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Pseudoephedrine Hydrochloride Extended-Release Tablets

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<https://www.uspnf.com/rb-pseudoephedrine-hcl-ert-20190222>

DEFINITION

Pseudoephedrine Hydrochloride Extended-Release Tablets 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: Triturate a number of Tablets, nominally equivalent to 180 mg of pseudoephedrine hydrochloride. Filter with about 10 mL of [chloroform](#) collected 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 [ammonium acetate](#) solution (1 in 250) (850:150). Filter, and degas

Standard solution: 1.2 mg/mL of [USP Pseudoephedrine Hydrochloride RS](#) in [alcohol](#)

Sample stock solution: Transfer NLT 20 Tablets to a suitable container, add 500 mL of [alcohol](#), and homogenize until the Tablets are dispersed. Quantitatively transfer the contents of the container to a 1000-mL volumetric flask, dilute with [alcohol](#) to volume, mix, and allow to stand for the solids to settle.

Sample solution: Transfer 25.0 mL of the supernatant from the *Sample stock solution* into a 50-mL volumetric flask, dilute with [alcohol](#) to volume, and mix. Pass a portion of this solution through a filter of 0.45-μm pore size.

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 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

Change to read:

- [DISSOLUTION \(711\)](#).

For Tablets labeled for dosing every 12 h

Test 1

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Times: 1, 3, and 6 h

Mobile phase and **System suitability:** Proceed as directed in the Assay.

Standard solution: 0.13 mg/mL of [USP Pseudoephedrine Hydrochloride RS](#) in [water](#)

Sample solution: Filter a portion of the solution under test.

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: 50 µL

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: See [Table 1](#).

Table 1

Time (h)	Amount Dissolved (%)
1	25–45
3	50–75
6	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 [Dissolution \(711\)](#), [Acceptance Table 2](#).

Test 3: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Times: 1, 3, and 6 h

Standard solution: A known concentration of [USP Pseudoephedrine Hydrochloride RS](#) in *Medium*.

Sample solution: Pass portions of the solution under test through a filter of 0.45-µm pore size, and suitably dilute with *Medium*.

Analysis: Calculate the percentage of the labeled amount of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) dissolved by comparing the maximum absorbance of *Sample solution* with that of *Standard solution* at about 214 nm.

Tolerances: See [Table 2](#).

Table 2