



IND-SWIFT LABORATORIES LTD.

SAMBA (J&K)

QUALITY CONTROL DEPARTMENT

RESTRICTED CIRCULATION

CERTIFICATE OF ANALYSIS

Product	Atorvaheal 10 (Atorvastatin tablets IP 10 mg)	Analytical Report No.	FFPOSD1017-25
Batch/Lot No.	DJSIK504	Mfg. Date	11/25
Ref. Specification No.	ISL/SPC/FPR/749-01	Expiry Date	10/27
Batch size	10.0 Lac Tablets	Sampled Quantity	100 Tablets
Date of Analysis	03/12/25	Date of Completion	04/12/25

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	8.05mm	
3	Thickness	2.96 ± 0.2 mm	2.95mm	
4	Average weight	153 ± 11 mg	151.53mg	
5	Uniformity of weight	± 7.5% of the average weight of the tablet	-1.80% to + 2.36 %	
6	Disintegration time	Not more than 30 minutes	03 Minutes 25 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. 98.62% Min. 96.54% Max. 100.05%	
9	Dissolution test	Q. Not less than 70 %	Avg. 91.9 % Min. 87.6% Max. 102.0%	
10	Related substances	Any individual impurity	Not more than 1.0%	0.25%
		Total impurity	Not more than 4.0%	0.48%
11	Assay: Each film coated tablet contains: Atorvastatin Calcium IP equivalent to Atorvastatin – 10mg	9.0 – 11.0 mg per tablet of average weight (90 - 110 % of the label claim)	9.95 mg per tablet of average weight. (99.46 % of the label claim)	
12	Microbial Purity*		Not Applicable	
	Total aerobic count	Not more than 1000 cfu / g		
	Yeast and moulds count	Not more than 100 cfu / g		
	Escherichia coli	Shall be absent/g		



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

Parent B.No. 25SK0942

Reported Date: 04/12/25

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.

	Prepared By Officer/Executive	Checked By Executive/Sr. Executive	Approved By Head QC
Sign			
Date	04/12/25	04/12/25	04/12/25
Name	Ranjeet Kumar	Sameer Kumar	Arvind Dargobari