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Pseudoephedrine Hydrochloride Extended-Release Capsules

DEFINITION

Pseudoephedrine Hydrochloride Extended-Release Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Sample: Mix a portion of Capsule contents equivalent to 180 mg of pseudoephedrine hydrochloride, filter with 10 mL of chloroform, and collect using vacuum filtration. Maintain the vacuum until no further filtrate can be collected, and evaporate the chloroform on a steam bath, taking care to avoid overheating. Recrystallize the residue from a small amount of dehydrated alcohol.

Acceptance criteria: Meet the requirements

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Alcohol and 4 mg/mL of ammonium acetate solution (17:3)

Standard solution: 1.2 mg/mL of USP Pseudoephedrine Hydrochloride RS in alcohol

Sample solution: 1.2 mg/mL of pseudoephedrine hydrochloride in 0.01 N hydrochloric acid, prepared by transferring an appropriate amount of the contents of NLT 20 Capsules to a suitable volumetric flask and dissolving in 10% of the flask volume of 0.01 N hydrochloric acid by sonicating for 10 min. Cool to room temperature, dilute with 0.01 N hydrochloric acid to volume, and filter.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 15-cm; packing L3

Flow rate: 0.7 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Capsules 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 = nominal concentration of pseudoephedrine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Times: 3, 6, and 12 h

Standard solution: USP Pseudoephedrine Hydrochloride RS of a known concentration similar to that of the *Sample solution*, in *Medium*

Sample solution: Filtered portion of sample

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) dissolved, using the *Mobile phase* and *Chromatographic system* in the *Assay*.

Tolerances: See *Table 1*.

Table 1

Time (h)	Amount Dissolved
3	20%–50%
6	45%–75%
12	NLT 75%

The percentages of the labeled amount of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) dissolved at the times specified conform to *Acceptance Table 2* in ⟨711⟩.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards** ⟨11⟩

USP Pseudoephedrine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULES	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

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