



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Prozcan-40	A.R. No.	FG/G/25A0003
Generic Name	Pantoprazole for Injection IP 40 mg	Sample Quantity	65 Vials
Batch No.:	AGD50101	Sample Received on	03/01/2025
Batch Size:	100500 Vials	Analysis Date	03/01/2025
Mfg. Date.	01/2025	Release Date	17/01/2025
Exp. Date	12/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	White lyophilized powder, hygroscopic, filled in 10 ml amber colour molded glass vial plugged with rubber stopper and sealed with green coloured flip off having aluminium seal.	White lyophilized powder, hygroscopic, filled in 10 ml amber colour molded glass vial plugged with rubber stopper and sealed with green coloured flip off having aluminium seal.
2.	Identification:		
	a) By IR	The IR Spectrum obtained with test should be concordant with that spectrum obtained from the pantoprazole sodium WS/RS or with the reference spectrum of pantoprazole sodium.	Complies
	b) By HPLC	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
	c) By Chemically	It gives the reactions of sodium salts.	Complies
3.	Average filled weight	$\pm 7.5\%$ of Target filled weight	128.06 mg
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight.	Min: 127.58 mg ; Max: 128.55 mg -0.37% ; + 0.38%
5.	Appearance of solution	Solution is clear and not more intensely colored than reference solution BS5 or BYSS	Complies
6.	Reconstitution Solution	When reconstitute with (0.9 %w/v) Sodium chloride solution, it is clear and free from suspended matters.	Clear Solution.
7.	Clarity of Solution	Solid should dissolve completely when, leaving no visible residue as undissolved matter.	Solid dissolve completely when, leaving no visible residue as undissolved matter.
8.	pH	Between 9.0 to 11.5	10.01
9.	Water	NMT 6.0%w/w	3.24%
10.	Particulate matter	The Sample Solution should be clear and free from any visible particles.	The Sample Solution is clear and free from any visible particles.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	17/01/2025	17/01/2025	17/01/2025



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Sr. No.	Test Parameter	Acceptance Criteria	Result		
11.	Bacterial Endotoxins Tests	NMT 1.25 EU/mg	Less than 1.25 EU/mg		
12.	Sterility	Should be sterile	Sterile		
13.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Pantoprazole Sodium IP Equivalent to Pantoprazole (As sterile lyophilized powder)	40 mg	Between 93.0 % to 105.0 % of labeled amount of Pantoprazole. (Between 37.2 mg to 42.0 mg)	39.2131 mg	98.03%

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In- House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	17/01/2025	17/01/2025	17/01/2025