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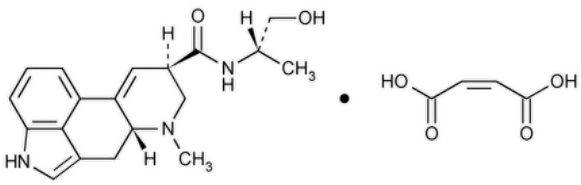
Ergonovine Maleate



$C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4$ 441.48

Ergoline-8-carboxamide, 9,10-didehydro-*N*-(2-hydroxy-1-methylethyl)-6-methyl-, 8β(*S*)-, (*Z*)-2-butenedioate (1:1) (salt).

9,10-Didehydro-*N*-[(*S*)-2-hydroxy-1-methylethyl]-6-methylergoline-8β-carboxamide maleate (1:1) (salt) CAS RN®: 129-51-1; UNII: YMH3D0ZJWV.

» Ergonovine Maleate contains not less than 97.0 percent and not more than 103.0 percent of $C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers, in a cold place.

USP Reference standards ⟨11⟩—

USP Ergonovine Maleate RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ *(CN 1-May-2020)* —

Solution: 20 µg per mL.

Medium: alcohol.

Absorptivities at 311 nm, calculated on the dried basis, do not differ by more than 3.0%.

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

Specific rotation ⟨781S⟩: between +51° and +56°.

Test solution: 5 mg per mL, in water.

Loss on drying ⟨731⟩—Dry it in vacuum at 80° for 3 hours: it loses not more than 2.0% of its weight.

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

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture.

Solvent mixture—Prepare a mixture of alcohol and ammonium hydroxide (9:1).

Standard preparation—Prepare a solution of USP Ergonovine Maleate RS in *Solvent mixture* having a known concentration of about 10 mg per mL.

Standard dilutions—Prepare a series of dilutions of the *Standard preparation* in *Solvent mixture* having known concentrations of about 0.20, 0.10, and 0.05 mg per mL. Use immediately after preparation.

Test preparation—Immediately prior to use, prepare a solution of Ergonovine Maleate in *Solvent mixture* having a concentration of about 10 mg per mL.

Application volume: 5 µL.

Developing solvent system: a mixture of chloroform, methanol, and water (75:25:3), equilibrated for 30 minutes.

Procedure—Apply 5-µL portions of the *Standard preparation*, each of the three *Standard dilutions*, and the *Test preparation*, and proceed as directed for *Thin-Layer Chromatography* under *Chromatography* ⟨621⟩. Locate the spots on the plate by spraying thoroughly and evenly with a solution prepared by dissolving 1 g of *p*-dimethylaminobenzaldehyde in a cooled mixture of 50 mL of alcohol and 50 mL of hydrochloric acid. Immediately dry in a stream of nitrogen for about 2 minutes: the R_F value of the principal spot obtained from the *Test preparation* corresponds to that obtained from the *Standard preparation*. Estimate the concentration of any other spots observed in the chromatogram of the *Test preparation* by comparison with the *Standard dilutions*. The spots from the 0.20, 0.10, and 0.05 mg per mL dilutions are equivalent to 2.0%, 1.0%, and 0.50% of impurities, respectively. The sum of the impurities is not greater than 2.0%.

Assay—

Standard preparation—Using a suitable quantity of USP Ergonovine Maleate RS, accurately weighed, prepare a solution in water having a known concentration of about 40 µg per mL.

Assay preparation—Transfer about 40 mg of Ergonovine Maleate, accurately weighed, to a 100-mL volumetric flask, dilute with water to volume, and mix. Dilute 10.0 mL of this solution with water to 100.0 mL.

Procedure—Transfer 5.0 mL each of the *Standard preparation*, the *Assay preparation*, and water to provide a blank, to separate conical flasks. Add 10.0 mL of *p*-dimethylaminobenzaldehyde TS with constant swirling to each, and allow to stand for 20 minutes. Concomitantly determine the absorbances of the solutions in 1-cm cells at the wavelength of maximum absorbance at about 555 nm, with a suitable spectrophotometer, against the blank. Calculate the quantity, in mg, of $C_{19}H_{23}N_3O_2 \cdot C_4H_4O_4$ taken by the formula:

$$C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Ergonovine Maleate RS in the *Standard preparation*, and A_U and A_S are the absorbances of the solutions 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	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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