# DEPARTMENT OF DRUG ADMINISTRATION
## National Medicines Laboratory
### ANALYTICAL METHOD VALIDATION COMMITTEE

# Itopride SR Tablets

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

Itopride SR Tablets contain not less than 90 per cent and not more than 110 per cent of the stated amount of Itopride Hydrochloride.

**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 Hydrochloride.

**Tests:**

**2. Dissolution:** *Determine by UV Spectrophotometry*

**2.1 Dissolution Parameter:**

| | |
|---|---|
| **Apparatus:** | Paddle |
| **Medium:** | 900 ml of 0.1 N HCl |
| **Speed and time:** | 75 rpm and 2, 4,8,12, 16 and 20 hours |
| **Temperature :** | 37˚C ± 0.5˚C |

Withdraw the suitable volume of the medium and filter.

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

**2.3 Reference Solution:** Weigh accurately about 30 mg Itopride HCl RS 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 diluent.

**2.4 Procedure:** Measure the absorbance of test solution and reference solution at 257 nm. Calculate the percentage release of Itopride HCl by comparison.

**2.5 Limit:**

20 % - 30 % of the stated amount in 2 hr

35 % - 50 % of the stated amount in 4 hr

55 % - 70 % of the stated amount in 8 hr

NLT 70 % of the stated amount in 12 hr

NLT 80 % of the stated amount in 16 hr

NLT 90 % of the stated amount in 20 hr

**3. Assay:** *Determine 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, 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. Filter the resulting solution with 0.2 micron membrane filter paper.

**3.2 Reference Solution:** Weigh accurately about 25 mg Itopride HCl RS 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 50 ml with same solvent. Filter through 0.2 micron membrane filter paper.

**3.3 Chromatographic System:**

**Column:** 250 X 4.6 mm Octadecylsilane 5 µm

**Flow rate:** 1.0 ml/min

**Wave length:** 220 nm

**Injection volume:** 5 µl

**Column Oven Temperature**: Ambient

**Mobile phase:** Buffer: ACN (70:30)

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

**3.4 Procedure:** Inject 5 µl of standard preparation five times as per above mentioned chromatographic condition. 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 in not more than 2.0 %. After the completion of the system suitability test parameter, inject 5 µl of each of the sample solution separately.

Calculate the content of Itopride HCl in SR tablet.

**4. Other tests:** As per pharmacopoeial requirements.