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Ergonovine Maleate Injection

» Ergonovine Maleate Injection is a sterile solution of Ergonovine Maleate in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4$.

Packaging and storage—Preserve in single-dose, light-resistant containers, preferably of Type I glass, and store in a cold place.

USP Reference standards ⟨11⟩—

USP Ergonovine Maleate RS

Identification—The R_F value of the principal blue spot obtained from the *Test preparation* corresponds to that obtained from *Standard preparation A* in the chromatogram prepared as directed in the test for *Related alkaloids*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 700.0 USP Endotoxin Units per mg of ergonovine maleate.

pH ⟨791⟩**:** between 2.7 and 3.5.

Related alkaloids— [Note—Conduct this test promptly, without exposure to daylight and with minimum exposure to artificial light.]

Solvent mixture, Standard preparation, and *Standard dilutions*—Prepare as directed in the test for *Related alkaloids* under *Ergonovine Maleate*.

Test preparation—Immediately prior to use, transfer a volume of Injection, equivalent to about 5 mg of ergonovine maleate, to a separator, and extract with three 5-mL portions of chloroform. Discard the chloroform extracts. Render alkaline to litmus with 6 N ammonium hydroxide, and extract with three 5-mL portions of chloroform. Evaporate the combined extracts with the aid of a stream of nitrogen, but without heat, to dryness. Dissolve the residue so obtained in 0.5 mL of *Solvent mixture*.

Procedure—Proceed as directed for *Procedure* in the test for *Related alkaloids* under *Ergonovine Maleate*.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay—

0.05 M Phosphate buffer—Dissolve 6.8 g of monobasic potassium phosphate in 600 mL of water and adjust with phosphoric acid to a pH of 2.1. Dilute with water to 1000 mL, and mix.

Mobile phase—Prepare a suitable and degassed solution of *0.05 M Phosphate buffer* and acetonitrile (80:20) such that the retention time is approximately 3 minutes with a flow rate of 1 mL per minute.

Standard preparation—Dissolve an accurately weighed quantity of USP Ergonovine Maleate RS in *Mobile phase*, adding sufficient water to equal 10% of the final volume, to obtain a solution having a known concentration of about 0.02 mg per mL.

Assay preparation—Quantitatively dilute an accurately measured volume of the Injection, equivalent to about 2 mg of ergonovine maleate, with *Mobile phase* and water, if necessary, to obtain a solution having a concentration of about 0.02 mg per mL in which the Injection volume plus any added water constitutes 10% of the final volume.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 312-nm detector and a 3-mm × 30-cm column that contains packing L1. Chromatograph five replicate injections of the *Standard preparation*, and record the peak responses as directed under *Procedure:* the relative standard deviation is not more than 3.0%.

Procedure—By means of a suitable sampling valve, introduce equal volumes (about 100 µL) of the *Assay preparation* and the *Standard preparation* into the chromatograph. Measure the peak responses of Ergonovine Maleate, at corresponding retention times, obtained from the *Assay preparation* and the *Standard preparation*. Calculate the quantity, in mg, of $C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4$ in each mL of the Injection taken by the formula:

$$(CD/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Ergonovine Maleate RS in the *Standard preparation*, V is the volume, in mL, of Injection taken, D is the dilution factor, and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ERGONOVINE MALEATE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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