

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	TICASMART 90 MG TABLETS		
Generic Name/Dosage Form Strength (mg)	Ticagrelor Tablets IP 90 mg		
Batch No.	TIC24002	A.R. No.	QC/FG/24/04778
Batch Size	20000 STRIP	Pack Size	01 X 10 TABLET
Mfg. Date	05/2024	Exp. Date	04/2026
Reference	I.P	Market	Domestic
Sample Received on	19/05/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/0342	Ref. SPS No.	WBL/FPS/FG/5655
Date of Analysis started on	22/05/2024	Date of Analysis completed on	28/05/2024
Page No.	01 of 03		

S.No.	Test	Specification	Result
1	Description	Light yellow coloured, round, biconvex, beveled edge, film coated tablets, plain on both sides.	Light yellow coloured, round, biconvex, beveled edge, 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 peak in the chromatogram obtained with the reference solution.	Complies
3	Disintegration Time	Not more than 30 minutes	02 Min 20 Sec.
4	Average weight	261.25 to 288.75 mg	276.87 mg
5	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 5.0%. No tablet deviate from the average weight by more than 10.0%.	deviation -4.35 to +2.77%

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Akshit Gaur	Rakesh Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Assistant Manager-QA	G. M.
Date	28/05/2024	28/05/2024	28/05/2024	29/05/2024

Printed By: Subodh Kumar

Date & Time : 23/08/2024 15:53:14

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	TICASMART 90 MG TABLETS		
Generic Name/Dosage Form Strength (mg)	Ticagrelor Tablets IP 90 mg		
Batch No.	TIC24002	A.R. No.	QC/FG/24/04778
Batch Size	20000 STRIP	Pack Size	01 X 10 TABLET
Mfg. Date	05/2024	Exp. Date	04/2026
Reference	I.P	Market	Domestic
Sample Received on	19/05/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/0342	Ref. SPS No.	WBL/FPS/FG/5655
Date of Analysis started on	22/05/2024	Date of Analysis completed on	28/05/2024
Page No.	02 of 03		

S.No.	Test	Specification	Result
6	Dissolution	Not less than 70% (Q) of the stated amount in 45 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-86.1% Max-91.4% Avg-89.2%
7	Uniformity of Dosage Unit (By Weight Variation)	Acceptance value should be less than 15	3.40
8	Related substances		
8a.	Any secondary impurity	Not more than 0.2%	Below Disregard Limit
8b.	Sum of all secondary impurities	Not more than 0.5%	Below Disregard Limit

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Akshit Gaur	Rakesh Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Assistant Manager-QA	G. M.
Date	28/05/2024	28/05/2024	28/05/2024	29/05/2024

Printed By: Subodh Kumar

Date & Time : 23/08/2024 15:53:14

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	TICASMART 90 MG TABLETS		
Generic Name/Dosage Form Strength (mg)	Ticagrelor Tablets IP 90 mg		
Batch No.	TIC24002	A.R. No.	QC/FG/24/04778
Batch Size	20000 STRIP	Pack Size	01 X 10 TABLET
Mfg. Date	05/2024	Exp. Date	04/2026
Reference	I.P	Market	Domestic
Sample Received on	19/05/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/0342	Ref. SPS No.	WBL/FPS/FG/5655
Date of Analysis started on	22/05/2024	Date of Analysis completed on	28/05/2024
Page No.	03 of 03		

S.No.	Test	Specification	Result
9	Assay Each film coated tablet contains:		
9a.	Ticagrelor IP...90mg	95.0 to 105.0% of labeled amount	99.9%

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	Akshit Gaur	Rakesh Kumar	Lakshay	Jogendra Singh
Designation	TRAINEE CHEMIST	Sr. Executive	Assistant Manager-QA	G. M.
Date	28/05/2024	28/05/2024	28/05/2024	29/05/2024

Printed By: Subodh Kumar

Date & Time : 23/08/2024 15:53:14

Copy No. 2

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

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