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Hyoscyamine Sulfate Tablets

DEFINITION
Hyoscyamine Sulfate Tablets contain NLT 90.0% and NMT 110.0% 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⟩:** A filtered solution of Tablets meets the requirements of the tests.

ASSAY
- **Procedure**

Buffer: Transfer 13.6 g of monobasic potassium phosphate to a 2000-mL volumetric flask, dissolve in about 1800 mL of water, and 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*

Tropic acid solution: 3 µg/mL of tropic acid in *Diluent*

System suitability solution: Transfer 3.0 mL of the *Standard stock solution* into a 100-mL volumetric flask, add 4.0 mL of the *Tropic acid solution*, and dilute with *Diluent* to volume.

Sample solution: Finely powder NLT 20 Tablets. Transfer a quantity of the powder equivalent to 0.125 mg of hyoscyamine sulfate to a 25-mL volumetric flask. Add 20 mL of *Diluent*, and sonicate for 15 min with occasional swirling. Allow to cool to room temperature, and dilute with *Diluent* to volume. 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: *System suitability solution*

[Note—The elution order is the tropic acid peak, followed by the hyoscyamine peak.]

Suitability requirements

Resolution: NLT 1.5 between tropic acid and hyoscyamine

Tailing factor: NMT 1.8 for the hyoscyamine peak

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 Tablets 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)

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **Disintegration ⟨701⟩:** 15 min
- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.
- **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 TABLETS	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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