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/24A0125
Generic Name	Esomeprazole Sodium for Injection 40 mg	**Sample Quantity**	65 Vials
Batch No.:	AGD41009	**Sample Received on**	17/10/2024
Batch Size:	50000 Vials	**Analysis Date**	17/10/2024
Mfg. Date.	10/2024	**Release Date**	04/11/2024
Exp. Date	09/2026	**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**	± 7.5% of Target filled weight.	136.81 mg
4.	**Uniformity of filled weight**	± 10% of its average filled weight.	Min: 135.24 mg ; Max: 138.62 mg -1.15% : + 1.32%
5.	**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.
6.	**pH**	Between 9.0 to 12.0	10.72
7.	**Water**	NMT 6.0%w/w	2.16%w/w
8.	**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.
9.	**Bacterial Endotoxins**	Not more than 0.125 EU/mg	Less than 0.125 EU/mg
10.	**Sterility**	Should be sterile	Sterile
11.	**Assay:**		

Each Vial contains:	Claim	Limit	mg	%
Esomeprazole sodium 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)	39.9726 mg	99.93%

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	Kuljeet Kaur	Bakhshish Singh
Designation	Executive	Head QC	Plant Head
Signature			
Date	04/11/2024	04/11/2024	04/11/2024