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Pseudoephedrine Hydrochloride Tablets

DEFINITION

Pseudoephedrine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of pseudo ephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$).

IDENTIFICATION

- **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Standard solution: 3 mg/mL of USP Pseudoephedrine Hydrochloride RS in water

Sample solution: Shake or mix 1 Tablet in 10 mL of water until the Tablet completely disintegrates. Sonicate for 5 min, centrifuge for 5 min, and pass through a nylon filter.

Chromatographic system

Developing solvent system: Butyl alcohol, glacial acetic acid, and water (8:2:2)

Analysis: Proceed as directed in the chapter.

Acceptance criteria: The R_F value and appearance of the principal spot from the *Sample solution* correspond to that from the *Standard solution*.

- **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 0.40% ammonium acetate solution (17:3)

Standard solution: 1.2 mg/mL of USP Pseudoephedrine Hydrochloride RS in 0.01 N hydrochloric acid

Sample solution: Nominally 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 Tablets to a suitable volumetric flask and dissolving in 0.01 N hydrochloric acid by sonicating. 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 × 25-cm; packing L3

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% from five replicate injections

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 Tablets 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,** *Procedure for a Pooled Sample*⟨711⟩

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Mobile phase: Alcohol and 0.40% ammonium acetate solution (17:3)

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 suitably diluted with *Medium*

Chromatographic system

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

Mode: LC

Detector: UV 214 nm

Column: 4.6-mm × 25-cm; packing L3

Flow rate: 1.5 mL/min

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% from five replicate injections

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.

Tolerances: NLT 75% (*Q*) of the labeled amount of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) is dissolved.

Change to read:

• **Uniformity of Dosage Units** ⟨905⟩▲**:** Meets the requirements▲ (ERR 1-May-2023)

Procedure for content uniformity▲, chewable tablets only▲ (ERR 1-May-2023)

Mobile phase: Alcohol and 0.40% ammonium acetate solution (17:3)

Standard solution: 0.15 mg/mL of USP Pseudoephedrine Hydrochloride RS in a mixture of methanol and 0.01 N hydrochloric acid (1:4)

Sample solution: Transfer 1 Tablet to a 100-mL volumetric flask, add 20 mL of methanol, and shake for 30 min. Add 25 mL of 0.01 N hydrochloric acid, and sonicate to dissolve. Cool to room temperature, dilute with 0.01 N hydrochloric acid to volume, and filter.

Chromatographic system and **System suitability:** Proceed as directed in the *Assay*.

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 Tablet 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)

▲▲ (ERR 1-May-2023)

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 TABLETS	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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