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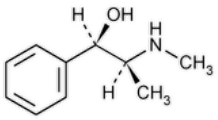
Ephedrine



$C_{10}H_{15}NO$ 165.23
Benzenemethanol, α-[1-(methylamino)ethyl]-, [*R*-(*R**,*S**)]-.
(−)-Ephedrine CAS RN®: 299-42-3; UNII: GN83C131XS.
Hemihydrate 174.24 CAS RN®: 50906-05-3; UNII: HH60WD6JQS.

» Ephedrine is anhydrous or contains not more than one-half molecule of water of hydration. It contains not less than 98.5 percent and not more than 100.5 percent of $C_{10}H_{15}NO$, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight, light-resistant containers, in a cold place.

Labeling—Label it to indicate whether it is hydrous or anhydrous. Where the quantity of Ephedrine is indicated in the labeling of any preparation containing Ephedrine, this shall be understood to be in terms of anhydrous Ephedrine.

USP Reference standards ⟨11⟩—
USP Ephedrine Sulfate RS

Identification—Accurately weigh about 100 mg, and add by buret the exact volume of 0.1 N sulfuric acid, determined in the *Assay,* to neutralize it. Dilute with water in a volumetric flask to 25 mL. Mix 2 mL with 10 mL of alcohol, and evaporate on a steam bath with the aid of a current of air to dryness: the residue so obtained responds to *Identification* test *A* under *Ephedrine Sulfate*.

Specific rotation ⟨781S⟩**:** between −40.3° and −43.3°.
Test solution: 25 mg per mL, in 0.6 N hydrochloric acid.

Water Determination, *Method Ib* ⟨921⟩ **:** between 4.5% and 5.5%, for hydrated Ephedrine; not more than 0.5% for anhydrous Ephedrine.

Residue on ignition ⟨281⟩**:** not more than 0.1%.

Chloride ⟨221⟩—A solution of 500 mg shows no more chloride than corresponds to 0.20 mL of 0.020 N hydrochloric acid (0.030%).

Sulfate—Dissolve 100 mg in 40 mL of water, and add 1 mL of 3 N hydrochloric acid and 1 mL of barium chloride TS: no turbidity develops within 10 minutes.

Ordinary impurities ⟨466⟩—
Test solution: methanol.
Standard solution: methanol.
Eluant: a mixture of isopropyl alcohol, ammonium hydroxide, and chloroform (80:15:5).
Visualization: 1, followed by 4.

Change to read:

Assay—Dissolve about 500 mg of Ephedrine, accurately weighed, in 10 mL of neutralized alcohol, and add 5 drops of methyl red TS and 40.0 mL of 0.1 N hydrochloric acid VS. Titrate the excess acid with 0.1 N sodium hydroxide VS. Perform a blank determination (see ▲*Titrimetry* ⟨541⟩ ▲ (CN 1-Aug-2024)). Each mL of 0.1 N hydrochloric acid is equivalent to 16.52 mg of $C_{10}H_{15}NO$.

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

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

Chromatographic Database Information: Chromatographic Database

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