SAI PRIMUS PHARMACEUTICALS PVT. LTD.	ACCELERATED STABILITY DATA	Page No: Page 1 of 2
		Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)		Storage Condition:40°C ±2°C & 75% RH ± 5%
B.No. : G1822106	Mfg. Date: JUL-2022 / Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: JUN-2025 / Pack Size: Blister (3x10'S)	Period: 6 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Date of Loading:24.07.2022

Tests	Limits	Initial 24.07.2022	3rd Month 24.10.2022	6th Month 24.01.2023
		Results	Results	Results
Description	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies
Average Weight	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)	193.40 mg	194.25 mg	195.13 mg
Hardness	NLT 3.0 kg/cm2	7.95 kg/cm2	7.15 kg/cm2	6.40 kg/cm2
Disintegration Time	Not more than 30 minutes	52 seconds	01 minutes 03 seconds	01 minutes 41 seconds
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.	Min 94.63 % / Max 96.43 % / Avg. 95.57 %	Min 95.36 % / Max 98.56 % / Avg. 96.96%	Min 91.12 % / Max 97.10 % / Avg. 95.78%
Related substances:(BY HPLC)				
Atorvastatin pyrrolidone Analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected
Atorvastatin related compound H	Not more than 1.0 %	0.08%	0.059%	0.080%
Atorvastatin epoxy pyrrolooxazin 6-hydroxy analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected
Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected
Atorvastatin epoxy THF analog	Not more than 1.0 %	Not Detected	Not Detected	Not Detected
Atorvastatin related compound D	Not more than 0.5 %	0.02%	0.039%	0.046%
Any other unspecified degradation product	Not more than 0.2 %	0.04%	0.076%	0.090%
Total degradation products	Not more than 4.0 %	0.23%	0.371%	0.505%
Assay: **Each Film coated tablet contains:** Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Not less than 94.50 % and Not more than 105.00 %	100.16 %	100.85 %	99.43 %

SAI PRIMUS PHARMACEUTICALS PVT. LTD.	ACCELERATED STABILITY DATA		Page No: Page 2 of 2
			Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)			Storage Condition:40°C ±2°C & 75% RH ± 5%
B.No. : G1822106	Mfg. Date: JUL-2022	Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: JUN-2025	Pack Size: Blister (3x10'S)	Period: 6 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg		Date of Loading:24.07.2022

Microbiological limits:				
Total Aerobic Microbial count	NMT 1000 cfu/g	20 cfu/g	NA	30 cfu/g
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g		<10 cfu/g
E.Coli	Should be Absent	Absent		Absent
Salmonella	Should be Absent	Absent		Absent
S.aureus	Should be Absent	Absent		Absent
P.aeruginosa	Should be Absent	Absent		Absent

Stability study: Complete [✓] Incomplete [✗]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for ..... 6th ..... months.

Reference: ICH Guidelines

PREPARED BY: M.M
DATE: 30/01/2023

CHECKED BY:
DATE: 30/01/2023

APPROVED BY:
DATE: 30/01/2023

SAI PRIMUS LIFE BIOTECH PVT. LTD.	LONG TERM STABILITY DATA		Page No: Page 1 of 2
			Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)			Storage Condition:30°C ±2°C & 75% RH ± 5%
B.No. : G1822106	Mfg. Date: JUL-2022	Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: JUN-2025	Pack Size: Blister (3x10'S)	Period: 36 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg		Date of Loading:24.07.2022

Tests	Limits	Initial 24.07.2022	3rd Month 24.10.2022	6th Month 24.01.2023	9th Month 24.04.2023	12th Month 24.07.2023	18th Month 24.01.2024	24th Month 24.07.2024
		Results	Results	Results	Results	Results	Results	Results
Description	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)	193.40 mg	194.21 mg	195.13 mg	194.95 mg	193.87 mg	194.15 mg	196.2 mg
Hardness	NLT 3.0 kg/cm2	7.95 kg/cm2	7.10 kg/cm2	6.90 kg/cm2	6.85 kg/cm2	6.75 kg/cm2	6.70 kg/cm2	6.03 kg/cm2
Disintegration Time	Not more than 30 minutes	52 seconds	01 minutes 56 seconds	01 minutes 11 seconds	01 minutes 13 seconds	01 minutes 19 seconds	05 minutes 23 seconds	06 minutes 28 seconds
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.	Min 94.63 % Max 96.43 % Avg. 95.57 %	Min 94.60 % Max 96.82 % Avg. 95.63%	Min 94.23 % Max 97.13 % Avg.95.68%	Min 95.28 % Max 103.19 % Avg.99.24%	Min 94.16 % Max 102.07 % Avg.98.75%	Min 95.40 % Max 101.18 % Avg.97.72%	Min 93.12 % Max 100.42 % Avg.96.08%
Related substances:(BY HPLC)								
Atorvastatin pyrrolidone Analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Atorvastatin related compound H	Not more than 1.0 %	0.08%	0.053%	0.063%	0.069%	0.065%	0.062%	0.074%
Atorvastatin epoxy pyrrolooxazin 6- hydroxy analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected

SAI PRIMUS LIFE BIOTECH PVT. LTD.	LONG TERM STABILITY DATA		Page No: Page 2 of 2
			Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)			Storage Condition:30°C ±2°C & 75% RH ± 5%
B.No. : G1822106	Mfg. Date: JUL-2022	Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: JUN-2025	Pack Size: Blister (3x10'S)	Period: 36 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg		Date of Loading:24.07.2022

Atorvastatin epoxy	Not more than 0.5 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
pyrrolooxazin 7-hydroxy	Not more than 1.0 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
analog								
Atorvastatin epoxy THF analog	Not more than 0.5 %	0.02%	0.031%	0.041%	0.046%	0.042%	0.040%	0.075%
Atorvastatin related compound D								
Any other unspecified degradation product	Not more than 0.2 %	0.04%	0.074%	0.079%	0.081%	0.083%	0.075%	0.095%
Total degradation products	Not more than 4.0 %	0.23%	0.368%	0.384%	0.394%	0.389%	0.372%	0.395%
Assay: **Each Film coated tablet contains:** Atorvastatin calcium USP Equivalent to	Not less than 94.50 % and Not more than 105.00 %	100.16 %	100.85 %	99.94 %	99.23 %	99.01 %	98.72 %	98.02 %
Microbiological limits:								
Total Aerobic Microbial count	NMT 1000 cfu/g	20 cfu/g	NA	NA	NA	NA	NA	NA
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g						
E.Coli	Should be Absent	Absent						
Salmonella	Should be Absent	Absent						
S.aureus	Should be Absent	Absent						
P.aeruginosa	Should be Absent	Absent						

Stability study: Complete [X] Incomplete [✓]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for ... 24th ... months.

Reference: ICH Guidelines

PREPARED BY: M.M
DATE: 05/08/2024

CHECKED BY:
DATE: 05/08/2024

APPROVED BY:
DATE: 05/08/2024

SAI PRIMUS LIFE	LONG TERM STABILITY DATA		Page No: Page 1 of 2
			Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)			Storage Condition:30°C ±2°C & 75% RH ± 5%
B.No. : G1822161	Mfg. Date: NOV-2022	Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: OCT-2025	Pack Size: Blister (3x10'S)	Period: 36 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg		Date of Loading:10.12.2022

Tests	Limits	Initial 10.12.2022	3rd Month 10.03.2023	6th Month 10.06.2023	9th Month 10.09.2023	12th Month 10.12.2023	18th Month 10.06.2024	24th Month 10.12.2024
		Results	Results	Results	Results	Results	Results	Results
Description	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)	193.20 mg	194.52 mg	193.53 mg	192.85 mg	193.05 mg	193.30 mg	194.78 mg
Hardness	NLT 3.0 kg/cm2	7.53 kg/cm2	7.90 kg/cm2	7.70 kg/cm2	7.65 kg/cm2	7.55 kg/cm2	7.50 kg/cm2	7.45 kg/cm2
Disintegration Time	Not more than 30 minutes	01 mins 20 seconds	01 minutes 44 seconds	01 minutes 35 seconds	01 minutes 52 seconds	02 minutes 29 seconds	02 minutes 51 seconds	03 minutes 22 seconds
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.	Min 97.93 % Max100.48 % Avg.98.98 %	Min 99.44 % Max 102.80 % Avg.101.05 %	Min 96.58 % Max 100.10 % Avg.98.67 %	Min 98.46 % Max 101.25 % Avg.98.13 %	Min 93.05 % Max 97.22 % Avg.95.47 %	Min 93.65 % Max 96.94 % Avg.95.84 %	Min 93.04 % Max 95.48 % Avg.94.39 %
Related substances:(BY HPLC)								
Atorvastatin	Not more than 0.5 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
pyrrolidone Analog	Not more than 1.0 %	0.057%	0.058%	0.055%	0.056%	0.057%	0.060%	0.065%
Atorvastatin related compound H	Not more than 0.5 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Atorvastatin epoxy pyrrolooxazin 6-	Not more than 0.5 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected

SAI PRIMUS LIFE	LONG TERM STABILITY DATA	Page No: Page 2 of 2
		Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)		Storage Condition:30°C ±2°C & 75% RH ± 5%
B.No. : G1822161	Mfg. Date: NOV-2022 / Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: OCT-2025 / Pack Size: Blister (3x10'S)	Period: 36 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Date of Loading:10.12.2022

hydroxy analog Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog Atorvastatin epoxy THF analog Atorvastatin related compound D Any other unspecified degradation product Total degradation products	Not more than 1.0 % Not more than 0.5 % Not more than 0.2 % Not more than 4.0 %	Not Detected 0.038% 0.074% 0.368%	Not Detected 0.040% 0.078% 0.373%	Not Detected 0.044% 0.076% 0.401%	Not Detected 0.039% 0.077% 0.405%	Not Detected 0.040% 0.078% 0.405%	Not Detected 0.041% 0.131% 0.410%	Not Detected 0.047% 0.135% 0.424%
Assay: **Each Film coated tablet contains:** Atorvastatin calcium USP Equivalent to	Not less than 94.50 % and Not more than 105.00 %	103.53 %	100.60 %	101.90 %	100.51 %	100.23 %	100.15 %	99.95 %
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	<10 cfu/g <10 cfu/g Absent Absent Absent	NA	NA	NA	NA	NA	NA

Stability study: Complete [✓] Incomplete [✓]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for ~~.....24.....~~ 24th months.

Reference: ICH Guidelines

PREPARED BY: Dube
DATE: 15/12/2024

CHECKED BY: J. Tenpe
DATE: 15/12/2024

APPROVED BY: M
DATE: 15/12/2024

SAI PRIMUS LIFE SCIENCES PVT. LTD.	ACCELERATED STABILITY DATA		Page No: Page 1 of 2
			Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)			Storage Condition:40°C ±2°C & 75% RH ± 5%
B.No. : G1822161	Mfg. Date: NOV-2022	Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: OCT-2025	Pack Size: Blister (3x10'S)	Period: 6 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg		Date of Loading:10.12.2022

Tests	Limits	Initial 10.12.2022	3rd Month 10.03.2023	6th Month 10.06.2023
		Results	Results	Results
Description	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies
Average Weight	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)	193.20 mg	193.50 mg	192.60 mg
Hardness	NLT 3.0 kg/cm2	7.53 kg/cm2	7.60 kg/cm2	7.65 kg/cm2
Disintegration Time	Not more than 30 minutes	01 mins 20 seconds	02 minutes 06 seconds	01 minutes 27 seconds
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.	Min 97.93 % Max 100.48 % Avg. 98.98 %	Min 96.98 % Max 101.46 % Avg. 99.22%	Min 93.71 % Max 98.12 % Avg. 96.28%
Related substances:(BY HPLC)				
Atorvastatin pyrrolidone Analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected
Atorvastatin related compound H	Not more than 1.0 %	0.057%	0.059%	0.064%
Atorvastatin epoxy pyrrolooxazin 6-hydroxy analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected
Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected
Atorvastatin epoxy THF analog	Not more than 1.0 %	Not Detected	Not Detected	Not Detected
Atorvastatin related compound D	Not more than 0.5 %	0.038%	0.039%	0.041%
Any other unspecified degradation product	Not more than 0.2 %	0.074%	0.076%	0.081%
Total degradation products	Not more than 4.0 %	0.368%	0.371%	0.379%

SAI PRIMUS LIFE SCIENCES PVT. LTD.	ACCELERATED STABILITY DATA			Page No: Page 2 of 2
				Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)				Storage Condition:40°C ±2°C & 75% RH ± 5%
B.No. : G1822161	Mfg. Date: NOV-2022	Batch Size: 6.0 L		Reason for stability: Validation Batch study
	Exp. Date: OCT-2025	Pack Size: Blister (3x10'S)		Period: 6 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg			Date of Loading:10.12.2022

Assay: **Each Film coated tablet contains:** Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Not less than 94.50 % and Not more than 105.00 %	103.53 %	100.85 %	101.13 %
Microbiological limits:				
Total Aerobic Microbial count	NMT 1000 cfu/g	<10 cfu/g		30 cfu/g
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g		<10 cfu/g
E.Coli	Should be Absent	Absent		Absent
Salmonella	Should be Absent	Absent	NA	Absent
S.aureus	Should be Absent	Absent		Absent
P.aeruginosa	Should be Absent	Absent		Absent

Stability study: Complete [✓] Incomplete [X]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for ..... 6th ..... months.

Reference: ICH Guidelines

PREPARED BY: M.M **DATE:** 21/06/2023

CHECKED BY: RJ **DATE:** 21/06/23

APPROVED BY: AV **DATE:** 21/06/23

SAI PRIMUS LIFE BIOTECH PVT. LTD.	ACCELERATED STABILITY DATA		Page No: Page 1 of 2
			Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)			Storage Condition:40°C ±2°C & 75% RH ± 5%
B.No. : G1822162	Mfg. Date: NOV-2022	Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: OCT-2025	Pack Size: Blister (3x10'S)	Period: 6 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg		Date of Loading:14.12.2022

Tests	Limits	Initial 14.12.2022	3rd Month 14.03.2023	6th Month 14.06.2023
		Results	Results	Results
Description	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies
Average Weight	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)	193.30 mg	194.11 mg	190.56 mg
Hardness	NLT 3.0 kg/cm2	7.5 kg/cm2	7.70 kg/cm2	7.75 kg/cm2
Disintegration Time	Not more than 30 minutes	01 mins 49 seconds	02 minutes 15 seconds	01 minutes 57 seconds
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.	Min 97.70 % Max 103.95 % Avg. 101.25 %	Min 97.43 % Max 100.12 % Avg. 98.51%	Min 94.71 % Max 97.79 % Avg. 96.29%
Related substances:(BY HPLC)				
Atorvastatin pyrrolidone Analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected
Atorvastatin related compound H	Not more than 1.0 %	0.051%	0.058 %	0.065 %
Atorvastatin epoxy pyrrolooxazin 6-hydroxy analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected
Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected
Atorvastatin epoxy THF analog	Not more than 1.0 %	Not Detected	Not Detected	Not Detected
Atorvastatin related compound D	Not more than 0.5 %	0.019%	0.025%	0.023%
Any other unspecified degradation product	Not more than 0.2 %	0.047%	0.051%	0.058%
Total degradation products	Not more than 4.0 %	0.217%	0.223%	0.242%
Assay: **Each Film coated tablet contains:** Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Not less than 94.50 % and Not more than 105.00 %	102.50 %	101.33 %	101.98 %

SAI PRIMUS LIFE BIOTECH PVT LTD	ACCELERATED STABILITY DATA		Page No: Page 2 of 2
			Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)			**Storage Condition:40°C ±2°C & 75% RH ± 5%**
B.No. : G1822162	**Mfg. Date: NOV-2022**	**Batch Size: 6.0 L**	**Reason for stability: Validation Batch study**
	Exp. Date: OCT-2025	**Pack Size: Blister (3x10'S)**	**Period: 6 Month**
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg		**Date of Loading:14.12.2022**

Microbiological limits:				
Total Aerobic Microbial count	NMT 1000 cfu/g	<10 cfu/g	NA	10 cfu/g
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g		<10 cfu/g
E.Coli	Should be Absent	Absent		Absent
Salmonella	Should be Absent	Absent		Absent
S.aureus	Should be Absent	Absent		Absent
P.aeruginosa	Should be Absent	Absent		Absent

Stability study: Complete [✓] Incomplete [x]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for ..... 6M ..... months.

Reference: ICH Guidelines

PREPARED BY: J. Dey
DATE: 22/06/2023

CHECKED BY:
DATE: 22/06/2023

APPROVED BY:
DATE: 22/06/2023

SAI PRIMUS LIFE	LONG TERM STABILITY DATA	Page No: Page 1 of 2
		Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)		Storage Condition:30°C ±2°C & 75% RH ± 5%
B.No. : G1822162	Mfg. Date: NOV-2022 / Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: OCT-2025 / Pack Size: Blister (3x10'S)	Period: 36 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Date of Loading:14.12.2022

Tests	Limits	Initial 14.12.2022	3rd Month 14.03.2023	6th Month 14.06.2023	9th Month 14.09.2023	12th Month 14.12.2023	18th Month 14.06.2024	24th Month 14.12.2024
		Results	Results	Results	Results	Results	Results	Results
Description	Pale yellow coloured, circular, biconvex film coated tablet with breakline on one side and plain on other side.	Complies	Complies	Complies	Complies	Complies	Complies	Complies
Average Weight	195.00 mg ± 5.0 % (185.25 mg to 204.75mg)	193.30 mg	194.05 mg	190.56 mg	192.10 mg	192.45 mg	192.68 mg	193.96 mg
Hardness	NLT 3.0 kg/cm2	7.5 kg/cm2	7.60 kg/cm2	7.60 kg/cm2	7.50 kg/cm2	7.35 kg/cm2	7.45 kg/cm2	7.57 kg/cm2
Disintegration Time	Not more than 30 minutes	01 minutes 49 seconds	01 minutes 54 seconds	01 minutes 53 seconds	01 minutes 59 seconds	02 minutes 29 seconds	02 minutes 59 seconds	03 minutes 09 seconds
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.	Min 97.70 % Max 103.95 % Avg.101.25 %	Min 98.77 % Max101.91 % Avg.99.82%	Min 96.25 % Max 99.76 % Avg.98.37%	Min 94.31 % Max 97.17 % Avg.96.03%	Min 94.81 % Max 97.66 % Avg.96.27%	Min 93.87 % Max 97.38 % Avg.95.88%	Min 93.11 % Max 97.20 % Avg.95.21%
Related substances:(BY HPLC)								
Atorvastatin pyrrolidone Analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Atorvastatin related compound H	Not more than 1.0 %	0.051%	0.061 %	0.066 %	0.064 %	0.062 %	0.067 %	0.070 %
Atorvastatin epoxy pyrrolooxazin 6-hydroxy analog	Not more than 0.5 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected
Atorvastatin epoxy pyrrolooxazin 7-	Not more than 0.5 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected

SAI PRIMUS LIFE	LONG TERM STABILITY DATA	Page No: Page 2 of 2
		Format No:F/QCGN/034/06
PRODUCT NAME: LOLIP 20 mg TABLETS(Atorvastatin Calcium Tablets USP 20 mg)		Storage Condition:30°C ±2°C & 75% RH ± 5%
B.No. : G1822162	Mfg. Date: NOV-2022 / Batch Size: 6.0 L	Reason for stability: Validation Batch study
	Exp. Date: OCT-2025 / Pack Size: Blister (3x10'S)	Period: 36 Month
	Label Claim: Each Film coated tablet contains: Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Date of Loading:14.12.2022

hydroxy analog Atorvastatin epoxy THF analog	Not more than 1.0 %	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected	Not Detected 0.011%	Not Detected 0.015%
Atorvastatin related compound D	Not more than 0.5 %	0.019%	0.029%	0.032%	0.031%	0.027%		
Any other unspecified degradation product	Not more than 0.2 %	0.047%	0.056%	0.054%	0.052%	0.049%	0.132%	0.142%
Total degradation products	Not more than 4.0 %	0.217%	0.229%	0.240%	0.238%	0.232%	0.253%	0.259%

Assay: **Each Film coated tablet contains:** Atorvastatin calcium USP Equivalent to Atorvastatin-20 mg	Not less than 94.50 % and Not more than 105.00 %	102.50 %	101.13 %	102.45 %	100.93 %	100.05 %	99.98%
Microbiological limits:							
Total Aerobic Microbial count	NMT 1000 cfu/g	<10 cfu/g	NA	NA	NA	NA	NA
Total Yeasts and mould counts	NMT 100 cfu/g	<10 cfu/g					
E.Coli	Should be Absent	Absent					
Salmonella	Should be Absent	Absent					
S.aureus	Should be Absent	Absent					
P.aeruginosa	Should be Absent	Absent					

Stability study: Complete [✗] Incomplete [✓]

Opinion: Based on the above stability studies, the product is ~~unstable~~ / stable for ……24th…. months.

Reference: ICH Guidelines

PREPARED BY: M. Vijay **DATE:** 28/12/2024

CHECKED BY: J. Kumar **DATE:** 28/12/2024

APPROVED BY: [illegible] **DATE:** 28/12/2024

KW.E by M. Vijay