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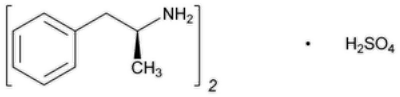
Dextroamphetamine Sulfate



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

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

(+)-α-Methylphenethylamine sulfate (2:1) CAS RN®: 51-63-8; UNII: JJ768O327N.

DEFINITION

Dextroamphetamine Sulfate, the dextrorotatory isomer of amphetamine sulfate, contains NLT 98.0% and NMT 102.0% of dextroamphetamine sulfate [$(C_9H_{13}N)_2 \cdot H_2SO_4$], calculated 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*.

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: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

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 about 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.

Sample solution: 2.0 mg/mL of Dextroamphetamine 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

Injection volume: 20 µL

System suitability

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

[NOTE—See *Table 2* for the relative retention times.]

Suitability requirements

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

Tailing factor: NMT 3.0 for dextroamphetamine, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dextroamphetamine sulfate $[(C_9H_{13}N)_2 \cdot H_2SO_4]$ in the portion of Dextroamphetamine Sulfate 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 Dextroamphetamine Sulfate RS in the *Standard solution* (mg/mL)

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

Acceptance criteria 98.0%–102.0% on the dried basis

IMPURITIES

- **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%
- **ORGANIC IMPURITIES**

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

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

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

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

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

F = relative response factor (see *Table 2*)

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Cathinone	0.81	55.6	0.25
Dextroamphetamine	1.0	1.0	—
Benzaldehyde	1.73	105.3	0.25
Dextroamphetamine related compound A	1.88	1.5	0.25
Dextroamphetamine related compound B	2.05	1.8	0.25

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Individual unspecified impurity	—	1.0	0.1
Total impurities	—	—	1.0

SPECIFIC TESTS

- **Optical Rotation,** *Specific Rotation*⟨781S⟩

  Sample solution: 40 mg/mL of Dextroamphetamine Sulfate in water

  Acceptance criteria: +20° to +23.5°

- **pH** ⟨791⟩

  Sample solution: 50 mg/mL of Dextroamphetamine Sulfate in water

  Acceptance criteria: 5.0–6.0

- **Loss on Drying** ⟨731⟩

  Analysis: Dry at 105° for 2 h.

  Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩

  USP Dextroamphetamine Related Compound A RS

  1-Phenyl-2-propanol.

  $C_9H_{12}O$ 136.19

  USP Dextroamphetamine Related Compound B RS

  Phenyl acetone.

  $C_9H_{10}O$ 134.18

  USP Dextroamphetamine Sulfate RS

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

Topic/Question	Contact	Expert Committee
DEXTROAMPHETAMINE SULFATE	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 34(4)

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