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 dr yness: 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, *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.

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 *Residual Titrations* under *Titrimetry* ⟨541⟩). Each mL of 0.1 N hydrochloric acid is equivalent to 16.52 mg of $C_{10}H_{15}NO$.

Ephedrine Hydrochloride

$C_{10}H_{15}NO \cdot HCl$ 201.69

Benzenemethanol, α-[1-(methylamino)ethyl]-, hydrochloride, [*R*-(*R**,*S**)]-.

(–)-Ephedrine hydrochloride [50-98-6].

» Ephedrine Hydrochloride contains not less than 98.0 percent and not more than 100.5 per cent of $C_{10}H_{15}NO \cdot HCl$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed, light-resistant containers.

USP Reference standards ⟨11⟩**—**
USP Ephedrine Sulfate RS

Identification—

A: Dissolve 100 mg in 5 mL of water, add 1 mL of potassium carbonate solution (1 in 5), and extract with 2 mL of chloroform: the IR absorption spectrum of the chloroform extract so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Ephedrine Sulfate RS.

B: A solution of it responds to the tests for *Chloride* ⟨191⟩.

Melting range, *Class I* ⟨741⟩**:** between 217° and 220°.

Specific rotation ⟨781S⟩**:** between –33.0° and –35.5°.

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 it at 105° for 3 hours: it loses not more than 0.5% of its weight.

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

Sulfate—Dissolve 50 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: alcohol.

Standard solution: alcohol.

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

Visualization: 1, followed by 4.

Assay—Dissolve about 500 mg of Ephedrine Hydrochloride, accurately weighed, in 25 mL of glacial acetic acid. Add 10 mL of mercuric acetate TS and 2 drops of cr ystal violet TS, and titrate with 0.1 N per chloric acid VS to an emerald-green endpoint. Perform a blank determination, and make any necessar y correction. Each mL of 0.1 N per chloric acid is equivalent to 20.17 mg of $C_{10}H_{15}NO \cdot HCl$.

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) [134-72-5].

» Ephedrine Sulfate contains not less than 98.0 percent and not more than 101.0 per cent 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—

A: *Infrared Absorption* ⟨197K⟩.

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. W ash 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,