ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Omeecan 40 mg	**A.R. No.**	FG/G/24A0100
Generic Name	Omeprazole for Injection 40 mg	**Sample Quantity**	65 Vials
Batch No.:	AGD40902	**Sample Received on**	14/09/2024
Batch Size:	50200 Vials	**Analysis Date**	14/09/2024
Mfg. Date.	09/2024	**Release Date**	NA
Exp. Date	08/2026	**Page No.:**	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	**Description**	White or almost white lyophilized powder, hygroscopic, filled in 10 ml amber colour molded glass vial plugged with rubber stopper and sealed with 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 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**	± 7.5% of Target filled weight.	138.32 mg
4.	**Uniformity of filled weight**	± 10% of its average filled weight.	Min: 130.68 mg ; Max: 144.81 mg -5.52% : + 4.69%
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	10.23
8.	**Water**	NMT 6.0%w/w	1.78%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**	Not more than 0.125 EU/mg	Less than 0.125 EU/mg
11.	**Sterility**	Should be sterile	Under test
12.	**Assay:**		

Each Vial contains:	Claim	Limit	mg	%
Sterile Omeprazole sodium IP Eq. to Omeprazole (As Lyophilized powder)	**40 mg**	Between 90.0 % to 110.0 % of labeled amount of Omeprazole. (Between 36.0 mg to 44.0 mg)	40.3249 mg	100.81%

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		Tanvej	
Date	27/09/2024	27/09/2024	27/09/2024