

**CERTIFICATE OF ANALYSIS**

Product	: Atorvaheal 10mg (Atorvastatin tablets IP 10 mg)	Analytical Report No.	: FFPOSD0093-25
Batch/Lot No.	: DJSIA502	Mfg. Date	: 01/25
Ref. Specification No.	: ISL/SPC/FPR/749-01	Exp. Date	: 12/26
Batch Size	: 10.0 Lac Tablets	Sampled Quantity	: 100 Tablets
Date of Analysis	: 07.02.2025	Date of Completion	: 20.02.2025

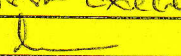


Sr.No.	Parameters	Limits	Results
1	Description	White coloured, round shaped, biconvex film coated tablets with both sides plain.	White coloured, round shaped, biconvex film coated tablets with both sides plain.
2	Diameter	8.0 ± 0.2 mm	8.16mm
3	Thickness	2.96 ± 0.2 mm	2.96mm
4	Average weight	153 ± 11 mg	154.39mg
5	Uniformity of weight	± 7.5% of the average weight of the tablet	-2.26% to + 1.17 %
6	Disintegration time	Not more than 30 minutes	01 Minutes 58 seconds
7	Identification (by HPLC )	Retention time of the principal peak of test corresponds to that of Atorvastatin calcium W.S.	Complies
8	Uniformity of Content (by HPLC )	85 – 115 % of the label claim	Avg. 98.37 % Min. 95.82% Max. 101.27%
9	Dissolution test	Q. Not less than 70 %	Avg. 84.8 % Min. 83.6% Max. 86.2%
10	Related substances	Any individual impurity	Not more than 1.0% 0.05%
		Total impurity	Not more than 4.0% 0.10%
11	Assay: Each film coated tablet contains: Atorvastatin Calcium IP equivalent to Atorvastatin – 10 mg	9.0 – 11.0 mg per tablet of average weight (90 - 110 % of the label claim)	9.87 mg per tablet of average weight. (98.73 % of the label claim)
12	Microbial Purity*		
	Total aerobic count	Not more than 1000 cfu / g	Not Applicable
	Yeast and moulds count	Not more than 100 cfu / g	
	Escherichia coli	Shall be absent/g	

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

Parent B.No. : 25SA0041

Reported Date: 20.02.2025

Remarks \* : First three batches and then after every 10<sup>th</sup>. batch as per specification. The provided batch number is not 10<sup>th</sup> batch. So microbial analysis has not been performed for it.

	Prepared By	Checked By	Approved By
Name	Sandeep Kumar	Amil Kumar Naag	Amind Pagotra
Designation	Area Executive	Sr. Executive	Manager
Sign & Date	 20.02.2025	 20.02.2025	 20.02.2025