Itopride Prolonged-release and Rabeprazole Gastro-resistant Capsules

Itopride Hydrochloride Prolonged-release and Rabeprazole Sodium Gastro-resistant Capsules

Rabeprazole Sodium Gastro-resistant and Itopride Hydrochloride Prolonged release Capsules manufactured by different manufacturers, whilst complying with therequirements of the monograph, are not interchangeable, as the dissolution profile of the itopride hydrochloride of different manufacturers may not be the same.

Rabeprazole Gastro-resistant and Itopride Prolonged release Capsules contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of rabeprazole sodium, $C_{18}H_{20}N_3O_3SNa$ and itopride hydrochloride, $C_{20}H_{26}N_2O_4HCl$.

Usual strength. Rabeprazole Sodium 20 mg and Itopride Hydrochloride 150 mg.

Identification

In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with the reference solution.

Tests

Dissolution (2.5.2).

For Rabeprazole Sodium -

NOTE-Prepare the solutions immediately before use, protect the solutions from light.

A. Apparatus No. 1,

Medium:750 ml of *0.1 M hydrochloric acid*,

Speed and time. 50 rpm and 120 minutes.

Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtered solution immediately, suitably diluted with the dissolution medium, if necessary, at the maximum at about 258 nm (2.4.7). Calculate the content of $C_{18}H_{20}N_3O_3SNa$ in the medium from the absorbance obtained from a solution of known concentration of *rabeprazole sodium RS* in the dissolution medium.

Complies with the acceptance criteria given under acid stage.

B. Apparatus No. 1,

Medium: 900 ml of buffer solution prepared by dissolving 19 g of *trisodium orthophosphate* in 900 ml of *water*, adjusted to pH 6.8 with *dilute hydrochloric acid* and dilute to 1000 ml with *water*,

Speed and time. 75 rpm and 60 minutes.

Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtered solution immediately, suitably diluted with the dissolution medium, if necessary, at the maximum at about 284 nm (2.4.7). Calculate the content of $C_{18}H_{20}N_3O_3SNa$ in the medium from the absorbance obtained from a solution of known concentration of *rabeprazole sodium RS* in the dissolution medium.

D. Not less than 70 per cent of the stated amount of $C_{18}H_{20}N_3O_3SNa$.

For Itopride Hydrochloride - Complies with the test stated under Capsules.

Related substances. Determine by liquid chromatography (2.4.14), as described under Assay with the following modification.

For Rabeprazole Sodium -

Test solution. Weigh a quantity of the mixed content of 20 capsules containing 0.12 g of Rabeprazole Sodium in the solvent mixture, with the aid of ultrasound and dilute to 100.0 ml with the solvent mixture and filter.

Inject the test solution. The area of any secondary peak is not more than 1.0 per cent and the sum of the areas of all secondary peaks is not more than 2.0 per cent, calculated by area normalisation. Ignore the peak due to itopride hydrochloride.

For Itopride Hydrochloride -
Test solution. Weigh a quantity of the mixed content of 20 capsules containing 0.25 g of Itopride Hydrochloride, disperse in 40 ml of *methanol*, with the aid of ultrasound and dilute to 100.0 ml with the same solvent and filter. Dilute 5.0 ml of the solution to 50.0 ml with the mobile phase.

Inject the test solution. The area of any secondary peak is not more than 0.75 per cent and the sum of the areas of all secondary peaks is not more than 1.0 per cent, calculated by area normalisation. Ignore the peak due to rabeprazole sodium.

Other tests. Comply with the tests stated under Capsules.

Assay. Determine by liquid chromatography (2.4.14).

For Rabeprazole Sodium -
NOTE — Use freshly prepared solutions and protected from light.
Buffer solution. Dissolve 3.4 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 7.6 with *triethylamine*.
Solvent mixture (a). Equal volumes of *acetonitrile* and *methanol*.
Solvent mixture (b). Equal volumes of solvent mixture (a) and the buffer solution.

Test solution. Mix the contents of 20 capsules. Disperse a quantity equivalent to 120 mg of Rabeprazole Sodium in 50 ml of the buffer solution, with the aid of ultrasound for about 15 minutes and dilute to 100.0 ml with solvent mixture (a) and filter. Dilute 5.0 ml of the solution to 50.0 ml with solvent mixture (b).

Reference solution. A 0.012 per cent w/v solution of *rabeprazole sodium RS* in solvent mixture (b).

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with octylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 60 volumes of buffer solution and 40 volumes of solvent mixture (a),
- flow rate: 1 ml per minute,
- spectrophotometer set at 284 nm,
- injection volume: 20 µl.

Inject the reference 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 is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{18}H_{20}N_3O_3SNa$.

For Itopride Hydrochloride -

Test solution. Mix the contents of 20 capsules. Disperse a quantity equivalent to 0.25 g of Itopride Hydrochloride in 70 ml of *methanol*, with the aid of ultrasound for about 15 minutes and dilute to 100.0 ml with the same solvent and filter. Dilute 5.0 ml of the solution to 50.0 ml with the mobile phase.

Reference solution. A 0.025 per cent w/v solution of *itopride hydrochloride RS* in the mobile phase.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 55 volumes of *0.05 M citric acid*, adjusted to pH 3.0 with *sodium hydroxide solution* and 45 volumes of *methanol*,
-flow rate: 1 ml per minute,
- spectrophotometer set at 258 nm,
- injection volume: 20 µl.

Inject the reference 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 is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{20}H_{26}N_2O_4HCl$.

Storage. Store protected from light and moisture, at a temperature not exceeding 30°.