

Pace

Add Pace To Health

Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title

:

Certificate of Analysis Finished Product

Product Name	PROZCAN 40 Injection	A.R. No.	NB/FP/25/148
Generic Name	Pantoprazole for Injection IP 40mg	Sampled qty.	45 Vials
Batch No.	N25130C	Sampled by	Rakesh
Batch Size	44,160 Vials	Sampled on	19/07/2025
Mfg. Date	06/2025	Date of Testing	19/07/2025
Exp. Date	05/2027	Date of Release	04/08/2025

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 $\pm 10\%$	-7.07% & +4.30%
4.	Average weight	Informative $\pm 2\%$.	125.8 mg
5.	pH	9.0 to 11.5	10.43
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%	Not detected
c.	Any secondary peak	Not More than 0.2%	Not detected
d.	Sum of all secondary peaks	Not More than 2.0%	Not detected

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

Approved by

NAME: SWATI DHAWAN

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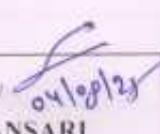
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8.	Particulate Contamination	NMT 6000/vial NMT 600/vial	1484/vial 13/vial		
	(A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visible particles				
	The reconstituted solution of 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	41.17 mg	102.93%	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 
NAME: NIKHIL SHARMA

Checked by 
NAME: SUFIYAN ANSARI

Approved by 
NAME: SWATI DHAWAN

