

**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.