



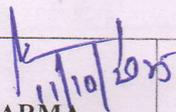
# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

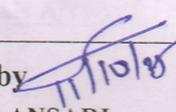
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

## Title : Certificate of Analysis Finished Product

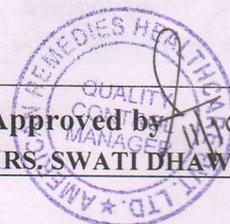
Product Name	PROZCAN 40 Injection	A.R. No.	ARN/FP/25/026
Generic Name	Pantoprazole for Injection IP 40mg	Sampled qty.	45 Vials
Batch No.	ARN2532A	Sampled by	Anuj Verma
Batch Size	1,00,000 Vials	Sampled on	25/09/2025
Mfg. Date	09/2025	Date of Testing	26/09/2025
Exp. Date	08/2027	Date of Release	11/10/2025

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 $\pm 10\%$	-4.52% & +4.71%
4.	Average weight	Informative $\pm 2\%$ .	126.7 mg
5.	pH	9.0 to 11.5	10.16
6.	Appearance of solution	Solution should be clear and not more intensely colored than reference solution BS <sub>5</sub> or BYS <sub>5</sub> .	Complies
7.	Related Substance (By HPLC)		
a.	Impurity A	Not More than 0.5%	0.12%
b.	Impurities D+F	Not More than 1.5%	0.38%
c.	Any secondary peak	Not More than 0.2%	Not detected
d.	Sum of all secondary peaks	Not More than 2.0%	0.50%

Analysis by   
NAME: NIKHIL SHARMA

Checked by   
NAME: SUFIYAN ANSARI

Approved by   
NAME: MRS. SWATI DHAWAN





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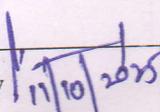
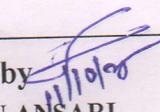
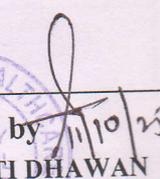
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8.	Particulate Contamination (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$  (B.) Visible particles	NMT 6000/vial NMT 600/vial  The reconstituted solution of injection should be free from any type of visual particles i.e mobile undissolved substances, other than gas bubbles, unintentionally that can be observed on visual inspection.	353/vial 3/vial  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	41.69 mg	104.22%	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/HS.

Analysis by  NAME: NIKHIL SHARMA	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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