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Ephedrine Sulfate Capsules

» Ephedrine Sulfate Capsules contain not less than 92.0 percent and not more than 108.0 percent of the labeled amount of $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$.

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

USP Reference standards ⟨11⟩—

USP Ephedrine Sulfate RS

Identification—Macerate the contents of a sufficient number of Capsules, equivalent to about 200 mg of ephedrine sulfate, with 15 mL of warm alcohol for 20 minutes, filter, and evaporate the filtrate on a steam bath to dryness: the residue so obtained responds to the *Identification* tests under *Ephedrine Sulfate*.

Dissolution ⟨711⟩—

Medium: water; 500 mL.

Apparatus 1: 100 rpm.

Time: 30 minutes.

Procedure—Dilute filtered portions of the solutions under test with water to a concentration of about 25 µg per mL. Transfer 5.0-mL portions to suitable tubes. Add 1 mL of a saturated sodium carbonate solution and 2 mL of sodium metaperiodate solution (2 in 100) to each, mix, and allow to stand for 10 minutes. Add 20.0 mL of hexanes, shake for 30 seconds, and allow the phases to separate. Measure the absorbances of the hexanes extract in 1-cm cells at the wavelength of maximum absorbance, at about 242 nm, with a suitable spectrophotometer, using hexanes as the blank. Determine the amount of $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$ dissolved by comparison with a similarly treated Standard solution having a known concentration of USP Ephedrine Sulfate RS in water. Remove the contents of 1 Capsule as completely as possible, with the aid of a current of air, dissolve the empty capsule shell in the *Medium*, determine the absorbance at the same dilution and in the same manner as for the Capsules, and make any necessary corrections.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Standard preparation—Weigh accurately about 25 mg of USP Ephedrine Sulfate RS, transfer to a 50-mL volumetric flask with the aid of 10 mL of water, add methanol to volume, and mix. Dilute 5.0 mL of this solution with water to 100.0 mL.

Assay preparation—Weigh accurately the contents of not less than 20 Capsules, and mix. Transfer an accurately weighed portion of the mixture, equivalent to about 25 mg of ephedrine sulfate, to a glass-stoppered conical flask, and add by pipet 50 mL of a 1 in 5 mixture of water in methanol. Shake by mechanical means for 10 minutes, and filter. Dilute 5.0 mL of the filtrate with water to 100.0 mL.

Procedure—Transfer 5-mL portions of the *Assay preparation* and the *Standard preparation* to separate glass-stoppered, 50-mL centrifuge tubes. Add 1 mL of saturated sodium carbonate solution and 2 mL of sodium metaperiodate solution (1 in 50) to each tube, mix, and allow to stand for 10 minutes. Pipet 20 mL of *n*-hexane into each tube, shake for 30 seconds, and allow the phases to separate. Concomitantly determine the absorbances of the *n*-hexane extracts in 1-cm cells at the wavelength of maximum absorbance at about 242 nm, with a suitable spectrophotometer, using *n*-hexane as the blank. Calculate the quantity, in mg, of $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$ in the portion of Capsule contents 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 hexane extracts of the *Assay preparation* and the *Standard preparation*, respectively.

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

Chromatographic Database Information: Chromatographic Database

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