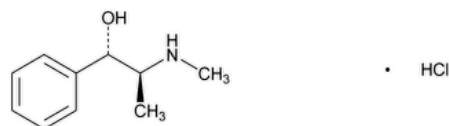


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Pseudoephedrine Hydrochloride



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

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

(+)-Pseudoephedrine hydrochloride CAS RN[®]: 345-78-8; UNII: 6V9V2RYJ8N.

DEFINITION

Pseudoephedrine Hydrochloride contains NLT 98.0% and NMT 102.0% of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#): Meets the requirements

ASSAY

PROCEDURE

Triethylamine–phosphoric acid solution: Mix 5 mL of triethylamine with 1 L of water. Adjust with phosphoric acid to a pH of 6.8.

Mobile phase: Methanol and *Triethylamine–phosphoric acid solution* (10:90)

System suitability solution: 0.1 mg/mL of [USP Pseudoephedrine Hydrochloride RS](#) and 0.002 mg/mL of [USP Ephedrine Sulfate RS](#) in water

Standard solution: 0.1 mg/mL of [USP Pseudoephedrine Hydrochloride RS](#) in water

Sample solution: 0.1 mg/mL of pseudoephedrine hydrochloride in water

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 206 nm

Column: 3.0-mm × 15-cm; packing L11

Flow rate: 0.6 mL/min

Injection volume: 10 μ L

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for ephedrine and pseudoephedrine are approximately 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2 between the pseudoephedrine and ephedrine peaks

Tailing factor: NMT 2.0 for the pseudoephedrine peak

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Pseudoephedrine Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

C_s = concentration of [USP Pseudoephedrine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Pseudoephedrine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

Sample solution: Proceed as directed in the Assay.

Analysis: Using the chromatogram of the *Sample solution*, calculate the percentage of each impurity in the portion of Pseudoephedrine Hydrochloride taken:

$$\text{Result} = (r_u/r_T) \times 100$$

r_u = peak response for each impurity

r_T = sum of all the peak responses

Acceptance criteria: NMT 2.0%, total impurities

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE, Class I \(741\)](#): 182°–186°. The range between beginning and end of melting does not exceed 2°.

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#).

Sample solution: 50 mg/mL

Acceptance criteria: +61.0° to +62.5°

- [pH \(791\)](#): 4.6–6.0, in a 50-mg/mL solution

- [LOSS ON DRYING \(731\)](#).

Analysis: Dry a sample at 105° for 3 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Ephedrine Sulfate RS](#)

[USP Pseudoephedrine Hydrochloride RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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