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Benztropine Mesylate Injection

DEFINITION

Benztropine Mesylate Injection is a sterile solution of Benztropine Mesylate in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of benztropine mesylate ($C_{21}H_{25}NO \cdot CH_4O_3S$).

IDENTIFICATION

• **A.**

Standard stock solution: 0.2 mg/mL of USP Benztropine Mesylate RS

Standard solution: In a separator containing the *Standard stock solution* add 2 mL of 1 N sodium hydroxide. Extract with three 10-mL portions of chloroform, collecting the chloroform extracts to a 50-mL beaker. Evaporate the chloroform extracts with the aid of gentle heat and a current of air to dryness, and dissolve the residue in 1 mL of chloroform.

Sample stock solution: Dilute a volume of Injection, equivalent to 10 mg of benztropine mesylate, in a separator to 50 mL with water (0.2 mg/mL).

Sample solution: In a separator containing the *Sample stock solution* add 2 mL of 1 N sodium hydroxide. Extract with three 10-mL portions of chloroform, collecting the chloroform extracts to a 50-mL beaker. Evaporate the chloroform extracts with the aid of gentle heat and a current of air to dryness, and dissolve the residue in 1 mL of chloroform.

Chromatographic system

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 1 µL

Developing solvent system: Chloroform, methanol, and a 1-in-4 solution of ammonium hydroxide (40:10:1)

Analysis

Samples: *Standard solution* and *Sample solution*

Allow the applications to dry, and develop the chromatogram in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by lightly spraying with potassium iodoplatinate TS.

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

ASSAY

• **Procedure**

Buffer: Transfer 0.83 mL of octylamine to a 1-L volumetric flask, dilute with water to volume, and adjust with phosphoric acid to a pH of 3.0.

Mobile phase: Acetonitrile and *Buffer* (65:35)

Standard solution: 1 mg/mL of USP Benztropine Mesylate RS

Sample solution: Nominally 1 mg/mL of benztropine mesylate from the volume of Injection

Chromatographic system

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

Mode: LC

Detector: UV 259 nm

Column: 4.6-mm × 25-cm; packing L7

Flow rate: 1.3 mL/min adjusted, as needed, to obtain a retention time of 7 min for benztropine mesylate

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of labeled amount of benztropine mesylate ($C_{21}H_{25}NO \cdot CH_4O_3S$) in each mL of the Injection:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Benztropine Mesylate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of benztropine mesylate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** NMT 55.6 USP Endotoxin Units/mg of benztropine mesylate
- **pH ⟨791⟩:** 5.0–8.0
- **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or in multiple-dose containers, preferably of Type I glass.
- **USP Reference Standards ⟨11⟩**
  USP Benztropine Mesylate RS

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

Topic/Question	Contact	Expert Committee
BENZTROPINE MESYLATE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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