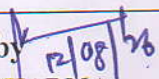
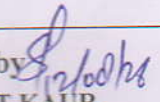
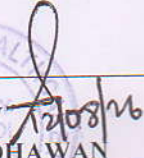


Title : Certificate of Analysis Finished Product

Product Name	PROZCAN Injection	A.R. No.	ARN/FP/26/040
Generic Name	Pantoprazole for Injection IP 40mg	Sampled qty.	45 Vials
Batch No.	ARN2637A	Sampled by	Rakesh
Batch Size	1,00,160Vials	Sampled on	28/07/2026
Mfg. Date	07/2026	Date of Testing	29/07/2026
Exp. Date	06/2028	Date of Conditionally Release	12/08/2026

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear glass vial.	A white dry powder filled in clear glass vial.
2.	Identification (By IR)	A. Compare the spectrum with that obtained with Pantoprazole sodium IPRS or with the reference spectrum of Pantoprazole sodium.	Complies
	(By HPLC)	B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a).	Complies
	(By Chemically)	C. It gives the reactions of sodium salts.	Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-1.66% & +1.93%
4.	Average weight	Informative $\pm 2\%$.	131.1mg
5.	pH	9.0 to 11.5	10.25
6.	Appearance of solution	Solution should be clear and not more intensely colored than reference solution BS ₅ or BYS ₅ .	Complies
7.	Related Substance (By HPLC)		
a.	Impurity A	Not More than 0.5%	Not Detected
b.	Impurities D+F	Not More than 1.5%	0.065%
c.	Any secondary peak	Not More than 0.2%	Not Detected
d.	Sum of all secondary peaks	Not More than 2.0%	0.065%

Analysis by  NAME: NIKHIL SHARMA	Checked by  NAME: SURJEET KAUR	Approved by  NAME: MRS. SWATI DHAWAN
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8.	Particulate Contamination	NMT 6000/vial NMT 600/vial	2,523/vial 11/vial Complies		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visible particles				
9.	Sterility	No microbial growth should be observed.	Under Process		
10.	Bacterial Endotoxins (IHS)	NMT 3.0 EU/mg of Pantoprazole Sodium.	Less than 3.0 EU/mg of Pantoprazole Sodium.		
11.	Assay: (By HPLC) Each glass vial contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Pantoprazole Sodium (Sterile) IP (Lyophilized) Eq. to Anhydrous Pantoprazole		40 mg	41.5197 mg	103.80%	93.0 to 105.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/not complies as per IP/BP/USP/PHS.

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SURJEET KAUR	Approved by NAME: MRS. SWATI DHAWAN
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