Ergometrine injection (Ergometrini injectio)

2015-01

Description. A colourless to faintly yellow solution.

Category. Oxytocic.

Storage. Ergometrine injection should be kept in a single-dose container, protected from light and stored at a temperature between 2° and 8 °C.

Labelling. Expiry date.

Additional information. Strength in the current WHO Model list of essential medicines (EML): 200 µg/mL.

Requirements

Complies with the monograph for *Parenteral preparations*.

Definition. Ergometrine injection is a sterile solution of ergometrine hydrogen maleate in water for injections. Ergometrine hydrogen maleate may contain a suitable stabilizer. The solution is sterilized by "Heating in an autoclave" or by another suitable method (see *5.8 Methods of sterilization*).

Ergometrine injection contains 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. To a volume of the injection equivalent to 0.1 mg of Ergometrine hydrogen maleate add 0.5 mL of water and 2 mL of 4-dimethylaminobenzaldehyde TS1; a blue colour is slowly produced.

pH value. pH of the injection, 2.7–3.5.

Related substances. Carry out the test protected from light as described under *1.14.1 Chromatography*, 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) evaporate a volume of the injection equivalent to 1 mg of Ergometrine hydrogen maleate to dryness at 20 °C under reduced pressure (not exceeding 0.6 kPa or 5 mm of mercury) and dissolve the residue in 0.25 mL of methanol R. Prepare solutions (B), (C), (D) and (E) in methanol R containing 0.1 mg/mL, 0.2 mg/mL, 0.4 mg/mL and 4 mg/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) and in daylight after spraying with 4-dimethylaminobenzaldehyde TS2.

Assess the intensity of every 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 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 that obtained with solution B.

Assay

The solutions must be protected from light throughout the assay.

Dilute an accurately measured volume of the injection with sufficient water to produce a concentration of about 0.04 mg of Ergometrine hydrogen maleate per mL. 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. 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 ergometrine hydrogen maleate RS.

Bacterial endotoxins. Carry out the test as described under *3.4 Test for bacterial endotoxins*; contains less than 700 IU of endotoxin per mg Ergometrine hydrogen maleate.