

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-352B495F-A5F0-4170-897E-A6CE07BE0345_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M71660_04_01
 DOI Ref: p34fn

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Pseudoephedrine Sulfate

$(C_{10}H_{15}NO)_2 \cdot H_2SO_4$ 428.54

Benzenemethanol, α -[1-(methylamino)ethyl]-, [S-(R*,R*)]-, sulfate (2:1) (salt).

(+)-Pseudoephedrine sulfate (2:1) (salt) CAS RN®: 7460-12-0; UNII: Y9DL7QPE6B.

» Pseudoephedrine Sulfate contains not less than 98.0 percent and not more than 100.5 percent of $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$, calculated on the dried basis.

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

USP REFERENCE STANDARDS (11)—

[USP Pseudoephedrine Sulfate RS](#)

Identification—

Change to read:

A: [▲Spectroscopic Identification Tests \(197\), Infrared Spectroscopy: 197K](#) ▲ (CN 1-May-2020)

Change to read:

B: [▲Spectroscopic Identification Tests \(197\), Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-May-2020)

Solution: 500 µg per mL.

Medium: water.

Absorptivities at 257 nm, calculated on the dried basis, do not differ by more than 3.0%.

C: A solution of it responds to the test for [Sulfate \(191\)](#).

MELTING RANGE, Class I (741): between 174° and 179°, but the range between beginning and end of melting does not exceed 2°.

SPECIFIC ROTATION (781S): between +56.0° and +59.0°.

Test solution: 50 mg per mL, in water.

pH (791): between 5.0 and 6.5 in a solution (1 in 20).

LOSS ON DRYING (731)—Dry it at 105° for 2 hours; it loses not more than 2.0% 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 0.4 mL of 0.02 N hydrochloric acid (0.14%).

ORDINARY IMPURITIES (466)—

Test solution: alcohol.

Standard solution: alcohol.

Eluant: a mixture of alcohol, glacial acetic acid, and water (10:3:1).

Visualization: Expose the plate for 24 hours to iodine vapors in a pre-equilibrated closed chamber, on the bottom of which there are iodine crystals.

Assay—Dissolve about 150 mg of Pseudoephedrine Sulfate, accurately weighed, in 50 mL of glacial acetic acid. Titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 42.85 mg of $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$.

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

Topic/Question	Contact	Expert Committee
PSEUDOEPHEDRINE SULFATE	Documentary Standards Support	SM22020 Small Molecules 2

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 41(6)

Current DocID: GUID-352B495F-A5F0-4170-897E-A6CE07BE0345_4_en-US

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