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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 FINISHED I	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				
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 $\pm 7.5 \%$ and none deviate by more than $\pm 15.0 \%$.	
05.	Dimensions:		deviate by more than ± 13.0 70.	
	Thickness	Min Max Avg. 3.46 mm 3.55 mm 3.51 mm	3.40 mm to 3.80 mm	
	Diameter	Min Max Avg. 8.06 mm 8.09 mm 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 Max Avg. 94.63 % 96.43 % 95.57 %	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.	
	Tested By	Checked By	Approved By	
Sign	T. Serial	CH -	Approved by	
Name	Kayal	Ramesh	Vallarasan	
Date 30/07/2022		30/07/2022	30/07/2022	

						5
SAI PRIMUS LIFE BIOTECH PYT LTD		SAI PRIMUS LIFE BIOT R.S. No. 4/3, plot No. 33, Ku Villianur Commune,	Page 2 of 2			
QUALITY CONTROL		CERTIFICATE	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	1:	18.07.2022	Release Date			30.07.2022

09.	Uniformity of dosage unit by HPL	·C	
	Atorvastatin calcium USP	L1=3.242	L1=15
	Equivalent to Atorvastatin-20 mg		
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 con	ntains:	8
	Atorvastatin calcium USP		Not less than 90.00 % and Not more
	Equivalent to Atorvastatin-20 mg	100.16 %	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
0	P.aeruginosa	Absent	Should be Absent

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

	Tested By	Checked By	Approved By	
Sign .	F. Cayal.	C4	· hr ·	
Name	Kayal ¶	Ramesh	Vallarasan	
Date	30/07/2022	30/07/2022	30/07/2022	



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:

TESTING AND RELEASE OF INTERMEDIATE AND FINISHED PRODUCTS

Format No.: F/QCGN/022/04

Revision No.: 01

TITLE:

CHECK LIST OF FINISHED PRODUCT

Review Period: 02 Years Effective Date: 09/08/202/

Name of the Product:	Lolip-20		D
Analytical Report No.	B& 140722/02	Batch No. い1822106	

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	9-
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	MA	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 pages	Total pages	73



SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Pict No.3, Kurumbapet Industrial Estate, Viilianur Commune, Puducherry-605009. SAMPLING POLICY Revision No: 01 TITLE TEST REQUEST FORM SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Pict No.3, Kurumbapet Industrial No.: F/QAGN/026/01 Revision No: 01 Review Period: 2 years Effective Date: 19 06 20 20

Date: 14/07/2022					
From (Dept):	PRODUCTION	To: Q.C. DEPARTMENT			
Name of the Item/: Product/ Previous: Product*	LOLIP 20	Quantity sampled 1			
Batch No.* :	G1822106	2. Conted stoge			
Batch Size* :	6.0L	3NA-			
Mfg. Date* :	07/2022	Sampled on: 14/07/2022			
Exp. Date* :	06/2025	Sampled by: G. SENTHIL KLOSARAN			
Stage* :	Coated Stage	Analyzed By: Laya			
		Analytical Reference No.			
Tests: 1A\$\(\rho\tau\)					
3					
4.		M4			
	14/07/2022 G. Junton Count				
TRF raised by Sign/l *wherever not applicab		by QA Sign/Date Head of QC Sign/Date			
MASTER	NA CONTRACTOR OF THE CONTRACTO				

SAI PRIMUS LIFE BIOTECH PVT LTD	SAI PRIMUS LIFE BIOTECH PVT LTD	Page 1 of 1	Issued by S. 106/122 QA/Date: 35/06/122		
	Factory: R.S. No. 4/3, Plot No.3, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009.		No.: F/QAGN/026/01		
	SAMPLING POLICY	Revision No: 01			
TITLE	TEST REQUEST FORM	Review Period: 2 years			
	TEST REQUEST FORM	Effective Da	nte: 19/06/2021		

Date: 23/07/22					
From (Dept):	PACKING		To: Q.C.	DEPARTMENT	
Name of the Item/:			Quantity	sampled	
Product/ Previous: Product*	LOUP	-20		to o o l a l	
			——— 1 <i>t</i> .	tinished goods	
Batch No.* :	G1182	2106	2	Lao tablits	
			3	MA.	
Batch Size* :	6.0	L	1		
	TE (C				
Mfg. Date* :	07/2	022	Sampled	on: 23 of 2012	
Exp. Date* :	0612	025	Sampled l	by: JESI	
Stage* :			Analyzed	By: Konya	
	FIN	ISHED GOODS		U I	
			An	nalytical Reference No.	
			FP1	280722101	
Tests:			o economic managements		
1A.S.	PER SPE	ECIELCATION			
2				al .	
2			·	•••••••••••••••••••••••••••••••••••••••	
3					
4.				4	
4.					

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5-1207127		Jey 04/2022	A	23/07/2022	
TRF raised by Si		TRF given to QC by	QA Sign/Date	Head of QC Sign/Date	
*wherever not applie	apple xymite NIA				

SAI PRIMUS LIFE BIOTECH PVT LTD		SAI PRIMUS LIFE BIOTE R.S. No. 4/3, plot No. 33, Kur Villianur Commune, I	Page 1 of 2			
QUALITY CONTROL		CERTIFICATE (FINISHED I	Format No: F/QCGN/022/08			
Product Name	:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets)	USP 20 mg)			
A.R.No.	:	BS/140722/02			t.	
Batch No.	:	: G1822106 Batch Size : 6.0 L				
Mfg. Date	:	: Jul-2022				
Sampling Date	:	: 14.07.2022				
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, biconvex film coated table breakline on one side and pother 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:		deviate by more than ± 15.0 %.		
	Thickness	Min Max Avg. 3.46 mm 3.55 mm 3.51 mm	3.40 mm to 3.80 mm		
	Diameter	Min Max Avg. 8.06 mm 8.09 mm 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 Max Avg. 94.63 % 96.43 % 95.57 %	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.		
	Tested By	Checked By	Approved By		
Sign	J. Sangal		M.		
Name	Kayal	Ramesh	Vallarasan		
Date	30/07/2022	30/07/2022	30/07/2022		

SAI PRIMUS LIFE BIOTECH PYT LTD		SAI PRIMUS LIFE BIOTE R.S. No. 4/3, plot No. 33, Kur Villianur Commune, I	rumbapet Industrial Estat		Pag	e 2 of 2
QUALITY CONTROL	-	CERTIFICATE FINISHED 1	Format N F/QCGN/			
Product Name	:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets				
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 HPI	C				
	Atorvastatin calcium USP	L1=3.242	L1=15			
	Equivalent to Atorvastatin-20 mg	50 800, 300				
10.	Related substances:(BY HPLC)					
3 5435	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 co	ntains:				
	Atorvastatin calcium USP		Not less than 90.00 % and Not more			
	Equivalent to Atorvastatin-20 mg	100.16 %	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			
ā	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	ficenal.	CH	pw
Name	Kayal 9	Ramesh	Vallarasan
Date	30/07/2022	30/07/2022	30/07/2022

S.No.	TEST	RESULTS	LIMITS
01	DESCRIPTION	Pale yellow Coloures	Pale yellow coloured, circular,
		Couled lable with bre	biconvex film coated tablet with breakline on one side and plain on other side.
02	IDENTIFICATION	On their side and plain	other side.
	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	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 \pm 7.5 % and none deviate by more than \pm 15.0 %
05	DIMENSIONS	Min. Max. Avg.	
	Thickness	3.46mm 3.55mm 3.51mm	_v 3.40 mm to 3.80 mm
	Diameter	8.06mm 8.09mm 8.08m	₂₇ 7.80 mm to 8.20 mm
06	HARDNESS	7.95 kg/cm2	NLT 3.0 kg/cm ²
07	DISINTEGRATION TIME	00 minutes 52 second	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- Lang J	(H)	77
Date	07/07/2022	07/07/2012	orlothon
Department: Quality Cont	rol	Date of Issue: 07/07/2015	2_

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BAAS	ILE	COL

SAI PRIMUS		RESULTS OF ANALYSIS			A No: ROA/L13-00	
QUALITY CONTROL		FINISHED PRODUCT	Page	age 2 of 2		
BRAND NAME	:	LOLIP 20 mg TABLETS				
GENERIC NAME	:	Atorvastatin Calcium Tal	Atorvastatin Calcium Tablets USP 20 mg			
B.No.	:	0118 2210b	A.R.No.	1:	B8 1140722102	
B. SIZE	:	6.0 L	MFG. DATE	:	07/2022	
SAMPLE QTY	:	120 raplets.	EXP. DATE	:	66/2025	
ANALYSIS STARTED ON	:	18/07/2022	DATE OF COMPLETION	:	30/07/2022	

S.No.	TEST	RESULTS	LIMITS
10	RELATED SUBSTANCES		*
	(By HPLC)		
	Atorvastatin pyrrolidone	ND	4 /
1	Analog		Not more than 0.5 %
	Atorvastatin related	0,08%	
	compound H	ND	Not more than 1.0 %
	Atorvastatin epoxy pyrrolooxazin 6-	0	
	hydroxy analog	ND D	Not more than 0.5 %
	Atorvastatin epoxy pyrrolooxazin 7-	100	
	hydroxy analog	ND	Not more than 0.5 %
	Atorvastatin epoxy THF analog Atorvastatin related compound D	0.02%	Not more than 1.0 %
	Any other unspecified degradation	0.024.	Not more than 0.5 %
	product		Not more than 0.2 %
	Total degradation products	0.23%	Not more than 0.2 % Not more than 4.0 %
11	ASSAY (By HPLC)		Not more than 4.0 %
11	Each Film coated tablet contains:		
	Atorvastatin calcium USP Equivalent		N 1 1 00 000
	to Atorvastatin-20 mg	100.167	Not less than 90.0% and not more
			than 110.0% of labeled claim.
12	MICROBIOLOGICAL LIMITS		
	Total Aerobic Microbial count	20 CFU/8	NMT 1000 CFU/g
	Total Yeasts and mould counts	<100019	NMT 100 CFU/g
	E.Coli	Absent	Should be Absent
	Salmonella	Absent	Should be Absent
	S.aureus	ab Sent	Should be Absent
	P.aeruginosa	Absent	Should be Absent

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

ANALYSED BY: J- Kay of	CHECKED BY:	APPROVED BY: K	
DATE: 30/07/2022	DATE: 30/07/202	DATE: 30/09/2022	

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	of- Layer	(July -	ht.
Date	07/07/2022	07/07/2012	07/21/2010
Department: Quality Con	trol	Date of Issue: 0 flo f 2022	

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Issued Date:	l by:	offon		: 	DE II	F	Format No.: F/QCGN/022/02
	SAL PRIM	US T CTG		ANALYTICAI	WORK RECORD	AV	VR No: AWR/L13-00
QUAI	LITY CON	TROL	FINISHED PRODUCT		Pa	ge 1 of 15	
BRAN	ND NAME		LOLIP	20 mg TABLET	rs		
GENI	ERIC NAM	E	Atorvasi	Atorvastatin Calcium Tablets USP 20 mg			
B.No.			: G18	22106	A.R. No.		: Be1440722102.
S.No		411		,	Name of the test	F e ci	, ,
1.	DESCRIP	TION:					
	Pale yellow colowed, biconvex film coated table with brusklin on one side and plain on both side.					side.	
				Analysed by:		Witness	ed by:
	lies/ Does-no				H8022	Date:	86/07/2022
2.	A. IDENT	IFICATIO	ON: A.By	UV			12 c
	Observation						
		Comp	· lus.				
							•
		*		Analysed by:	76.1	Witness	ed by: †
Compl	lies/ Does no	t-comply.				Date:	C# 30 67 12022
	B. IDENTI	FICATIO	N: By HI	PLC		£	111 2
	Observation		plies.				
Compl	ies/ Does-no	t-comply.	0	Analysed by: Date: 18 6	J-12022	Checked Date:	by: \$ 12022
3.	AVERAGI	E WEIGH		a			7,1,527
	Details of I						
	S. No.		Instrum	omt	Instrument ID		7-11
	1.	Analytica		lent	Instrument ID.		Calibration due date
		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			WELLING	1216	
			P	repared by	Checked	by	Approved by
Design	ation		Jr. I	Executive-QC	Sr. Executive	e-QC	Manager-QC
Signat	ure			S. koujal	Chi	,	kr
Date	1			7/04/2022	07/07/5	2022	07/57/2022
Depar	Department: Quality Control				Date of Issue: 67		

SAI PRIMUS	ANALYTICAL WORK RECORD	AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT	Page 2 of 15
BRAND NAME	LOLIP 20 mg TABLETS	
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg	
B.No.	: 61822106 A.R. No	0. :BS/140722/02

Weight of 20 tablets 3.868 g 3.868 Average weight = ----- x 1000 = <u>193. </u> mg 20

Complies/ Does not comply.

Analysed by: Date:

Checked by:

Date:

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	0.196
7	0-193	- 17	0.196
8	0.192	18	0.191
9	0.196	19	0.195
10	0-193	20	0.196
9	Average	0 -1934	
	Minimum	0-190	
	Maximum		0.198

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J- kangal	(ig	MY
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Co	ntrol	Date of Issue: 07 10 7 2022	



SAI PRIMUS	ANALYTICAL WORK RECORD		AWR	R No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT		Page	3 of 15
BRAND NAME	LOLIP 20 mg TABLETS			
GENERIC NAME	Atorvastatin Calcium Tablets USP 2	0 mg		
B.No.	: 41822106	A.R. No.		: BS/160722/00

Calculation:

Lowest % =

<u>0.190</u> °x 100 − 100 = − 1.76%

0-193.4

Highest % =

 $0.198 \times 100 - 100 = +2.38\%$ 0.193.4

Complies/ Does not comply.

Analysed by:

Checked by:

Date:

2167/2022

Date:

80/07/2002

5. DIMENSION: A) Thickness

Details of Instrument:

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

Minimum: 8-46 mm.		Maximum: 3.56 mm		Average: 3.51 mm	
	3.52	3.53	3.51	3.55	3.46
In mm	Tablet 6	Tablet 7	Tablet 8	Tablet 9	Tablet 10
	3.54	3-49	3.53	3-48	3.52
Thickness	Tablet 1	Tablet 2	Tablet 3	Tablet 4	Tablet 5

Complies/ Does not comply.

Analysed by:

Date: 2167

107/don

Checked by:

Date:

e: #301071202

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. key a	C LY	hr
Date	07/07/2022	07/07/2022	1001/1010
Department: Quality Contr	rol	Date of Issue: 0+10+12022	

SAI PRIMUS	ANALYTICAL WO	ORK RECORD	AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PR	Page 4 of 15	
BRAND NAME	LOLIP 20 mg TABLETS		
GENERIC NAME	Atorvastatin Calcium Table	ts USP 20 mg	
B.No.	: 61822106	A.R. No.	: BS/140722/02

DIMENSION: B) Diameter

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Digital Vernier caliper	Oc/OVC (00)	27/07/2002

Length	Tablet 1	Tablet 2	Tablet 3	Tablet 4	Tablet 5
In mm	8 · 0 7 Tablet 6	g.o8 Tablet 7	8.06 Tablet 8	8 · 09 Tablet 9	용-0구 Tablet 10
	8.08	8.08	8.08	8.09	8.06
Minimum:	8.06 mm	Maximum: g	-09 mm	Average: 8.0	8 mm

Complies/ Does not comply.

Analysed by:

Date:

Checked by:

Date:

(H30/07/2002

6. HARDNESS:

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Tablet Hardness Tester	QC/TMT 1001	27/07/2022

Hardness	Tablet 1	Tablet 2	Tablet 3	Tablet 4	Tablet 5
	7.0	8.8	8.5	8.8	7.5
In kg	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	& kg/cm²	Average:	.95 kglom2

Complies/ Does not comply.

Analysed by:

Date:

Checked by:
Date: A 30 07 1002

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kangel	Tay	M
Date	07/07/2022	07/07/2022	orbillon
Department: Quality Cont	rol	Date of Issue: effet 12022	

SAI PRIMUS LIFE BIOTECH PUT LTO ANALYTICAL WORK REC		AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT	Page 5 of 15
BRAND NAME	BRAND NAME LOLIP 20 mg TABLETS	
GENERIC NAME Atorvastatin Calcium Tablets USP 20 mg		g
B.No.	: 01822106 AR	No Polysta also

7. **DISINTEGRATION TIME:**

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Disintegration apparatus	OCLATA 1001	18/08/2022

Medium: wouter

Temperature: 36.8 °C

No of Tablets used: 06

Discs: used/Not-used.

Observed time: <u>DO</u> minutes <u>52</u> seconds.

Analysed by:

Date: 21/07/2022

Checked by:

(# 30) 0 F 1002c

Date:

Complies/ Dees not comply.

DISSOLUTION: (By UV)

Details of Instrument:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Analytical balance	Oc/ABL/002	12/08/2022
2.	Dissolution	Oc/DIS/001	30/05/2023
3.	HPLC UV_VIS Spectrophotomater	Oc/us/001	27/09/2022
4.	pH meter	OC/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	28 107/2025
3.	Acetonitrile	Rankam	HPLC	T050A 22	25/07/2024

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J-Ray J	CH-	ht.
Date	07/67/2022	07/07/2022	arealtalto
Department: Quality C	ontrol	Date of Issue: http://www.	A to you have a second and a second a second and a second a second and

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SAI PRIMUS	ANALYTICAL WORK REC	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.	: 41822106 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	wscalloby	08/06/2023	01	08/06/2023	94 42%

Dissolution parameters

Apparatus : Taclello (Paddle)

Medium : PH 6.8 phosphate buffer)

Volume : 900 mL (900 mL)
Time intervals : 15 min (15 min)

Speed : _______ RPM (75 RPM)

Temperature : 37.6° °C (37 °C \pm 0.5 °C)

Instrumental Conditions:

Mode : Un-VISIble Septetroscopy (Ultraviolet - visible spectroscopy)

Cell : 0.5 (0.5 cm)

Blank : Medium (Medium)

Wavelength : Jun (244 nm)

Preparation of 0.05 M phosphate Buffer solution:

Dissolved 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_8g 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 _____to__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 ______ml(2 ml) of above solution to _____ml(100 ml) using disso medium.

7 T =	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kengal	CH	M
Date	67/07/2022	07(c7/2c22	otlotlen
Department: Quality Control		Date of Issue: offof 1022	X , V a y Xiii



SAI PRIMUS	ANALYTICAL WORK RECORD		AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT		Page 7 of 15
BRAND NAME	LOLIP 20 mg TABLETS		
SENERIC NAME Atorvastatin Calcium Tablets USP 20 mg			
B.No.	: 91822106	A.R. No.	: 85/140722/02

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

Preparation of Sample Solution:

Place one tablets in each vessel containing 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:

Roter to Exed Sheet

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

$$= ---- x ---- x ---- x ---- x ---- x ---- x 0.967$$

$$= ---- x ---- x ---- x 0.967$$

Complies/ Does not comply.

Analysed by:

Date:

Date:

Date:

Date:

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		

* - 4	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	7 kengal	Oq-	m
Date	07/07/2022	07/07/2022	07/07/2022
Department: Quality Control		Date of Issue: of of 107/1022	and the state of t

SAI PRIMUS	ANALYTICAL WORK RECORD	AWR No: AWR/L13-00			
QUALITY CONTROL	FINISHED PRODUCT	Page 8 of 15			
BRAND NAME	LOLIP 20 mg TABLETS				
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg				
B.No.	: 61822106 A.R. No.	: 85/140722/02			

Details of chemical /Reagents:

S. No.	Chemicals/Reagents Name	Make	Grade	Batch No.	Valid up to
1.	Monobasic ammonium phosphate		0		
2.	Acetic acid				, · · · · · · · · · · · · · · · · · · ·
3.	Ammonium hydroxide		1 - 1 - 1 - 1		* a - 1 a -
4.	Acetonitrile				e y * 2 h
5.	Tetrahydrofuran				
6.	Methanol				
7.	N, N-Dimethylformide			V	

Details of standard:

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

Chromatographic Conditions:

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('0	umn	trino	
	lumn	LYDE	

or Equivalent)

(C18 4.6 mm x 150 mm, 3.5 μm

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

41F	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Com	(H	kr
Date	07/07/2022	07/07/2022	orbothorn
Department: Quality Control		Date of Issue: 07/07/2022	

SAI PRIMUS	ANALYTICAL WORK RECORD	AWR No: AWR/L13-00
QUALITY CONTROL	FINISHED PRODUCT	Page 9 of 15
BRAND NAME	LOLIP 20 mg TABLETS	
GENERIC NAME		
B.No.	: 41822106 A.R. N	0. : BS/140722/02

For the standard solution, the run time is only 30 min. For the system suitability solution and Samthe run time is 65 min. Preparation of Buffer:	er. Adjust
Preparation of Buffer:	
Dissolvedg(5.75 g) of monobasic ammonium phosphate inml(1000 ml) of water	$f 4.3 \pm 0.05$).
with dilute Acetic acid (10 % v/v) or dilute ammonium hydroxide (10 % v/v) to a pH(pH of	
Preparation of Solution A:	
Prepared the solution ofml(925 ml) of acetonitrile andml(75 ml) of sta	bilizer- free
tetrahydrofuran solution.	
Preparation of Mobile phase A:	
Mixed ofml(420 ml) of solution A andml(580 ml) of buffer. Sonicate and Filter	r through 0.45
micron membrane filter and degas.	
Preparation of Mobile phase B:	
Mixed ofml(600 ml) of methanol andml(200 ml) of solution A andn	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 accuratelymg(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 inml(100 ml) volume	metric flask.
Addml(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 transfermg(50 mg) of Atorvastatin calcium working	standard in
ml(100 ml) volumetric flask. Addml(70 ml) of Diluent and dissolve the substan	ice. Sonicate
to dissolve, if Necessary. Dilute up to the mark with Diluent. Further diluteml(1 ml) of	this solution
withml(100 ml) of diluent.	

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Ceryal	(Fe	M
Date	67/07/2022	07/07/2020	otlethor
Department: Quality Control		Date of Issue: 07/07/2029	A The Control of Spatial Section Secti

SAI PRIMUS	ANALYTICAL WORK	AWR No: AWR/L13-00	
QUALITY CONTROL	FINISHED PRODUCT		Page 10 of 15
BRAND NAME	LOLIP 20 mg TABLETS		
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg		
B.No.	: 41822106	A.R. No.	: BS/140722/02

	(Concentration: 5 µg/ml of USP Atorvastatin calcium working standard)					
	Preparation of Placebo solution:					
	Transfer themg(438 mg) of placebo (equivalent to about 50 mg of atorvastatin), to aml(50					
	ml) volumetric Flask. Addml(30 ml) of diluent and shake mechanically formins(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 accurately20 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 themg(488 mg) of powder (equivalent to about 50 mg of atorvastatin), to aml(50					
	ml) volumetric Flask. Addml(30 ml) of diluent and shake mechanically formins(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).					
l	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.					
	1 50 P 100					
	= x x x 0.967 x					
	100 100 100 : 20					
1						

E	Prepared by	Checked by	Approved by	
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC	
Signature	J. Kong J	(Jy	per	
Date	67/07/2022	07/07/2022	07/07/2022	
Department: Quality Conti	rol	Date of Issue: 07/07/2022		

	Analysed by:	Checked by:	-1
Complies/ Does not comp	Date:	Date:	

11 ASSAY AND CONTENT UNIFORMITY(By HPLC):

Details of Instruments:

S. No.	Instrument	Instrument ID.	Calibration due date
1.	Analytical balance	ac/ABL/002	12/08/2022
· 2.	HPLC	QC/MPC/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. Kangal	(Fig.	Kr	
Date	07/07/2022	07/07/2022	orbithon	
Department: Quality Control		Date of Issue: 07/07/2022		

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SAI PRIMUS	ANALYTICAL WORK REC	ANALYTICAL WORK RECORD		
QUALITY CONTROL	FINISHED PRODUCT		Page 12 of 15	
BRAND NAME	LOLIP 20 mg TABLETS			
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg			
B.No.	: 61822106	A.R. No.	: 88/160722/00	

Details of chemical /Reagents:

S. No.	Chemicals/Reagents Name	Make	Grade	Batch No.	Valid up to
1.	Anhydrous Citric acid	Finan	AR	, 796410321R	16/09/2024
2.	Ammonium hydroxide	Rankem	AR	B002A22	15/07/2024
3.	Acetonitrile	Rankem	HPLC	T050A22	17/07/2024
4.	Tetrahydrofuran	Emplusa	AR	SBISF 71084	
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	wslanclow	08/06/2022	01	08/06/2023	94.42%

Chromatographic Conditions:

Column type

: C18 (4-6mm x 250mm, 5 μm) ac-1 c-010

or Equivalent)

Flow rate

Detector wavelength

: 244 nm (244 nm)

Column temperature

:______°C (30°C)

Injection volume

: 20 μL (20 μL)

Preparation of 0.05 M ammonium citrate buffer pH 4.0:

Dissolved 19.23 (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 5 H o 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 3000 ml(1000ml)

y 4 12	Prepared by	Checked by	Approved by	
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC	
Signature	J. Kangal	Cat.	Arr	
Date	07/07/2022	07/07/2022	othellon	
Department: Quality Contro	ol	Date of Issue: 07/07/1022		

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SAI PRIMUS	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/14 672 2/62

	Preparation of Diluent:
	Mixed of <u>loco</u> ml(1 ml) of acetonitrile and <u>loco</u> ml(1 ml) of Solution A.
	System suitability solution: No
	Weigh accuratelymg(10 mg) of USP Atorvastatin calcium working standard andmg(1 mg) of
	USP Atorvastatin Related Compound H RS in aml(100 ml) volumetric flask. Addml(70 ml)
	of Diluent and dissolve the substance. Shake mechanically formin(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 \(\ldots \omega \text{ml}(100 ml)\) of diluent. Shake for \(\ldots \omega \text{mins}(15 minutes)\),
	Dissolve make up with same solvent. (Concentration: 0.1 mg/ml of Atorvastatin calcium working standard)
	Preparation of Sample powder:
	Weigh accurately 3.87520 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 1942-10 mg (10 tablets) (equivalent to 200 mg of Atorvastatin) in a
	200 ml(200 ml) volumetric flask. Add about 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
	diluteml(5 ml) of this solution in too_ml(50 ml) of volumetric flask with diluent.(Concentration:
	0.1 mg/ml of atorvastatin Calcium)
	Preparation of content uniformity:
	Take1 tablet into200 ml(200 ml) of volumetric flask, Add about ml(50 ml) of diluent.
	Shake for 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
	Description Charles by Assessed by Assessed by Charles by Assessed

	Prepared by	Checked by	Approved by	
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC	
Signature	J. Coura	CH	Wh	
Date	07/07/2022	07/07/2022	orbillour	
Department: Quality Contro	ol	Date of Issue: 67/04/1022		

SAI PRIMUS	ANALYTICAL W	AWR No: AWR/L13-00		
QUALITY CONTROL	FINISHED PRODUCT Page 14 of 15			
BRAND NAME	LOLIP 20 mg TABLETS			
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg			
B.No.	: 41822106	A.R. No.	: 85/140722/02	

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 standar	d
solution should <u>0.2</u> (not more than 1.00)	
solution should <u>O. 2</u> (not more than 1.00) Calculation: (ASSAY) Refer to Excel gheet	
1)Calculated the content of Atorvastatin tablet by using following formula,	
200 50 100	
= x x x x x 0.967	
200 5 100 20	-
2) Calculate the average content of assay by using following formula,	
+	
=	
2	
3) Calculations (Uniformity content): Regen to Exal Shoot	
Calculated the content of Atorvastatin tablet by using following formula	
Calculated the content of Atorvastatin tablet by using following for mula	
200	
200 100	
= x x x 0.967	
200 1 100 20	
	1

	Prepared by	Checked by	Approved by	
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC	
Signature	J- keng	CH	kr	
Date	07/07/2022	07/07/2022	orbitation	
Department: Quality Con	trol	Date of Issue: Offor 12022		

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SAI PRIMUS	ANALYTICAL WORK RE	CORD	AWR	No: AWR/L13-00	
QUALITY CONTROL	FINISHED PRODUCT	Γ	Page	15 of 15	. n
BRAND NAME	LOLIP 20 mg TABLETS				i e
GENERIC NAME	Atorvastatin Calcium Tablets USP 20 mg				
B.No.	: 61822106	A.R. No.		· 20/11. 170 2/22	

Analysed by: J. bey Checked by: Complies/ Does not comply. A 36/05/2022 Date: 18/07/2022 Date: °12. **MICROBIOLOGICAL LIMITS:**

Observation:

Polon MLT Report

Analysed by: 10/mg 28/07/2022 Checked by: Complies/ Does not comply. A 30 los thon Date: Date:

	Prepared by	Checked by	Approved by
Designation	Jr. Executive-QC	Sr. Executive-QC	Manager-QC
Signature	F- kompel	Cty.	M
Date	07/07/2022	07/07/2022	orbiller
Department: Quality C	ontrol	Date of Issue: OF 107 2022	en o's

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4 1111 M Markey W 2 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		

SACEL SHEET FOR DISSOLUTION CALCULATION Sample Weight (SW) 1 1 1 1 1 1 1 1 1													
of Product LOLIP 20 MG TABLET (COATED) Joseph (WS) 26.88 2 1 1 1 1 1 1 1 1 1	SAI PE	J LYNA HO	STO			EXC	EL SHEET	FOR DE	SSOLUTIO	N CALCULA	ATION		
of Analysis 21/07/2022 Batch No. G1822106 Date Jul-22 S.P. Date Jun-55 Os. We21-032 % Pack 1.032 % Pack 1.032 Aceight (WS) 26.88 2 1<	Name of Produ	ct	LOLIP 20 M		T_(COATE	(D)							
Date (b) Color) Jui-25 bate (b) Color) Jui-25 bate (b) Color) Jui-25 bate (b) Color) Jui-25 bate (b) Color) Lui-25 bate (b) Color) Jui-25 bate (b) Color)	Date of Analysi	S	21/07/2022				Batch No.		G1822106				
No. No. Standard Area/Abs Standard Area/Abs Standard Area/Abs Standard Area Standard Broken Standard Broken Standard Broken Standard Broken Standard Area/Abs Standard Broken Standard B	Mfg. Date		Jul-22				Exp. Date		Jun-25	10			
New Neight (New New Neight (New Neight (Neight (WS No.		WS-21-032				% Purity		94.42				
Page	WS Weight (W	S)	26.88				WS Valid	ity	09/04/202	3			
1	Sample Weight	(SW)	1				Label Cla	im (LC)	20				
1			,			,	,	_					
Seed By Seed	Std. Dilution	26.88	2	-	-	-	_			(F1	0.0	2967	
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loo 1									J	JF3		1	
ion 900 1 1 1 1 1 1 1 1 1 Indition CF3 CF3 CF3 Result % Result % indation Sinp. Area/Abs Standard Area/Abs Standard RT 100 CF2 CF4 Result % Result % ir. No. Standard Area/Abs Standard RT Tablet Area/Abs Result % 1 0.393 0 Table 0.423 95.53 3 0.393 0 Tabb 0.424 95.30 6 0.393 0.000 Areage 0.424 95.30 ge 0.393 0.000 Areage 0.424 95.30 B 0.0 Minimum Minimum 94.63 95.30 R Minimum Minimum 96.43 96.43 B 0.0 Minimum 96.43 96.43 B 0.0 Minimum 96.43 96.43 96.43 B 0.0	Sample	1	1	1	1	1	1)F4		1	
lation Smp. Area/Abs Std Dilution 94.42 100 CF1 CF3 No. Standard Area/Abs Standard Area/Abs Standard RT Tablet Area/Abs Result % 1 0.393 0 0 7 Tabl 0.425 95.53 2 0.393 0 0 7 Tabl 0.425 94.63 3 0.393 0 0 7 Tabl 0.424 96.20 4 0.393 0 0 7 Tabl 0.424 96.30 6 0.393 0 0 7 Tabl 0.424 96.30 6 0.393 0 0 7 Tabl 0.424 96.30 6 0.393 0 0 7 Tabl 0.424 96.33 9 0 0 Minimum 94.63 94.63 1 Maximum 96.43 96.43 96.43	Dilution	006	1	1	1	1	1						
lation Smp. Area/Abs Std Dilution 94.42 100 CF1 CF3 vir. No. Standard Area/Abs Standard RT Table Area/Abs. Result % 1 0.393 0 0 0.425 0.425 95.53 2 0.393 0 0 7 Tabl 0.428 96.20 3 0.393 0 0 7 Tabl 0.424 96.20 4 0.393 0 0 7 Tabl 0.424 96.30 5 0.393 0 0 7 Tabl 0.424 95.30 6 0.0393 0 0 7 Tabl 0.424 95.30 6 0.0393 0 0 7 Tabl 0.424 95.30 9 0 0 0 Minimum 94.63 94.63 1 0 0 0 0 0 0 0 1 0 0 0 0 0 0													
ula Std. Area/Abs Sample Dilution 100 20 CF2 CF4 ir. No. Standard Area/Abs Standard RT Tablet Area/Abs Result % 1 0.393 0 7 Tabl 0.425 94.63 2 0.393 0 7 Tabl 0.428 96.20 4 0.393 0 7 Tabl 0.428 96.20 5 0.393 0 7 Tabl 0.428 96.20 8e 0.393 0 7 Tabl 0.424 95.30 9e 0 7 Tabl 0.424 95.30 10 0 1 Tabl 0.424 95.30 10 0 1 Minimum 94.63 10 0 1 Minimum 94.63 10 1 Minimum 96.43 10 1 Maximum 96.43	Calculation	Smp. A	rea/Abs		ilution	94.42	100	CF1	CF3				
ir. No. Standard Area/Abs Standard RT Tablet Area/Abs. Result % 1 0.393 0 95.53 2 0.393 0 94.63 3 0.393 0 94.63 4 0.393 0 7 Tabb 94.29 5 0.393 0 7 Tabb 96.20 6 0.393 0.000 Average 95.30 9 0 0 95.30 D 0.0 Minimum 94.63 9 0.424 95.30 9 95.57 95.57 Average Maximum 94.63 96.43 96.43	Formula	Std. A	rea/Abs	Sample	Dilution	100	20	CF2	CF4				
ir. No. Standard Area/Abs Standard RT Tablet Area/Abs. Result % 1 0.393 0 0 95.53 2 0.393 0 7 Tabl 0.421 94.63 3 0.393 0 0 94.63 4 0.393 0 0 96.43 6 0.393 0.000 Average Average 95.30 8e 0.393 0.000 Average 95.30 D 0.0 Maximum 94.63 sed By Average Average 95.57 Date Average 95.43	2.5		¥.			-				8 - 10 10			
1 0.393 0 Tabl 0.425 2 0.393 0 0 4 0.421 3 0.393 0 0 7 Tab2 0.428 4 0.393 0 0 7 Tab5 0.424 5 0.393 0.000 Average Average 0 0 Minimum Minimum vsed By Average Average Average Average Average Maximum Maximum	Sr. No.	Standard	Area/Abs	Standa	ırd RT	e.		T	ablet	Area/Abs.		Result %	Result mg
2 0.393 0 Tab2 0.421 3 0.393 0 Maximum Maximum Maximum Maximum 0	1	0	393		0				[ab]	0.425		95.53	19.11
3 0.393 0 Tab3 0.428 4 0.393 0 0 424 6 0.393 0.000 Tab5 0.429 age 0.393 0.000 Average D 0 Minimum vsed By Maximum Checked By Checke	2	0.3	393)				Fab2	0.421		94.63	18.93
4 0.393 0 Tab4 0.424 5 0.393 0 Tab5 0.429 6 0.393 0.000 Average 0.424 D 0 0 Minimum Need By Average Maximum	3	0.3	393)				Fab3	0.428		96.20	19.24
5 0.393 0 Tab5 0.429 6 0.393 0.000 Average Average D 0 Minimum Maximum /sed By **Sed By **Assort Local By	4	0.3	393)				Fab4	0.424		95.30	19.06
6 Tab6 0.424 age 0.393 0.000 Average D Minimum Maximum rsed By #DIV/0! rsed By Pate H solot Lost	5	0.3	393)				Fab5	0.429		96.43	19.29
age 0.393 0.000 Average 0 0 Minimum D 0.0 #DIV/0! /sed By Aximum Solot 2201 Solot 2201 Date Solot 2201	9								Fab6	0.424		95.30	19.06
D 0 Minimum D 0.0 #DIV/0! /sed By Checked By 1/20/0-1/2024	Average	0.3	393	0.0	000			A	/erage			95.57	19.12
D 0.0 #DIV/0! Maximum Sed By Checked By Assort Sed By As	SD		0))			Mi	nimum			94.63	18.93
rsed By Checked By Date	%RSD	0	0.	#DI	V/0!			Ma	ximum	-		96.43	19.29
/sed By Checked By Date		0								Ŷ			
Date	Analysed By	3	John The State of					Checked	By	+ 1 2 1	John		
	Date	1	3,			-		Date		(H Solo.	in land		

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:

Wavelength:

WL244.0 244.00 nm

[Calibration Curve]

Cal. Curve Type:

Raw Data

[Measurement Parameters(Standard)]

[Measurement Parameters(Sample)]

Data Acquired by:

İnstrument

Delay sample read:

Disabled

Repeat:

Disabled

[Equations]

[Pass Fail]

[Method Summary]

Title: Date/Time:

Comments:

21/07/2022 17:49:07

Sample Preparations:

[Instrument Properties]

Instrument Type: Measuring Mode:

UV-1900 Series Absorbance

Slit Width: Light Source Change Wavelength: 340.8 nm

1.0 nm

S/R Exchange:

Normal

Software Information

Software Name:

UVProbe Version: 2.70

Security Mode

Mode:

Data Information

Filename:

D:\UV DATA\Data\DATA 2022\JULY 2022\2107202

\LOLIP_20_G1822106_DS_STD_.unk

Title:

dissolution **BOOBALAN**

Analyst: 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:

Page 1/1

Checked By

Date:

File Name:

D:\UV DATA\Data\DATA 2022\U ULY 2022\21072022\LOLIP_20_G1822106_DS_SPL_.unk

Sample Table

Sample ID	Conc	WL244.0	Comments
JAR_1	95.577	0.425	LOLIP_20_G1822106
JAR_2	94.578	0.421	COATED
JAR_3	96.198	0.428	
JAR_4	95.299	0.424	2,12
JAR_5	96.458	0.429	
JAR_6	95.419	0.424	
	JAR_1 JAR_2 JAR_3 JAR_4 JAR_5	JAR_1 95.577 JAR_2 94.578 JAR_3 96.198 JAR_4 95.299 JAR_5 96.458	JAR_1 95.577 0.425 JAR_2 94.578 0.421 JAR_3 96.198 0.428 JAR_4 95.299 0.424 JAR_5 96.458 0.429

[Wavelengths]

Wavelength Name:

Wavelength:

WL244.0 244.00 nm

WL244.0

K Factor

mg/l

[Calibration Curve]

Column for Cal. Curve:

Cal. Curve Type:

Cal. Curve Unit:

Selected Wavelength:

Calibration Equation:

WL244.0 (Conc) = K1(unk abs) +

K1: K0: 224.8120 0.0000

[Measurement Parameters(Standard)]

[Measurement Parameters(Sample)]

Data Acquired by: Delay sample read: Înstrument Disabled

Repeat:

Disabled

[Equations]

[Pass Fail]

[Method Summary]

Title:

Date/Time:

21/07/2022 17:52:45

Comments:

Sample Preparations:

Software Information

Software Name:

Version:

2.70

Mode:

Security Mode

UVProbe

Data Information

Filename:

D:\UV DATA\Data\DATA 2022\JULY 2022\2107202

\LOLIP_20_G1822106 DS SPL .unk DOSSOLUTION

Title: 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:

Checked By

Date:

File Name:

D:\UV DATA\Data\DATA 2022\UULY 2022\18072022\LOLIP-20_G1822106_IDENTIFICATIO N.unk

Sample Table

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

[Wavelengths]

Wavelength Name: Wavelength:

WL244.0 244.00 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:

Measuring Mode:

UV-1900 Series Absorbance 1.0 nm

Sat Width: Light Source Change Wavelength: 340.8 nm

S/R Exchange:

Normal

Software Information

Software Name:

Version:

UVProbe 2.70

Mode:

Security Mode

Data Information

Filename:

D:\UV DATA\Data\DATA 2022\JULY 2022\1807202 \LOLIP-20_G1822106_IDENTIFICATION.unk

LOLIP-20

Title:

KAYAL

Analyst: Date/Time:

18/07/2022 11:54:41

Comments:

IDENTIFICATION

Instrument Information

Instrument Name: UV1900 Instrument Type:

Model (S/N):

UV-1900 Series

UV1900 (A12425780886)

Analysed By: Date:

Page 1 / 1

Checked By Date:

LOLI	P-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=K	S
	K	2.4
	S	1.351

RESULT	3.242

J. payal 18/07/2022 A solotleen

Column LOLIP 20MG TABLETS	COLIP_20MG 18.07.2022 18.07.2022 18.07.2022 19.1-22 19	0.10 Assav (%) SPL-1	Assay (mg) SPL-1 20.0236 Assay (%) SPL-2 100.12 Assay (mg) SPL-2 20.0385 100.19 AVERAGE 20.0311 100.16	Analysed By T. Co. J. Checked By
-----------------------------	--	----------------------	--	----------------------------------

SAI PR	1 × 1	St			EXC	EL SHEET	FOR UP	EXCEL SHEET FOR UNIFORMITY OF CONTENT	OF CON	TENT	
Name of Product	uct	LOLIP_20MG									
Date of Analysis	sis	18/07/2022				Batch No.		G1822106	Conversion	Conversion Factor1	0.967
Mfg. Date		Jul-22			8	Exp. Date		Jun-25	Conversion	Conversion Factor2	1
WS No.		WS/CAL/064				% Purity		94.42	Conversion	Conversion Factor3	-
WS Weight (WS)	VS)	20.74				WS Validity	y	08/06/2023	Conversion	Conversion Factor4	-
Sample Weight (SW)	t (SW)	1				Label Claim (LC)	n (LC)	20			
	20.74	1	1	1		_	39-			-	
Sta. Duution	200	1	1	1	1						
Sample	1	1	1	-	1						
Dilution	200	1	1	1	1						
Calculation	Smp. Area	Area	Std Di	Std Dilution	94.42	100	Convers	Conversion Factor1	Conversion	Conversion Factor3	
Formula	Std.	Std. Area	Sample Dilution	Dilution	100	20	Convers	Conversion Factor2	Conversion	Conversion Factor4	% Assay
Sr. No.	Standard Area	Standard RT					Sa	Sample			
1	3100559	8.709	v	UC	AREA	Smp. Weight	'eight	%	mg	Minimum %	Ι.
2	3094531	8.712		UCI	3336856	1		102.12	20.42		Ī
3	3091842	8.704		UC2	3258523	1		99.72	19.94	6	
4	3083247	8.695		UC3	3244790	1		99.30	19.86	99.30	
5	3099405	8.693	1	UC4	3299625	1		100.98	20.20		,
9				UC5	3288654	1		100.64	20.13	Maximum %	
7				9DN	3268251	1	14	100.02	20.00	1	
8				UC7	3390388	1		103.76	20.75		
Average	3093917	8.703		UC8	3290881	1		100.71	20.14	103.76	
SD	6942.006713	0.00838451	1	UC9	3274873	1		100.22	20.04		
RSD	0.2	0.1		UC10	3252574	1		99.54	19.91		
						Avg	5.0	100.70		-	
Analysed By Date	J. 10-7	1 2022			E		Checked By Date	Α.	(#30 los (2022	12022	
						-			,		

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- 607/2022

off 13/07/2022



INSTRUMENT METHOD



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 Time Constant

Absorbance 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 2690/5

Channel Name

Description Use Channel Monitor

244 On

Monitor Parameter

System Pressure

Analysed by: J. Consul

Date

Checked by

Date

fl810712022

Reported by User: KAYAL (KAYAL)

Report Method: INSTRUMENT METHOD

Report Method ID: 1000

Page: 1 of 3

Project Name:

2022\QC_HPL_003\JUL-2022

Printed Date:

18/07/2022

Printed Time:

11:20:56 Asia/Calcutta

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 copied into project. (from Full Audit Trail project) Version 1 01/06/2022 16:46:25 IST User Vallarasan into project. (from Full Audit Trail project) Version 1 02/05/2022 09:06:31 IST User Vallarasan copied into project. (from Full Audit Trail project)

Method (\Hplc\2022\QC_HPL_003\JUN-2022 : 1942)

Method (\Hplc\2022\QC_HPL_003\MAY-2022: 2289) copie

Method (\Hplc\2022\QC_HPL_003\APR-2022:6916)

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

Checked by: A 18/07/2012 Date

Reported by User: KAYAL (KAYAL)

Report Method: INSTRUMENT METHOD

Report Method ID: 1000

Page: 2 of 3

Project Name: 2022\QC_HPL_003\JUL-2022

Printed Date: 18/07/2022

Printed Time:

11:20:56 Asia/Calcutta

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. Karfal
Date: 18/07/2022

Reported by User: KAYAL (KAYAL) Report Method: INSTRUMENT METHOD

Report Method ID: 1000

Page: 3 of 3

Checked by:

Date

HISTO Floor

Project Name: 2022\QC_HPL_003\JUL-2022

Printed Date: 18/07/2022

Printed Time:

11:20:56 Asia/Calcutta



CHROMATOGRAPHIC DATA

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INFORMATION SAMPLE

Sample Name:

BLANK AS

Sample Type:

Control

Vial: Injection #: 49

Injection Volume:

20.00 ul

Run Time:

20.0 Minutes

Date Acquired:

18/07/2022 11:30:06 IST

Date Processed:

19/07/2022 13:03:27 IST

KAYAL

Acquired By:

Sample Set Name: 18072022_LOLIP_AS_FP_SS
Acq. Method Set: LOLIP_AS_FP_MSET
Processing Methoc LOLIP_AS_FP_PM

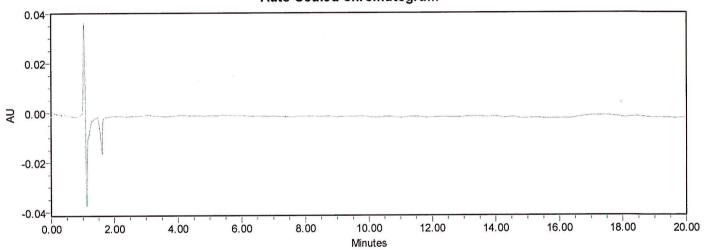
Channel Name:

W2489 ChA

Proc. Chnl. Descr.:

W2489 ChA 244nm

Auto-Scaled Chromatogram



Peak Results

	Name	Injection	RT	Area	% Area
1	ATORVASTATIN CALCIUM	1	8.700		

Analysed by: J. lay J

Date : 20/07/2022

Checked by:

Date

A30 07 bess

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:

15:36:03 Asia/Calcutta





SAMPLE INFORMATION

Sample Name:

STANDARD AS

Sample Type:

Standard

Vial:

50

Injection #:

1, 2, 4, 5, 3 20.00 ul

Injection Volume: Run Time:

20.0 Minutes

Acquired By:

KAYAL

Sample Set Name: 18072022_LOLIP_AS_FP_SS LOLIP_AS_FP_MSET

Aca. Method Set:

Processing Methoc LOLIP_AS_FP_PM

Channel Name:

W2489 ChA

Proc. Chnl. Descr.: W2489 ChA 244nm

Date Acquired:

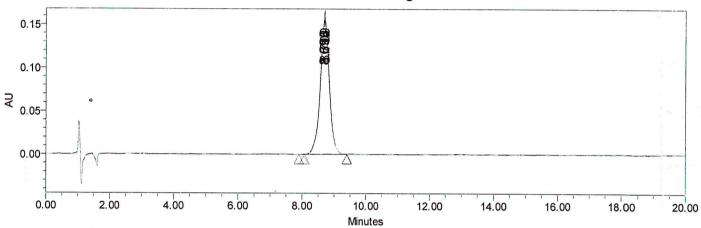
18/07/2022 11:51:15 IST, 18/07/2022 12:12:09 IST, 18/07/2022 12:33:05 IST, 18/07/2022

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. Kary J Date: 20/07/2022

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

Report Method ID: 3000

Page: 1 of 1

Checked by:

Date

30/07/2021

Project Name: 2022\QC_HPL_003\JUL-2022

Printed Date:

20/07/2022

Printed Time:

15:36:51 Asia/Calcutta



CHROMATOGRAPHIC DATA



SAMPLE INFORMATION

Sample Name:

BLANK AS

Sample Type: Vial:

Control

Injection #:

49

Injection Volume: Run Time:

1

20.0 Minutes

20.00 ul

Acquired By:

KAYAL

Sample Set Name: 18072022_LOLIP_AS_FP_SS

Acq. Method Set: LOLIP_AS_FP_MSET Processing Methoc LOLIP_AS_FP_PM

Channel Name:

Proc. Chnl. Descr.: W2489 ChA 244nm

W2489 ChA

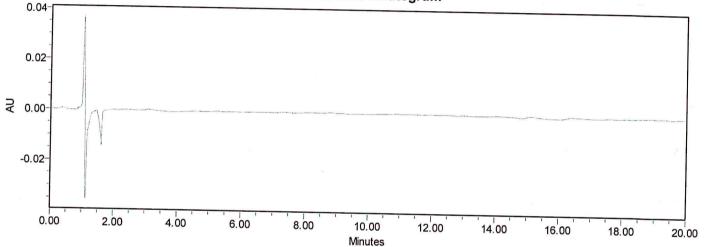
Date Acquired:

18/07/2022 13:36:18 IST

Date Processed:

19/07/2022 13:03:28 IST





Peak Results

Name	Injection	RT	Area	% Area
1 ATORVASTATIN CALCIUM	1	8.700		

Analysed by: J. Kong J

Date

Checked by:

Date

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:

15:37:13 Asia/Calcutta



CHROMATOGRAPHIC DATA



SAMPLE INFORMATION

Sample Name:

LOLIP-20_G1822106 SP 01

Sample Type:

Unknown

Vial:

Injection #:

51 1

Injection Volume:

20.00 ul

Run Time:

20.0 Minutes

Date Acquired:

18/07/2022 13:57:17 IST

Date Processed:

19/07/2022 13:03:28 IST

Acquired By:

KAYAL

Sample Set Name: 18072022_LOLIP_AS_FP_SS

Acq. Method Set: LOLIP_AS_FP_MSET

Processing Methoc LOLIP_AS_FP_PM

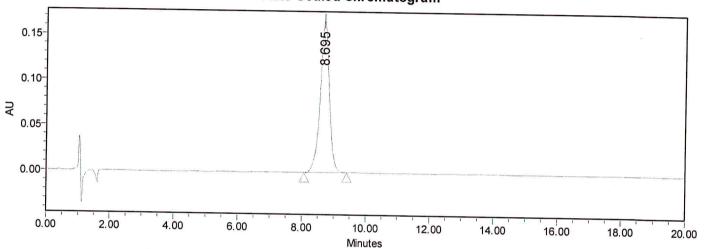
Channel Name:

W2489 ChA

Proc. Chnl. Descr.:

W2489 ChA 244nm

Auto-Scaled Chromatogram



Peak Results

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

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

Checked by:

Date

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



CHROMATOGRAPHIC DATA



SAMPLE INFORMATION

Sample Name:

LOLIP-20_G1822106_SP_02

Sample Type:

Unknown

Vial:

52

Injection #:

1

Injection Volume:

20.00 ul

Run Time:

20.0 Minutes

Date Acquired:

18/07/2022 14:18:11 IST

Date Processed:

19/07/2022 13:03:28 IST

KAYAL

Acquired By:

Sample Set Name: 18072022_LOLIP AS FP SS Acq. Method Set:

LOLIP_AS_FP MSET

Processing Methoc LOLIP_AS_FP_PM

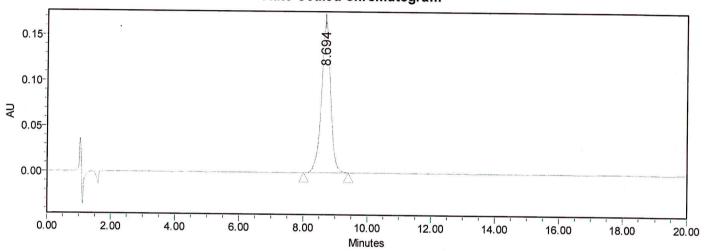
Channel Name:

W2489 ChA

Proc. Chnl. Descr.:

W2489 ChA 244nm

Auto-Scaled Chromatogram



Peak Results

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

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

Checked by:

Date

30 10 Flan

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:

15:39:07 Asia/Calcutta





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: Injection #: 50

Aca. Method Set:

LOLIP AS FP MSET Processing Methoc LOLIP_AS_FP_PM

Injection Volume:

1, 2, 4, 5, 3

W2489 ChA

Run Time:

20.00 ul

Channel Name:

20.0 Minutes

Proc. Chnl. Descr.:

W2489 ChA 244nm

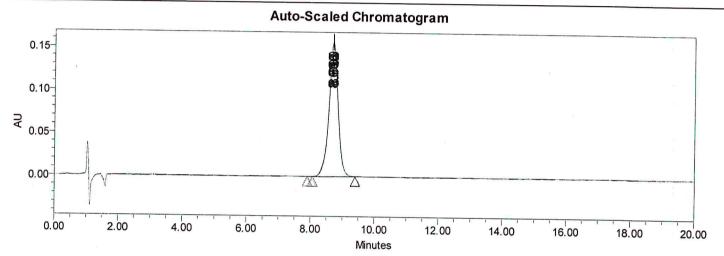
Date Acquired:

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



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. bay Date

20/07/2022

Checked by:

Date

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



SAMPLE INFORMATION

Sample Name:

LOLIP-20_G1822106_UC_04,

Acquired By:

KAYAL

Sample Type: Vial:

Unknown

Sample Set Name: 18072022_LOLIP_AS_FP SS

Injection #:

55, 54, 56, 53, 57 1

Acq. Method Set:

LOLIP_AS_FP_MSET

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

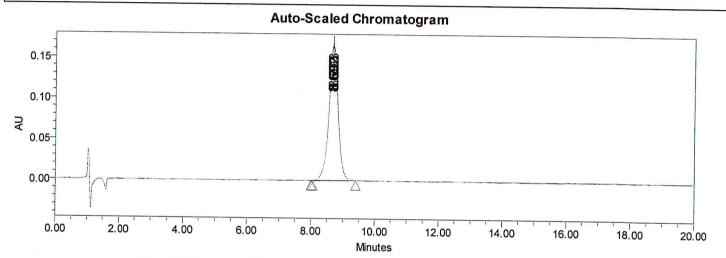
Date Acquired:

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



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: 3

Date

Checked by:

Date

30 07 0022

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:

15:40:20 Asia/Calcutta





SAMPLE INFORMATION

Sample Name:

STANDARD AS, STANDARD AS BKT 2

Acquired By:

KAYAL

Sample Type:

Vial:

Standard

Sample Set Name: 18072022_LOLIP_AS_FP_SS

50

LOLIP AS FP MSET

Injection #:

Acq. Method Set: Processing Methoc LOLIP_AS_FP_PM

Injection Volume:

1, 2, 4, 5, 3

20.00 ul

Channel Name:

W2489 ChA

Run Time:

20.0 Minutes

Proc. Chnl. Descr.:

W2489 ChA 244nm

Date Acquired:

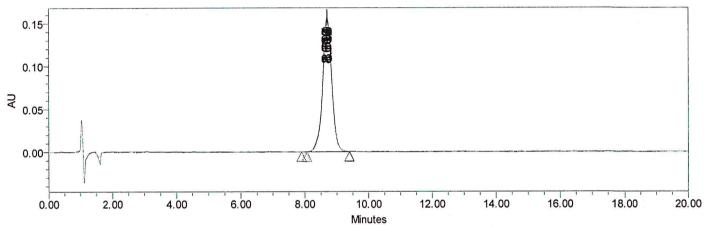
18/07/2022 11:51:15 IST, 18/07/2022 12:12:09 IST, 18/07/2022 12:33:05 IST, 18/07/2022

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. coursell
Date: 20/07/2022

Checked by:

Date

130 07/2000

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:

15:42:02 Asia/Calcutta





INFORMATION SAMPLE

Sample Name:

LOLIP-20_G1822106_UC_07,

Sample Type:

Unknown

Vial:

58, 61, 59, 60, 62

Injection #:

Injection Volume: Run Time:

20.00 ul 20.0 Minutes

KAYAL Acquired By:

Sample Set Name: 18072022_LOLIP_AS_FP_SS

LOLIP_AS_FP_MSET Aca. Method Set:

Processing Methoc LOLIP_AS_FP_PM

Channel Name:

W2489 ChA

Proc. Chnl. Descr.:

W2489 ChA 244nm

Date Acquired:

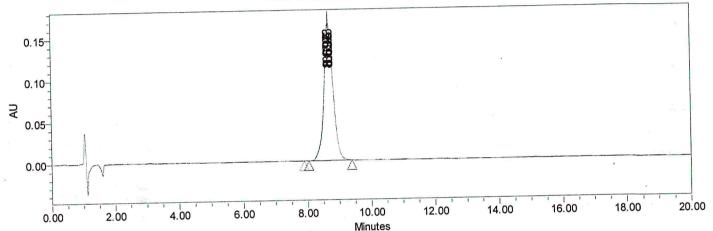
Date Processed:

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

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	· .		8.69,4	3295393
Std. Dev.		5.7	0.001	54853.576
% RSD			0.0	1.7

Analysed by: J- kay 1

Date: 2010712022

Checked by

Date

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





SAMPLE INFORMATION

Sample Name:

STANDARD AS, STANDARD AS BKT 3

Acquired By:

KAYAL

Sample Type:

Standard

Vial:

Sample Set Name: 18072022_LOLIP_AS_FP_SS LOLIP_AS_FP_MSET Aca. Method Set:

50

Injection #:

1, 2, 4, 5, 3 20.00 ul

Processing Methoc LOLIP_AS_FP_PM

Injection Volume: Run Time:

20.0 Minutes

Channel Name:

W2489 ChA

Proc. Chnl. Descr.: W2489 ChA 244nm

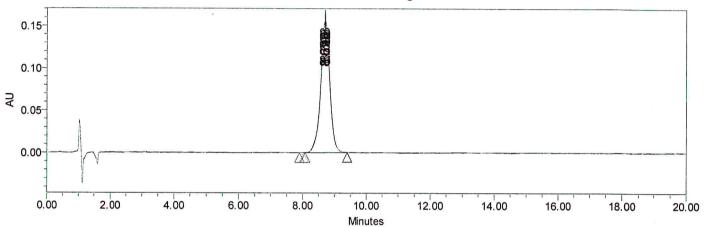
Date Acquired:

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

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

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		19	0.1	0.9		

Analysed by: J- kay J
Date: 20107/2022

Checked by:

Date

A30/07/2002

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:

15:46:37 Asia/Calcutta



PROCESSING METHOD



Processing Method: LOLIP_AS_FP_PM

Type: LC

Stored: 18/07/2022 15:49:56 IST

Method Information

Method Comments

Method Modified User

Method Locked Method Id

Old Id

Method Version

Method Edit User

Source S/W Info

Integration Algorithm

MS Ret Time Window

MS Ret Time Presearch

MS Search Depth

Start Mass Limit

End Mass Limit

PBM Search Mode **Duplicate Spectra**

PBM Reference Sets

Search Threshold

Noise Baseline

Peak Separation

Baseline Multiplier

Spectra To Average

Noise Threshold Combine Type

Expected Mass Peak Separation

Expected Mass Calculation Type

Include the uncorrected Target or Base Mass in the list of expected masses

Expected Mass Base Value

Expected Mass Base Intensity

Centroid Center Type

Centroid Top (%)

Centroid Intensity

Min. Peak Width at Half-Height

Smoothing Type

Average By

RT Window %

Date

Analysed by: J. (comp.) 20107/2022 PROCESSING METHOD

CREATED

KAYAL

No

6244 5268

7

Empower 3 Software Build 3471

SPs Installed: Service Release 3

DB ID: 2530846615

Traditional

10.0

No

3

(m/z)

(m/z)Pure

No

SET1

50.000(%)

(min)

1.0000(Da)

1.000

0.000(%)

Average

1.00(Da)

None

No

100.00(Da)

80.0(%)

Centroid Top(%)

80.00

Heights

0.500(Da) None

None

5.00

Checked by:

Date

Reported by User: KAYAL (KAYAL) Report Method: PROCESSING METHOD

Report Method ID: 1001

Page: 1 of 4

Project Name: 2022\QC_HPL_003\JUL-2022

Printed Date:

20/07/2022

Printed Time:

15:47:15 Asia/Calcutta

Update RT

CCalRef1

Include Internal Standard Amounts in Amount Calculation

Vial/Default Value Type

RT Reference Used to Name Unnamed Peaks by RRT

Never

Yes

Amount

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

Maximum Noise Maximum Drift

Baseline Noise Minimum

30 Seconds

Baseline Start Baseline End Calculate Peak Statistical Moments

(min) (min) No

5.0

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)	Туре	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

Checked by

Date

Reported by User: KAYAL (KAYAL)

Report Method: PROCESSING METHOD

Report Method ID: 1001

Page: 2 of 4

Project Name: 2022\QC HPL 003\JUL-2022

Printed Date:

20/07/2022

Printed Time:

15:47:15 Asia/Calcutta

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	MINIMAR SHAMES ST	TO STATE OF THE PARTY OF THE STATE OF

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	Туре
1				1.000000	1.0000	No	No		2020000		Single

Component Table

Impurity								he -		
Impurity C	CompRef1	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

0.05

Qualification Threshold

Impurity Response

Total Impurities Threshold

w Value

Main Component

Reporting Threshold

Maximum Impurity Threshold

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. Longa

Date

20107/2022

Checked by:

Reported by User: KAYAL (KAYAL)

Report Method: PROCESSING METHOD

Report Method ID: 1001

Page: 3 of 4

Project Name: 2022\QC HPL 003\JUL-2022

Printed Date:

20/07/2022

Printed Time:

15:47:15 Asia/Calcutta

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
	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

P.400	BESTER HARDEN BESTER BOOK STORY	MANAGEM AND SHOWING	SURE BRANCH BOOK	AND DESCRIPTION OF THE PARTY OF	COUNTY CONTRACTOR		TOTAL SERVICE STREET,		
				S	ource S/W	Info			
1	Empower 3	Software	Build 34	71 SPs	Installed:	Service	Release	3 DB ID:	2530846615
2	Empower 3	Software	Build 34	71 SPs	Installed:	Serv ice	Release	3 DB ID:	2530846615
3	Empower 3	Software	Build 34	71 SPs	Installed:	Service	Release	3 DB ID:	2530846615
4	Empower 3	Software	Build 34	71 SPs	Installed:	Serv ice	Release	3 DB ID:	2530846615
5	Empower 3	Software	Build 34	71 SPs	Installed:	Service	Release	3 DB ID:	2530846615
6	Empower 3	Software	Build 34	71 SPs	Installed:	Serv ice	Release	3 DB ID:	2530846615
7	Empower 3	Software	Build 34	71 SPs	Installed:	Service	Release	3 DB ID:	2530846615
	Empower 3	Software	Build 34	71 SPs	Installed:	Service	Release	3 DB ID:	2530846615

Analysed by: J. Cong J. Date: 20107/2022

Project Name:

2022\QC_HPL_003\JUL-2022

Checked by

Report Method: PROCESSING METHOD Report Method ID: 1001

Reported by User: KAYAL (KAYAL)

Printed Date:

20/07/2022

Printed Time:

15:47:15 Asia/Calcutta

Page: 4 of 4



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:

MICROBIAL LIMIT TEST

No.: F/QCMB/006/02

TITLE:

MICROBIAL LIMIT TEST REPORT

Revision No.: 01

Review Period: 02 years

Effective Date: 01012021

MICROBIOLOGICAL TEST REPORT

Name of Product:	-	L01120 mg							
Type of Product:					duct				
Batch No./ Lot No.		G182		Qı	uality Co	ntrol	A.R. No.	FP 230	722/01
Microbiology A.R. No	0.	MA 072	210445	M	fg. Date	Jul	2022	Exp.Date	Jun-205
Date of Receipt	23	07/2022	Date of te	st	23/07/	2022	Date of Co	ompletion	28/07/2022

S.No:	Test Required	Result	Specification '
i.	Total aerobic microbial count	20 CFU/g	Not more than 1000 cfu g or ml
2.	Total yeast and mould count	ciocfulg	Not more than 100 cfu g or ml
3.	Pathogens	7 7 7	
	a.E.coli	Absent	Should be absent in g or ml
	b.Salmonella sp.	Absent Absent Absent Absent	Should be absent in 10g or 10ml
	c.Pseudomonas aeruginosa	Systemst	Should be absent in g or ml
	d.Staphylococcus aureus	Shreyt	Should be absent in g or ml
	e.Shigella sp.	NA	Should be absent in 10g or 10ml
, ,	f.Enterobacteria	NA	Not more than No cfu g or ml /
			Should be absent in g or ml

Analysed by:	O ching	Reported by:	D'ais	Checked by:
	23/07/2022	Date:	28/07/2022	Date: 30/07/2020

MASTER COPY



SAI PRIMUS LIFE BIOTECH PVT LTD

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

12	ige	Z	01	O	

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

MB/MAP/003

Media and Accessories used:

Autoclave Id. No: MB/ACE/001

MB/MOPIDOS Micropipette Id. No: MB/MOP/DOB

S. No.	Name of the Media	Media P	reparation Details	Media Batch No.	
S. 10.	Name of the Media	Date	Sterilization cycle No.	Media Batch No.	
1	SCDM	22/07/2022	MS-22-0201	MP 22 0521	
2	BSC-Peptone	NA	NÐ	NO	
3	SCDA	22/07/2002	MS-22-0203	MP/20/0532	
4	SDA	23/07/2022	MS-22-0203	MP 22 0533	
5	МСВ	23/07/2002	MS-22-0203	MP/22/0534	
6	MCA	23/07/2022	MS-22-0203	MP120 10536	
7	RVSE	NO	NA	40	
8	XLDA	22/07/0002	NB	Mp/22/0535	
9	MSA	2107/2022	MS-22-0199	MP/22/0522	
10	CA	21/07/2002	MS-22-0199	mp/22/0521	
11	GN Broth		,		
12	XLDA	7			
13	EE Broth	7.3	. ~~		
14	VRBGA			1	

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

Media Mfg.: Manage Media Lot No: PUSER-2160 Expiry at: 14/11/2022

Note: GN broth (Readymade form):

MASTER COPY

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



TITLE:

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

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°C	MB BODIOO2
2	20-25 °C	MB18001001
3	42-44 °C	MB 1801003

LAF Id. No: MB/LAF/ OOD

BSC Id. No: MB/BSc | OOL

a) Sample Preparation.

Take 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 ______ 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.

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TITLE:

SAI PRIMUS LIFE BIOTECH PVT LTD

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

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MICROBIAL LIMIT TEST

No.: F/QCMB/006/02

MICROBIAL LIMIT TEST REPORT

Revision No.: 00
Review Period: 02 years
Effective Date: 01/01/2021

TAMC & TYMC: Incubated on Observed on **Incubation details** Observed Done by Tested for Date Time Date Time by Temp. Duration (°C) (days) 30-35 3-5 **TAMC** 18:06 20-25 5-7 **TYMC**

Enrichment:								
Play to the contract of	Incubation details		Incubated on		Observed on			Observed
Tested for	Temp.	Duration (hours)	Date	Time	Date	Time	Done by	by
Pre enrichment for E. coli, P. aeruginosa, S. aureus	30-35	18-24	22/07/2020	10:06	25kH omo	12:51	Deling- 20101/2022	0-his- 25/07/2022
Pre enrichment for Salmonella abony & Shigella Species	30-35	18-24	23/07/2002		25/01/2022 25/07/2022		0 · 6 · 6 · 6 · 6 · 6 · 6 · 6 · 6 · 6 ·	000
Enterobacteria gram negative	30-35	24-48	1		- 51011202	NO		

Test for Specified Microorganisms:

- E. coli: Transfer 1 ml of enrichment sample to 100 ml of Mac Conkey broth and incubate at 42-44°C for 24-48 hrs. After incubation, subculture on Mac Conkey agar and incubate at 30-35°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°C for 24-48 hrs. After incubation subculture on Xylose lysine deoxycholate agar and incubate at 30-35°C for 24-48 hrs.
- 3. *Pseudomonas aeruginosa*: Subculture on plate of cetrimide agar and incubation at 30-35°C for 18-72 hrs.

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TITLE:

SAI PRIMUS LIFE BIOTECH PVT LTD

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

Page 5 of 6

MICROBIAL LIMIT TEST

No.: F/QCMB/006/02

Revision No.: 00

MICROBIAL LIMIT TEST REPORT

Review Period: 02 years
Effective Date: 01/01/2021

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.

i A	selective	一個本學是一個的人的人們可以可以完成	bațion tails	Incubated on		Observed on		Done by	Observed
Tested for	Media	Temp.	Duration (Hours)	Date	Time	Date	Time	Done by	by
E. coli	МСВ	42 -44	24 – 48	05/4/2000	16536	27/07/2022	14:10	25/07/2022	12°Cmg-
	MCA	30 -35	18 – 72	27/07/2020	16:25	28/07/000	18:05	12 hig 27 107 12022	28/07/2022
Salmonella	RVSE	30 -35	24 –48	25/07/2000	16:31	07/07/000	14:06	25/07/2002	27/07/2020
Species.	XLDA	30 -35	24 – 48	2-101/2002			18:05	27/07/2022	28/07/2022
S. aureus	MSA	30 -35	18 –72			28/07/2002		25/07/2021	28/07/2022
P. aeruginosa	CA	30 -35	18 –72	25/07/2000		202100p		25/07/2022	28/03/2022
Shigella	GN	30-35	24-48	-		Sivope			
Species.	XLDA	30-35	24-48	38	-		NO.		
Enterobacteria gram negative	VRBGA	30-35	18-24	£.			-		10 ching

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V 3
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

P	age	6	of	6

MICROBIAL LIMIT TEST

No.: F/QCMB/006/02

Revision No.: 00

Review Period: 02 years

Effective Date: 01/01/2021

TITLE:

MICROBIAL LIMIT TEST REPORT

Observation:

Parameter	TA	MC	TYMC		
	Plate 1	Plate 2	Plate 1	Plate 2	
Count per plate	0.2	01	< \	∠ 1	
Average		02	21	D .	

Calculation:

TAMC: Average Count X Dilution factor Countx10 Countx10 Cfu/gm/ml.

TYMC: Average Count X Dilution factor Countx10 Cfu/gm/ml.

				r Specifie	d Microo	organisms			
Enrichme MCB	MCA	RVSE	Test:	MSA	CA	GN Broth	XLDA	EE Broth	VRBGA
V	×	8	×	M	~	NA	NO	NO	NA

- 1) Positive Control: Shown growth/ not-shown growth.
- 2) Negative Control: Shown growth / not shown growth.

Note: $\sqrt{-}$ Shown Growth, X - Not Shown Growth

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

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

Analysed by: Alas	Reported by: Acay	Checked by:
Date: 23/07/2022	Date: 28/07/2022	Date: A 300 Those

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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

2. Ref No.: N.M.

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

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.

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

(d) Sample Qty.: 50 Tablets

(f) D/M: 07/2022

6. Analysis Started On: 19/07/2022

8. Date of Amendment: N.A.

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

(b) Batch No.: G1822106

(e) B. Size: N.M.

(g) D/E: 06/2025

7. Analysis Completion On: 21/07/2022

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 Not Detected NMT 0.5 % 6 hydroxy analog Atorvastatin methyl ester Not Detected Atorvastatin epoxy pyrrolooxazin Not Detected NMT 0.5 % 7hydroxy analog Atorvastatin epoxy THF analog Not Detected NMT 1.0 % Atorvastatin Related compound D 0.02 % NMT 0.5 % Not Detected Atorvastatin tertbutyl ester Any other unspecified 0.04 % NMT 0.2 % degradation product Total degradation products 0.23 % NMT 4.0 %

As per party Requirements



A.C. Mathur (Add. Person Incharge) Authorised Signatory

OUR MISSION: OUR AIM IS TO BECOME THE MOST ECONOMICAL, EFFICIENT & RELIABLE TESTING FACILITY FOR DRUGS, WATER & FOOD.

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

Confidential DR	Con	fide	ntia	DR	A
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Work	sheet – Finishe	d Product (Tablets/C	apsules)
Worksheet ID DRA-FP-	221158		DA FR- 180722/005
Sample Received On	18/07/22	Reference No.	
Name of Sample		mg Tabs	
M.L.No		B.No.	41822106
Sample Qty.	SUTUBS	B.Size	
Mfg. Date	67/22	Exp. Date	06/25
Analysis start Date	19/07/22	Analysis completion date	21/07/22
Protocol of Test Applied	As her	USP	
Description: Light Yellow		shaped biconvex Pile	a cooked tablet back line

		Observation	Limits	Analysed By
Identification				
Average weight		191.30 mg		niterrul
Average Fill	manials in a minimum, or as sittle shoot.		The second secon	19/07/22
Uniformity of weight		Atomastation Amile > 0.04.1.		1
Uniformity of content		Alconastation Related compound A > Alconastation pyrrolidous analy > no Atomastation felated compound B > not Atomastation related compound (> not	of Defected NMT 0.57	
Dissolution	-	Atomostation Related companio (> not	pereces.	
Disintegration Time		Atervathin pyrodilar lection -> Au Atervathin Related comband H -> a. Atervathin Chary pyrodoxiczia 6 -		ritaland
Loss on Drying / Water		Aforestation relief fater -> nut D		22/07/22
Related Substances (For RS by HLPC/GC, use separate sheet, if required)	-	Atomition Thux, by socioticin 7- bythory analy > No.	trateded NMT 0.51.	
	•	Atomutation Epoxy Analy THE - > 10	t Defected NH7 1.0-1.	

Assay:

Labeled ingredients	Result	Label Claim	Limit	Analysed By
Atomandatin Related compound 0 ->	0.02 1		NM 0.5-1.	,,
Afonwholis Test budy Ester -> 1	of octocked			nitural
Any other inspection depolition frederit	The second secon		Nr7 0.2 -1.	1 1
Total Devodetion brodute >	0.22.1.		NM7 4.01.	21/02/2
mystow production	0.23.11.		NM7 4.0.1.	
				2

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.

0			
1.2	CH	ations	

ARNO.: DA/FP-180722 /005

Test Parameter (s)	Observation (s) & Calculation (s)	Analysed By / Date
	Chromotographic condition, Gradient	
	programme, preparation of Solwin-A,B	
*	and C, Dilumb, Preparation of	
	System suitability solution Preparation	
	of Standard solution, Balance I.D,	
	Instrument I.D one refer to	
	the AP sheet no. DA/FP-180722 (004)	
	20 tablete (WT) Test(WI.) Statistics	

20 tel	, lete (wit)	Test (₹·)
		Stat	istics
	tatistics	20.07.2022	12:45
19.07.20	22 12:23	Balance Tup	e XS105DU
Balance '	Type X5105DU	WeighBridge	
WeighBri	dge SNR:		B548764715
	B548764715	Terminal SN	R: B548764715
Terminal	SNR: 8548764715	Balance ID	
Balance :	ID AB-04	1	477.95 mg
1	3.82604 g	2	0.73 mg
n 💮	1	n	2
x	3.826040 g	×	239.340 mg
S		S	2070010 113
s.rel		s.rel	and and table start from these
Min	3.82604 g	Min	0.73 mg
Max	3.82604 g	Max	477.95 mg
Diff.	0.00000 q	Diff.	477.22 mg
Sum	3.82604 q		
		Sum	478.68 mg
Signature	• \	Signature	
1:	when !	i Lev	(m)
·····	100 100	M	2/22
And also give the shift here they also the	V.	201	0.11

Nited 11/2 20102/22

Checked By / Date:

Format No: SOP-QA012/F05/04

Reviewed By Date:

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

ADNO. 00/60 180222 100 C

Calculations	-180722/105	
Test Parameter (s)	Observation (s) & Calculation (s)	Analysed By / Date
Avg. wt. f 20 tablets.	3.82604 × 1000 => 191.302 mg.	
Preparation > af Test	weigh accurately 477.22 mg of Sample in 50 ml volumetric flook make up with 30 ml Dilut and mix and shake mechanically for IT min. Dilute with Dilumb to wolume and pass the solution thought switched filter of 0.45 sur pore size	
		Mital rill 20107/2
Checked By / Date:	Re	Viewed By / Date :
Format No: SOP-QA012/F0:	5/04 Pa	age No of

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

Test Parameter (s)		Observation (s) & Calculation (s)	o.: <u>palfp-</u> k	Analysed By / Date	
	Standard	Area		Dy / Date	
	01	2504530			
	0.2	25-64479	2000 A		
	03	2606819			
	04	2506321	Market v		
	05	2438 565			
	06	2 5. 3 ±822_	in the book of		
	Arg 2	526488			
	SHO. DEV ->				
	RSO ->	2.08 1.			
aleulation ->	Atomastal	in Amide >			
	218344 × 5.09 x	50 X 422.22 X 34.6 X 528.64	× 191.3	×100 ×2 =	
	0.0	04 4.			
				21/02/22	

Checked By / Date:

Format No: SOP-QA012/F05/04

Reviewed By Date

Page No. of

alculations	A R No. : <u>DA FP</u>	Analysed
l'est Parameter (s)	Observation (s) & Calculation (s)	By / Date
20 P	Atomvartation Related Compound D:	
	124439 × 5.09 × 50 × 50 × 50 × 50 × 50 × 50 × 50 ×	1.30 Xloox 2x
	=) 6.02 -1.	
Atomastalin	Related compound H:	
	$\frac{479587}{2526428} \times \frac{5.09}{100} \times \frac{5}{50} \times \frac{50}{427.22} \times \frac{94.6}{100} \times \frac{558.64}{1155.34} \times \frac{19}{2}$	1.30 × 100 × 2 ×
	-) 0.08 -1.	
	Total UNK (UNK OI + UNK OL)	
	$\frac{279326}{2526428} \times \frac{5.09}{100} \times \frac{5}{50} \times \frac{5}{492.22} \times \frac{94.6}{100} \times \frac{158.64}{1835.24} \times \frac{19}{2}$	1.30 × 100 ×2 =
	0.05 1.	
	UNK 03 :-	
	206576 x 5.09 x 50 x 50 x 427.22 x 100 x 1155.34 x 20	(loo x 2 =)
	0.04 7.	Mital and
A	R	7)

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

Calculations ARNO .: DA/FP -180722 1005 Test Parameter (s) Analysed Observation (s) & Calculation (s) By / Date Atomorphian Related Compound A - N.O Atomorphia Related compound 3 - N.D Atomoration Lebert compound C -> NO Horastalin Pyrolidon laton - NO Aformertation Pyonolooxazin -1 NO Atometation Pysolidam analog o N.D Atompahn Medge Ester -> N.P Atomustation Test May Ester - N. D Aforestation. Exexy THF Andy - N.O Atomatatin Epocy hyprologiczin 6 hydroxy conalay + NO Atomnstation Epony byroloxisis 7 hydring andy-1 ND Total Degradation produst -) 0.23 1.

Checked By / Date:

Reviewed By ADate:

Page No. of

Area % Report

Sample ID: Blank

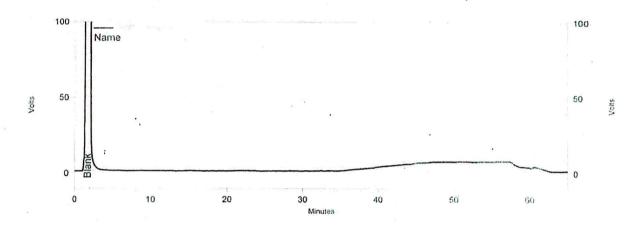
Data File: D:\Enterprise\Projects\HP-08
Jul-2022\Result\Lolip_RS_200722.rslt\Blank.dat

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:

Checked By/Date 216H22

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:

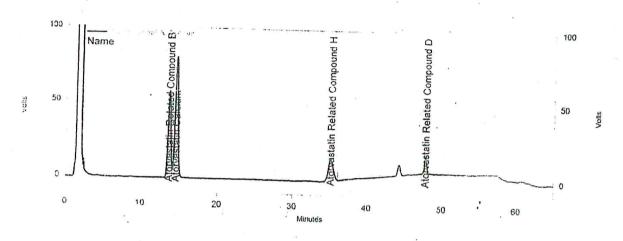
D:\Enterprise\Projects\HP-08

Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met

A.cquired:

7/20/2022 14:42:46 (GMT +05:30)

Instrument Id: HP-08 (Offline)



VWD:	Signal
A, 244	nm
Results	1

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

Totals			
	70056369	100.00	
:1-1-5		The same of the sa	

Analysed By/Date:

Checked By/Date

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:

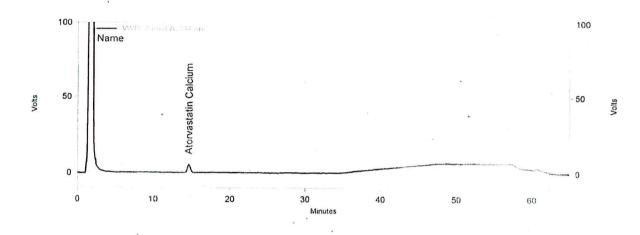
D:\Enterprise\Projects\HP-08

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	٠.	The state of the s

Analysed By/Date:

Checked By/Date
2167/22

Area % Report

Sample ID: , Standard Solution_02

Data File:

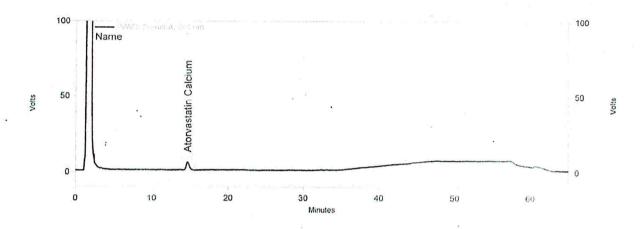
Solution 02

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		

Analysed By/Date:

Checked By

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:

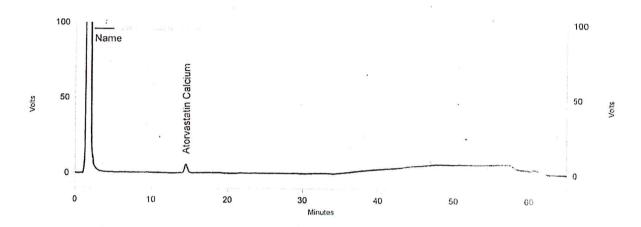
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Jul-2022\Result\Lolip_RS 200722.rslt\Lolip_RS_200722.met

Acquired:

7/20/2022 18:01:15 (GMT +05:30)

Instrument Id: HP-08 (Offline)



VWD: Signal A, 244

nm Results :

Retention Time	Area	Area %	Theoretical plates (USP)	Asymmetry (10%)
14.553	2606819	100.00	6287	1.09
	2606819	100 00		
	Time	Time	Time 14.553 2606819 100.00	Time plates (USP) 14.553 2606819 100.00 6287

Analysed By/Date:

Checked B

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:

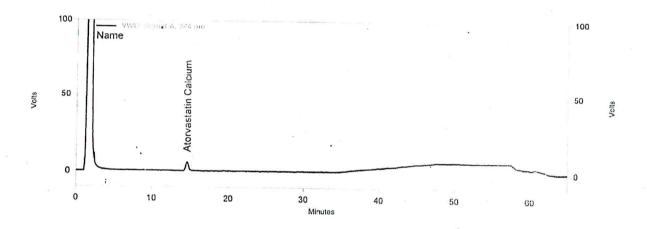
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Jul-2022\Result\Lolip_RS_200722.rslt\Lolip_RS_200722.met

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:

Checked By/Date

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:

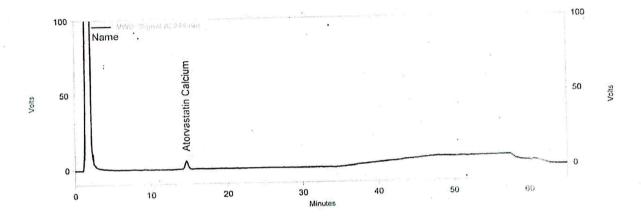
D:\Enterprise\Projects\HP-08

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 Calcin		2438565	100.00	6122	1.07
Totals		2438565	100.00		

Analysed By/Date:

Checked By

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:

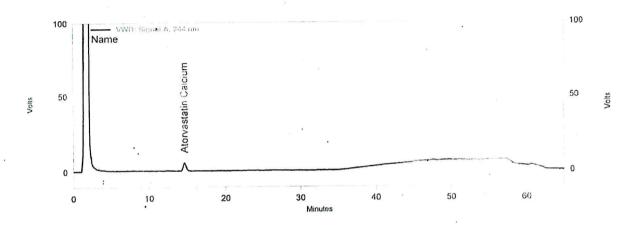
D:\Enterprise\Projects\HP-08

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				Control of the second s	

2537855

100.00

LA ru

Analysed By/Date:

Checked ipy/Date

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:

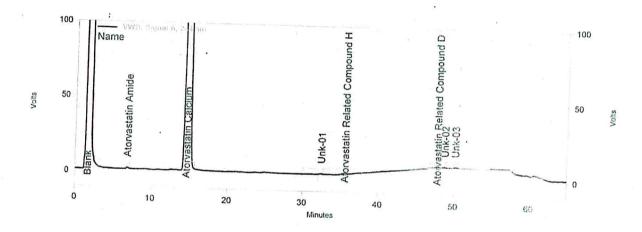
D:\Enterprise\Projects\HP-08

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	A 0.7
Blank	1.683	692142392	Area %
Atorvastatin Amide	6.967		62.23
Atorvastatin	14.660	218344	0.02
Calcium	14.000	418704323	37.65
Unk-01 Atorvastatin Related Compound H	32.553 35.683	121603 479587	0.01 0.04
Atorvastatin Related Compound D	47.867	124439	0.01
Unk-02 Unk-03	48.837 50.240	157723 206576	0.01 0.02
Totals	•		
<u>:</u>		1112154987	100.00

Analysed By/Date:

Checked B

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:

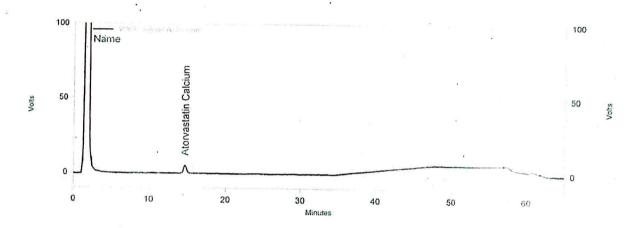
D:\Enterprise\Projects\HP-08

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		And the second s
	L	2409331	100.00		

Analysed By/Date:

Checked By/Date

21/07/22



ANALYTICAL DATA SHEET

Page No. 6367

SPL BIOTE A Model: SVN: ID: Date: Start:	6- DS-STD 0 AUW220 0450041599 BC/ABL/002 2022/07/21 16:42:52
881 662	26.88 m9 26.88 m9 9.00 m9
n total max min diff X srel	2 26.88 m9 26.88 m9 0.80 m9 26.88 m9 13.440 m9 19.887030 m9
Date: End: Signatur	2022/07/21 16:42:56

Analysed by: Date:

Checked by:

Date:

F/QCGN/003/01-0

73.

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	2022/07/18	Date.			18:32:87
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500		7750	THE CO. ST.	OI CA	3,44
The same and was not any or and any		a representation of the same o		The same time paint and paint and paint and paint and	Agent states and constraint and constraint.
	C. C. L. I. S. C.				N
	7	total		total.	336,69 Mg
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UTU	e,elms		942,18 mg		
			Bu 082 175		968, 345, mg
×		1.69	Em 080272.2	(1)	
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	And the same and t	10100	01/10/278	Date	
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Signature	O. perto	STEPSTING	18/07/2022	- Standard and a	1867/2022
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SAI PRIMUS LIFE BIOTECH PVT LTD		SAI PRIMUS LIFE BIOTE R.S. No. 4/3, plot No. 33, Kur Villianur Commune, I	umbapet Industrial Estat		Page 1 of 2	
QUALITY CONTROL		CERTIFICATE	OF ANALYSIS		Format No: F/QCGN/022/08	
CONTROL		FINISHED I	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 \pm 7.5 % and none deviate by more than \pm 15.0 %.
05.	Dimensions:		
	Thickness	Min Max Avg. 3.60 mm 3.71 mm 3.64 mm	3.40 mm to 3.80 mm
,	Diameter	Min Max Avg. 8.08 mm 8.13 mm 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	HULL	(H	let .	
Name	Vinothini	Ramesh	Vallarasan	
Date	10/12/2022	10/12/2022	10/12/2022	

SAI PRIMUS LIFE BIOTECH PVT LTD		SAI PRIMUS LIFE BIOTE R.S. No. 4/3, plot No. 33, Kun Villianur Commune, I	Page 2 of 2			
QUALITY CONTROL		Format No: F/QCGN/022/08				
		FINISHED I				
Product Name		(Atorvastatin Calcium Tablets				
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	Min Max Avg.	Not less than 85.0 % of the labeled			
	Equivalent to Atorvastatin-20 mg	97.93 % 100.48 % 98.98 %	amount of atorvastatin dissolved in 15 minutes.			
09.	Uniformity of dosage unit by HPL	C				
	Atorvastatin calcium USP	L1=5.287	L1=15			
	Equivalent to Atorvastatin-20 mg					
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 con	ntains:				
	Atorvastatin calcium USP		Not less than 94.50 % and Not more			
	Equivalent to Atorvastatin-20 mg	103.53 %	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/ $\frac{1}{1}$ with the prescribed standard of quality with reference to $\frac{1}{1}$ BP/USP and $\frac{1}{1}$ house Specification.

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

SAI PRIMUS LIFE BIOTECH PVT LTD		SAI PRIMUS LIFE BIO R.S. No. 4/3, plot No. 33, 1 Villianur Commun	Page 1 of 2				
QUALITY	CERTIFICATE OF ANALYSIS					Format No: F/QCGN/022/08	
CONTROL	FINISHED PRODUCT						
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	:	O	ct-2025	
Sampling Date	:	05.12.2022	Sample Qty	:	12	20 Tablets	
Analysis Date	:	05.12.2022	Release Date	:	14	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 \pm 7.5 % and none deviate by more than \pm 15.0 %.
05.	Dimensions:		
33,	Thickness	Min Max Avg. 3.56 mm 3.61 mm 3.59 mm	
	Diameter	Min Max Avg. 8.06 mm 8.09 mm 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	MUP	Cit.	M
Name	Vinothini	Ramesh	Vallarasan
Date	14/12/2022	14/12/2022	14/12/2022

SAI PRIMUS LIFE BIOTECH PVT LTD		R S No. 4/3, plot No. 33	OTECH PRIVATE LIMI , Kurumbapet Industrial E ine, Pondicherry- 605009	rial Estate,		Page 2 of 2
QUALITY	CERTIFICATE OF ANALYSIS				Format No: F/QCGN/022/08	
CONTROL	FINISHED PRODUCT			. 1		
Product Name	: LOLIP 20 mg TABLETS : (Atorvastatin Calcium Tablets USP 20 mg)					
A.R.No.	:	BSD/051222/02			Τ.	0.7
Batch No.	1:	G1822162	Batch Size	:	-	0 L
	1.	Nov-2022	Exp. Date		O	et-2025
Mfg. Date	+	05.12.2022	Sample Qty	:	12	20 Tablets
Sampling Date Analysis Date	\\ \cdot \cd	05.12.2022	Release Date	:	1	4.12.2022

18.	Dissolution by UV	Min Max Avg.	Not less than 85.0 % of the labeled		
	Atorvastatin calcium USP	IVIIII	amount of atorvastatin dissolved in		
	Equivalent to Atorvastatin-20 mg	97.70 % 103.95 % 101.25 %	15 minutes.		
		~	10 111111111111111111111111111111111111		
09.	Uniformity of dosage unit by HPLO	L1=8.421	L1=15		
	Atorvastatin calcium USP	L1-6.421	El 10		
	Equivalent to Atorvastatin-20 mg				
10.	Related substances:(BY HPLC)	Not Detected	Not more than 0.5 %		
	Atorvastatin pyrrolidone	Not Detected	1,00		
	Analog	0.051%	Not more than 1.0 %		
	Atorvastatin related	0.03170	1,00 11.51		
	compound H	Not Detected	Not more than 0.5 %		
	Atorvastatin epoxy pyrrolooxazin	Not Detected			
	6- hydroxy analog	Not Detected	Not more than 0.5 %		
	Atorvastatin epoxy pyrrolooxazin	Not Detected			
	7-hydroxy analog Not Detected		Not more than 1.0 %		
	Atorvastatin epoxy THF analog	0.019%	Not more than 0.5 % Not more than 0.2 %		
	Atorvastatin related compound D				
	Any other unspecified degradation	0.047%			
	product		Not more than 4.0 %		
	Total degradation products 0.217%		Not more than 4.0 70		
11.	Assay: Each Film coated tablet co	ntains:	Not less than 94.50 % and Not more		
	Atorvastatin calcium USP		than 105.00 %		
	Equivalent to Atorvastatin-20 mg	102.50 %	than 103.00 70		
12.	Microbiological limits:	10.67	NMT 1000 cfu/g		
	Total Aerobic Microbial count	<10 cfu/g	NMT 100 cfu/g		
	Total Yeasts and mould counts	<10 cfu/g	Should be Absent		
	E.Coli	Absent	Should be Absent		
	Salmonella	Absent	Should be Absent		
	S.aureus	Absent	Should be Absent		
	P.aeruginosa	Absent	Should be Absolit		

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
ign M.VID.		Vallarasan
ame Vinothini rate 14/12/2022	Ramesh 14/12/2022	14/12/2022