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Ephedrine Sulfate

$(C_{10}H_{15}NO)_2 \cdot H_2SO_4$ 428.54
Benzenemethanol, α -[1-(methylamino)ethyl]-, [R-(R*,S*)]-, sulfate (2:1) (salt).
(-)-Ephedrine sulfate (2:1) (salt) CAS RN®: 134-72-5; UNII: U6X61U5ZEG.
» Ephedrine Sulfate contains not less than 98.0 percent and not more than 101.0 percent of $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$, calculated on the dried basis.
Packaging and storage—Preserve in well-closed, light-resistant containers.

USP REFERENCE STANDARDS (11).—
[USP Ephedrine Sulfate RS](#)

Identification—

- Change to read:**
- A:** ▲ [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-May-2020) ·
- B:** A solution of it responds to the tests for [Sulfate \(191\)](#).

SPECIFIC ROTATION (781S): between -30.5° and -32.5° .
Test solution: 50 mg per mL, in water.

Acidity or alkalinity—Dissolve 1.0 g in 20 mL of water, and add 1 drop of methyl red TS. If the solution is yellow, it is changed to red by not more than 0.10 mL of 0.020 N sulfuric acid. If the solution is pink, it is changed to yellow by not more than 0.20 mL of 0.020 N sodium hydroxide.

LOSS ON DRYING (731).—Dry about 500 mg, accurately weighed, at 105° for 3 hours: it loses not more than 0.5% of its weight.

RESIDUE ON IGNITION (281): not more than 0.1%.

CHLORIDE (221).—A 200-mg portion shows no more chloride than corresponds to 0.40 mL of 0.020 N hydrochloric acid (0.14%).

ORDINARY IMPURITIES (466).—
Test solution: alcohol.

Standard solution: alcohol.

Eluant: a mixture of isopropyl alcohol, ammonium hydroxide, and chloroform (80:15:5).

Visualization: 1, followed by 4.

Assay—Transfer about 300 mg of Ephedrine Sulfate, accurately weighed, to a separator, and dissolve in about 10 mL of water. Saturate the solution with sodium chloride (about 3 g), add 5 mL of 1 N sodium hydroxide, and extract with four 25-mL portions of chloroform. Wash the combined chloroform extracts by shaking with 10 mL of a saturated solution of sodium chloride, and filter through chloroform-saturated purified cotton into a beaker. Extract the wash solution with 10 mL of chloroform, and add to the main chloroform extract. Add methyl red TS, and titrate with 0.1 N perchloric acid in dioxane VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 21.43 mg of $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Chromatographic Database Information: [Chromatographic Database](#)

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