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Ephedrine Sulfate Nasal Solution

» Ephedrine Sulfate Nasal Solution contains not less than 93.0 percent and not more than 107.0 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—It responds to the *Identification* tests under [Ephedrine Sulfate Injection](#).

MICROBIAL ENUMERATION TESTS (61) and TESTS FOR SPECIFIED MICROORGANISMS (62)—It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Assay—

Standard preparation—Weigh accurately about 26 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. Pipet 5 mL of the resulting solution into a 100-mL volumetric flask, dilute with water to volume, and mix.

Assay preparation—Transfer an accurately measured volume of Nasal Solution, equivalent to about 26 mg of ephedrine sulfate, to a 50-mL volumetric flask, dilute with a 1 in 5 mixture of water in methanol to volume, and mix. Pipet 5 mL of the resulting solution into a 100-mL volumetric flask, dilute with water to volume, and mix.

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 each mL of the Nasal Solution taken by the formula:

$$(C/V)(A_U/A_S)$$

in which V is the volume, in mL, of Nasal Solution taken, 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.

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

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

Chromatographic Database Information: [Chromatographic Database](#)

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