

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	ROSUFREE 5 TABLETS (SALE)		
Generic Name/Dosage Form Strength (mg)	Rosuvastatin Tablets IP 5 mg		
Batch No.	WRF5324003	A.R. No.	QC/FG/24/05737
Batch Size	10000 STRIP	Pack Size	1 X 10 TABS
Mfg. Date	06/2024	Exp. Date	05/2026
Reference	I.P	Market	Domestic
Sample Received on	14/06/2024	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	15/06/2024	Date of Analysis completed on	23/06/2024
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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: 7.07 mm Max: 7.15 mm
4	Thickness	2.60 mm to 3.20 mm	Min: 2.83 mm Max: 2.92 mm
5	Disintegration Time	Not more than 30 minutes	05 Min 18 Sec
6	Average weight	117.80 to 130.20 mg	122.481 mg
7	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 7.5%. No tablet deviates from the average weight by more than 15%.	Devation%: - 2.170% to + 1.497%
8	Dissolution	Not less than 70% (Q) of the stated amount in 30 minutes	Min: 106.2% Max: 111.6% Avg: 108.6%
9	Uniformity of Dosage Unit (By Content uniformity)	Acceptance value should be less than 15	AV= 10.21
10	Related substances		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	ARVIND SINGH	Shubham Juyal	sumit kumar	Nripendra Asthana
Designation	Officer	Officer	Officer	Manager
Date	23/06/2024	24/06/2024	24/06/2024	25/06/2024

Printed By: sumit kumar

Date & Time : 02/07/2024 11:23:46

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S.No.	Test	Specification	Result
10a.	Any secondary peak	Not more than 1.5%	Not Detected
10b.	Sum of all secondary peak	Not more than 3.0%	Not Detected
11	Assay Each film coated tablet contains:		
11a.	Rosuvastatin Calcium IP eq. to Rosuvastatin...5mg	90.0 to 110.0%	104.6%

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

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