



**CERTIFICATE OF ANALYSIS**

Product : Atorvaheal 20 (Atorvastatin Tablet IP) Analytical Report No. : FFPOSD0708-24  
 Batch/Lot No. : KISIG401 Mfg. Date : 07/24  
 Ref. Specification No. : ISL/SPC/FPR/748-00 Exp. Date : 06/26  
 Batch Size : 5.0 Lac. Tablets Sampled Quantity : 100 Tablets  
 Date of Analysis : 11.10.2024 Date of Completion : 14.10.2024

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	8.14 mm
3	Thickness	4.1 ± 0.2 mm	4.10 mm
4	Average weight	255 mg ± 18mg	255.54 mg
5	Uniformity of weight	± 5.0% of the average weight of the tablet	-2.29 % to + 2.41 %
6	Disintegration Time	Not more than 30 minutes	01 minutes 28 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)	85.0%-115.0%	Avg. 101.25 % Min. 96.25 % Max.112.53 %
9	Dissolution test	D.Not less than 70 %	Avg. 88.2 % Min. 85.3 % Max. 91.3 %
10	Related Substances		
	Any individual impurity	Not more than 1.0%	Not Detected
	Total impurity	Not more than 4.0%	Not Detected
11	Assay: Each film coated tablet contains: Atorvastatin calcium IP equivalent to Atorvastatin – 20 mg	18.0mg – 22.0mg per tablet of average weight (90 to 110% of label claim)	20.80 mg per tablet of average mass. (104.00 % 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. : 24SG0540

Reported Date: 14.10.2024

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	Rajiv Kumar	Sandeep Kumar	Amit Kumar Naag
Designation	Sr. officer	Sr officer	Executive
Sign & Date	14.10.2024	14.10.2024	14.10.2024