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

Analytical profile of Itopride HCl Tablet

Analytical Profile No.: ITO 074/075/ AP 024

Itopride HCl Tablet contains not less than 90.0% and not more than 110.0% of the stated amount of Itopride HCl.

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:

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900ml of 0.1 N HCl

Speed and Time: 50 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute 5 ml of the filtrate to 25 ml with dissolution medium.

2.3 Reference Solution: Weigh accurately about 20 mg of Itopride HCl RS in 100 ml volumetric flask and add dissolution medium in it. Sonicate for about 10 min and make volume with same solvent. Dilute 5 ml of the filtrate to 100 ml with same solvent. (10 ppm)

2.4 Procedure: Measure the absorbance of both standard and sample solution at about 258 nm taking dissolution medium as blank. Calculate the % release of Itopride HCl.

2.5 Limit: NLT 75% D of the stated amount

3. Assay:

3.1 Test Solution: Weigh and powder 20 tablets. Weigh powder eq. to 50 mg of Itopride HCl, dissolve with mobile phase by sonicating for about 10 minutes and make the volume to 100 ml with same solvent. Filter or centrifuge the resulting solution and dilute 2 ml of the filtrate to 50 ml with same solvent. (20 ppm)

3.2 Standard Solution: Weigh accurately about 20 mg of Itopride HCl RS and transfer in 100 ml volumetric flask. Add 70 ml mobile phase and sonicate for about 10 min and make volume to 100 ml with same solvent. Centrifuge or filter the solution. Dilute 5 ml of the resulting solution to 50 ml with same solvent. (20 ppm)

3.3 Chromatographic system

Column: Octyldecylsilane (C18), (250*4.6 mm), 5 µm

Flow rate: 1.0 ml/min

Detector: UV Detector

Wavelength: 220 nm

Injection volume: 20 µl

Oven temperature: 30 °C

Mobile phase: 70 volume of Buffer and 30 volume of Acetonitrile

Buffer: Prepared by adding 1 ml of Orthophosphoric acid in 1000 ml water, adjust pH to 3.0 ± 0.05 with Triethylamine

3.4 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 Silodosin.

4. Other tests: As per pharmacopoeial requirements.