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Benztropine Mesylate Tablets

DEFINITION
Benztropine Mesylate Tablets contain 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: Dissolve a portion of finely powdered Tablets, equivalent to 10 mg of benztropine mesylate, in 50 mL of water, shake by mechanical means for 30 min, and filter into a separator (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.

Diluent: Isopropyl alcohol, water, and phosphoric acid (40:60:0.1)

Mobile phase: Acetonitrile and *Buffer* (45:55)

Standard solution: 0.04 mg/mL of USP Benztropine Mesylate RS in *Diluent*

Sample solution: Nominally 0.04 mg/mL of benztropine mesylate from a suitable amount of powdered Tablets in *Diluent* prepared as follows. Add a suitable amount of fine powder from NLT 20 Tablets to a portion of *Diluent* corresponding to 60% of the final volume. Mix by mechanical means for NLT 60 min, and dilute with *Diluent* to volume. Centrifuge a portion of this mixture, and filter the supernatant layer.

Chromatographic system

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

Mode: LC

Detector: UV 259 nm

Column: 4.6-mm × 25-cm; packing L7

Flow rate: 0.7 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 4.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of benztropine mesylate ($C_{21}H_{25}NO \cdot CH_4O_3S$) in the portion of Tablets 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 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%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Determine the amount of benztropine mesylate ($C_{21}H_{25}NO \cdot CH_4O_3S$) dissolved by using the following method.

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

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

Standard solution: USP Benztropine Mesylate RS in *Medium*. Dilute to obtain a solution having a known concentration similar to that of the *Sample solution*.

Sample solution: Use a filtered portion of the solution under test from the dissolution vessel.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; packing L7

Flow rate: 2 mL/min

Injection volume: 300 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

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)

V = volume of the *Medium*, 900 mL

L = label claim (mg/Tablet)

Acceptance criteria: NLT 80% (*Q*) of the labeled amount of benztropine mesylate ($C_{21}H_{25}NO \cdot CH_4O_3S$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **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 TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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