

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.	RTY24002	A.R. No.	QC/FG/24/04152
Batch Size	10000 STRIP	Pack Size	01 X 10 TABLET
Mfg. Date	04/2024	Exp. Date	03/2026
Reference	I.P	Market	Domestic
Sample Received on	04/05/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/1148	Ref. SPS No.	WBL/FPS/FG/6006
Date of Analysis started on	04/05/2024	Date of Analysis completed on	13/05/2024
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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	05 Min 08 Sec
4	Average weight	417.10 to 442.90 mg	433.02 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%.	-2.56% to +1.81%
6	Dissolution		
6a.	Rosuvastatin Calcium IP eq. to Rosuvastatin	Not less than 70% (Q) of the stated amount in 60 minutes	Min-98.0% Max-102.4% Avg-100.9%
6b.	Fenofibrate (Micronised) IP	Not less than 70% (Q) of the stated amount in 60 minutes	Min-95.5% Max-99.9% Avg-98.3%
7	Uniformity of Dosage Units		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Akshit Gaur	Rakesh Kumar	Manoj Gautam	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Sr. Executive	G. M.
Date	13/05/2024	15/05/2024	17/05/2024	17/05/2024

Printed By: Subodh Kumar

Date & Time : 06/08/2024 09:42:00

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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	10.08
7b.	(By Weight Variation) Fenofibrate (Micronised) IP	Acceptance value should be less than 15	4.80
8	Related substances		
8a.	Any secondary peak	Not more than 1.0%	Not Detected
8b.	Sum of all secondary peak	Not more than 2.0%	Not Detected
9	Assay Each film coated tablet contains:		
9a.	Rosuvastatin Calcium IP eq. to Rosuvastatin...20mg	90.0 to 110.0%	103.5%
9b.	Fenofibrate (Micronised) IP...160mg	90.0 to 110.0%	104.4%

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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