

CERTIFICATE OF ANALYSIS

Product	: Atorvaheal 10 (Atorvastatin tablets IP 10 mg)	Analytical Report No.	: FFPOSD0201-25
Batch/Lot No.	: DJSIC503	Mfg. Date	: 03/25
Ref. Specification No.	: ISL/SPC/FPR/749-01	Exp. Date	: 02/27
Batch Size	: 10.0 Lac Tablets	Sampled Quantity	: 100 Tablets
Date of Analysis	: 17.03.2025	Date of Completion	: 20.03.2025

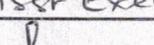
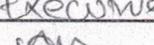
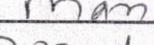
Sr.No.	Parameters	Limits	Results	
1	Description	White coloured, round shaped, biconvex film coated tablets with both sides plain.	White coloured, round shaped, biconvex film coated tablets with both sides plain.	
2	Diameter	8.0 ± 0.2 mm	8.13mm	
3	Thickness	2.96 ± 0.2 mm	3.06mm	
4	Average weight	153 ± 11 mg	153.10mg	
5	Uniformity of weight	± 7.5% of the average weight of the tablet	-2.09% to + 1.96 %	
6	Disintegration time	Not more than 30 minutes	03 Minutes 18 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. 92.78 % Min. 91.50% Max. 94.19%	
9	Dissolution test	Q. Not less than 70 %	Avg. 95.1 % Min. 94.3% Max. 95.6%	
10	Related substances	Any individual impurity	Not more than 1.0%	0.82%
		Total impurity	Not more than 4.0%	1.18%
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)	9.703 mg per tablet of average weight. (97.03 % 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. : 25SC0152

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

Reported Date: 20.03.2025

	Prepared By	Checked By	Approved By
Name	Sanjeer Kumar	Amit Kumar Nag	Amit Pagora
Designation	Asst Executive	Sr. Executive	Manager
Sign & Date	 20.03.2025	 20.03.2025	 20.03.2025