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/23A0129
Generic Name	Pantoprazole for Injection 40 mg	**Sample Quantity**	65 Vials
Batch No.:	AGD31102	**Sample Received on**	01/12/2023
Batch Size:	0.76 Lac	**Analysis Date**	01/12/2023
Mfg. Date.	11/2023	**Release Date**	NA
Exp. Date	10/2025	**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 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 (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 the reference solution.	Complies
3.	**Average filled weight**	± 7.5% of target filled weight.	122.28 mg
4.	**Uniformity of filled weight**	± 10% of its average filled weight.	Min: 117.44 mg ; Max: 126.21 mg -3.96% : + 3.21%
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.	10.21
8.	**Water**	NMT 6.0%w/w	4.46%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	Under Observation
12.	**Assay (By HPLC):**		

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)	39.15 mg	97.88%

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	Baveen Kumar	Tanvej	Rautan Singh
Designation	Executive	Sr. Executive	Head- QA
Signature		Tanvej	
Date	05/12/2023	05/12/2023	05/12/2023