



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Esomecan 40 mg	A.R. No.	FG/G/24A0104
Generic Name	Esomeprazole Sodium for Injection 40 mg	Sample Quantity	65 Vials
Batch No.:	AGD40903	Sample Received on	21/09/2024
Batch Size:	35200 Vials	Analysis Date	21/09/2024
Mfg. Date.	09/2024	Release Date	15/10/2024
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 light pink 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 light pink 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.	133.15 mg		
4.	Uniformity of filled weight	$\pm 10\%$ of its average filled weight.	Min: 130.38 mg ; Max: 137.28 mg -2.08% ; + 3.10%		
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	10.61		
8.	Water	NMT 6.0%w/w	3.63%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	%
	Esomeprazole sodium IP Eq. to Esomeprazole (Sterile)	40 mg	Between 90.0 % to 110.0 % of labeled amount of Esomeprazole. (Between 36.0 mg to 44.0 mg)	39.469 mg	98.67%

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	Harveen Kumar	Kuljeet Kaur	Ram Awadh Yad
Designation	Executive	Head QC	Head QA
Signature			
Date	15/10/2024	15/10/2024	15/10/2024