

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	ROSUFREE F 20 TABLETS (SALE)		
Generic Name/Dosage Form Strength (mg)	Rosuvastatin 20 mg and Fenofibrate 160 mg Tablets IP		
Batch No.	RTY24004	A.R. No.	QC/FG/24/08964
Batch Size	20000 STRIP	Pack Size	1 X 10 TABLET
Mfg. Date	08/2024	Exp. Date	07/2026
Reference	I.P	Market	Domestic
Sample Received on	01/09/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/1148	Ref. SPS No.	WBL/FPS/FG/6006
Date of Analysis started on	03/09/2024	Date of Analysis completed on	09/09/2024
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S.No.	Test	Specification	Result
1	Description	White to off white coloured, round, biconvex, film coated tablets, plain on both sides.	White 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 standard solution.	Complies
3	Disintegration Time	Not more than 30 minutes	02 Min 28 Sec
4	Average weight	417.10 to 442.90 mg	425.04 mg
5	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 5%. No tablet deviate from the average weight by more than 10%.	-1.25% to +1.51%
6	Dissolution		
6a.	Rosuvastatin Calcium IP eq. to Rosuvastatin	Not less than 70% (Q) of the stated amount in 60 minutes	Min-105.3% Max-108.9% Avg- 107.2%
6b.	Fenofibrate (Micronised) IP	Not less than 70% (Q) of the stated amount in 60 minutes	Min-94.4% Max-97.5% Avg-95.8%
7	Uniformity of Dosage Units		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Ayushi Sharma	Deepu	Manoj Gautam	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager	Assistant Manager	G. M.
Date	09/09/2024	09/09/2024	10/09/2024	10/09/2024

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S.No.	Test	Specification	Result
7a.	(By Content Uniformity) Rosuvastatin Calcium IP eq. to Rosuvastatin	Acceptance value should be less than 15	6.80
7b.	(By Weight Variation) Fenofibrate (Micronised) IP	Acceptance value should be less than 15	3.60
8	Related substances		
8a.	Any secondary peak	Not more than 1.0%	0.036%
8b.	Sum of all secondary peak	Not more than 2.0%	0.036%
9	Assay Each film coated tablet contains:		
9a.	Rosuvastatin Calcium IP eq. to Rosuvastatin...20mg	90.0 to 110.0%	104.2%
9b.	Fenofibrate (Micronised) IP...160mg	90.0 to 110.0%	102.7%

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	Ayushi Sharma	Deepu	Manoj Gautam	Jogendra Singh
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