



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/25A0006 |
| Generic Name | Esomeprazole Sodium for Injection 40 mg | Sample Quantity | 65 Vials |
| Batch No.: | AGD50103 | Sample Received on | 17/01/2025 |
| Batch Size: | 30,000 Vials | Analysis Date | 17/01/2025 |
| Mfg. Date. | 01/2025 | Release Date | 31/01/2025 |
| Exp. Date | 12/2026 | 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. | 134.62 mg | | |
| 4. | Uniformity of filled weight | $\pm 10\%$ of its average filled weight. | Min: 132.04 mg ; Max: 137.75 mg -1.91% : + 2.33% | | |
| 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 | 10.13 | | |
| 7. | Water | NMT 6.0%w/w | 2.28%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) | 39.44 mg | 98.60% |

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 | Kavita Nandwani |
| Designation | Executive | Head QC | QA Manager |
| Signature | | | |
| Date | 31/01/2025 | 31/01/2025 | 31/01/2025 |