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Ephedrine Sulfate Injection

DEFINITION

Ephedrine Sulfate Injection is a sterile solution of Ephedrine Sulfate in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of ephedrine sulfate $[(C_{10}H_{15}NO)_2 \cdot H_2SO_4]$.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Sample: Mix 1 mL of Injection with 5 mL of alcohol, and evaporate on a steam bath with the aid of a current of air to dryness.

Acceptance criteria: The residue obtained from the *Sample* meets the requirements.

• **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: To 1 L of water add 4 mL of triethylamine. Adjust with phosphoric acid to a pH of 4.0.

Mobile phase: Acetonitrile and *Solution A* (1:99)

System suitability solution: 0.1 mg/mL of USP Ephedrine Sulfate RS and 0.01 mg/mL of USP Pseudoephedrine Sulfate RS in water

Standard solution: 0.1 mg/mL of USP Ephedrine Sulfate RS in water

Sample solution: Nominally 0.1 mg/mL of ephedrine sulfate in water prepared as follows. Transfer a portion of Injection to a suitable volumetric flask. Dilute with water to volume, and mix well.

Chromatographic system

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

Mode: LC

Detector: UV 206 nm

Column: 2.1-mm × 10-cm; 2.6-µm packing L11

Column temperature: 30°

Flow rate: 0.6 mL/min

Injection volume: 10 µL

Run time: NLT 3 times the retention time of ephedrine

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between ephedrine and pseudoephedrine, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ephedrine sulfate $[(C_{10}H_{15}NO)_2 \cdot H_2SO_4]$ in the portion of Injection taken:

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

r_U = peak response of ephedrine from the *Sample solution*

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

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

C_U = nominal concentration of ephedrine sulfate in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

IMPURITIES

• **Organic Impurities**

Mobile phase, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 1.0 µg/mL of USP Ephedrine Sulfate RS in water

Sample solution: Nominally 500 µg/mL of ephedrine sulfate in water prepared as follows. Transfer a portion of Injection to a suitable volumetric flask. Dilute with water to volume, and mix well.

System suitability

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

[NOTE—See *Table 1* for the relative retention times.]

Suitability requirements

Resolution: NLT 2.0 between ephedrine and pseudoephedrine, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual impurity in the portion of Injection taken:

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

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

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

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

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

Acceptance criteria: See *Table 1*. Disregard any peak less than 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Ephedrine	1.0	—
Pseudoephedrine[a]	1.2	—
Any individual impurity	—	0.2
Total impurities	—	2.0

[a] Process impurity included in the table for identification only. Process impurities are controlled in the drug substance, and are not to be reported or included in the total impurities of the drug product.

SPECIFIC TESTS

- **pH ⟨791⟩:** 4.5–7.0
- **OTHER REQUIREMENTS:** Meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*
- **BACTERIAL ENDOTOXINS TEST ⟨85⟩:** NMT 1.7 USP Endotoxin Units/mg of ephedrine sulfate

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose or multiple-dose, light-resistant containers, preferably of Type I glass. Store at controlled room temperature.
- **USP REFERENCE STANDARDS ⟨11⟩**

USP Ephedrine Sulfate RS		
USP Pseudoephedrine Sulfate RS	$(C_{10}H_{15}NO)_2 \cdot H_2SO_4$	428.54

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

Topic/Question	Contact	Expert Committee
EPHEDRINE SULFATE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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