



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/24A0019
Generic Name	Pantoprazole for Injection 40 mg	Sample Quantity	65 Vials
Batch No.:	AGD40301	Sample Received on	07/03/2024
Batch Size:	1.0 Lac	Analysis Date	07/03/2024
Mfg. Date.	03/2024	Release Date	21/03/2024
Exp. Date	02/2026	Page No.:	Page 1 of 1

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 sky blue 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 sky blue coloured flip off having aluminium seal.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Average filled weight	115.00 mg \pm 5.0%	118.42 mg		
4.	Uniformity of filled weight	\pm 10% of its average filled weight.	Min: 118.09 mg ; Max: 118.56 mg -0.28% ; + 0.11%		
5.	Reconstitution Solution	When reconstitute with (0.9 %w/v) Sodium chloride solution, it is clear and free from suspended matters.	Clear Solution.		
6.	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.		
7.	pH	Between 9.0 to 12.0, determine on 10 % w/v Solution.	10.14		
8.	Water	NMT 6.0%w/w	4.52%w/w		
9.	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.		
10.	Bacterial Endotoxins Tests	NMT 1.25 EU/mg	Less than 1.25 EU/mg		
11.	Sterility	Should be sterile	Sterile		
12.	Assay:				
	Each Vial contains:	Claim	Limit	mg	%
	Pantoprazole Sodium IP eq. to Pantoprazole (As sterile lyophilized powder)	40 mg	Between 90.0 % to 110.0 % of labeled amount of Pantoprazole. (Between 36.0 mg to 44.0 mg)	38.9604 mg	97.40%

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	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	21/03/2024	21/03/2024	21/03/2024