ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON PHARMACOPOEIAL PRODUCT

DEPARTMENT OF DRUG ADMINISTRATION

Esomeprazole Capsules

Esomeprazole Capsules contains not less than 90 % and not more than 110 % of the stated amount of Esomeprazole.

1. Identification:

1.1. Esomeprazole

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference standard solution of Esomeprazole.

2. Dissolution Test: Esomeprazole

2.1 Procedure: As per IP 2014 monograph of Esomeprazole Gastro Resistant Tablets

2.2 Tolerance Limit:

Acid Stage: Not more than 10 % of the stated amount
Buffer Stage: Not less than 70 % D of the stated amount

3. Assay: As per IP 2014 monograph of Esomeprazole Gastro resistant Tablets

Note

1. Weight variation test should be as per the Pharmacopoeia recognized by Government of Nepal.