SAI PRIMUS LIFE BIOTECH PVT. LTD	SAI PRIMUS LIFE BIOTECH PVT LTD Factory: R.S. No. 4/3, Plot No.33, Kurumbapet Industrial Estate, Villianur Commune, Puducherry-605009	Page 1 of 8 No.: FPS: L13
	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)	Review Period: 3 Years
	Product Code: L13	Effective Date: 22/12/2023

01	GENERAL	Pharmacopoeia Reference	USP
02	Composition	Label Claim	
	Each Film coated tablet contains:		
	Atorvastatin calcium USP Equivalent to Atorvastatin	20 mg	
03	Shelf life	36 months	
04	Quantity of sample taken for analysis	Lubricated granules: 100 gm Bulk sample : 120 's (For complete analysis) Finished product: 4(3 x 10's) (For Physical parameter &Microbial Limit test only)	
05	Control sample	7 [3 x 10's]	
06	Storage of Finished pack	Store in cool and dry place, Protect from light & moisture. Do not store above 30°C.	

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
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	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)	Review Period: 3 Years
	Product Code: L13	Effective Date: 22/12/2023

BULK GRANULES SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	DESCRIPTION	White coloured granular powder.	Follow section I of Method of analysis
02	ASSAY (By HPLC) **Each 190 mg Granules Contains:**		Follow section XII of Method of analysis
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Not Less than 94.5 % and Not more than 105.0 %	

	Prepared by	Checked by	Approved by
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Signature			
Date	22/12/2023	22/12/2023	22/12/2023
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	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)	Review Period: 3 Years
	Product Code: L13	Effective Date: 22/12/2023

BULK PRODUCT SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	**DESCRIPTION**	White coloured, circular, biconvex uncoated tablet with breakline on one side and plain on other side.	Follow section I of Method of analysis
02	**AVERAGE WEIGHT**	190.00 mg ± 5.0 % (180.50 mg to 199.50 mg)	Follow section III of Method of analysis
03	**UNIFORMITY OF WEIGHT**	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 %	Follow section IV of Method of analysis
04	**DIMENSIONS** Thickness Diameter	 3.30 mm to 3.70 mm 7.80 mm to 8.20 mm	Follow section V of Method of analysis
05	**HARDNESS**	NLT 3 kg/cm^2	Follow section VI of Method of analysis
06	**FRIABILITY**	Not More Than 1.0 %	Follow section VII of Method of analysis
07	**DISINTEGRATION TIME**	Not more than 15 minutes	Follow section VIII of Method of analysis
08	**DISSOLUTION By UV** Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	 Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.	Follow section IX of Method of analysis
09	**ASSAY (By HPLC)** **Each Uncoated tablet contains:** Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	 Not Less than 94.5 % and Not more than 105.0 %	Follow section XII of Method of analysis

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
Date	22/12/2023	22/12/2023	22/12/2023
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		No.: FPS: L13
	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)	Review Period: 3 Years
	Product Code: L13	Effective Date: 22/12/2023

RELEASE SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	**DESCRIPTION**	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Follow section I of Method of analysis
02	**IDENTIFICATION**		Follow section II of Method of analysis
	A) By HPLC	The UV absorption spectrum of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay.	
	B) By HPLC	The retention time of the major Peak of the sample solution corresponds to that of sample solution, as obtained in Assay.	
03	**AVERAGE WEIGHT**	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)	Follow section III of Method of analysis
04	**UNIFORMITY OF WEIGHT**	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 %	Follow section IV of Method of analysis
05	**DIMENSIONS** Thickness Diameter	 3.40 mm to 3.80 mm 7.80 mm to 8.20 mm	Follow section V of Method of analysis
06	**HARDNESS**	NLT 3 kg/cm^2	Follow section VI of Method of analysis
07	**DISINTEGRATION TIME**	Not more than 30 minutes	Follow section VIII of Method of analysis
08	**DISSOLUTION By UV** Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.	Follow section IX of Method of analysis

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kagal		
Date	22/12/2023	22/12/2023	22/12/2023
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	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)	Review Period: 3 Years
	Product Code: L13	Effective Date: 22/12/2023

S.No.	TEST	LIMIT	METHOD
09	**UNIFORMITY OF DOSAGE UNIT BY HPLC** Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	L1=15	Follow section X of Method of analysis
10	**RELATED SUBSTANCES (By HPLC)**		Follow section XI of Method of analysis
	Atorvastatin pyrrolidone Analog	NMT 0.5 %	
	Atorvastatin related compound H	NMT 1.0 %	
	Atorvastatin epoxy pyrrolooxazin 6- hydroxy analog	NMT 0.5 %	
	Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	NMT 0.5 %	
	Atorvastatin epoxy THF analog	NMT 1.0 %	
	Atorvastatin related compound D	NMT 0.5 %	
	Any other unspecified degradation product	NMT 0.2 %	
	Total degradation products	NMT 4.0 %	
11	**ASSAY (By HPLC)** **Each Film coated tablet contains:**		
	Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Not Less than 94.5 % and Not more than 105.0 %	Follow section XII of Method of analysis

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S.No.	TEST	LIMIT	METHOD
12	**MICROBIOLOGICAL LIMITS**		Follow section XIII of Method of analysis
	Total Aerobic Microbial count	NMT 1000 CFU/g	
	Total Yeasts and mould counts	NMT 100 CFU/g	
	E.Coli	Should be Absent	
	Salmonella	Should be Absent	
	S.aureus	Should be Absent	
	P.aeruginosa	Should be Absent	

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		No.: FPS: L13
	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)	Review Period: 3 Years
	Product Code: L13	Effective Date: 22/12/2023

SHELF LIFE SPECIFICATION

S.No.	TEST	LIMIT	METHOD
01	DESCRIPTION	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Follow section I of Method of analysis
02	AVERAGE WEIGHT	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)	Follow section III of Method of analysis
03	HARDNESS	NLT 3 kg/cm^2	Follow section VI of Method of analysis
04	DISINTEGRATION TIME	Not more than 30 minutes	Follow section VIII of Method of analysis
05	DISSOLUTION By UV Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Not less than 85.0 % of the labeled amount of atorvastatin dissolved in 15 minutes.	Follow section IX of Method of analysis
06	RELATED SUBSTANCES (By HPLC)		Follow section XI of Method of analysis
	Atorvastatin pyrrolidone Analog	NMT 0.5 %	
	Atorvastatin related compound H	NMT 1.0 %	
	Atorvastatin epoxy pyrrolooxazin 6- hydroxy analog	NMT 0.5 %	
	Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	NMT 0.5 %	
	Atorvastatin epoxy THF analog	NMT 1.0 %	
	Atorvastatin related compound D	NMT 0.5 %	
	Any other unspecified degradation product	NMT 0.2 %	
	Total degradation products	NMT 4.0 %	

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
Date	22/12/2023	22/12/2023	22/12/2023
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	FINISHED PRODUCT SPECIFICATION	Revision No: 01
Title:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)	Review Period: 3 Years
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S.No.	TEST	LIMIT	METHOD
07	**ASSAY (By HPLC)** **Each Film coated tablet contains:** Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	 Not Less than 94.5 % and Not more than 105.0 %	Follow section XII of Method of analysis
08	**MICROBIOLOGICAL LIMITS** Total Aerobic Microbial count Total Yeasts and mould counts E.Coli Salmonella S.aureus P.aeruginosa	 NMT 1000 CFU/g NMT 100 CFU/g Should be Absent Should be Absent Should be Absent Should be Absent	Follow section XIII of Method of analysis

HISTORY:

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New Specification No: FPS: L13
2	Revision No.: 01	A note given in section XI for Related substance by HPLC with reference to the change control CC/23/069.

END OF DOCUMENT

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
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		No.: FPSTP: L13
	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 01
Title:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)	Review Period: 3 Years
	Product Code: L13	Effective Date: 22/12/2023

METHOD OF ANALYSIS

SECTION – I

DESCRIPTION: (By Visual Inspection)

Check physical aspects – Colour, shape and nature of tablets, presence of foreign material, mottling etc.,

SECTION – II

IDENTIFICATION

A. By HPLC

The UV absorption of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay

B. By HPLC

The retention time of the major peak of the sample solution corresponds to that of Sample solution, as obtained in the Assay.

SECTION – III

AVERAGE WEIGHT

Weigh 20 tablets and note down weight in g.

Determine the average weight. Report the result of average weight in mg.

$$\text{Average weight} = \frac{\text{Weight of 20 tablets in g}}{20} \times 1000 = \_\_\_\_\_ \text{ mg}$$

SECTION – IV

UNIFORMITY OF WEIGHT

Weigh individually 20 tablets taken for average weight. Calculate the percentage of highest and lowest variation of the tablets with maximum and minimum weight from the average weight of tablets by the following expression.

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Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. Kaur		
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Calculation:

$$\left(\frac{\text{Lowest Wt. of Tablet}}{\text{Avg. Wt. of Tablet}} \times 100 \right) - 100 = - \%$$

$$\left(\frac{\text{Highest Wt. of Tablet}}{\text{Avg. Wt. of Tablet}} \times 100 \right) - 100 = + \%$$

SECTION – V

DIMENSIONS

Measure the Thickness and Diameter of 10 tablets using Digital Vernier Calipers. Record the reading in mm.

SECTION – VI

HARDNESS

Take 10 tablets randomly from sample drawn for analysis. Place one tablet diagonally in between the space provided in the hardness tester. Operate the instrument for tablet hardness tester. Note down the reading when tablet breaks. Repeat the test for remaining 9 tablets and record the values in Kg/cm^2. Express the results as the minimum and maximum values in Kg/cm^2.

SECTION – VII

FRIABILITY

Weigh accurately about 6.5 g of tablets note down the mass in grams (a).Place weighed tablets in friability test apparatus and operate the instrument as per SOP for tablet friability test apparatus, for 100 rotations. After completion of test collect the tablets from the sample collector carefully. Remove broken particles, chipped pieces (if any) by means of gentle brushing. Weigh the tablet and record the mass in grams (b).

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Calculate the weight loss (c= a-b).

Calculate the percentage as follows:

Calculation

$$\frac{c \times 100}{a} = \%\ w/w$$

SECTION – VIII

DISINTEGRATION TIME

Determine on 6 tablets using water at 37°C ± 2°C.Place one tablet each in six tubes of the disintegration test apparatus, add a disc and suspend the assembly in water maintained at 37 ± 2°C.Operate the apparatus till all residue passes through the mesh and note down the time taken.The time taken should not be more than the limit indicated in the product specification.If the tablets adhere to the disc repeat the test omitting the disc.

SECTION – IX

DISSOLUTION By UV

Dissolution Parameters:

Medium	:	pH 6.8 Phosphate Buffer
Volume	:	900 mL
Apparatus	:	USP Apparatus 2 (Paddle)
RPM	:	75
Temperature	:	37°C ± 0.5°C
Time	:	15 minutes

Instrumental Conditions:

Mode	:	Ultraviolet - visible spectroscopy
Cell	:	0.5 cm

Blank	:	Medium
Wavelength	:	244 nm

Preparation of 0.05 M phosphate Buffer solution:

Dissolve 6.8 g of monobasic potassium Phosphate in 900 ml of water, adjust with 6N sodium hydroxide to a pH of 6.8 and dilute with Water to 1000 ml.

Preparation of Diluent:

Mixture of 50 ml of Acetonitrile and 50 ml of water, mix well.

Preparation of Standard Stock Solution:

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

Preparation of Standard Solution:

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

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

Preparation of Sample Solution:

Place one tablets in each vessel containing 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:

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

$$= \frac{A}{B} \times \frac{W1}{25} \times \frac{2}{100} \times \frac{900}{1} \times \frac{P}{100} \times \frac{100}{LC} \times CF$$

Where,

A = Area of peak obtained due to sample solution

B = Area of peak obtained due to standard solution

P = Purity of Atorvastatin Calcium working standard

CF = Conversion Factor (0.967)

LC = Label claim (mg / tablet)

SECTION – X

CONTENT UNIFORMITY (By HPLC):

For chromatographic parameters & preparation of mobile phase & Standard preparation & System suitability and Diluent follow as under Assay.

Preparation of content uniformity:

Take 1 tablet into 200 ml of volumetric flask, Add about 100 ml of diluent. Shake for 15 minutes or until dissolved and make up with diluent and centrifuge or Pass through a suitable filter of 0.45 µm pore size.(Concentration: 0.1 mg/ml of atorvastatin Calcium).

Repeat the same procedure for another 9 tablets.

Calculations (Uniformity content):

Calculated the content of Atorvastatin tablet by using following formula

$$= \frac{A}{B} \times \frac{W1}{200} \times \frac{200}{1} \times \frac{P}{100} \times \frac{100}{LC} \times CF$$

Where,

A= Peak area of sample preparation

B= Average peak area of standard solution

W1= Weight of standard taken

LC = Label claim

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P = % Purity of standard (on as is basis)

CF = Conversion factor (0.967)

SECTION – XI

RELATED SUBSTANCES (By HPLC)

Note: A freshly prepared solution should be used for the injection after establishing system suitability with standard and placebo.

Chromatographic Conditions:

Column	:	C18, 4.6- mm x 250 mm; 5-µm (or) equivalent
Detector	:	UV 244 nm
Sample Temperature	:	10°C
Column Temperature	:	30°C
Flow rate	:	See the table mentioned below
Injection volume	:	20 µL

Mobile phase:

Time	Solution B (%)	Solution C (%)	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
65	100	0	1.8

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

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		No.: FPSTP: L13
	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 01
Title:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)	Review Period: 3 Years
	Product Code: L13	Effective Date: 22/12/2023

Preparation of Buffer:

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

Preparation of Solution-A:

Prepare the solution of 925 ml of Acetonitrile and 75 ml of stabilizer- free tetrahydrofuran solution.

Preparation of Solution-B:

Mixture of 420 ml of solution-A and 580 ml of buffer. Sonicate and Filter through 0.45 micron membrane filter and degas.

Preparation of Solution-C:

Mixture of 600 ml of methanol and 200 ml of solution-A and 200 ml of buffer. Sonicate and Filter through 0.45 micron membrane filter and degas.

Diluent:

N, N-Dimethylformide.

Preparation of System Suitability solution:

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

Preparation of Standard solution:

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

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

Preparation of Placebo solution:

Transfer the 438 mg of placebo (equivalent to about 50 mg of atorvastatin), to a 50 ml volumetric flask. Add 30 ml of diluent and shake mechanically for 15 min. Dilute with diluent to volume and pass the solution through a

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suitable filter of 0.45-µm pore Size, discarding the first few ml of the filtrate.

Preparation of Sample powder:

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

Preparation of Sample solution:

Transfer the 488 mg of powder (equivalent to about 50 mg of atorvastatin), to a 50 ml volumetric flask. Add 30 ml of diluent and shake mechanically for 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)

Sequence of Injections:

1) Blank
2) Standard solution 6
3) Blank
4) Placebo solution
5) Blank
6) Sample solution
7) Standard solution (B)

System suitability:

Sample: system suitability solution

[Note: The relative retention times of the all peaks eluting before atorvastatin related Compound-H as given in table are calculated with respect to the atorvastatin peak. The relative retention times of the all peaks eluting after atorvastatin related compound-H are calculated with respect to Atorvastatin related compound-H.]

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 1.5.

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

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

Calculations:

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

$$= \frac{A}{B} \times \frac{W1}{100} \times \frac{1}{100} \times \frac{50}{W2} \times \frac{P}{100} \times \frac{100}{LC} \times CF \times AW \times \frac{1}{RRF}$$

Where,

A = Area of peak obtained due to sample solution

B = Area of peak obtained due to standard solution

W1 = Weight of standard Atorvastatin Calcium working standard in mg

W2 = Weight of sample in g

CF = Conversion factor (0.967)

P = Purity of Atorvastatin Calcium working standard

AW = Average Weight of tablet (in g)

RRF= Relative response factor of individual impurities.

Acceptance criteria:

Name	RRT	RRF	Limits
Atorvastatin amide	0.44	--	--
Atorvastatin related compound A	0.84	--	--
Atorvastatin pyrrolidone analog	0.88	0.68	0.5
Atorvastatin related compound B	0.94	--	--
Atorvastatin	1.00	--	--
Atorvastatin related compound C	1.09	--	--
Atorvastatin pyrrolidone lactone	1.62	--	--

Atorvastatin related compound H	1.00	1.18	1.0
Atorvastatin epoxy pyrrolooxazin 6-hydroxy analog	1.06	0.53	0.5
Atorvastatin methyl ester	1.12	--	--
Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	1.14	0.53	0.5
Atorvastatin epoxy THF analog	1.20	1.12	1.0
Atorvastatin related compound D	1.27	1.12	0.5
Atorvastatin tert-butyl ester	1.49	--	--
Any other unspecified degradation product		1.00	0.2
Total degradation products		--	4.0

SECTION-XII

ASSAY (By HPLC):

Chromatographic conditions:

Column	:	C18,4.6-mm × 250 mm; 5-µm or equivalent
Detector	:	Assay: UV 244 nm Identification A: Diode array; UV 200–400 nm
Column temperature	:	30 °C
Flow rate	:	1.5 ml/min
Injection volume	:	20 µL

Preparation of 0.05 M ammonium citrate buffer pH 4.0:

Dissolve 9.62 g of anhydrous Citric acid in 950 ml of water. Adjust with dilute ammonium hydroxide to a pH of 4.0 and dilute with water to 1000 ml.

Preparation of Mobile phase:

Mix 270 volumes of Acetonitrile and 200 volumes of stabilizer-free tetrahydrofuran and 530 volumes of buffer. Sonicate and Filter through 0.45 micron membrane filter and degas.

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		No.: FPSTP: L13
	FINISHED PRODUCT STANDARD TEST PROCEDURE	Revision No: 01
Title:	LOLIP 20 mg TABLETS (Atorvastatin Calcium Tablets USP 20 mg)	Review Period: 3 Years
	Product Code: L13	Effective Date: 22/12/2023

Preparation of Solution-A:

Dissolve 9.62 g of anhydrous citric acid in 950 ml of water, adjust with ammonium hydroxide to a pH of 7.4 and dilute with water to 1000ml.

Preparation of Diluent:

Mixture of 1 volume of Acetonitrile and 1 volume of Solution-A.

System suitability solution:

Weigh accurately 10 mg of USP Atorvastatin calcium working standard and 1 mg of USP Atorvastatin Related Compound H RS in a 100 ml volumetric flask. Add 70 ml of Diluent and dissolve the substance. Shake mechanically for 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 20.70 mg of Atorvastatin calcium working standard to a 200 ml volumetric flask. Add about 100 ml of diluent. Shake for 15 minutes, Dissolve make up with same solvent.

(Concentration: 0.1 mg/ml of Atorvastatin calcium working standard)

Preparation of Sample solution:

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

Note: Prepare sample solution in duplicate.

Sequence of Injections:

1) Blank
2) Standard solution 5
3) Blank solution
4) Sample solution.....1
5) Sample solution.....2
6) Standard solution (B)

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
Date	22/12/2023	22/12/2023	22/12/2023
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7)Sample CU-1----------5

8) Standard solution (B)

9)Sample CU-6----------10

10) Standard solution (B)

System suitability requirement:

1)The Resolution between the peaks corresponding to Atorvastatin and Atorvastatin related compound-H obtained with standard solution should not less than 5.0.

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

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

Calculation:(ASSAY)

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

$$= \frac{A}{B} \times \frac{W1}{200} \times \frac{200}{W2} \times \frac{50}{5} \times \frac{P}{100} \times \frac{100}{LC} \times AW \times CF$$

Where,

A = Area of peak obtained due to sample solution

B = Area of peak obtained due to standard solution

W1= Weight of atorvastatin Calcium standard in mg

W2= Weight of sample in g

P = Purity of Atorvastatin Calcium working standard

LC = Label claim

AW = Average Weight of tablet (in g)

CF = Conversion factor (0.967)

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature	J. kayal		KV
Date	22/12/2022	22/12/2022	22/12/2022
Department: Quality Control		Date of Issue: 22/12/2022	

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

$$= \frac{\text{Assay value obtained with sample 1} + \text{Assay value obtained with sample 2}}{2}$$

SECTION-XIII

MICROBIOLOGICAL LIMITS

Refer to SOP No. QCMB 006.

HISTORY:

S. No.	Revision Number	Reason for Revision
1	Revision No.: 00	New STP No:FPSTP: L13
2	Revision No.: 01	A note given in section XI for Related substance by HPLC with reference to the change control CC/23/069.

END OF DOCUMENT

	Prepared by	Checked by	Approved by
Designation	Executive-QC	Sr. Executive-QC	Manager-QC
Signature			
Date	22/12/2023	22/12/2023	22/12/2023
Department: Quality Control		Date of Issue: 22/12/2023	