AMERICAN REMEDIES
Care & Cure with Research

AMERICAN REMEDIES HEALTHCARE PVT. LTD.
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

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 ±10%	-1.66% & +1.93%
4.	Average weight	Informative ±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	Checked by	Approved by
NAME: NIKHIL SHARMA 12/08/26	NAME: SURJEET KAUR 12/08/26	NAME: MRS. SWATI DHAWAN 12/08/26

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8.	Particulate Contamination		
	(A.) Light Obscuration Particle Count Test (1.) Particles ≥10µm (2.) Particles ≥25µm (B.) Visible particles	 NMT 6000/vial NMT 600/vial The reconstituted solution of injection should be free from any type of visual particles i,e mobile undissolved substances, other than gas bubbles, unintentionally that can be observed on visual inspection.	 2,523/vial 11/vial Complies
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/IHS~~.

Analysis by	Checked by	Approved by
12/08/26		12/08/26
NAME: NIKHIL SHARMA	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN