

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	AZEETOP-500 TABLETS		
Generic Name/Dosage Form Strength (mg)	Azithromycin Tablets IP 500 mg		
Batch No.	AZY24003	A.R. No.	QC/FG/24/05286
Batch Size	100000 STRIP	Pack Size	01 X 05 TABLET
Mfg. Date	May., 2024	Exp. Date	Apr., 2026
Reference	I.P.	Market	Domestic
Sample Received on	04/06/2024	Sample Qty.	1x75 TABLET
Ref. STP No.	WBL/STP/FG/0579	Ref. SPS No.	WBL/FPS/FG/5819
Date of Analysis started on	06/06/2024	Date of Analysis completed on	12/06/2024
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S.No.	Test	Specification	Result
1	Description	White to off white coloured, elongated, biconvex, film coated tablets, scored on one side & plain on other side.	White coloured, elongated, biconvex, film coated tablets, scored on one side & plain on other side.
2	Identification	In the assay, the retention time of the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3	Disintegration Time	Not more than 30 minutes	07 Min 05 Sec
4	Average weight	843.90 to 896.10 mg	863.27 mg
5	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 5%. No tablets deviates from the average weight by more than 10%.	-2.40% to +3.52%
6	Dissolution	Not less than 75.0% (Q) of the stated amount in 45 minutes	Min-95.4% Max-102.2% Avg-97.4%
7	Uniformity of Dosage Unit (By Weight Variation)	Acceptance value should be less than 15	4.90
8	Related substances		
8a.	Azithromycin impurity B	Not more than 2.0%	Not Detected
8b.	Sum of all secondary peak	Not more than 3.0%	Below Disregard Limit

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By-Head-QC/Designee
Name	Ayushi Sharma	Deepu	Nidhi Rani	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager	Sr. Officer	G. M.
Date	12/06/2024	12/06/2024	12/06/2024	12/06/2024

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S.No.	Test	Specification	Result
9	Assay Each film coated tablet contains:		
9a.	Azithromycin Dihydrate IP eq. to Azithromycin (Anhydrous)...500mg	90.0 to 110.0%	97.5%

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	Ayushi Sharma	Deepu	Nidhi Rani	Jogendra Singh
Designation	TRAINEE CHEMIST	Assistant Manager	Sr. Officer	G. M.
Date	12/06/2024	12/06/2024	12/06/2024	12/06/2024

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