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Ephedrine Sulfate Oral Solution

» Ephedrine Sulfate Oral Solution contains, in each 100 mL, not less than 360 mg and not more than 440 mg of ephedrine sulfate $[(C_{10}H_{15}NO)_2 \cdot H_2SO_4]$.

Packaging and storage—Preserve in tight, light-resistant containers, and avoid exposure to excessive heat.

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

Identification, [Angular rotation \(781A\)](#)—Use the 0.1 N sulfuric acid extract of the chloroform solution obtained as directed for Assay preparation: the angular rotation is levorotatory.

ALCOHOL DETERMINATION (611) : between 2.0% and 4.0% of C_2H_5OH .

Assay—

Standard preparation—Dissolve an accurately weighed quantity of [USP Ephedrine Sulfate RS](#) in 0.1 N sulfuric acid to obtain a solution having a known concentration of about 20 µg per mL.

Assay preparation—Transfer 5 mL of Oral Solution to a separator, add 1 mL of 1 N sulfuric acid, and extract with 10 mL of chloroform. Discard the extract, and add 5 mL of potassium carbonate solution (1 in 5). After gas evolution has ceased, extract the solution with three 10-mL portions of chloroform, and combine the extracts in a second separator. Extract the chloroform solution with 50.0 mL of 0.1 N sulfuric acid. Filter the acid layer through paper, and dilute 5.0 mL of it with 0.1 N sulfuric acid to 100.0 mL.

Procedure—Proceed as directed for *Procedure* in the Assay under [Ephedrine Sulfate Capsules](#). Calculate the quantity, in mg, of ephedrine sulfate $[(C_{10}H_{15}NO)_2 \cdot H_2SO_4]$ in the portion of Oral Solution taken by the formula:

$$C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of [USP Ephedrine Sulfate RS](#) in the *Standard preparation*; and A_U and A_S are the absorbances of the solutions from the Assay preparation and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
EPHEDRINE SULFATE ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

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