

and the same  $R_f$  value, and any spot from the sample solution other than that corresponding to the spot from the standard solution does not appear.

**Loss on drying** Not more than 2.0% (0.2 g, silica gel, 4 hours).

**Assay** Weigh accurately about 0.01 g each of Ergometrine Maleate and Ergometrine Maleate Reference Standard, previously dried in a desiccator (silica gel) for 4 hours, dissolve in water to make exactly 250 mL, and use these solutions as the sample solution and the standard solution, respectively. Pipet 2 mL of each solution into a separate brown glass-stoppered tube. To each tube add 4 mL of 4-dimethylaminobenzaldehyde-ferric chloride TS, exactly measured, while cooling in an ice bath, then warm at 45°C for 10 minutes. Allow to stand at room temperature for 20 minutes, and perform the test with these solutions as directed under the Ultraviolet-visible Spectrophotometry, using a solution, prepared with 2 mL of water in the same manner, as the blank. Determine the absorbances,  $A_T$  and  $A_S$ , of the subsequent solutions of the sample solution and the standard solution at 550 nm, respectively.

$$\begin{aligned} & \text{Amount (mg) of } C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4 \\ & = \text{amount (mg) of Ergometrine Maleate} \\ & \quad \text{Reference Standard} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

**Containers and storage** Containers—Tight containers.  
Storage—Light-resistant.

## Ergometrine Maleate Injection

マ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 ( $C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4$ ; 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 ( $C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4$ ), 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.

$$\begin{aligned} & \text{Amount (mg) of ergometrine maleate } (C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4) \\ & = \text{amount (mg) of Ergometrine Maleate} \\ & \quad \text{Reference Standard} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

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

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

## Ergometrine Maleate Tablets

マ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 ( $C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4$ ; 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 L-tartaric acid (1 in 100) to make exactly  $V$  mL of a solution containing about 0.04 mg of ergometrine maleate ( $C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4$ ) 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, 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-