DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Itopride HCl Tablet

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

Itopride HCl Tablet contains not less than 90 per cent and not more than 110 per cent of the stated amount of Itopride HCl.

1. Identification: In the assay, the principle peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution of Itopride HCl.

Tests:

2. Dissolution:

2.1 Dissolution Parameter: *Determine by UV spectrophotometry*

Apparatus:	Paddle
Medium:	900 ml of 0.1 N hydrochloric acid
Speed and time:	50 rpm and 30 minutes
Temperature :	37˚C ± 0.5˚C

Withdraw the 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 reference and test solution at about 258 nm taking dissolution medium as blank. Calculate the % release of Itopride HCl by comparison.

2.5 Limit: Not less than 75 % (D) of the stated amount.

3. Assay: *Determine by Liquid Chromatography*

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 resulting solution to 50 ml with same solvent. Filter the resulting solution through 0.2 micron membrane filter. (20 ppm)

3.2 Reference 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. Filter the resulting solution through 0.2 micron membrane filter. (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: Buffer: Acetonitrile (70:30)

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 20 µl of reference solution five times as per above mentioned chromatographic condition. In the chromatogram obtained from the standard preparation, the column efficiency determined from the major peak should not be less than 2000 theoretical

plates, the tailing factor should be not more than 2.0 and the relative standard deviation of five replicate injections should not more be than 2.0 %. Inject 20 µl of the sample preparation and chromatograph as per above mentioned chromatographic condition. Calculate the content of Itopride hydrochloride in each tablet.

4. Other tests: As per pharmacopoeial requirements