

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	ROSUFREE-F 5 TABLETS (SALE)		
Generic Name/Dosage Form Strength (mg)	Rosuvastatin 5 mg & Fenofibrate 160 mg Tablets IP		
Batch No.	RFF24004	A.R. No.	QC/FG/24/08935
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/1138	Ref. SPS No.	WBL/FPS/FG/5935
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 reference solution (c).	Complies
3	Disintegration Time	Not more than 30 minutes	02 Min 41 Sec
4	Average weight	397.70 to 422.30 mg	406.41 mg
5	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 5.0%. No tablet deviates from the average weight by more than 10.0%.	-2.44% to +2.00%
6	Dissolution		

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

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S.No.	Test	Specification	Result
6a.	Rosuvastatin Calcium IP eq. to Rosuvastatin	Not less than 70% (Q) of labeled amount in 60 minutes Stage: S1 Number tested: 6 Each unit is not less than Q+5 percent of the labelled content. Stage: S2 Number tested: 6 Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15 percent of the labelled content. Stage: S3 Number tested: 12 Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2 units are less than Q-15 percent of the labelled content and no unit is less than Q-25 percent of the labelled content.	Min-103.7% Max-106.2% Avg-104.7%

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S.No.	Test	Specification	Result
6b.	Fenofibrate IP	Not less than 70% (Q) of labeled amount in 60 minutes Stage: S1 Number tested: 6 Each unit is not less than Q+5 percent of the labelled content. Stage: S2 Number tested: 6 Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15 percent of the labelled content. Stage: S3 Number tested: 12 Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2 units are less than Q-15 percent of the labelled content and no unit is less than Q-25 percent of the labelled content.	Min-89.8% Max-97.6% Avg-93.4%
7	Uniformity of Dosage Units		
7a.	(By Content Uniformity) Rosuvastatin Calcium IP eq. to Rosuvastatin	Acceptance value should be less than 15	5.60
7b.	(By Weight Variation) Fenofibrate IP	Acceptance value should be less than 15	3.20

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S.No.	Test	Specification	Result
8	Related substances		
8a.	Any other secondary impurity	Not more than 1.0%	0.109%
8b.	Sum of all the secondary impurities	Not more than 2.0%	0.109%
9	Assay Each film coated tablet contains:		
9a.	Rosuvastatin Calcium IP eq. to Rosuvastatin...5mg	90.0 to 110.0% of labeled amount	104.6%
9b.	Fenofibrate (Micronised) IP...160mg	90.0 to 110.0% of labeled amount	99.1%

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

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