

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	ROSUFREE 40 TABLETS (SALE)		
Generic Name/Dosage Form Strength (mg)	Rosuvastatin Tablets IP 40 mg		
Batch No.	WUFR324001	A.R. No.	QC/FG/24/05303
Batch Size	10000	Pack Size	1 X 10 TABS
Mfg. Date	05/2024	Exp. Date	04/2026
Reference	I.P	Market	Domestic
Sample Received on	31/05/2024	Sample Qty.	1x100 TABLET
Ref. STP No.	WBL/STP/FG/P3/0027(Current Version)	Ref. SPS No.	WBL/FPS/FG/P3/1411
Date of Analysis started on	06/06/2024	Date of Analysis completed on	10/06/2024
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S.No.	Test	Specification	Result
1	Description	Yellow Coloured, round, biconvex, coated tablets, plain on both sides.	Yellow Coloured, round, biconvex, 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	9.40 mm to 9.80 mm	Min : 9.56 mm Max : 9.63 mm
4	Thickness	3.50 mm to 3.90 mm	Min : 3.67 mm Max : 3.74 mm
5	Disintegration Time	Not more than 30 minutes	02 min 11 sec
6	Average weight	257.05 to 272.95 mg	261.848 mg
7	Uniformity of weight	Not more than 2 tablets in 20 deviate from the average weight by more than 5.0%. No tablet deviates from the average weight by more than 10%.	Deviation : - 1.536 % to +1.418 %
8	Dissolution 70% (Q)	Not less than 75.0 % of labeled amount in 30 minutes	Min : 86.1 % Max : 91.6 % Avg : 89.3 %
9	Uniformity of Dosage Unit (By Content uniformity)	Acceptance value should be less than 15	2.36
10	Related substances		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	DEEPENDRA SINGH	Shubham Juyal	Amitesh Singh	Nripendra Asthana
Designation	TRAINEE CHEMIST	Officer	Chemist-QA	Manager
Date	10/06/2024	18/06/2024	18/06/2024	19/06/2024

Printed By: MAHENDRA KUMAR

Date & Time : 22/06/2024 15:40:00

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S.No.	Test	Specification	Result
10a.	Single Highest Impurity	Not more than 1.5 %	0.311 %
10b.	Total Impurities	Not more than 3.0 %	1.123 %
11	Assay Each film coated tablet contains:		
11a.	Rosuvastatin Calcium IP eq. to Rosuvastatin...40 mg	90.0 to 110.0%	102.5 %

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

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