2489 ChA
Run Time:	20.0 Minutes	Proc. Chnl. Descr.:	W2489 ChA 244nm

Date Acquired: 18/07/2022 11:51:15 IST, 18/07/2022 12:12:09 IST, 18/07/2022 12:33:05 IST, 18/07/2022 12:54:00 IST, 18/07/2022 13:14:55 IST, 18/07/2022 18:50:20 IST

Date Processed: 19/07/2022 13:03:28 IST, 19/07/2022 13:03:29 IST

Auto-Scaled Chromatogram



Peak Name: ATORVASTATIN CALCIUM

	Peak Name	Injection	RT	Area	USP Tailing	USP Plate Count
1	ATORVASTATIN CALCIUM	1	8.709	3100559	1.0	4835
2	ATORVASTATIN CALCIUM	1	8.698	3163085	1.0	4826
3	ATORVASTATIN CALCIUM	2	8.712	3094531	1.0	4796
4	ATORVASTATIN CALCIUM	3	8.704	3091842	1.0	4761
5	ATORVASTATIN CALCIUM	4	8.695	3083247	1.0	4733
6	ATORVASTATIN CALCIUM	5	8.693	3099405	1.0	4748
Mean			8.702	3105445	1.0	4783
Std. Dev.			0.008	28912.410		
% RSD			0.1	0.9		

Analysed by : J. Kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

Reported by User: KAYAL (KAYAL)
Report Method: RSD REPORT SYSTEM SUITABILITY
Report Method ID: 3000

Project Name: 2022\QC_HPL_003\JUL-2022
Printed Date: 20/07/2022
Printed Time: 15:46:37 Asia/Calcutta

Processing Method: LOLIP_AS_FP_PM

Type: LC *Stored: 18/07/2022 15:49:56 IST*

Method Information

Method Comments	PROCESSING METHOD CREATED
Method Modified User	KAYAL
Method Locked	No
Method Id	6244
Old Id	5268
Method Version	7
Method Edit User	
Source S/W Info	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
Integration Algorithm	Traditional
MS Ret Time Window	10.0
MS Ret Time Presearch	No
MS Search Depth	3
Start Mass Limit	(m/z)
End Mass Limit	(m/z)
PBM Search Mode	Pure
Duplicate Spectra	No
PBM Reference Sets	SET1
Search Threshold	50.000(%)
Noise Baseline	(min)
Peak Separation	1.0000(Da)
Baseline Multiplier	1.000
Spectra To Average	5
Noise Threshold	0.000(%)
Combine Type	Average
Expected Mass Peak Separation	1.00(Da)
Expected Mass Calculation Type	None
Include the uncorrected Target or Base Mass in the list of expected masses	No
Expected Mass Base Value	100.00(Da)
Expected Mass Base Intensity	80.0(%)
Centroid Center Type	Centroid Top(%)
Centroid Top (%)	80.00
Centroid Intensity	Heights
Min. Peak Width at Half-Height	0.500(Da)
Smoothing Type	None
Average By	None
RT Window %	5.00

Analysed by : J. Kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

Update RT	Never
CCalRef1	
Include Internal Standard Amounts in Amount Calculation	Yes
Vial/Default Value Type	Amount
RT Reference Used to Name Unnamed Peaks by RRT	

System Suitability Information

Void Volume Time	0.100(min)
Calculate Suitability	Yes
Flag Outside	Yes
Calculate Unknowns	Yes
Pharmacopoeia	All
Tangent Percent (USP Plate Count)	61
Tangent Percent (USP Resolution)	50
Calculate USP, EP, and JP s/n	No
Use noise centered on peak region in blank injection	Yes
Half Height Multiplier for USP s/n Noise Region	
Half Height Multiplier for EP s/n Noise Region	
Half Height Multiplier for JP s/n Noise Region	
Noise Value for s/n	
% Runtime	5.0
Maximum Noise	
Maximum Drift	
Baseline Noise Minimum	30 Seconds
Baseline Start	(min)
Baseline End	(min)
Calculate Peak Statistical Moments	No

Integration Parameters

Minimum Area	10000(µV*sec)
Minimum Height	0(µV)
Threshold	10.000(µV/sec)
Peak Width	100.00(sec)

Integration Events

	Time (min)	Type	Value	Stop (min)
1	0.000	Valley to Valley		20.000
2	0.000	Inhibit Integration		7.900
3	9.400	Inhibit Integration		20.000

Component Table

	Name	Component Type	Peak Label	Retention Time (min)	RT Window (min)	Peak Match	Calculate Suit Results
1	ATORVASTATIN CALCIUM			8.700	0.615	Closest	Yes

Analysed by : J. Kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

Component Table

	Flag Outside Limits	3D Channel Name (Description)	Channel	Y Value	X Value	Fit	Weighting	Internal Std	RT Reference
1	Yes			Area	Amount	Linear	None		

Component Table

	Rel RT Reference	RRT	Rel Resol Reference	Curve Reference	Relative Response	Impurity RRF	Must	Default Pk	Default Pk Start (min)	Default Pk End (min)	Default Units	Type
1					1.000000	1.0000	No	No				Single

Component Table

	Impurity Type	CCompRef1	CCompRef2	CCompRef3	CConst1	CConst2	CConst3	CConst4	CConst5	CConst6	CConst7
1											

Processing Method Group 'Name Groups' table contains no data.

Processing Method Group 'Time Groups' table contains no data.

Processing Method Group 'Suit Limits-'ATORVASTATIN CALCIUM'' table contains no data

Processing Method Group 'Relative Limits-'ATORVASTATIN CALCIUM'' table contains no data

Processing Method Group 'Def Amts-'ATORVASTATIN CALCIUM'' table contains no data

Processing Method Group 'Primary Peaks (Primary MS Ions)' table contains no data.

Noise and Drift Parameters

Calculate Detector Noise and Drift	No
Detector Noise and Drift Start Time	(Minutes)
Detector Noise and Drift End Time	(Minutes)
Detector Noise and Drift Segment Width	60(sec)

Concentration Smoothing/Offset Parameters

Time Offset	0.000(Minutes)
Smoothing Type	None
Smoothing Level	None
Empty parameters supersede the derived channel's smoothing and offset parameters	No

Impurity Parameters

Calculate Total Impurities	No	Qualification Threshold	
Impurity Response		Total Impurities Threshold	
w Value		Maximum Impurity Threshold	
Main Component			
Reporting Threshold	0.05		
Identification Threshold			

Excluded Component Types

Internal Standard Peaks

Revision History

Version 7 18/07/2022 15:49:56 IST User KAYAL PEAK WIDTH CHANGED

Analysed by : J. Kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

Version 6 09/07/2022 20:09:39 IST User KAYAL PEAK WIDTH CHANGED
Version 5 09/07/2022 18:13:26 IST User KAYAL PEAK WIDTH CHANGED
Version 4 09/07/2022 09:22:00 IST User KAYAL PEAK WIDTH CHANGED
Version 3 08/07/2022 14:30:58 IST User KAYAL PEAK WIDTH CHANGED
Version 2 30/06/2022 19:09:59 IST User Vallarasan Method (\Hplc\2022\QC_HPL_003\JUN-2022 : 1917) copied into project. (from Full Audit Trail project)
Version 2 01/06/2022 16:46:20 IST User Vallarasan Method (\Hplc\2022\QC_HPL_003\MAY-2022 : 2615) copied into project. (from Full Audit Trail project)
Version 2 02/05/2022 09:06:54 IST User Vallarasan Method (\Hplc\2022\QC_HPL_003\APR-2022 : 7500) copied into project. (from Full Audit Trail project)
Version 2 22/04/2022 09:33:16 IST User KAYAL PEAK WIDTH CHANGED
Version 1 20/04/2022 13:26:05 IST User KAYAL Created method 'LOLIP_AS_FP_PM'. PROCESSING METHOD CREATED

Method Version Summaries

	Method Name	Method Type	Method Comments	Method Date	Method Modified User
1	LOLIP_AS_FP_PM	Processing	PROCESSING METHOD CREATED	18/07/2022 15:49:56 IST	KAYAL
2	LOLIP_AS_FP_PM	Processing	PROCESSING METHOD CREATED	09/07/2022 20:09:39 IST	KAYAL
3	LOLIP_AS_FP_PM	Processing	PROCESSING METHOD CREATED	09/07/2022 18:13:26 IST	KAYAL
4	LOLIP_AS_FP_PM	Processing	PROCESSING METHOD CREATED	09/07/2022 09:22:00 IST	KAYAL
5	LOLIP_AS_FP_PM	Processing	PROCESSING METHOD CREATED	08/07/2022 14:30:58 IST	KAYAL
6	LOLIP_AS_FP_PM	Processing	PROCESSING METHOD CREATED	30/06/2022 19:09:59 IST	KAYAL
7	LOLIP_AS_FP_PM	Processing	PROCESSING METHOD CREATED	30/06/2022 19:09:59 IST	KAYAL

Method Version Summaries

	Method Locked	Method Id	Old Id	Method Version
1	No	6244	5268	7
2	No	5268	5245	6
3	No	5245	5128	5
4	No	5128	5048	4
5	No	5048	1960	3
6	No	1960	6938	2
7	No	1959		1

Method Version Summaries

	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
2	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
3	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
4	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
5	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
6	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615
7	Empower 3 Software Build 3471 SPs Installed: Service Release 3 DB ID: 2530846615

Analysed by : J. Kayal
Date : 20/07/2022

Checked by :
Date : 20/07/2022

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 1 of 6	Issued by QA/Date: 22/06/2022
	MICROBIAL LIMIT TEST		No.: F/QCMB/006/02
TITLE:	MICROBIAL LIMIT TEST REPORT		Revision No.: 01 Review Period: 02 years Effective Date: 01/01/2021

MICROBIOLOGICAL TEST REPORT

Name of Product:	Lolip 20 mg				
Type of Product:	Finished product				
Batch No./ Lot No.	G1822106	**Quality Control A.R. No.**		FP/230722/01	
Microbiology A.R. No.	MA/0722/0445	**Mfg. Date**	Jul - 2022	**Exp.Date**	Jun - 2025
Date of Receipt	23/07/2022	**Date of test**	23/07/2022	**Date of Completion**	28/07/2022

S.No:	Test Required	Result	Specification
1.	Total aerobic microbial count	20 cfu/g	Not more than 1000 cfu g or ml
2.	Total yeast and mould count	<10 cfu/g	Not more than 100 cfu g or ~~ml~~
3.	Pathogens		
	a.E.coli	Absent	Should be absent in g or ml
	b.Salmonella sp.	Absent	Should be absent in 10g or 10ml
	c.Pseudomonas aeruginosa	Absent	Should be absent in g or ml
	d.Staphylococcus aureus	Absent	Should be absent in g or ml
	e.Shigella sp.	NA	Should be absent in 10g or 10ml
	f.Enterobacteria	NA	Not more than NA cfu g or ml / Should be absent in g or ml

Analysed by:	Reported by:	Checked by:
Date: 23/07/2022	Date: 28/07/2022	Date: 30/07/2022

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Media and Accessories used:

Autoclave Id. No: MB/ACE/001 **Micropipette Id. No:** MB/MOP/003, MB/MOP/005, MB/MOP/006

S. No.	Name of the Media	Media Preparation Details		Media Batch No.
		Date	Sterilization cycle No.	
1	SCDM	22/07/2022	MS-22-0201	MP/22/0527
2	BSC-Peptone	NA	NA	NA
3	SCDA	23/07/2022	MS-22-0203	MP/22/0532
4	SDA	23/07/2022	MS-22-0203	MP/22/0533
5	MCB	23/07/2022	MS-22-0203	MP/22/0534
6	MCA	23/07/2022	MS-22-0203	MP/22/0536
7	RVSE	NA	NA	NA
8	XLDA	23/07/2022	NA	MP/22/0535
9	MSA	21/07/2022	MS-22-0199	MP/22/0522
10	CA	21/07/2022	MS-22-0199	MP/22/0521
11	GN Broth	NA		
12	XLDA			
13	EE Broth			
14	VRBGA			

23/07/2022

Note: Rappaport Vassiliadis Salmonella Enrichment Broth (Readymade form):

Media Mfg.: Microxpress **Media Lot No:** RVSEB-2160 **Expiry at:** 14/11/2022

Note: GN broth (Readymade form):

Media Mfg.: NA **Media Lot No:** NA **Expiry at:** NA

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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 6
	MICROBIAL LIMIT TEST	No.: F/QCMB/006/02
TITLE:	MICROBIAL LIMIT TEST REPORT	Revision No.: 00 Review Period: 02 years Effective Date: 01/01/2021

S. No.	Temperature	Incubator Id. No.
1	30-35^{0}C	MB/BOD/002
2	20-25^{0}C	MB/BOD/001
3	42-44^{0}C	MB/BOD/003

LAF Id. No: MB/LAF/001 **BSC Id. No:** MB/BSC/001

a) Sample Preparation.

Take 10.01178 10g/~~10ml~~ of sample and dissolve in 90 /100 ml Buffered sodium chloride- peptone solution pH 7.0. or suitable mixer.

b) Procedure:

Pipette 1ml of the diluted sample in to each of four sterile Petri dishes.

Promptly add two plates with 15-20ml of Soyabean casein digest agar and two plates Sabouraud Dextrose agar that previously has been sterilized and cooled to approximately 45°C.Cover the Petri dishes, mix the sample with agar by tilting or rotating the dishes and allow the contents to solidify at Room temperature. Invert the Petri dishes and incubate the Soyabean casein digest agar at 30 - 35°C for 3- 5 days and 20 - 25°C for 5-7 days for Sabouraud Dextrose agar.

c) Pathogen Testing for *E. coli, S. aureus* & *P.aeruginosa*:

Take 10 ml of diluted sample (Solution A) transfer in to 90 ml of Soyabean casein digest medium and incubate at 30 -35˚C for not less than 18-24 hours.

d) Pathogen testing for *salmonella abony / Shigella Species...*

Take 10.02047 10g /~~10ml~~ of sample and dissolve in 90 /100 ml of Soyabean casein digest medium incubate at 30 -35˚C for not less than 18-24 hours.

e) Pathogen Testing for Enterobacteria gram negative:

Take NA 1.0 g, 0.1 g, 0.01 g and 0.001 g or 1.0 ml, 0.1 ml, 0.01 ml, and 0.001 ml Suitable quantity of sample transfer in to Enterobacteria Enrichment Broth (EE Broth) Incubate at 30° to 35° for 24 to 48 hours.

TAMC & TYMC :

Tested for	Incubation details		Incubated on		Observed on		Done by	Observed by
	Temp. (^{0}C)	Duration (days)	Date	Time	Date	Time		
TAMC	30-35	3-5	23/07/2022	18:06	28/07/2022	14:12	23/07/2022	28/07/2022
TYMC	20-25	5-7	23/07/2022	18:02	28/07/2022	14:20	23/07/2022	28/07/2022

Enrichment :

Tested for	Incubation details		Incubated on		Observed on		Done by	Observed by
	Temp. (^{0}C)	Duration (hours)	Date	Time	Date	Time		
Pre enrichment for *E. coli*, *P. aeruginosa*, *S. aureus*	30-35	18-24	23/07/2022	18:06	25/07/2022	13:51	23/07/2022	25/07/2022
Pre enrichment for *Salmonella abony* & *Shigella* Species	30-35	18-24	23/07/2022	18:06	25/07/2022	13:51	23/07/2022	25/07/2022
Enterobacteria gram negative	30-35	24-48	—	—	—	NO	—	—

23/07/2022

Test for Specified Microorganisms:

1. ***E. coli*:** Transfer 1 ml of enrichment sample to 100 ml of Mac Conkey broth and incubate at 42-44^{0}C for 24-48 hrs. After incubation, subculture on Mac Conkey agar and incubate at 30-35^{0}C for 18-72 hrs.
2. ***Salmonella* sp.:** Transfer 0.1 ml of enrichment sample to 10 ml of Rappaport vassiliadis salmonella enrichment broth and incubate at 30-35^{0}C for 24-48 hrs. After incubation subculture on Xylose lysine deoxycholate agar and incubate at 30-35^{0}C for 24-48 hrs.
3. ***Pseudomonas aeruginosa*:** Subculture on plate of cetrimide agar and incubation at 30-35^{0}C for 18-72 hrs.

4. ***Staphylococcus aureus*:** Subculture on plate of mannitol salt agar and incubation at 30-35°C for 18-72 hrs.
5. **Enterobacteria gram negative:** Subculture on a plate of Violet red bile glucose agar with dextrose. Incubate at 30° to 35° for 18 to 24 hours. Growth of well-developed reddish colonies of Gram negative bacteria is considered positive.
6. ***Shigella* Species:** Transfer 1 ml of enrichment sample in100 ml or 0.1ml to 10 ml of GN broth and incubate at 30-35°C for 24 to 48 hours. After incubation, Subculture on Xylose lysine deoxycholate agar and incubate at 30-35°C for 24 to 48 hours.

Test for Specified Microorganisms:

Tested for	selective Media	Incubation Details		Incubated on		Observed on		Done by	Observed by
		Temp. (°C)	Duration (Hours)	Date	Time	Date	Time		
E. coli	MCB	42 -44	24 – 48	25/07/2022	16:36	27/07/2022	14:10	25/07/2022	27/07/2022
	MCA	30 -35	18 – 72	27/07/2022	16:25	28/07/2022	18:05	27/07/2022	28/07/2022
Salmonella Species.	RVSE	30 -35	24 –48	25/07/2022	16:31	27/07/2022	14:06	25/07/2022	27/07/2022
	XLDA	30 -35	24 – 48	27/07/2022	16:25	28/07/2022	18:05	27/07/2022	28/07/2022
S. aureus	MSA	30 -35	18 –72	25/07/2022	16:31	28/07/2022	14:12	25/07/2022	28/07/2022
P. aeruginosa	CA	30 -35	18 –72	25/07/2022	16:31	28/07/2022	14:12	25/07/2022	28/07/2022
Shigella Species.	GN	30-35	24-48						
	XLDA	30-35	24-48			NO			
Enterobacteria gram negative	VRBGA	30-35	18-24						25/07/2022

Observation:

Parameter	TAMC		TYMC	
	Plate 1	Plate 2	Plate 1	Plate 2
Count per plate	02	01	<1	<1
Average	02		<1	

Calculation:

TAMC: Average Count X Dilution factor= 02 Countx10= 20 cfu/gm/~~ml.~~

TYMC: Average Count X Dilution factor= <1 Countx10= <10 cfu/gm/~~ml.~~

Test for Specified Microorganisms									
Enrichment and Conformation Test:									
MCB	MCA	RVSE	XLDA	MSA	CA	GN Broth	XLDA	EE Broth	VRBGA
X	X	X	X	X	X	NA	NA	NA	NA

1) **Positive Control:** Shown growth / ~~not shown growth~~.

2) **Negative Control:** ~~Shown growth~~ / not shown growth.

Note: √ - Shown Growth, X - Not Shown Growth

Result: The above sample complies/~~does not comply~~ with the Specification No.

Pol001 GHPL as per IP/BP/USP/IHS.

Analysed by:	Reported by:	Checked by:
Date: 23/07/2022	Date: 28/07/2022	Date: 30.07.2022

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Dove Research & Analytics

(A unit of Dove Chemicals Ltd.)

A Govt. Approved GLP Certified, and FSSAI Approved Laboratory

Test Report

A Govt. Approved GLP Certified, IS/ISO/IEC 17025 Accredited and FSSAI Approved Laboratory
NABL Certificate No. : T-5978,
(FSSAI No. : 30/N/FSSAI/2016)

A.R. No. : DA/FP-180722/005

1. SAMPLE SENT BY: **SAI PRIMUS LIFE BIOTECH PVT. LTD**
FACTORY: R.S. No 4/3, PLOT No.33,
KURUMBAPET INDUSTRIAL ESTATE
VILLIANUR COMMUNE, PUDUCHERRY-605009

2. Ref No.: N.M.

3. SAMPLE RECEIVED ON: **18/07/2022**

4. NAME OF SAMPLE: **LOLIP 20 MG TABLETS**

5. Detail of ~~Raw material~~/ final product (~~in bulk~~/finished pack)

(a) Manufactured by: N.M.

(b) Batch No.: **G1822106**

(c) Mfg. Lic. No.: N.M.

(d) Sample Qty.: 50 Tablets

(e) B. Size: N.M.

(f) D/M: 07/2022

(g) D/E: 06/2025

6. Analysis Started On: **19/07/2022**

7. Analysis Completion On: **21/07/2022**

8. Date of Amendment: N.A.

9. Protocol of test applied: USP 42/NF-37

10. Issue Date : 22/07/2022

Description: Light yellow colour round shaped biconvex film coated tablet breakline on one side and plain on other side.
Average weight : 191.30 mg

CONTENTS	OBTAINED	LIMIT
Related Substances (by HPLC)		
Atorvastatin amide	0.04 %	
Atorvastatin Related compound A	Not Detected	
Atorvastatin pyrrolidone analog	Not Detected	NMT 0.5 %
Atorvastatin Related compound B	Not Detected	
Atorvastatin Related compound C	Not Detected	
Atorvastatin pyrrolidone lactone	Not Detected	
Atorvastatin Related compound H	0.08 %	NMT 1.0 %
Atorvastatin epoxy pyrrolooxazin 6 hydroxy analog	Not Detected	NMT 0.5 %
Atorvastatin methyl ester	Not Detected	
Atorvastatin epoxy pyrrolooxazin 7hydroxy analog	Not Detected	NMT 0.5 %
Atorvastatin epoxy THF analog	Not Detected	NMT 1.0 %
Atorvastatin Related compound D	0.02 %	NMT 0.5 %
Atorvastatin tertbutyl ester	Not Detected	
Any other unspecified degradation product	0.04 %	NMT 0.2 %
Total degradation products	0.23 %	NMT 4.0 %

As per party Requirements

Dove Research & Analytics Verified By QA Panchkula

22/07/22
A.C. Mathur
(Add. Person Incharge)
Authorised Signatory

Plot No. : 298, Industrial Area, Phase II, Panchkula - 134 109 (Haryana)
Tel. : +91-172-2595298, 5010126 E-mail : drachd@gmail.com
URL : www.doveresearchlab.com

Dove Research & Analytics
Panchkula (Haryana)

Confidential DRA

Worksheet – Finished Product (Tablets/Capsules)

Worksheet ID DRA-FP-	221158	**A.R. No.**	DA/FP-180722/005
Sample Received On	18/07/22	**Reference No.**	
Name of Sample	Lolip 20 mg Tabs		
M.L.No		**B.No.**	G1822106
Sample Qty.	50 Tabs	**B.Size**	—
Mfg. Date	07/22	**Exp. Date**	06/25
Analysis start Date	19/07/22	**Analysis completion date**	21/07/22
Protocol of Test Applied	As per USP		

Description: Light yellow colour round shaped biconvex film coated tablet break line on one side and plain on another side.

		Observation	Limits	Analysed By
Identification				
Average weight		191.30 mg		mitalrwl 19/07/22
Average Fill				
Uniformity of weight	—	Atorvastatin Amide → 0.04 %.		
	—	Atorvastatin Related compound A → Not Detected		
Uniformity of content	—	Atorvastatin pyrrolidone analog → Not Detected NMT 0.5 %		
	—	Atorvastatin Related compound B → Not Detected		
Dissolution	—	Atorvastatin related compound C → Not detected.		
	—	Atorvastatin pyrrolidone lactone → Not Detected		
Disintegration Time	—	Atorvastatin Related compound H → 0.08 %. NMT 1.0 %		mitalrwl
	—	Atorvastatin Epoxy pyrrolozazin 6-hydroxy analog → Not Detected NMT 0.5 %		21/07/22
Loss on Drying / Water	—	Atorvastatin methyl Ester → Not Detected		
Related Substances (For RS by HLPC/GC, use separate sheet, if required)	—	Atorvastatin Epoxy pyrrolozazin 7-hydroxy analog → Not Detected NMT 0.5 %		
	—	Atorvastatin Epoxy Analog THF → Not Detected NMT 1.0 %		

Assay :

Labeled ingredients	Result	Label Claim	Limit	Analysed By
Atorvastatin Related compound D →	0.02 %.		NMT 0.5 %.	mitalrwl 21/07/22
Atorvastatin Tert-butyl Ester → Not detected				
Any other unspecified degradation product →	0.04 %.		NMT 0.2 %.	
~~Total Unknown~~ # →	0.05 %.		~~NMT 0.2 %.~~	
Total Degradation products →	0.23 %.		NMT 4.0 %.	

Sample referred above is of standard quality / not of standard quality as per above specifications.

Checked By / Date: 21/7/22

wrongly written mitalrwl 21/7/22

Reviewed By/ Date: 21/07/22

Please mention test parameter, equipment ID, working std potency, standard weight and dilutions, test sample weight and dilutions and any other relevant parameters.

Calculations A R No. : DA/FP-180722/005

Test Parameter (s)	Observation (s) & Calculation (s)	Analysed By / Date

Chromatographic condition, Gradient programme, preparation of Solution-A, B and C, Diluent, Preparation of System suitability solution, Preparation of standard solution, Balance I.D, Instrument I.D are refer to the AR sheet no. DA/FP-180722/004

20 tablets (wt.)

```
------ Statistics ------
19.07.2022          12:23
Balance Type      XS105DU
WeighBridge SNR:
                B548764715
Terminal SNR: B548764715
Balance ID          AB-04
 1              3.82604 g
n                       1
x              3.826040 g
s                  ------
s.rel              ------
Min            3.82604 g
Max            3.82604 g
Diff.          0.00000 g
Sum            3.82604 g
```

Signature Nitai nw 20/07/22

Test (wt.)

```
------ Statistics ------
20.07.2022          12:45
Balance Type      XS105DU
WeighBridge SNR:
                B548764715
Terminal SNR: B548764715
Balance ID          AB-04
 1              477.95 mg
 2                0.73 mg
n                       2
x              239.340 mg
s                  ------
s.rel              ------
Min              0.73 mg
Max            477.95 mg
Diff.          477.22 mg
Sum            478.68 mg
```

Signature Nitai nw 20/07/22

Nitai nw 20/07/22

Checked By / Date: 21/07/22

Reviewed By / Date: 21/07/22

Format No: SOP-QA012/F05/04

Dove Research & Analytics
Panchkula (Haryana)

Please mention test parameter, equipment ID, working std potency, standard weight and dilutions, test sample weight and dilutions and any other relevant parameters.

Calculations A R No. : DA/FP-180722/805

Test Parameter (s)	Observation (s) & Calculation (s)	Analysed By / Date
Avg. wt. of 20 tablets.	$\frac{3.82604 \times 1000}{20} \Rightarrow 191.302$ mg. $\simeq 191.30$ mg.	
Preparation of Test →	Weigh accurately 477.22 mg of Sample in 50 ml volumetric flask make up with 30 ml Diluent and Mix and shake mechanically for 15 min. Dilute with Diluent to volume and pass the solution through switchel filter of 0.45 µm pore size	Mitali 20/07/22

Checked By / Date : 21/07/22

Reviewed By / Date : 21/7/22

235018

DOVE RESEARCH & ANALYTICS
Panchkula (Haryana)

Please mention test parameter, equipment ID, working std potency, standard weight and dilutions, test sample weight and dilutions and any other relevant parameters.

Calculations

A R No. : DA/FP-180722/005

Test Parameter (s)	Observation (s) & Calculation (s)	Analysed By / Date

Standard Area

01 2504530

02 2564479

03 2606819

04 2506321

05 2438565

06 2537835

Avg. → 2526428

Std. DEV → 52670.18

RSD → 2.08 %.

Calculation → Atorvastatin Amide →

$$\frac{218344}{2526428} \times \frac{5.09}{100} \times \frac{5}{50} \times \frac{50}{477.22} \times \frac{94.6}{100} \times \frac{558.64}{1155.34} \times \frac{191.3}{20} \times 100 \times 2 \Rightarrow$$

0.04 %.

nitakwal 21/07/22

Checked By / Date : 21/07/22

Reviewed By / Date : 21/07/22

Format No: SOP-QA012/F05/04

Page No. ..... of .....

Dove Research & Analytics
Panchkula (Haryana)

Please mention test parameter, equipment ID, working std potency, standard weight and dilutions, test sample weight and dilutions and any other relevant parameters.

Calculations A R No. : DA/FP-180722/1005

Test Parameter (s)	Observation (s) & Calculation (s)	Analysed By / Date
	Atorvastatin Related Compound D :-	
	$\frac{124439}{2526428} \times \frac{5.09}{100} \times \frac{5}{50} \times \frac{50}{477.22} \times \frac{94.6}{100} \times \frac{558.64}{1155.34} \times \frac{191.30}{20} \times 100 \times 2 \times \frac{1}{1.12}$	
	=> 0.02 %.	
Atorvastatin	Related Compound H :-	
	$\frac{479587}{2526428} \times \frac{5.09}{100} \times \frac{5}{50} \times \frac{50}{477.22} \times \frac{94.6}{100} \times \frac{558.64}{1155.34} \times \frac{191.30}{20} \times 100 \times 2 \times \frac{1}{1.18}$	
	=> 0.08 %.	
	Total UNK (UNK 01 + UNK 02)	
	$\frac{279326}{2526428} \times \frac{5.09}{100} \times \frac{5}{50} \times \frac{50}{477.22} \times \frac{94.6}{100} \times \frac{558.64}{1155.34} \times \frac{191.30}{20} \times 100 \times 2 =>$	
	0.05 %.	
	UNK 03 :-	
	$\frac{206576}{2526428} \times \frac{5.09}{100} \times \frac{5}{50} \times \frac{50}{477.22} \times \frac{94.6}{100} \times \frac{558.64}{1155.34} \times \frac{191.30}{20} \times 100 \times 2 =>$	
	0.04 %.	Nitai Nit 21/07/22

Checked By / Date : 21.07.22

Reviewed By / Date : 21/7/22

235019

DOVE RESEARCH & ANALYTICS
Panchkula (Haryana)

Please mention test parameter, equipment ID, working std potency, standard weight and dilutions, test sample weight and dilutions and any other relevant parameters.

Calculations

A R No. : DA/FP-180722/005

Test Parameter (s)	Observation (s) & Calculation (s)	Analysed By / Date
Atorvastatin	Related compound A → N.D	
Atorvastatin	Related compound B → N.D	
Atorvastatin	Related compound C → N.D	
Atorvastatin	Pyrrolidone lactone → N.D	
Atorvastatin	Pyrroloxazin → N.D	
Atorvastatin	Pyrrolidone analog → N.D	
Atorvastatin	Methyl Ester → N.D	
Atorvastatin	Tert butyl Ester → N.D	
Atorvastatin	Epoxy THF Analog → N.D	
Atorvastatin	Epoxy pyrroloxazin 6 hydroxy analog → N.D	
Atorvastatin	Epoxy pyrroloxazin 7 hydroxy analog → N.D	
	Total Degradation products → 0.23 %.	

mitalrod
21/07/22

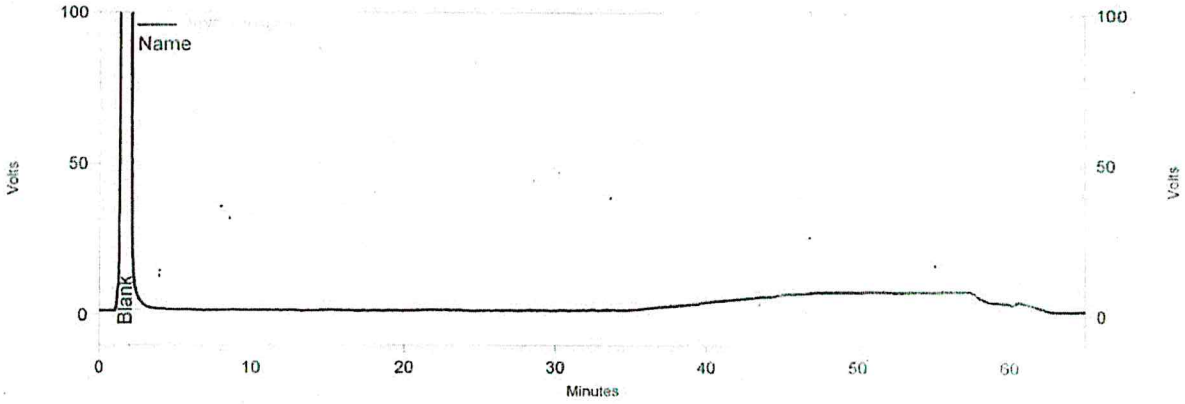
Checked By / Date : 21/07/22

Reviewed By / Date : 21/7/22

Dove Research & Analytics
Panchkula(Haryana)

Area % Report

Sample ID: Blank
Data File: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Blank.dat
Method: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met
Acquired: 7/20/2022 13:36:38 (GMT +05:30)
Instrument Id: HP-08 (Offline)



VWD: Signal A,
244 nm Results

Name	Retention Time	Area	Area %
Blank	1.700	697165156	100.00
Totals		697165156	100.00

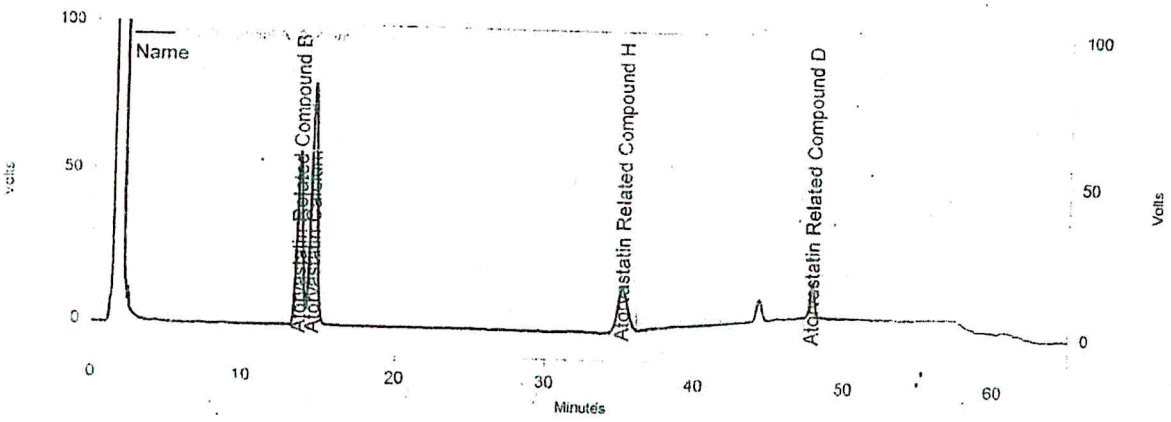
Analysed By/Date: Nitai 21/07/22

Checked By/Date 21/07/22

Dove Research & Analytics
Panchkula(Haryana)

Area % Report

Sample ID: System Suitability Solution
Data File: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\System Suitability Solution
Method: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met
Acquired: 7/20/2022 14:42:46 (GMT +05:30)
Instrument Id: HP-08 (Offline)



VWD: Signal A, 244 nm
Results

Name	Retention Time	Area	Area %	Asymmetry (10%)	Signal Noise USP	Resolution (USP)
Atorvastatin Related Compound B	13.643	21799203	31.12	1.08	486.14	0.00
Atorvastatin Calcium	14.540	33766064	48.20	1.18	686.66	1.42
Atorvastatin Related Compound H	35.220	10786008	15.40	1.10	124.01	20.85
Atorvastatin Related Compound D	47.790	3705094	5.29	1.07	99.67	14.02
Totals		70056369	100.00			

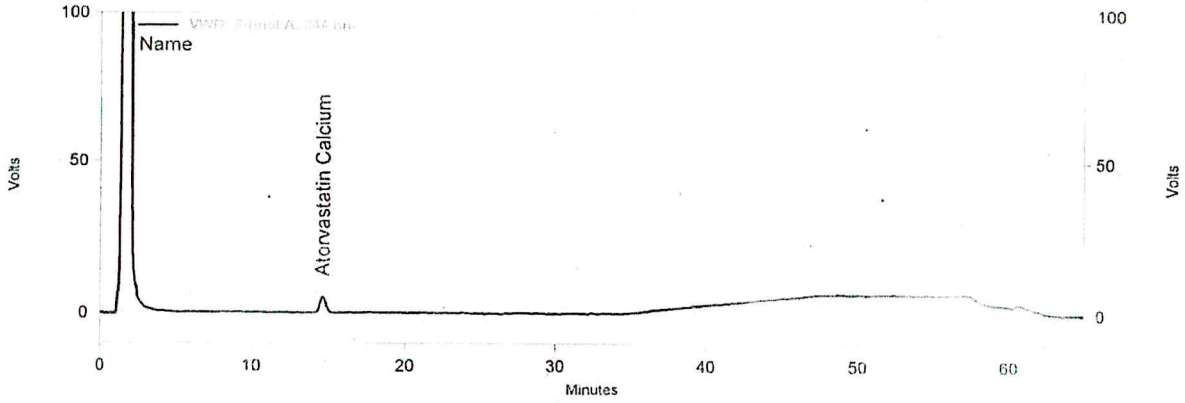
Analysed By/Date: Mitali 21/07/22

Checked By/Date 21/07/22

Dove Research & Analytics
Panchkula(Haryana)

Area % Report

Sample ID: Standard Solution_01
Data File: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Standard Solution_01
Method: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met
Acquired: 7/20/2022 15:48:58 (GMT +05:30)
Instrument Id: HP-08 (Offline)



VWD: Signal A, 244 nm Results

Name	Retention Time	Area	Area %	Theoretical plates (USP)	Asymmetry (10%)
Atorvastatin Calcium	14.627	2504530	100.00	6241	1.20
Totals		2504530	100.00		

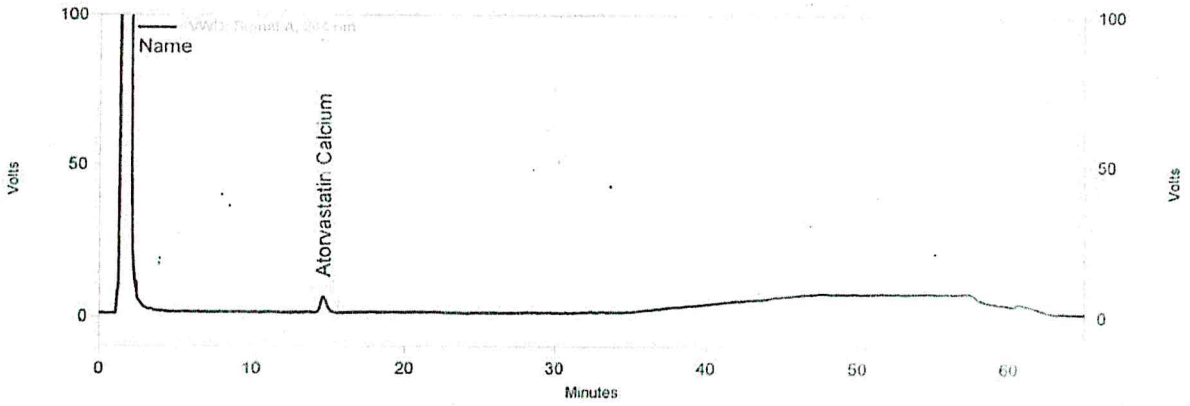
Analysed By/Date: 21/07/22

Checked By/Date 21/07/22

Dove Research & Analytics
Panchkula(Haryana)

Area % Report

Sample ID: Standard Solution_02
Data File: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Standard Solution_02
Method: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met
Acquired: 7/20/2022 16:55:05 (GMT +05:30)
Instrument Id: HP-08 (Offline)



VWD: Signal A, 244 nm Results

Name	Retention Time	Area	Area %	Theoretical plates (USP)	Asymmetry (10%)
Atorvastatin Calcium	14.660	2564479	100.00	6158	1.20
Totals		2564479	100.00		

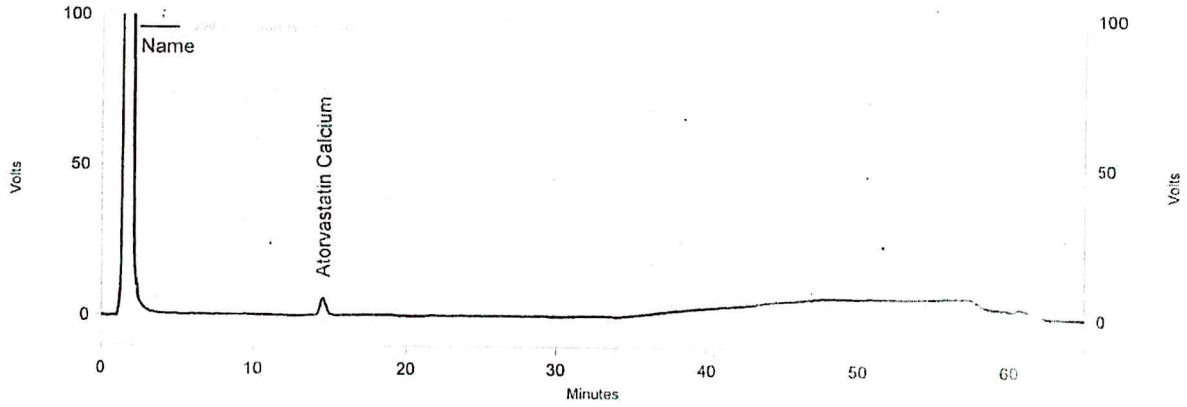
Mitul 21/07/22
Analysed By/Date:

Checked By/Date
21/07/22

Dove Research & Analytics
Panchkula(Haryana)

Area % Report

Sample ID: Standard Solution_03
Data File: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Standard Solution_03
Method: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met
Acquired: 7/20/2022 18:01:15 (GMT +05:30)
Instrument Id: HP-08 (Offline)



VWD: Signal A, 244 nm Results :

Name	Retention Time	Area	Area %	Theoretical plates (USP)	Asymmetry (10%)
Atorvastatin Calcium	14.553	2606819	100.00	6287	1.09
Totals		2606819	100.00		

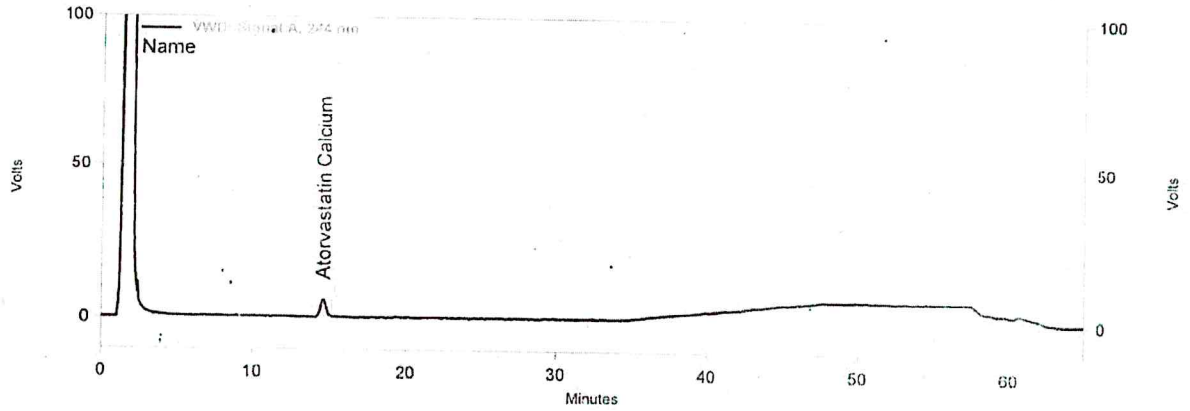
Analysed By/Date: 21/07/22

Checked By/Date 21/07/22

Dove Research & Analytics
Panchkula(Haryana)

Area % Report

Sample ID: Standard Solution_04
Data File: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Standard Solution_04
Method: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met
Acquired: 7/20/2022 19:07:22 (GMT +05:30)
Instrument Id: HP-08 (Offline)



VWD: Signal A, 244 nm Results

Name	Retention Time	Area	Area %	Theoretical plates (USP)	Asymmetry (10%)
Atorvastatin Calcium	14.563	2506321	100.00	6177	1.12
Totals		2506321	100.00		

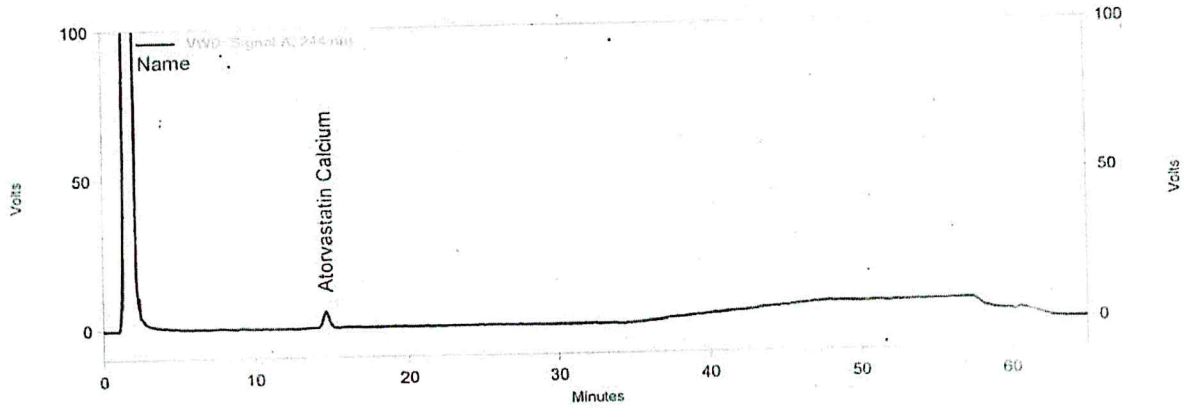
Analysed By/Date: 21/07/22

Checked By/Date 21/07/22

Dove Research & Analytics
Panchkula(Haryana)

Area % Report

Sample ID: Standard Solution_05
Data File: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Standard Solution_05
Method: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met
Acquired: 7/20/2022 20:13:30 (GMT +05:30)
Instrument Id: HP-08 (Offline)



VWD: Signal A, 244 nm Results

Name	Retention Time	Area	Area %	Theoretical plates (USP)	Asymmetry (10%)
Atorvastatin Calcium	14.603	2438565	100.00	6122	1.07
Totals		2438565	100.00		

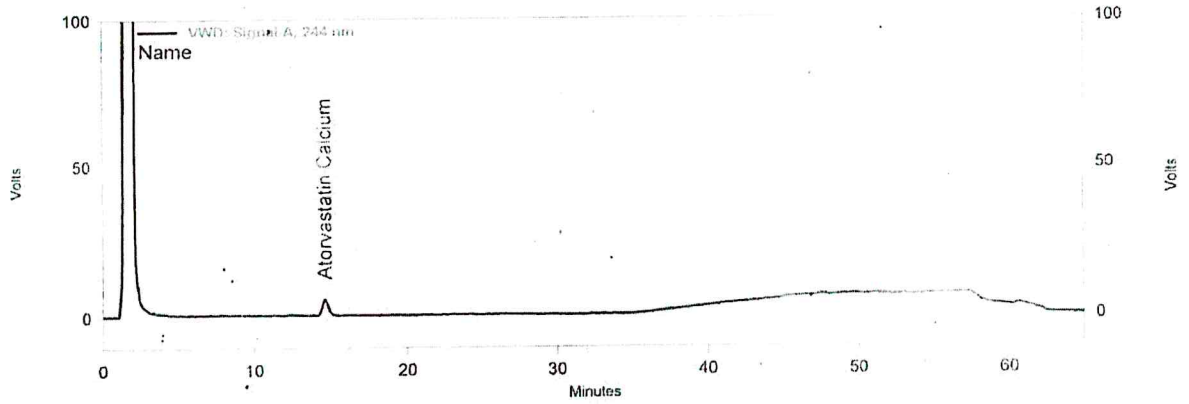
Analysed By/Date: 21/07/22

Checked By/Date 21/07/22

Dove Research & Analytics
Panchkula(Haryana)

Area % Report

Sample ID: Standard Solution_06
Data File: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Standard Solution_06
Method: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met
Acquired: 7/20/2022 21:19:38 (GMT +05:30)
Instrument Id: HP-08 (Offline)



VWD: Signal A, 244 nm Results

Name	Retention Time	Area	Area %	Theoretical plates (USP)	Asymmetry (10%)
Atorvastatin Calcium	14.610	2537855	100.00	6089	1.15
Totals		2537855	100.00		

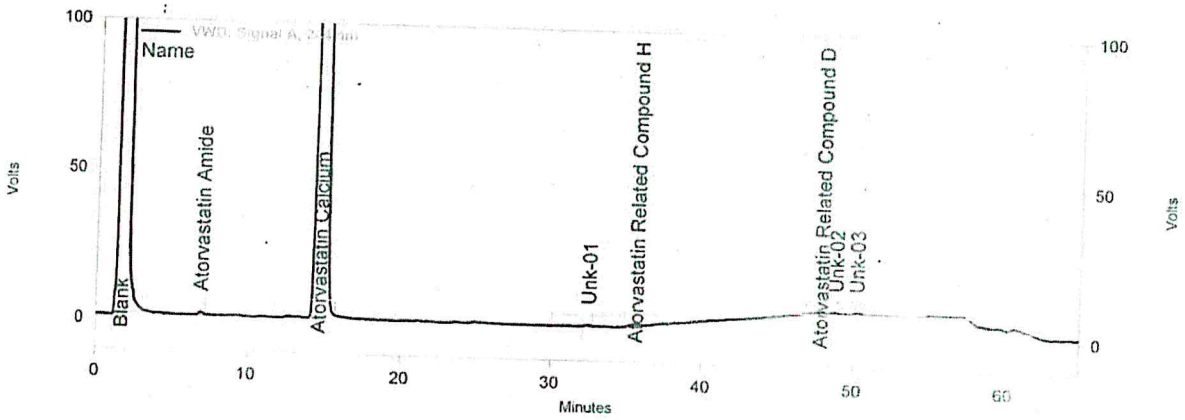
Analysed By/Date: 21/07/22

Checked By/Date 21/07/22

Dove Research & Analytics
Panchkula(Haryana)

Area % Report

Sample ID: Lolip_Tab_#G1822106_RS
Data File: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_Tab_#G1822106_RS
Method: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met
Acquired: 7/20/2022 23:31:54 (GMT +05:30)
Instrument Id: HP-08 (Offline)



VWD: Signal A, 244 nm Results

Name	Retention Time	Area	Area %
Blank	1.683	692142392	62.23
Atorvastatin Amide	6.967	218344	0.02
Atorvastatin Calcium	14.660	418704323	37.65
Unk-01	32.553	121603	0.01
Atorvastatin Related Compound H	35.683	479587	0.04
Atorvastatin Related Compound D	47.867	124439	0.01
Unk-02	48.837	157723	0.01
Unk-03	50.240	206576	0.02
Totals		1112154987	100.00

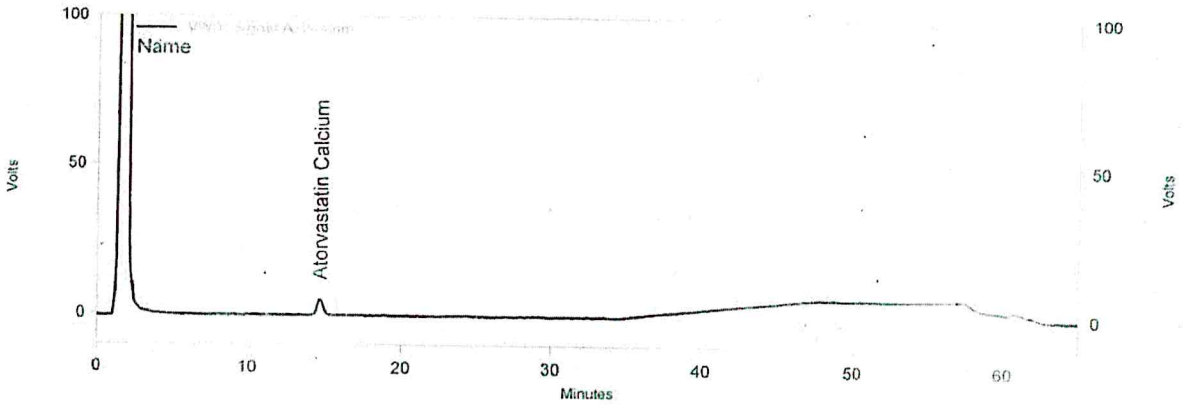
21/07/22
Analysed By/Date:

Checked By/Date
21/07/22

Dove Research & Analytics
Panchkula(Haryana)

Area % Report

Sample ID: Standard Solution_Bkt
Data File: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Standard Solution_Bkt
Method: D:\Enterprise\Projects\HP-08 Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met
Acquired: 7/21/2022 0:38:03 (GMT +05:30)
Instrument Id: HP-08 (Offline)



VWD: Signal A, 244 nm Results

Name	Retention Time	Area	Area %	Theoretical plates (USP)	Asymmetry (10%)
Atorvastatin Calcium	14.673	2409351	100.00	6463	1.11
Totals		2409351	100.00		

Analysed By/Date: 21/07/22

Checked By/Date 21/07/22

SAI PRIMUS
LIFE BIOTECH PVT LTD

ANALYTICAL DATA SHEET

Page No. 6367

C1822106 - DS-STD

SPL BIOTE
Model: AUW220
S/N: D450041599
ID: WC/ABL/002
Date: 2022/07/21
Start: 16:42:52

<START>

001 26.88 mg
002 0.00 mg

<RESULT>

n	2
total	26.88 mg
max	26.88 mg
min	0.00 mg
diff	26.88 mg
x̄	13.440 mg
s	19.007030 mg
srel	141.421356 %

Date: 2022/07/21
End: 16:42:56

Signature 21/07/2022

Analysed by: 21/07/2022
Date:

Checked by:
Date: 21/07/2022

SAI PRIMUS
LIFE BIOTECH PVT LTD

ANALYTICAL DATA SHEET

Page No. 6328

As-Std

SPL BIOTE..H
Model: AUW220
S/N: D450041599
ID: WC/ABL/002
Date: 2022/07/18
Start: 10:00:37

<START>

001 20.75 mg
002 0.01 mg

<RESULT>

n 2
total 20.76 mg
max 20.75 mg
min 0.01 mg
diff 20.74 mg
x̄ 10.380 mg
s 14.665395 mg
srel 141.285112 %

Date: 2022/07/18
End: 10:00:53

Signature J. Long 18/07/2022

SPL-1 G1822106

SPL.BIOTE..H
Model: AUW220
S/N: D450041599
ID: WC/ABL/002
Date: 2022/07/18
Start: 10:30:45

<START>

001 1942.43 mg
002 0.33 mg

<RESULT>

n 2
total 1942.76 mg
max 1942.43 mg
min 0.33 mg
diff 1942.10 mg
x̄ 971.380 mg
s 1373.272080 mg
srel 141.373312 %

Date: 2022/07/18
End: 10:31:04

Signature J. Long 18/07/2022

SPL-2 G1822106

SPL BIOTE..H
Model: AUW220
S/N: D450041599
ID: WC/ABL/002
Date: 2022/07/18
Start: 10:32:07

<START>

001 1936.25 mg
002 0.44 mg

<RESULT>

n 2
total 1936.69 mg
max 1936.25 mg
min 0.44 mg
diff 1935.81 mg
x̄ 968.345 mg
s 1368.824378 mg
srel 141.357097 %

Date: 2022/07/18
End: 10:32:37

Signature J. Long 18/07/2022

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009	Page 1 of 2
QUALITY CONTROL	CERTIFICATE OF ANALYSIS FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	**LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)**			
A.R.No.	:	**BSD/031222/03**			
Batch No.	:	**G1822161**	**Batch Size**	:	**6.0 L**
Mfg. Date	:	**Nov-2022**	**Exp. Date**	:	**Oct-2025**
Sampling Date	:	**03.12.2022**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**05.12.2022**	**Release Date**	:	**10.12.2022**

S.No.	TEST	RESULTS	LIMITS
01.	**Description**	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.
02.	**Identification** A) By UV	Complies	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	Complies	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.
03.	**Average weight of tablets**	193.20 mg	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)
04.	**Uniformity of weight**	+1.97 % to -3.73 %	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15.0 %.
05.	**Dimensions:**		
	Thickness	Min 3.60 mm Max 3.71 mm Avg. 3.64 mm	3.40 mm to 3.80 mm
	Diameter	Min 8.08 mm Max 8.13 mm Avg. 8.10mm	7.80 mm to 8.20 mm
06.	**Hardness**	7.53 kg/cm2	NLT 3.0 kg/cm2
07.	**Disintegration time**	01 mins 20 seconds	Not more than 30 minutes

	Tested By	Checked By	Approved By
Sign	M.V		
Name	Vinothini	Ramesh	Vallarasan
Date	10/12/2022	10/12/2022	10/12/2022

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009	Page 2 of 2
QUALITY CONTROL	CERTIFICATE OF ANALYSIS FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	**LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)**			
A.R.No.	:	**BSD/031222/03**			
Batch No.	:	**G1822161**	**Batch Size**	:	**6.0 L**
Mfg. Date	:	**Nov-2022**	**Exp. Date**	:	**Oct-2025**
Sampling Date	:	**03.12.2022**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**05.12.2022**	**Release Date**	:	**10.12.2022**

08.	**Dissolution by UV**		
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Min Max Avg. 97.93 % 100.48 % 98.98 %	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.
09.	**Uniformity of dosage unit by HPLC**		
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	L1=5.287	L1=15
10.	**Related substances:(BY HPLC)**		
	Atorvastatin pyrrolidone Analog	Not Detected	Not more than 0.5 %
	Atorvastatin related compound H	0.057%	Not more than 1.0 %
	Atorvastatin epoxy pyrrolooxazin 6- hydroxy analog	Not Detected	Not more than 0.5 %
	Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	Not Detected	Not more than 0.5 %
	Atorvastatin epoxy THF analog	Not Detected	Not more than 1.0 %
	Atorvastatin related compound D	0.038%	Not more than 0.5 %
	Any other unspecified degradation product	0.074%	Not more than 0.2 %
	Total degradation products	0.368%	Not more than 4.0 %
11.	**Assay: Each Film coated tablet contains:**		
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	103.53 %	Not less than 94.50 % and Not more than 105.00 %
12.	**Microbiological limits:**		
	Total Aerobic Microbial count	<10 cfu/g	NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g	NMT 100 cfu/g
	E.Coli	Absent	Should be Absent
	Salmonella	Absent	Should be Absent
	S.aureus	Absent	Should be Absent
	P.aeruginosa	Absent	Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to ~~BP~~/USP ~~and In-house~~ Specification.

	Tested By	Checked By	Approved By
Sign	M.V.H		
Name	Vinothini	Ramesh	Vallarasan
Date	10/12/2022	10/12/2022	10/12/2022

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009	Page 1 of 2
QUALITY CONTROL	CERTIFICATE OF ANALYSIS FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	**LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)**			
A.R.No.	:	**BSD/051222/02**			
Batch No.	:	**G1822162**	**Batch Size**	:	**6.0 L**
Mfg. Date	:	**Nov-2022**	**Exp. Date**	:	**Oct-2025**
Sampling Date	:	**05.12.2022**	**Sample Qty**	:	**120 Tablets**
Analysis Date	:	**05.12.2022**	**Release Date**	:	**14.12.2022**

S.No.	TEST	RESULTS	LIMITS
01.	**Description**	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.
02.	**Identification** A) By UV	Complies	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	Complies	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.
03.	**Average weight of tablets**	193.30 mg	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)
04.	**Uniformity of weight**	+1.91 % to -1.71 %	Not more than 2 of the individual weights deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15.0 %.
05.	**Dimensions:**		
	Thickness	Min 3.56 mm / Max 3.61 mm / Avg. 3.59 mm	3.40 mm to 3.80 mm
	Diameter	Min 8.06 mm / Max 8.09 mm / Avg. 8.08mm	7.80 mm to 8.20 mm
06.	**Hardness**	7.5 kg/cm2	NLT 3.0 kg/cm2
07.	**Disintegration time**	01 mins 49 seconds	Not more than 30 minutes

	Tested By	Checked By	Approved By
Sign	M.V.P.		
Name	Vinothini	Ramesh	Vallarasan
Date	14/12/2022	14/12/2022	14/12/2022

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PRIVATE LIMITED R.S. No. 4/3, plot No. 33, Kurumbapet Industrial Estate, Villianur Commune, Pondicherry- 605009	Page 2 of 2
QUALITY CONTROL	CERTIFICATE OF ANALYSIS FINISHED PRODUCT	Format No: F/QCGN/022/08

Product Name	:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)			
A.R.No.	:	BSD/051222/02			
Batch No.	:	G1822162	Batch Size	:	6.0 L
Mfg. Date	:	Nov-2022	Exp. Date	:	Oct-2025
Sampling Date	:	05.12.2022	Sample Qty	:	120 Tablets
Analysis Date	:	05.12.2022	Release Date	:	14.12.2022

08.	**Dissolution by UV**				
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Min 97.70 %	Max 103.95 %	Avg. 101.25 %	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.
09.	**Uniformity of dosage unit by HPLC**				
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	L1=8.421			L1=15
10.	**Related substances:(BY HPLC)**				
	Atorvastatin pyrrolidone Analog	Not Detected			Not more than 0.5 %
	Atorvastatin related compound H	0.051%			Not more than 1.0 %
	Atorvastatin epoxy pyrrolooxazin 6- hydroxy analog	Not Detected			Not more than 0.5 %
	Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	Not Detected			Not more than 0.5 %
	Atorvastatin epoxy THF analog	Not Detected			Not more than 1.0 %
	Atorvastatin related compound D	0.019%			Not more than 0.5 %
	Any other unspecified degradation product	0.047%			Not more than 0.2 %
	Total degradation products	0.217%			Not more than 4.0 %
11.	**Assay: Each Film coated tablet contains:**				
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	102.50 %			Not less than 94.50 % and Not more than 105.00 %
12.	**Microbiological limits:**				
	Total Aerobic Microbial count	<10 cfu/g			NMT 1000 cfu/g
	Total Yeasts and mould counts	<10 cfu/g			NMT 100 cfu/g
	E.Coli	Absent			Should be Absent
	Salmonella	Absent			Should be Absent
	S.aureus	Absent			Should be Absent
	P.aeruginosa	Absent			Should be Absent

Remark : The product complies/~~not complies~~ with the prescribed standard of quality with reference to ~~BP~~/USP ~~and In-house~~ Specification.

	Tested By	Checked By	Approved By
Sign	M.V.D.		
Name	Vinothini	Ramesh	Vallarasan
Date	14/12/2022	14/12/2022	14/12/2022