



LUCENT BIOTECH LIMITED (UNIT-II)
Works: 165/3, Nalhera, Anantpur, Puhana, Roorkee Distt. Haridwar (Uttarakhand)

Regd. Office: 10/4, Havclock Road, Lucknow-226001 (Uttar Pradesh)

DEPARTMENT		QUALITY CONTROL		
TITLE		CERTIFICATE OF ANALYSIS		
Product Name	PROZCAN 40 TABLETS	A.R. No.	F-0535/25-26	
Generic Name	Pantoprazole Sodium Gastro- resistant Tablets IP	Batch Size	5.0 Lacs	
Batch No.	5H09	Mfg. Date	06/2025	
Mfg. By	Lucent Biotech Ltd. (Unit-II)	Exp. Date	05/2027	
Marketed By	AMERICAN REMEDIES HEALTHCARE PVT.LTD.	Date of Receipt	26/08/2025	
Sample Quantity	60 Tablets	Date of Released	29/08/2025	
Mfg. Licence No.	43/UA/2016 & 45/UA/SC/P-2016	WHO- GMP & GLP Certified Company		
Test Results				
S.No.	Tests	Specification	Obtained	
1	Description	Yellow coloured round shape biconvex plain on both side enteric coated tablets.	Yellow coloured round shape biconvex plain on both side enteric coated tablets.	
2	Identification:	A) By HPLC : In the Assay, the principal peak in. the-chromatogram obtained with the test solution should be correspond to the principal peak inthe chromatogram obtained with the reference solution.	In the Assay, the principal peak in. the-chromatogram obtained with the test solution corresponds to the principal peak inthe chromatogram obtained with the reference solution.	
		B) By UV : When examined in the range 230 nm to 350 nm (2.4.7), a 0.001 per cent w/v solution in methanol shows absorption maxima at about 289 nm.	Complies	
3	Average weight	200.0 mg \pm 7.5 % Between 185.0 mg to 215.0 mg	198.11	mg
4	Uniformity of weight	Average weight \pm 7.5 %		
		Minimum	3.03	%
		Maximum	5.75	%
5	Disintegration Time	In Acid Medium: Tablets should be no change in appearance for 120 minutes.	Complies	
		In Buffer Medium: Not more than 60 minutes	23	minutes 15 seconds
6	Dissolution	In Acid Medium: Not more than 10% of the stated amount.	1.72	%
		In Buffer Medium: Not less than 75% (Q) of the stated amount.	91.67	%
7	Assay : Each Enteric coated Tablets Contains:			
	Pantoprazole Sodium Sesquihydrate IP eq. to Pantoprazole 40mg	Between 36.0 mg to 44.0 mg Limit: 90.0 % to 110.0 % of the Label claim	39.91	mg 102.52 %
Report: In the opinion of the undersigned the sample referred above is of Standard Quality / is not of standard Quality as per IP-Specification.				
	Prepared By	Checked By	Approved By	Approved By
Name	Mr. Ayush Sharma	Mr. Vikanshu	Mr. Ashish Shukla	Mr. R.K. Srivastav
Sign. & Date				
Designation	Officer-QC	Asst. Manager-QC	Head -QC	Head-QA