Edition: BP 2025 (Ph. Eur. 11.6 update)

Ergometrine Injection

General Notices

Action and use

Oxytocic.

DEFINITION

Ergometrine Injection is a sterile solution of Ergometrine Maleate in Water for Injections. The acidity of the solution is adjusted to pH 3 by the addition of maleic acid.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of ergometrine maleate, $C_{19}H_{23}N_3O_2,C_4H_4O_4$

90.0 to 110.0% of the stated amount.

CHARACTERISTICS

A colourless or faintly yellow solution.

IDENTIFICATION

A. In the test for Related substances, the principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (5).
B. Exhibits a blue fluorescence.
C. To a volume containing 0.1 mg of Ergometrine Maleate, add 0.5 mL of *water* and 2 mL of *dimethylaminobenzaldehyde solution R6*. A deep blue colour is produced after about 5 minutes.

TESTS

Acidity

pH, 2.7 to 3.5, Appendix V L.

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, in subdued light, using the following solutions in *methanol*. Protect from light any solutions not used immediately.

(1) Evaporate a volume of the injection containing 1 mg of Ergometrine Maleate to dryness at 20° at a pressure of 2 kPa and dissolve the residue in 0.25 mL.
(2) 0.010% w/v of *ergometrine maleate BPCRS*.

(3) 0.020% w/v of *ergometrine maleate BPCRS*.
(4) 0.040% w/v of *ergometrine maleate BPCRS*.
(5) 0.40% w/v of *ergometrine maleate BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a suspension of *silica gel G* in 0.1M *sodium hydroxide* to prepare the plate.
(b) Use the mobile phase as described below.
(c) Apply 5 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air and examine under *ultraviolet light (365 nm)*.

MOBILE PHASE

10 volumes of *methanol* and 90 volumes of *chloroform*.

LIMITS

Assess the intensities of any *secondary spots* in the chromatogram obtained with solution (1) by reference to the spots in the chromatograms obtained with solutions (2), (3) and (4). The total of the intensities so assessed does not exceed 10% of the intensity of the principal spot.

ASSAY

Carry out the following procedure protected from light using the following two solutions prepared at the same time.

(1) Dilute a suitable volume with sufficient *water* to produce a solution containing 0.004% w/v of Ergometrine Maleate. To 3 mL add 6 mL of *dimethylaminobenzaldehyde solution R6*, mix, cool to room temperature and allow to stand for 30 minutes.
(2) To 3 mL of a 0.004% w/v solution of *ergometrine maleate BPCRS* add 6 mL of *dimethylaminobenzaldehyde solution R6*, mix, cool to room temperature and allow to stand for 30 minutes.

Measure the *absorbance* of solution (2) at the maximum at 545 nm, Appendix II B, using in the reference cell a solution prepared by mixing 6 mL of *dimethylaminobenzaldehyde solution R6* and 3 mL of *water*. Without delay replace solution (2) with solution (1), using the same cell, and measure the *absorbance* of solution (1) at the same wavelength. Calculate the content of $C_{19}H_{23}N_3O_2,C_4H_4O_4$ using the declared content of $C_{19}H_{23}N_3O_2,C_4H_4O_4$ in *ergometrine maleate BPCRS*.

STORAGE

Ergometrine Injection should be protected from light and stored at a temperature of 2° to 8°.