



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

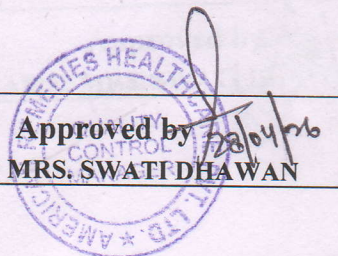
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title : Certificate of Analysis Finished Product

Product Name	PROZCAN Injection	A.R. No.	ARN/FP/26/002
Generic Name	Pantoprazole for Injection IP 40mg	Sampled qty.	45 Vials
Batch No.	ARN25118A	Sampled by	Rakesh
Batch Size	1,00,960Vials	Sampled on	11/04/2026
Mfg. Date	03/2026	Date of Testing	11/04/2026
Exp. Date	02/2028	Date of Release	28/04/2026

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) (By HPLC) (By Chemically)	A. Compare the spectrum with that obtained with Pantoprazole sodium IPRS or with the reference spectrum of Pantoprazole sodium. 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). C. It gives the reactions of sodium salts.	Complies Complies Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-6.42% & +5.80%
4.	Average weight	Informative $\pm 2\%$.	126.1mg
5.	pH	9.0 to 11.5	9.95
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%	0.127%
b.	Impurities D+F	Not More than 1.5%	0.169%
c.	Any secondary peak	Not More than 0.2%	0.152%
d.	Sum of all secondary peaks	Not More than 2.0%	0.448%

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DHAWAN
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8.	Particulate Contamination	NMT 6000/vial NMT 600/vial	174/vial 3/vial		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$				
	(B.) Visible particles	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.	Complies		
9.	Sterility	No microbial growth should be observed.	Complies		
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	41.4575 mg	103.64%	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 <u>28/04/2026</u> NAME: NIKHIL SHARMA	Checked by <u>28/04/26</u> NAME: SUFIYAN ANSARI	Approved by <u>28/04/26</u> NAME: MRS. SWATI DHAWAN
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