

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

Analytical profile of Illaprazole Tablets

Analytical Profile No.: ILL 074/075/AP 027

Illaprazole Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Illaprazole.

Usual Strength: 10 mg

1. Identification:

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 solution.

2. Dissolution Test:

2.1 Acid Phase

2.1.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900ml of 0.1 N HCl

Speed and Time: 100 rpm and 2 hrs

Withdraw a suitable volume of the medium and filter. Remove each tablet from individual vessels and subject them to the test in buffer stage.

2.1.2 Test Solution: Use the filtrate.

2.1.3 Reference Solution: Weigh accurately about 28 mg of Illaprazole RS and transfer into 100 ml volumetric flask. Dissolve with 0.1 N HCl and make up the volume to 100 ml with 0.1 N HCl. Dilute 2 ml of this solution to 50 ml with 0.1 M HCl.

2.1.4 Procedure: Measure absorbance of both the reference solution & test solution at about 220 nm using 0.1 N HCl as blank. Calculate the percentage release of Illaprazole in acid medium.

2.1.5 Limit: Not more than 10 % D of the stated amount

2.2 Buffer Phase

2.2.1 Dissolution Parameters:

Apparatus: Paddle

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Medium: 900ml of Tris-Acetate buffer pH 8.5 [Dissolve 0.249 g of calcium chloride and 12.11 g of tris(hydroxymethyl) aminomethane in 1000 ml water. Adjust pH to 8.5 ± 0.05 with 5 M acetic acid.]

Speed and Time: 100 rpm and 45 minutes

Place 1 tablet (taken out from the acid stage) in each dissolution vessel and run the apparatus as per above condition. Withdraw a suitable volume of the medium and filter.

2.2.2 Test Solution: Use the filtrate.

2.2.3 Reference Solution: Weigh accurately about 28 mg of Illaprazole RS and transfer into 50 ml volumetric flask. Dissolve with methanol and make up the volume to 50 ml with methanol. Dilute 2 ml of this solution to 100 ml with dissolution medium.

2.2.4 Procedure: Measure absorbance of both the reference solution & test solution at about 220 nm using dissolution medium as blank. Calculate the percentage release of Illaprazole in buffer medium.

2.2.5 Limit: Not Less than 75 % D of the stated amount

3. Uniformity of content

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

Test Solution: Place one tablet in a 100 ml volumetric flask; add about 60 ml of methanol to dissolve with the help of sonicator. Cool and make up the volume to 100 ml with methanol.

4. Assay:

4.1 Test Solution: Weigh individually 20 tablets and crush the tablet to fine powder. Weigh accurately the powder equivalent to 50 mg of Illaprazole and transfer into 100 ml volumetric flask. Add about 60 ml of methanol, sonicate for about 10 minutes and cool the solution to room temperature and make up the volume to 100 ml with diluents. Centrifuge the solution. Dilute 5 ml of the resulting solution to 25 ml with methanol.

4.2 Reference Solution: Weigh accurately about 25 mg of Illaprazole RS and transfer into 50 ml volumetric flask. Dissolve in the methanol and make up the volume to 50 ml with methanol. Dilute 5 ml of the resulting solution to 50 ml with methanol.

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4.3 Chromatographic system:

Column: 150 X 4.6 mm (C 18)

Flow rate: 1.0 ml/min

Wave length: 237 nm

Injection volume: 10 µl

Column Oven Temperature: Ambient

Mobile phase: A mixture of 50 volume of Buffer and 50 volume of ACN

Buffer: Solution containing 2.727 g potassium dihydrogen phosphate and 1 g sodium hydroxide in 1000 ml water.

4.4 Procedure: Inject the reference solution five times and sample solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Illaprazole.

5. Other tests: As per pharmacopoeial requirements.