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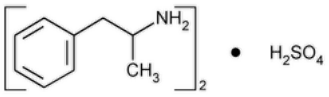
Amphetamine Sulfate



$(C_9H_{13}N)_2 \cdot H_2SO_4$ 368.49

Benzeneethanamine, α-methyl-, sulfate (2:1), (±)-;

(±)-α-Methylphenethylamine sulfate (2:1) CAS RN®: 60-13-9; UNII: 6DPV8NK46S.

DEFINITION

Amphetamine Sulfate contains NLT 98.0% and NMT 102.0% of $(C_9H_{13}N)_2 \cdot H_2SO_4$ on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (CN 1-May-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **C.** **Identification Tests—General, *Sulfate*⟨191⟩:** Meets the requirements

Sample solution: 100 mg/mL

ASSAY

- **Procedure**

Solution A: Add 5.0 mL of trifluoroacetic acid to 900 mL of water, adjust with ammonium hydroxide to a pH of 2.2 ± 0.1, and add 100 mL of acetonitrile.

Solution B: Use degassed acetonitrile.

Mobile phase: See the gradient table below.

Time (min)	Solution A (%)	Solution B (%)
0	100	0
15	65	35
20	0	100
22	0	100
23	100	0
30	100	0

Standard solution: 2.0 mg/mL of USP Dextroamphetamine Sulfate RS in *Solution A*

System suitability solution: Transfer 40 mL of the *Standard solution* to a 50-mL volumetric flask. Using a microliter syringe, add 1 µL each of USP Dextroamphetamine Related Compound A RS and USP Dextroamphetamine Related Compound B RS. Dilute with *Standard solution* to volume, and mix.

Sample solution: 2.0 mg/mL of Amphetamine Sulfate in *Solution A*

Chromatographic system

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

Mode: LC

Detector: UV 257 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

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Injection size: 20 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

[NOTE—Identify the peaks by the relative retention times in *Impurity Table 1* under *Organic Impurities*. Amphetamine and dextroamphetamine have exactly the same retention time.]

Suitability requirements

Resolution: NLT 3.0 between dextroamphetamine related compound A and dextroamphetamine related compound B, *System suitability solution*

Tailing factor: NMT 3.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $(C_9H_{13}N)_2 \cdot H_2SO_4$ in the portion of Amphetamine Sulfate taken:

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

r_U = peak response for amphetamine sulfate from the *Sample solution*

r_S = peak response for dextroamphetamine sulfate from the *Standard solution*

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

C_U = concentration of Amphetamine Sulfate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

Inorganic Impurities

- **Residue on Ignition ⟨281⟩:** NMT 0.2%

Organic Impurities

- **Procedure**

Solution A, Solution B, Mobile phase, System suitability solution, Standard solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—Identify the impurities by the relative retention times in *Impurity Table 1*.]

Calculate the percentage of each impurity in the portion of Amphetamine Sulfate taken:

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

r_U = peak response for each impurity from the *Sample solution*

r_S = peak response for dextroamphetamine from the *Standard solution*

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

C_U = concentration of Amphetamine Sulfate in the *Sample solution* (mg/mL)

F = relative response factor (see *Impurity Table 1*)

Acceptance criteria

Individual impurities: See *Impurity Table 1*.

Total impurities: NMT 1.0%

Impurity Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Cathinone	0.81	55.6	0.25
Amphetamine	1.0	1.0	—
Benzaldehyde	1.73	105.3	0.25

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Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Dextroamphetamine related compound A	1.88	1.5	0.25
Dextroamphetamine related compound B	2.05	1.8	0.25
Individual unspecified impurity	—	1.0	0.1

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩:** Dry a sample at 105° for 2 h: it loses NMT 1.0% of its weight.

• **Dextroamphetamine:** A solution (20 mg/mL) is optically inactive.

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Dextroamphetamine Sulfate RS

USP Dextroamphetamine Related Compound A RS

1-Phenyl-2-propanol.

$C_9H_{12}O$ 136.20 CAS RN®: CAS-14898-87-4.

USP Dextroamphetamine Related Compound B RS

Phenyl acetone.

$C_9H_{10}O$ 134.18 CAS RN®: CAS-103-79-7.

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

Topic/Question	Contact	Expert Committee
AMPHETAMINE SULFATE	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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