

CERTIFICATE OF ANALYSIS

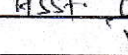
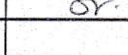
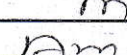
Product	: Atorvaheal 40 (Atorvastatin Tablet IP 40mg)	Analytical Report No.	: FFPOSD0197-25
Batch/Lot No.	: KXSIB502	Mfg. Date	: 02/25
Ref. Specification No.	: ISL/SPC/FPR/757-00	Exp. Date	: 01/27
Batch Size	: 2.0 Lac Tablets	Sampled Quantity	: 180 Tablets
Date of Analysis	: 09.03.2025	Date of Completion	: 21.03.2025

Sr.No.	Parameters	Limits	Results
1	Description	Yellow coloured, round shaped, biconvex film coated tablets with both side plain.	Yellow coloured, round shaped, biconvex film coated tablets with both side plain.
2	Diameter	8.1 ± 0.2 mm	8.12 mm
3	Thickness	4.1 ± 0.2 mm	4.11 mm
4	Average weight	255 mg ± 18mg	254.83mg
5	Uniformity of weight	± 5.0% of the average weight of the tablet	-1.97 % to + 1.56%
6	Disintegration Time	Not more than 30 minutes	05 minutes 56Seconds
7	Identification (By HPLC)	Retention time of the principal peak of test corresponds to that of Atorvastatin calcium W.S.	Complies
8	Dissolution test	Q. Not less than 70 %	Avg. 93.7 % Min. 92.8 % Max.94.9 %
9	Related Substances		
	Any individual impurity	Not more than 1.0%	0.47%
	Total impurity	Not more than 4.0%	0.67%
10	Assay: Each film coated tablet contains: Atorvastatin calcium IP equivalent to Atorvastatin – 40 mg	36.0mg – 44.0mg per tablet of average weight (90 to 110% of label claim)	38.83 mg per tablet of average mass. (97.08 % of the label claim)
11	Microbial Purity		
	Total aerobic count	Not more than 1000 cfu /g	<10 cfu /g
	Yeast and moulds count	Not more than 100 cfu /g	<10 cfu /g
	Escherichia coli	Shall be Absent/g	Absent/g

Remarks : The sample complies / does not comply as per above specification.

Parent B.No. : 25SB0117

Reported Date: 21.03.2025

	Prepared By	Checked By	Approved By
Name	Ranjit	Amil Kumar Singh	Amind Poojara
Designation	Asst. Executive	Sr. Executive	Manager
Sign & Date	 21.03.2025	 21.03.2025	 21.03.2025