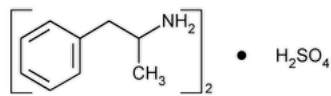


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Amphetamine Sulfate



$(C_9H_{13}N)_2 \cdot H_2SO_4$ 368.49
Benzeneethanamine, α -methyl-, sulfate (2:1), ($\pm$);
($\pm$)- 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 μ L 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 $\times$ 15-cm; 5- μ m packing L1
Column temperature: 40°
Flow rate: 1.5 mL/min

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	