Department of Drug Administration
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON PHARMACOPOEIAL PRODUCT

Esomeprazole Fast Releasing Tablets

Analytical Profile No.: Esmo FR 076/077/AP061

Esomeprazole Tablet containes 90% and 110% of Esomeprazole of stated amount.

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. Dissolution: Determine by liquid chromatography

2.1 Dissolution Test Parameter:

- Apparatus: Paddle
- Medium: 900 ml of phosphate buffer pH 7.4
- Speed and Time: 75 rpm & 30 minutes
- Temperature: 37+/-0.5℃

Withdraw a suitable volume of the medium and filter

2.2Test Solution:

Dilute 5 ml of the filtrate to 10 ml with dissolution media. Finally filter through 0.2 µm membrane filter paper.

2.3Reference Solution:

Transfer carefully about 23 mg of Esomeprazole Magnesium WSinto 100 ml volumetric flask and dissolve with 10 ml of methanol and finally make up the volume with dissolution media. Further dilute 5 ml of this solution to 50 ml with the dissolution media and filter through 0.2 µm membrane filter paper.

2.4 Chromatographic system:

Use the chromatographic system as described in the Assayusing 20µl as injection volume.

2.5 Procedure:

Proceed as described in assay, using 20 µl injection volumes.Calculate the release of the drug in each tablet.

2.7 Limit:

D. Not less than 75% of the stated amount

3. Uniformity of Content:

Determine by liquid chromatography, as described in the Assay, using the following solution as the test solution.

3.1 Test solution: Weigh 10 tablets and transfer each into 100 ml volumetric flask. Add 70 ml of solvent mixture shake to disperse, sonicate for 15 minutes; cool and make up the volume to the mark with solvent mixture. Centrifuge the solution at 2000 rpm for 10 minutes and further dilute 5 ml of this solution to 50 ml with the mobile phase. Finally filter the solution through 0.2 micron filter paper.

3.2 Limit: 85 – 115 % of the stated amount

4. Assay: Determine by Liquid Chromatography

4.1 Solvent Mixture: Methanol

4.2Test Solution:

Determine the average weight of 20 tablets. Crush them into homogeneous mixture in mortar and pestle. Transfer carefully powder equivalent to 40 mg of Esomeprazole into 100 ml volumetric flask, add 70 ml of solvent mixture, shake gently to disperse, sonicate for 15 minutes, cool and make up the volume to the mark with solvent mixture. Centrifuge the solution at 2000 rpm for 10 minutes and further dilute 5 ml of the solution to 50 ml with the mobile phase.

4.3Reference Solution:

Transfer carefully about 44 mg of Esomeprazole Magnesium WSinto 100 ml volumetric flask. Add 70 ml of solvent mixture, shake for few minutes and sonicate for 5 minutes; cool and make up the volume to 100 ml with the solvent mixture. Further dilute 5 ml of this solution to 50 ml with the mobile phase.

4.4Chromatographic system:

- **Column:** C8, (150*4.6 mm), 5 µm
- **Flow rate:** 1.0 ml/min
- **Wavelength:** 300 nm
- **Injection volume:** 10 µl
- **Column temperature:** Ambient
- **Detector:** UV

Mobile phase: A mixture of equal volume of methanol and buffer solution prepared by dissolving 6.8 g of potassium dihydrogen phosphate and about 1 g of sodium hydroxide in 1000 ml of water, and adjusting pH to 7.0 with orthophosphoric acid.

4.5 Procedure: Inject the reference 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%. Inject the reference solution and the test solution.

Calculate the content of Esomeprazole in the tablets.

5. Other tests: As per pharmacopoeial requirement.