DEPARTMENT OF DRUG ADMINISTRATION

National Medicines Laboratory

ANALYTICAL METHOD VALIDATION COMMITTEE

Esomeprazole Sodium Powder for Injection

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

Esomeprazole Sodium powder for Injection contains not less than 90.0 percent and not more than 110.0 percent of the stated amount of Esomeprazole.

1. Identification: In the assay, the principle peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution of Esomeprazole.

Tests:

2. pH: 10.0 to 12.0 (20 mg/ml)

3. Water Content: NMT 5.0 %

4. Particulate matter: As per IP latest edition

5. Sterility: Absence of microorganisms by membrane filtration method (As per IP)

6. Bacterial Endotoxins: Not more than 0.125 EU/mg (As per IP)

***7.* Assay:** *Determine by Liquid Chromatography*

7.1 Test solution: Weigh individually contents of 20 vials and mix them. Weigh lyophilized powder equivalent to 400 mg 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 50 ml with the solvent mixture. Filter the resulting solution through 0.2 µm membrane filter.

7.2 Reference Solution: Weigh accurately 43 mg of Esomeprazole Sodium RS and transfer to 50 ml volumetric flask. Add about 20 – 25 ml of solvent mixture and sonicate to dissolve. Make up the volume to the mark with same solvent and mix. Dilute 10 ml of this solution to 50 ml with same solvent. Filter the resulting solution through 0.2 µm membrane filter.

7.3 Chromatographic system:

Column: a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm)

Flow rate: 1.5 ml per minute

Wavelength: 300 nm

Injection volume: 20 µl

Column Temperature: ambient

Detector: UV

Solvent mixture: Buffer : Acetonitrile (50:50)

Mobile phase: a mixture of 70 volumes of buffer solution prepared by dissolving 1.42 g of disodium hydrogen phosphate in 1000 ml water, adjusted to pH 7.7 with orthophosphoric acid and 30 volumes of acetonitrile

7.4 Procedure: Inject 20 µl of standard preparation five times and test solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates; the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections in not more than 2.0 %. After the completion of the system suitability test parameter, inject 20 µl of each of the sample solution separately. Inject blank solution to check any interference.

Calculate the content of Esomeprazole in injection.

8. Other tests: As per pharmacopoeial requirements.