Ergometrine Maleate Tablets

マイレイン酸エルゴメトリン錠

Ergometrine Maleate Tablets contain not less than 90% and not more than 110% of the labeled amount of ergometrine maleate (C_{19}H_{23}N_2O_2.C_4H_4O_4: 441.48).

Method of preparation

Prepare as directed under Tablets, with Ergometrine Maleate.

Identification

To a quantity of powdered Ergometrine Maleate Tablets, equivalent to 3 mg of Ergometrine Maleate according to the labeled amount, add 15 mL of warm water, shake, and filter: the filtrate shows a blue fluorescence. Proceed with this solution as directed in the Identification (2) and (3) under Ergometrine Maleate.

Content uniformity

Transfer 1 tablet of Ergometrine Maleate Tablets to a glass-stoppered centrifuge tube, and add a solution of t-tartaric acid (1 in 100) to make exactly V mL of a solution containing about 0.04 mg of ergometrine maleate (C_{19}H_{23}N_2O_2.C_4H_4O_4) per ml. Stopper the tube, shake for 30 minutes vigorously, centrifuge, and use the supernatant liquid as the sample solution. Separately, weigh accurately about 4 mg of Ergometrine Maleate Reference Standard, previously dried in a desiccator (silica gel) for 4 hours, and dissolve in water to make exactly 100 mL, and use this solution as the standard solution. Pipet 4 mL each of the sample solution and the standard solution into separate brown glass-stoppered test tubes, add exactly 8 mL each of 4-

Ergometrine Maleate Injection

マイレイン酸エルゴメトリン注射液

Ergometrine Maleate Injection is an aqueous solution for injection. It contains not less than 90% and not more than 110% of the labeled amount of ergometrine maleate (C_{19}H_{23}N_2O_2.C_4H_4O_4: 441.48).

Method of preparation

Prepare as directed under Injections, with Ergometrine Maleate.

Description

Ergometrine Maleate Injection is a clear, colorless to pale yellow liquid.

pH: 2.7 - 3.5

Identification

(1) Measure a volume of Ergometrine Maleate Injection, equivalent to 3 mg of Ergometrine Maleate according to the labeled amount, if necessary, dilute with water or evaporate on a water bath to make 15 mL, and use this solution as the sample solution. The sample solution shows a blue fluorescence.

(2) To 1 mL of the sample solution obtained in (1) add 1 mL of ammonia TS, and extract with 20 mL of diethyl ether. To the diethyl ether extract add 1 mL of dilute sulfuric acid, shake, and warm to remove diethyl ether in a water bath. Cool, to the residue obtained add 2 mL of 4-dimethylaminobenzaldehyde-ferric chloride TS, and allow to stand for 5 to 10 minutes: a deep blue color develops.

(3) To 5 mL of the sample solution obtained in (1) add 1 drop of potassium permanganate TS: a red color disappears immediately.

Assay

Transfer an exactly measured volume of Ergometrine Maleate Injection, equivalent to about 2 mg of ergometrine maleate (C_{19}H_{23}N_2O_2.C_4H_4O_4), and add sodium chloride in a ratio of 0.3 g to 1 mL of the solution. To this mixture add 20 mL of diethyl ether and 2 mL of ammonia TS, shake, and extract. Further, extract with three 15-mL portions of diethyl ether, combine all the extracts, add 5 g of anhydrous sodium sulfate, filter through a pledget of absorbent cotton, and wash with three 5-mL portions of diethyl ether. Add the washings to the filtrate, shake with 5 mL of dilute sulfuric acid, evaporate the diethyl ether by warming in a current of nitrogen, to the remaining solution add water to make exactly 50 mL, and use this solution as the sample solution. Weigh accurately about 2 mg of Ergometrine Maleate Reference Standard, previously dried in a desiccator (silica gel) for 4 hours, add water to make exactly 50 mL, and use this solution as the standard solution. Transfer 2 mL each of the sample solution and the standard solution, accurately measured, to separate glass-stoppered test tubes, and proceed as directed in the Assay under Ergometrine Maleate.

Amount (mg) of ergometrine maleate (C_{19}H_{23}N_2O_2.C_4H_4O_4) = amount (mg) of Ergometrine Maleate Reference Standard \times \frac{A_T}{A_S}

Containers and storage

Containers—Hermetic containers, and colored containers may be used.

Storage—Light-resistant, and in a cold place.