

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	ROSUFREE 10 TABLETS IP		
Generic Name/Dosage Form Strength (mg)	Rosuvastatin Tablets IP		
Batch No.	WRUF324004	A.R. No.	QC/FG/24/07007
Batch Size	20000 STRIP	Pack Size	1 X 10 TABS
Mfg. Date	07/2024	Exp. Date	06/2026
Reference	I.P	Market	Domestic
Sample Received on	15/07/2024	Sample Qty.	1x100 TABLET
Ref. STP No.	WBL/STP/FG/0048 (Current Version)	Ref. SPS No.	WBL/FPS/FG/P3/1143
Date of Analysis started on	19/07/2024	Date of Analysis completed on	24/07/2024
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S.No.	Test	Specification	Result
1	Description	Faint Orange coloured, round, biconvex, film coated tablet, scored on one side and plain on other side.	Faint Orange coloured, round, biconvex, film coated tablet, scored on one side and plain on other side.
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 : 6.98 mm Max : 7.05 mm
4	Thickness	2.80 mm to 3.20 mm	Min : 2.97 mm Max : 3.04 mm
5	Disintegration Time	Not more than 30 minutes	08 min 32 sec
6	Average weight	128.25 to 141.75 mg	131.858 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%.	Deviation : - 2.456 % to + 2.944 %
8	Dissolution 70% (Q)	Not less than 75.0% of the stated amount in 30 minutes	Min : 97.0 % Max : 99.5 % Avg : 98.0 %
9	Uniformity of Dosage Unit (By Content uniformity)	Acceptance value should be less than 15	1.25

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	DEEPENDRA SINGH	Shubham Juyal	sumit kumar	Nripendra Asthana
Designation	TRAINEE CHEMIST	Officer	Officer	Manager
Date	24/07/2024	26/07/2024	26/07/2024	26/07/2024

Printed By: Sandeep Kumar

Date & Time : 26/07/2024 18:17:51

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S.No.	Test	Specification	Result
10	Related substances		
10a.	Any secondary peak	Not more than 1.5%	0.110 %
10b.	Sum of all secondary peak	Not more than 3.0%	0.244 %
11	Assay Each film coated tablet contains:		
11a.	Rosuvastatin Calcium IP eq. to Rosuvastatin...10mg	90.0 to 110.0%	101.6 %

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

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