WINDLAS BIOTECH LIMITED

40/1 Mohabewala Industrial Area Dehradun-248110 (Uttarakhand)
Approved by: FDA Uttarakhand, GLP certified Lab
FORM 39 [See rule 150E(f)]
Report of Analysis by Approved Institution ***Lic. No.: 1/UA/CTL*/2024***

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	ATORVAHEAL 10 TABLET (SALE)		
Generic Name/ Dosage Form Strength (mg)	Atorvastatin Tablets IP 10 mg		
Batch No.	AVU26007	**Booking ID/A.R. No.**	QC/FG/26/13505
Batch Size	200000 STRIP	**Pack Size**	40 X 10 TABLET
Mfg. Date	09/2026	**Exp. Date**	08/2028
Reference	I.P	**Sample Qty.**	1x80 TABLET
Sample Received on	26/09/2026	**Manufacturer Lic. No**	34/UA/2013,55/UA/SC/P-2013
Protocol/STP No.	WBL/STP/FG/0418	**Ref. SPS No.**	WBL/FPS/FG/8473.
Date of Analysis started on	28/09/2026	**Date of Analysis completed on**	29/09/2026
Sample Send by and Address	WINDLAS BIOTECH LIMITED (PLANT-2) ,Khasra No. 141 to 143 & 145, Mohabewala Industrial Area, Dehradun-248110 UK		
Manufactured By	WINDLAS BIOTECH LIMITED (PLANT-2)	**Page No.**	01 of 04

S.No.	Test	Specification	Result
1	Description	White to off white coloured, round, biconvex, film coated tablets, plain on both sides.	White coloured, round, biconvex, film coated tablets, plain on both sides.
2	Identification	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3	Disintegration Time	Not more than 30 minutes	03 Min 41 Sec
4	Average weight	93.10 to 102.90 mg	98.91 mg
5	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 10%. No tablet deviates from the average weight by more than 15%.	-4.01% to +11.73%

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By- Person-in-charge
Name	MOHIT KUMAR	Ravindra Singh	Jatin Kumar	Jogendra Singh
Designation	Assistant Officer	Assistant Manager	Executive	G. M.
Date	29/09/2026	30/09/2026	30/09/2026	30/09/2026

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S.No.	Test	Specification	Result
6	Dissolution	Not less than 80% (Q) of labeled amount in 30 minutes Stage: S1 Number tested: 6 Each unit is not less than Q+5 percent of the labelled content. Stage: S2 Number tested: 6 Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15 percent of the labelled content. Stage: S3 Number tested: 12 Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2 units are less than Q-15 percent of the labelled content and no unit is less than Q-25 percent of the labelled content.	Min-96.5%, Max-101.0%, Avg-99.2%
7	Uniformity of Dosage Unit (By Content uniformity)	Acceptance value should be less than 15.	4.49
8	Related substances		

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S.No.	Test	Specification	Result
8a.	Atorvastatin pyrrolidone analog impurity	Not more than 0.5 %	0.025%
8b.	Atorvastatin epoxy pyrrolooxazin 6-hydroxy analog impurity	Not more than 0.5 %	Not Detected
8c.	Atorvastatin Related Compound D impurity	Not more than 0.5 %	Not Detected
8d.	Atorvastatin Related Compound H Impurity	Not more than 1.0 %	Not Detected
8e.	Atorvastatin epoxy pyrrolooxazin 7-hydroxy analog impurity	Not more than 1.0 %	Not Detected
8f.	Atorvastatin epoxy THF analog impurity	Not more than 1.0 %	0.01%
8g.	Any other secondary impurity	Not more than 0.2 %	0.023%
8h.	Total impurity	Not more than 4.0 %	0.130%
9	Assay Each film coated tablet contains:		
9a.	Atorvastatin Calcium IP eq. to Atorvastatin...10mg	90.0 to 110.0%	101.1%

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S.No.	Test	Specification	Result

Remarks : The results of analysis relate only to the analysis applied.
In the opinion of the undersigned, the sample referred to above is of standard Quality as defined in the Act and the rules made thereunder for the reason given below.

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By- Person-in-charge
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