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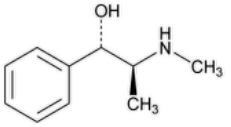
Pseudoephedrine Hydrochloride



• HCl

$C_{10}H_{15}NO \cdot HCl$ 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 µL

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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