

CERTIFICATE OF ANALYSIS

Product

Batch/Lot No.

Ref. Specification No.

Batch Size

Date of Analysis

: Atovaheal 10 (Atorvastatin tablets IP
10 mg)
: DJSIA501
: ISL/SPC/FPR/749-01
: 10.0 Lac Tablets
: 07.02.2025

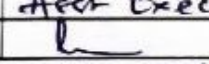
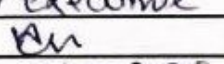
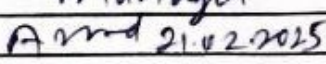
Analytical Report No. : FFPOSD0091-25
Mfg. Date : 01/25
Exp. Date : 12/26
Sampled Quantity : 230 Tablets
Date of Completion : 21.02.2025

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	8.01mm
3	Thickness		2.96 ± 0.2 mm	2.92mm
4	Average weight		153 ± 11 mg	154.44mg
5	Uniformity of weight		± 7.5% of the average weight of the tablet	-2.55% to + 2.57 %
6	Disintegration time		Not more than 30 minutes	01 Minutes 29 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. 93.52 % Min. 87.07% Max. 100.94%
9	Dissolution test		Q. Not less than 70 %	Avg. 86.0 % Min. 83.7% Max. 93.5%
10	Related substances	Any individual impurity	Not more than 1.0%	0.36%
		Total impurity	Not more than 4.0%	0.46%
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)	9.96 mg per tablet of average weight. (99.59 % of the label claim)
12	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. : 25SA0040

Reported Date: 21.02.2025

	Prepared By	Checked By	Approved By
Name	Sanjeer Kumar	Amil Kumar Nag	Arvind Pagotra
Designation	Asst Executive	Sr Executive	Manager
Sign & Date	 21.02.2025	 21.02.2025	 Arvind 21.02.2025