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Hyoscyamine Sulfate Injection

DEFINITION

Hyoscyamine Sulfate Injection is a sterile solution of Hyoscyamine Sulfate in Water for Injection. It contains NLT 93.0% and NMT 107.0% of the labeled amount of hyoscyamine sulfate $[(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4 \cdot 2H_2O]$.

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

• **B.** **Identification Tests—General, *Sulfate* ⟨191⟩:** After evaporation to dryness, or appropriate adjustment of concentration, it meets the requirements of the tests.

• **C.** The angular rotation of the Injection is levorotatory.

ASSAY

• **Procedure**

Buffer: Transfer 13.6 g of monobasic potassium phosphate to a 2000-mL volumetric flask, and dissolve in about 1800 mL of water. Adjust with phosphoric acid to a pH of 3.0 ± 0.1, dilute with water to volume, and filter.

Mobile phase: With continuous stirring, add 0.3 mL of triethylamine to 1800 mL of *Buffer*. Add 200 mL of acetonitrile, and degas.

Diluent: 0.01 N hydrochloric acid

Standard stock solution: 0.16 mg/mL of anhydrous hyoscyamine sulfate from USP Hyoscyamine Sulfate RS in *Diluent*. [Note—This solution may be stored in a refrigerator for 30 days.]

Standard solution: 4.8 µg/mL of anhydrous hyoscyamine sulfate from the *Standard stock solution* in *Diluent*

Sample solution: 5.0 µg/mL of hyoscyamine sulfate from an appropriate volume of Injection in *Diluent*. Pass an aliquot through a suitable filter of 0.45-µm pore size, and discard the first 5 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 205 nm

Columns

Guard: 3-mm × 4-mm; packing L11

Analytical: 4.6-mm × 15-cm; 4-µm packing L11

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.8

Relative standard deviation: NMT 2.0% for six replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of hyoscyamine sulfate $[(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4 \cdot 2H_2O]$ in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of anhydrous hyoscyamine sulfate in the *Standard solution* (µg/mL)

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

M_{r1} = molecular weight of hyoscyamine sulfate, 712.85

M_{r2} = molecular weight of anhydrous hyoscyamine sulfate, 676.83

Acceptance criteria: 93.0%–107.0%

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 3.0–6.5
- **Bacterial Endotoxins Test** ⟨85⟩**:** It contains NMT 714.3 USP Endotoxin Units/mg of hyoscyamine sulfate.
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, and store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩
  USP Hyoscyamine Sulfate RS

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

Topic/Question	Contact	Expert Committee
HYOSCYAMINE SULFATE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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