

WINDLAS BIOTECH LIMITED

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	PANTODICE-40 TABLETS		
Generic Name/Dosage Form Strength (mg)	Pantoprazole Gastro-Resistant Tablets IP 40 mg		
Batch No.	PND24002	A.R. No.	QC/FG/24/09939
Batch Size	66667 STRIP	Pack Size	20 X 15 TABLET
Mfg. Date	08/2024	Exp. Date	07/2026
Reference	I.P	Market	Domestic
Sample Received on	23/09/2024	Sample Qty.	1x90 TABLET
Ref. STP No.	WBL/STP/FG/0205	Ref. SPS No.	WBL/FPS/FG/5888
Date of Analysis started on	28/09/2024	Date of Analysis completed on	30/09/2024
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S.No.	Test	Specification	Result
1	Description	Yellow coloured, round, biconvex, enteric coated tablets, plain on both sides.	Yellow coloured, round, biconvex, enteric coated tablets, plain on both sides.
2	Identification		
2a.	By HPLC	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with the reference solution.	Complies
2b.	By UV	When examined in the range 230 nm to 350 nm, a 0.001 % w/v solution in methanol shows absorption maxima at about 289 nm.	Complies
3	Disintegration Time		
3a.	In 0.1M Hydrochloric Acid	Tablet should not disintegrate for 2 hrs. in 0.1 M Hydrochloric acid.	Complies
3b.	In phosphate buffer pH 6.8	Not more than 60 minutes in Phosphate buffer pH 6.8	18 Min 25 Sec
4	Average weight	121.25 to 128.75 mg	124.25 mg
5	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 7.5%. No tablet deviates from the average weight by more than 15%.	-1.67% to +2.33%

	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	30/09/2024	30/09/2024	30/09/2024	30/09/2024

Printed By: Subodh Kumar

Date & Time : 30/09/2024 12:48:45

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S.No.	Test	Specification	Result
6	Dissolution		
6a.	In 0.1M Hydrochloric acid	Not more than 10.0% of labeled amount in 120 minutes	Min-0.0% Max-0.0% Avg-0.0%
6b.	In phosphate buffer pH 6.8.	Not less than 75% (Q) of the stated amount in 45 minutes	Min-85.1% Max-104.3% Avg-91.4%
7	Related Substances (By HPLC)		
7a.	Pantoprazole related compound A	Not more than 0.5%	0.062%
7b.	Pantoprazole Related Compound D and F	Not more than 0.5%	Not Detected
7c.	Pantoprazole related compound B	Not more than 0.3%	Not Detected
7d.	Any other secondary impurity	Not more than 0.2%	Not Detected
7e.	Sum of all secondary impurities	Not more than 1.0%	0.062%
8	Assay Each enteric coated tablet contains:		
8a.	Pantoprazole Sodium IP eq. to Pantoprazole...40mg	90.0 to 110.0%	101.4%

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

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