

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	ROSUFREE 20 TABLETS		
Generic Name/Dosage Form Strength (mg)	Rosuvastatin Tablets IP		
Batch No.	WRFE324002	A.R. No.	QC/FG/24/03976
Batch Size	20000 STRIP	Pack Size	1 X 10 TABS
Mfg. Date	03/2024	Exp. Date	02/2026
Reference	I.P	Market	Domestic
Sample Received on	30/04/2024	Sample Qty.	1x100 TABLET
Ref. STP No.	WBL/STP/FG/0358 (Current Version)	Ref. SPS No.	WBL/FPS/FG/P3/1151
Date of Analysis started on	30/04/2024	Date of Analysis completed on	02/05/2024
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S.No.	Test	Specification	Result
1	Description	Pink coloured, round, biconvex, film coated tablet, scored on one side and plain on other side.	Pink 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 : 7.05 mm Max : 7.07 mm
4	Thickness	2.80 mm to 3.20 mm	Min : 2.92 mm Max : 3.10 mm
5	Disintegration Time	Not more than 30 minutes	08 min 04 sec
6	Average weight	128.25 to 141.75 mg	133.756 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 : - 3.304 % to + 4.047 %
8	Dissolution 70% (Q)	Not less than 75.0% of the stated amount in 30 minutes	Min : 80.8 % Max : 108.2 % Avg : 101.4 %

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Santoshi Rawat	Shubham Juyal	ANKITA GAUR	Nripendra Asthana
Designation	Sr. Officer	Officer	Sr. Officer	Manager
Date	02/05/2024	08/05/2024	09/05/2024	09/05/2024

Printed By: MAHENDRA KUMAR

Date & Time : 09/05/2024 16:26:50

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S.No.	Test	Specification	Result
9	Uniformity of dosage units (By Content uniformity) Rosuvastatin Calcium IP eq. to Rosuvastatin	Acceptance value should be less than 15.	7.21
10	Related substances		
10a.	Any secondary peak	Not more than 1.5%	0.034 %
10b.	Sum of all secondary peak	Not more than 3.0%	0.045 %
11	Assay Each film coated tablet contains:		
11a.	Rosuvastatin Calcium IP eq. to Rosuvastatin...20mg	90.0 to 110.0% of labeled amount	99.5 %

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
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