

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.	RFF24001	A.R. No.	QC/FG/24/03024
Batch Size	100000 TABLET	Pack Size	10 X 10 TABLET
Mfg. Date	03/2024	Exp. Date	02/2026
Reference	I.P	Market	Domestic
Sample Received on	24/03/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/1138	Ref. SPS No.	WBL/FPS/FG/5935
Date of Analysis started on	30/03/2024	Date of Analysis completed on	03/04/2024
Page No.	01 of 04		

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	06 Min 31 Sec
4	Average weight	397.70 to 422.30 mg	405.75 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%.	-2.36% to +4.63%
6	Dissolution		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Vandana Benwal	Ravi Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Assistant Manager-QA	G. M.
Date	03/04/2024	04/04/2024	04/04/2024	04/04/2024

Printed By: Shubham Pal

Date & Time : 10/04/2024 7:43:43 PM

Copy No. 2

This is a electronically signed document, hence does not require any signatures

Format No. : QC/CM/013/F/12-01

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.	RFF24001	A.R. No.	QC/FG/24/03024
Batch Size	100000 TABLET	Pack Size	10 X 10 TABLET
Mfg. Date	03/2024	Exp. Date	02/2026
Reference	I.P	Market	Domestic
Sample Received on	24/03/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/1138	Ref. SPS No.	WBL/FPS/FG/5935
Date of Analysis started on	30/03/2024	Date of Analysis completed on	03/04/2024
Page No.	02 of 04		

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-93.2% Max-97.0% Avg-94.6%

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Vandana Benwal	Ravi Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Assistant Manager-QA	G. M.
Date	03/04/2024	04/04/2024	04/04/2024	04/04/2024

Printed By: Shubham Pal

Date & Time : 10/04/2024 7:43:43 PM

Copy No. 2

This is a electronically signed document, hence does not require any signatures

Format No. : QC/CM/013/F/12-01

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.	RFF24001	A.R. No.	QC/FG/24/03024
Batch Size	100000 TABLET	Pack Size	10 X 10 TABLET
Mfg. Date	03/2024	Exp. Date	02/2026
Reference	I.P	Market	Domestic
Sample Received on	24/03/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/1138	Ref. SPS No.	WBL/FPS/FG/5935
Date of Analysis started on	30/03/2024	Date of Analysis completed on	03/04/2024
Page No.	03 of 04		

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-94.7% Max-98.7% Avg-96.3%
7	Uniformity of Dosage Units		
7a.	(By Content Uniformity) Rosuvastatin Calcium IP eq. to Rosuvastatin	Acceptance value should be less than 15	13.25
7b.	(By Weight Variation) Fenofibrate IP	Acceptance value should be less than 15	5.50

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Vandana Benwal	Ravi Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Assistant Manager-QA	G. M.
Date	03/04/2024	04/04/2024	04/04/2024	04/04/2024

Printed By: Shubham Pal

Date & Time : 10/04/2024 7:43:43 PM

Copy No. 2

This is a electronically signed document, hence does not require any signatures

Format No. : QC/CM/013/F/12-01

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.	RFF24001	A.R. No.	QC/FG/24/03024
Batch Size	100000 TABLET	Pack Size	10 X 10 TABLET
Mfg. Date	03/2024	Exp. Date	02/2026
Reference	I.P	Market	Domestic
Sample Received on	24/03/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/1138	Ref. SPS No.	WBL/FPS/FG/5935
Date of Analysis started on	30/03/2024	Date of Analysis completed on	03/04/2024
Page No.	04 of 04		

S.No.	Test	Specification	Result
8	Related substances		
8a.	Any other secondary impurity	Not more than 1.0%	Not Detected
8b.	Sum of all the secondary impurities	Not more than 2.0%	Not Detected
9	Assay Each film coated tablet contains:		
9a.	Rosuvastatin Calcium IP eq. to Rosuvastatin...5mg	90.0 to 110.0% of labeled amount	97.0%
9b.	Fenofibrate (Micronised) IP...160mg	90.0 to 110.0% of labeled amount	98.5%

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	Vandana Benwal	Ravi Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Assistant Manager-QA	G. M.
Date	03/04/2024	04/04/2024	04/04/2024	04/04/2024

Printed By: Shubham Pal

Date & Time : 10/04/2024 7:43:43 PM

Copy No. 2

This is a electronically signed document, hence does not require any signatures

Format No. : QC/CM/013/F/12-01