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

Analytical Profile of Itopride SR Tablets

Analytical Profile No.: ISR 074/075/ AP 033

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

1. Identification:

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. Dissolution Test:

2.1 Dissolution Parameters: *Deteremine by UV-Vis spectrophotometry*

Apparatus: Paddle

Medium: 900ml of 0.1 N HCl

Speed and Time: 75 rpm and 2 hr, 4 hr, 8 hr, 12 hr, 16 hr, 20 hr

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute the filtrate if required with dissolution medium.

2.3 Reference Solution: Weigh accurately about 30 mg of working standard of Itopride HCl in 100 ml volumetric flask. Add 70 ml of dissolution medium and sonicate for 15 min and make up volume with same medium. Dilute 2 ml of this solution to 50 ml with same diluents.

2.4 Procedure: Record the observed absorbance on the UV spectrophotometer at 257nm of the reference solution and test solution. Calculate the percentage release of Itopride HCl.

2.5 Limit:

2 hr	NLT 20 % - NMT 30 % of the stated amount
4 hr	NLT 35% and NMT 50% of the stated amount
8hr	NLT 55% and NMT 70% of the stated amount
12 hr	NLT 70% of the stated amount
16 hr	NLT 80% of the stated amount
20 hr	NLT 90% of the stated amount

3. Assay: *Deteremine by liquid chromatography*

3.1 Test Solution: Weigh individually 20 tablets and crush the tablet to fine powder. Weigh accurately the powder equivalent to 25 mg of Itopride HCl and transfer into 100 ml volumetric flask. Add about 70 ml of mobile phase, sonicate for about 5 minutes and cool the solution to room temperature and make up the volume to 100 ml with same solvent. Filter the solution. Dilute 5 ml of the resulting solution to 50 ml with same solvent.

3.2 Reference Solution: Weigh accurately about 25 mg of working standard of Itopride HCl in 100 ml volumetric flask. Add about 70 ml of mobile phase, sonicate for 5 min and make upto mark with same solvent. Further dilute 5 ml of resulting solution to 50ml with same solvent.

3.3 Chromatographic system:

Column: C18, 250 X 4.6 mm, 5µ

Flow rate: 1.0 ml/min

Injection volume: 5 µl

Wave length: 220 nm

Column Oven Temperature: Ambient

Mobile phase: A mixture of 70 volume of Buffer & 30 volume of Acetonitrile

Buffer: 1 ml of Orthophosphoric acid in 1000 ml of water, adjust pH to 3.0 with Triethylamine.

3.4 Procedure: Inject test solution five times & test solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates. The tailing factor is not more than 2.0 and the relative standard deviation for replicate injections in not more than 2.0%. Measure the peak response. Calculate the content of Itopride in Itopride SR tablet.

4. Other tests: As per pharmacopoeial requirements.