

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	ROSUFREE 5 TABLETS		
Generic Name/Dosage Form Strength (mg)	Rosuvastatin Tablets IP 5 mg		
Batch No.	WRF5324002	A.R. No.	NA
Batch Size	100000 TABLETS	Pack Size	1 X 10 Tablets
Mfg. Date	03/2024	Exp. Date	02/2026
Reference	I.P	Market	Domestic
Sample Received on	10/04/2024	Sample Qty.	1x100 TABLET
Ref. STP No.	WBL/STP/FG/0524 (Current version)	Ref. SPS No.	WBL/FPS/FG/P3/1158
Date of Analysis started on	11/04/2024	Date of Analysis completed on	09/05/2024
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S. No.	Test	Specification	Result
1	Description	Light Pink coloured, round, biconvex, film coated tablets, plain on both sides.	Light Pink 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	Diameter	6.90 mm to 7.30 mm	Min : 7.03 mm Max : 7.11 mm
4	Thickness	2.60 mm to 3.20 mm	Min : 2.73 mm Max : 2.88 mm
5	Disintegration Time	Not more than 30 minutes	08 min 14 sec
6	Average weight	117.80 to 130.20 mg	121.247 mg
7	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 7.5%. No table deviates from the average weight by more than 15%.	Deviation -3.018 % to +3.792%
8	Dissolution	Not less than 70.0% (Q) of the stated amount in 30 minutes	Min : 89.7% Max : 98.5% Avg : 94.4%
9	Uniformity of Dosage Unit (By Content Uniformity)	Acceptance value should be less than 15	12.61
10	Related substances		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-HeadQC/Designee
Name	Santosh Kumar	Shubham Jyoti	Sumit Kumar	Unipendra Pratap Asthana
Designation	Sr. Officer	Officer	Sr. Officer	Manager
Date/Sign	10/05/24	10/05/24	10/05/24	10/05/24

Format No. : QC/CM/013/F/12-01

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S. No.	Test	Specification	Result
10a.	Any secondary peak	Not more than 1.5%	0.011%
10b.	Sum of all secondary peak	Not more than 3.0%	0.015%
11	Assay Each film coated tablet contains:		
11a.	Rosuvastatin Calcium IP eq. to Rosuvastatin.....5mg	90.0 to 110.0%	103.4%

Remarks: In the opinion of undersigned the sample refer to above specifications complies with I.P

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head QC/Designee
Name	Santosh Kumar	Shubham Jyoti	Sumit Kumar	Nipendra Pratap Asthana
Designation	Jr. Officer	Officer	Sr. Officer	Manager
Date/Sign	10/05/24	10/05/24	10/05/24	10/05/24

Format No. : QC/CM/013/F/12-0