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Methylergonovine Maleate Injection

DEFINITION

Methylergonovine Maleate Injection is a sterile solution of Methylergonovine Maleate in Water for Injection. Each mL contains NLT 90.0% and NMT 110.0% of the labeled amount of methylergonovine maleate ($C_{20}H_{25}N_3O_2 \cdot C_4H_4O_4$).

IDENTIFICATION

• **A.** The R_F values of the principal fluorescent spot and the principal blue spot of the *Sample solution* correspond to those of the *Standard stock solution*, as obtained in the procedure for *Organic Impurities, Related Alkaloids*.

• **B. Procedure**

Sample solution: 0.67 mg/mL of methylergonovine maleate from Injection in water

Analysis: The *Sample solution* exhibits a bluish fluorescence under UV light. To this solution add 2 mL of a solution of glacial acetic acid in ethyl acetate (1:2), and stratify 2 mL of sulfuric acid, by pipetting, under the solution.

Acceptance criteria: A bluish-purple ring appears at the interface of the two liquids.

ASSAY

• **Procedure**

[Note—Conduct this procedure with minimum exposure to light.]

Mobile phase: Acetonitrile and 0.015 M monobasic potassium phosphate solution (1:4)

Diluent: 5 mg/mL of tartaric acid in water and methanol (1:1). Allow the mixture to cool before use. [Note—Dissolve tartaric acid with water, then add an equal volume of methanol.]

Standard solution: 100 µg/mL of USP Methylergonovine Maleate RS in *Diluent*. [Note—Shake by mechanical means for 15 min or until completely dissolved.]

Sample solution: 100 µg/mL of methylergonovine maleate from Injection in *Diluent*

Chromatographic system

(See *Chromatography (621), System Suitability*.)

Mode: LC

Detector: UV 240 nm

Column: 4-mm × 25-cm; packing L7

Column temperature: 30°

Flow rate: 2 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{20}H_{25}N_3O_2 \cdot C_4H_4O_4$ in each mL of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Methylergonovine Maleate RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

Organic Impurities

• **Procedure: Related Alkaloids**

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

Diluent: Alcohol and ammonium hydroxide (9:1)

[Note—All solutions should be prepared immediately before use.]

Standard stock solution: 10 mg/mL of USP Methylergonovine Maleate RS in *Diluent*

Standard solution A: 0.50 mg/mL of USP Methylergonovine Maleate RS from the *Standard stock solution* in *Diluent*

Standard solution B: 0.20 mg/mL of USP Methylergonovine Maleate RS from the *Standard stock solution* in *Diluent*

Standard solution C: 0.10 mg/mL of USP Methylergonovine Maleate RS from the *Standard stock solution* in *Diluent*

Standard solution D: 0.05 mg/mL of USP Methylergonovine Maleate RS from the *Standard stock solution* in *Diluent*

Sample solution: Transfer the equivalent of 5 mg of methylergonovine maleate from Injection 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 current of air, but without heat, to dryness. Dissolve the residue so obtained in 0.5 mL of *Diluent*.

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Chloroform, methanol, and water (75:25:3), equilibrated for 30 min

Spray reagent: 10 mg/mL of *p*-dimethylamino benzaldehyde in a cooled mixture of alcohol and hydrochloric acid (1:1)

Analysis

Samples: *Standard stock solution*, *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, and *Sample solution*

Proceed as directed in the chapter. Locate the spots on the plate by spraying thoroughly and evenly with *Spray reagent*. Immediately dry in a stream of nitrogen for 2 min.

Acceptance criteria: The R_F value of the principal spot from the *Sample solution* corresponds to that from the *Standard stock solution*.

Estimate the concentration of any other spots observed in the lane for the *Sample solution* by comparison with *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Standard solution D*: the spots from the 0.50-, 0.20-, 0.10-, and 0.05-mg/mL dilutions are equivalent to 5.0%, 2.0%, 1.0%, and 0.50% of impurities, respectively. The sum of the impurities is NMT 5.0%.

SPECIFIC TESTS

• **pH ⟨791⟩:** 2.7–3.5

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 1.7 USP Endotoxin Units/µg of methylergonovine maleate

• **Other Requirements:** Meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose, light-resistant containers, preferably of Type I glass. Store in a refrigerator.

• **USP Reference Standards ⟨11⟩**

USP Methylergonovine Maleate RS

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

Topic/Question	Contact	Expert Committee
METHYLERGONOVINE 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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