Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section

Analytical Profile of Esomeprazole Sodium for Injection

Analytical Profile No.: Esmo I 076/077/AP 071

Esomeprazole Sodium for Injection contains not less than 90.0% & not more than 110.0% of the stated amount of esomeprazole.

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. pH: As per manufacturer's specification

3. Sterility: As per IP (latest edition) by membrane filtration method.

4. Bacterial Endotoxins: As per IP (latest edition)

Limit: NMT 0.125 EU/mg of Esomeprazole

5. Assay: *Determine by Liquid Chromatography*

5.1 Solvent mixture: Buffer:Acetonitrile (50:50)

5.2 Test solution: Weigh individually 20 vials and mix 20 vials content. Weigh lyophilized powder equivalent to 400mg of Esomeprazole sodium and transfer into a 100 ml volumetric flask, add about 50 ml of water, sonicate to dissolve, cool to room temperature and make up the volume to 100 ml with solvent mixture. Dilute 2 ml of this solution to 50ml with the solvent mixture.

5.3 Reference Solution: Weigh accurately 43 mg of Esomeprazole Sodium WS and transfer to 50ml volumetric flask. Add about 20-25ml of solvent mixture and sonicate to dissolve. Make up the volume to the mark with same solvent and mix. Dilute 10ml of this solution to 50ml with same solvent.

5.4 Chromatographic system

- Column: C18 (25 cm x 4.6 mm), 5 µm,
- Flow rate: 1.5 ml per minute

- Wavelength: 300 nm
- Injection volume: 20 µl
- Column temperature: Ambient
- Mobile phase: A mixture of 70 volumes of buffer solution prepared by dissolving 1.42 gm of disodium hydrogen phosphate in 1000 ml water, adjusted to pH 7.7 with orthophosphoric acid and 30 volumes of Acetonitrile.

5.5 Procedure: Inject reference solution five times and test solution. The test is not valid unless the column efficiency determined from the major peak is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation of replicate injections is not more than 2.0 %. Measure the peak response. Calculate the content of Esomeprazole in injection.

6. Other tests: As per pharmacopoeial requirement.