



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/25A0947
Generic Name	Omeprazole for Injection 40 mg	Sample Quantity	65 Vials
Batch No.:	AGD50601	Sample Received on	15/06/2025
Batch Size:	45000 Vials	Analysis Date	15/06/2025
Mfg. Date.	06/2025	Release Date	29/06/2025
Exp. Date	05/2027	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.	135.49 mg		
4.	Uniformity of filled weight	± 10% of its average filled weight.	Min: 132.27 mg ; Max: 137.51 mg -2.38% : + 1.49%		
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	2.55%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	Sterile		
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)	41.5317 mg	103.83%

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	Kamprant	Kuljeet Kaur
Designation	Executive	Executive	Head Qc.
Signature			
Date	29/06/2025	29/06/2025	29/06/2025