



CERTIFICATE OF ANALYSIS

Product	: Atorvaheal 40 (Atorvastatin Tablet IP 40mg)	Analytical Report No.	: FFPOSD0723-24
Batch/Lot No.	: KXSIH401	Mfg. Date	: 08/24
Ref. Specification No.	: ISL/SPC/FPR/757-00	Exp. Date	: 07/26
Batch Size	: 2.0 Lac Tablets	Sampled Quantity	: 100 Tablets
Date of Analysis	: 20.10.2024	Date of Completion	: 22.10.2024

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	4.10 mm
4	Average weight	255 mg ± 18mg	251.47mg
5	Uniformity of weight	± 5.0% of the average weight of the tablet	-1.54 % to + 1.84 %
6	Disintegration Time	Not more than 30 minutes	06 minutes 13Seconds
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. 82.6 % Min. 80.4 % Max.85.0 %
9	Related Substances		
	Any individual impurity	Not more than 1.0%	0.03%
	Total impurity	Not more than 4.0%	0.03%
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)	41.28 mg per tablet of average mass. (103.19 % of the label claim)
11	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. : 24SH0594

Reported Date: 22.10.2024

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	Checked By	Approved By
Name	Ranjit	Sangeer Kumar	Amit Kumar Nay
Designation	Sr. Officer	Sr. Officer	Executive
Sign & Date			

22/10/2024

22/10/2024

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