



ALVENTA PHARMA LIMITED

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

Quality Control Department CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Omeccan 40 mg	A.R. No.	FG/G/24A0115
Generic Name	Omeprazole for Injection 40 mg	Sample Quantity	65 Vials
Batch No.:	AGD40909	Sample Received on	05/10/2024
Batch Size:	0.50 Lac	Analysis Date	05/10/2024
Mfg. Date.	09/2024	Release Date	19/10/2024
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	$\pm 7.5\%$ of Target filled weight.	139.48 mg		
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight.	Min: 133.20 mg ; Max: 147.23 mg -4.50% ; + 5.56%		
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	10.42		
8.	Water	NMT 6.0%w/w	1.74%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)	39.69 mg	99.23%

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	Amit Kumar	139 Pk Singh
Designation	Executive	Executive	Plant Head
Signature			
Date	19/10/2024	19/10/2024	19/10/2024