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/24A0072
Generic Name	Pantoprazole for Injection IP 40 mg	**Sample Quantity**	65 Vials
Batch No.:	AGD40803	**Sample Received on**	05/08/2024
Batch Size:	1.0 Lac	**Analysis Date**	05/08/2024
Mfg. Date.	08/2024	**Release Date**	NA
Exp. Date	07/2026	**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 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:**		
	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**	± 7.5% of Target filled weight	126.70 mg
4.	**Uniformity of filled weight**	± 10% of its average filled weight.	Min: 120.14 mg ; Max: 130.66 mg -5.17% : + 3.13%
5.	**Appearance of solution**	Solution is clear and not more intensely colored than reference solution BS5 or BYS5	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	9.8
9.	**Water**	NMT 6.0%w/w	3.99%
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	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	14/08/2024	14/08/2024	14/08/2024

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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	Under test
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)	38.9468 mg	97.37%

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	DURGESH KUMAR	Gautam singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	14/08/2024	14/08/2024	14/08/2024