Ergometrine hydrogen maleate tablets (Ergometrini hydrogenomaleatis compressi)

Category. Oxytocic.

Storage. Ergometrine hydrogen maleate tablets should be kept in a tightly closed container.

Labelling. Expiry date.

Requirements

Comply with the monograph for *Tablets*.

Ergometrine hydrogen maleate tablets contain not less than 90.0% and not more than 110.0% of the amount of $C_{19}H_{23}N_3O_2,C_4H_4O_4$ stated on the label.

Identity tests

A. See the test described below under "Related substances". The principal spot obtained with solution A corresponds in position, appearance and intensity with that obtained with solution E.

B. Extract a quantity of the powdered tablets equivalent to 2 mg of Ergometrine hydrogen maleate with 20 mL of water, filter and wash the residue with sufficient water to produce 20 mL; the solution has a blue fluorescence. To 2 mL add 4 mL of 4-dimethylaminobenzaldehyde TS1; a blue colour is slowly produced.

Related substances

Carry out the test protected from direct light as described under *1.14.1 Thin-layer chromatography* using a suspension of silica gel R1 in sodium hydroxide (0.1 mol/l) VS as the coating substance and a mixture of 9 volumes of chloroform R and 1 volume of methanol R as the mobile phase. Apply separately to the plate 5 µl of each of the following five solutions. For solution (A) triturate a quantity of the powdered tablets equivalent to 1 mg of Ergometrine hydrogen maleate with 0.2 mL of domiphen bromide (10 g/l) TS, add 2 mL of methanol R, centrifuge and remove the supernatant liquid. Extract the residue with two further quantities, each of 1 mL, of methanol R. Evaporate the combined extracts to dryness at 20 °C under reduced pressure (0.6 kPa or 5 mm of mercury) and dissolve the residue in 0.25 mL of methanol R; centrifuge if necessary. Solutions (B), (C), (D) and (E) are solutions in methanol R containing 0.1 mg per mL, 0.2 mg per mL, 0.4 mg per mL and 4 mg per mL, respectively, of ergometrine hydrogen maleate RS. After removing the plate from the chromatographic chamber allow it to dry in air and examine the chromatogram in ultraviolet light (365 nm).

Assess the intensity of each spot, other than the principal spot, obtained with solution A by reference to the spots obtained with solutions B, C and D; the total of the intensities so assessed does not exceed 10% of the intensity of the principal spot. In addition, no single spot, other than the principal spot, obtained with solution A is more intense than the spot obtained with solution B.

Assay

Weigh and powder 20 tablets. Shake a quantity of the powder equivalent to about 2 mg of Ergometrine hydrogen maleate, accurately weighed, with 50 mL of tartaric acid (10 g/l) TS for 30 minutes, centrifuge and use the supernatant liquid. Dilute a suitable volume to produce a solution containing 0.040 mg per mL of ergometrine hydrogen maleate. To 3 mL add 6 mL of 4-dimethylaminobenzaldehyde TS1, mix, cool to room temperature and allow to stand for 30 minutes.

Measure the absorbance of a 1 cm layer at the maximum at about 545 nm against a solvent cell containing a reagent blank composed of 6 mL of 4-dimethylaminobenzaldehyde TS1 and 3 mL of water. Calculate the amount in mg of $C_{19}H_{23}N_3O_2,C_4H_4O_4$ in the sample being examined by comparison with a solution containing 0.04 mg/mL of ergometrine hydrogen maleate RS.

Uniformity of content.

Individually transfer 10 powdered tablets to 10 separate stoppered test-tubes, add 10 mL of tartaric acid (10 g/l) TS, shake for 30 minutes and centrifuge. Dilute a suitable volume to produce a solution containing 0.040 mg per mL of ergometrine hydrogen maleate. To 3 mL of a clear solution add 6 mL of 4 dimethylaminobenzaldehyde TS1, mix, cool to room temperature and allow to stand for 30 minutes.

Measure the absorbance of a 1 cm layer at the maximum at about 545 nm against a solvent cell containing a reagent blank composed of 6 mL of 4-dimethylaminobenzaldehyde TS1 and 3 mL of water. Calculate the amount in mg of $C_{19}H_{23}N_3O_2,C_4H_4O_4$ in the sample being examined by comparison with a solution containing 0.04 mg/mL of ergometrine hydrogen maleate RS.

The tablets comply with the test for *5.1 Uniformity of content for single-dose preparations*.