

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	ROSUFREE-F 10 TABLETS		
Generic Name/Dosage Form Strength (mg)	Rosuvastatin 10 mg and Fenofibrate 160 mg Tablets IP		
Batch No.	RFW24003	A.R. No.	QC/FG/24/07478
Batch Size	20000 STRIP	Pack Size	01 X 10 TABLET
Mfg. Date	07/2024	Exp. Date	06/2026
Reference	I.P	Market	Domestic
Sample Received on	26/07/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/0182	Ref. SPS No.	WBL/FPS/FG/5828
Date of Analysis started on	06/08/2024	Date of Analysis completed on	06/08/2024
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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 11 Sec
4	Average weight	378.30 to 401.70 mg	388.45 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%.	-2.52% to +2.89%
6	Dissolution		
6a.	Rosuvastatin Calcium IP eq. to Rosuvastatin	Not less than 70% (Q) of the stated amount in 60 minutes	Min-97.7% Max-105.0% Avg-100.0%
6b.	Fenofibrate (Micronised) IP	Not less than 70% (Q) of the stated amount in 60 minutes	Min-88.6% Max-95.1% Avg-90.7%
7	Uniformity of Dosage Units		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Ayushi Sharma	Pradeep Mishra	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Assistant Manager-QA	G. M.
Date	06/08/2024	07/08/2024	07/08/2024	08/08/2024

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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	3.39
7b.	(By Weight Variation) Fenofibrate (Micronised) IP	Acceptance value should be less than 15	4.49
8	Related substances		
8a.	Any secondary peak	Not more than 1.0%	0.024%
8b.	Sum of all secondary peak	Not more than 2.0%	0.085%
9	Assay Each film coated tablet contains:		
9a.	Rosuvastatin Calcium IP eq. to Rosuvastatin...10mg	90.0 to 110.0%	99.3%
9b.	Fenofibrate (Micronised) IP...160mg	90.0 to 110.0%	100.7%

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
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