Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2014
Document Type: USP Monographs
DocId: GUID-08FC5286-8F86-4F14-9EED-EC76A77E5F60_1_en-US
DOI: https://doi.org/10.31003/USPNF_M4576_01_01
DOI Ref: 3ztz9

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Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets

DEFINITION

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$).

IDENTIFICATION

A. The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Cetirizine Hydrochloride**

Buffer: 3.5 g/L of monobasic ammonium phosphate and 1.0 g/L of tetrabutylammonium bisulfate in water. Adjust with phosphoric acid to a pH of 2.5.

Diluent: Methanol and *Buffer* (2:3)

Solution A: Acetonitrile, methanol, and *Buffer* (9:2:29)

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
27.0	100	0
30.0	0	100
30.1	100	0
35.0	100	0

Standard stock solution: 0.5 mg/mL of USP Cetirizine Hydrochloride RS in *Diluent*. [Note—Sonicate to dissolve.]

Standard solution: 0.025 mg/mL of USP Cetirizine Hydrochloride RS in *Diluent* from the *Standard stock solution*

Sample solution: 0.025 mg/mL of cetirizine hydrochloride (from NMT 10 finely powdered Tablets) prepared as follows. Dissolve the Tablets first in methanol, using 22.5% of the final flask volume. Sonicate for NLT 20 min with vigorous swirling every 5 min. To the solution add a volume of *Buffer* equal to 26% of the final flask volume. Allow the solution to equilibrate to room temperature. Dilute with *Diluent* to volume. Pass a portion through a membrane filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 15-cm; 3.5-µm packing L1

Temperatures

Column: 30°

Autosampler: 5°

Flow rate: 1 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

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Full document details: Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets

Column efficiency: NLT 3000 theoretical plates

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) in the portion of Tablets taken:

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

r_U = peak response of cetirizine from the *Sample solution*

r_S = peak response of cetirizine from the *Standard solution*

C_S = concentration of USP Cetirizine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of cetirizine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

- **Pseudoephedrine Hydrochloride**

Buffer: 0.8 g/L of ammonium acetate in water. To 1 L of the solution add 1.0 mL of triethylamine. Adjust with glacial acetic acid to a pH of 4.5.

Mobile phase: Acetonitrile and *Buffer* (3:7)

Standard solution: 0.5 mg/mL of USP Pseudoephedrine Hydrochloride RS in *Mobile phase*. [Note—Sonicate to dissolve.]

Sample stock solution: 2.4 mg/mL of pseudoephedrine hydrochloride (from 5 finely powdered Tablets) prepared as follows. Dissolve the crushed Tablets first in acetonitrile, using 24% of the final flask volume. Sonicate for NLT 15 min. To the solution add a volume of *Buffer* equal to 56% of the final flask volume. Sonicate for NLT 15 min. Shake the flask for NLT 10 min. Allow the solution to equilibrate to room temperature. Dilute with *Mobile phase* to volume. Centrifuge a portion for 15 min to obtain a clear supernatant.

Sample solution: 0.5 mg/mL of pseudoephedrine hydrochloride in *Mobile phase* from the *Sample stock solution.* Pass the solution through a membrane 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; 5-µm packing L9

Flow rate: 1.5 mL/min

Injection volume: 25 µL

Run time: 2 times the retention time of pseudoephedrine

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1000 theoretical plates

Tailing factor: NMT 2.0

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 Tablets taken:

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

r_U = peak response of pseudoephedrine from the *Sample solution*

r_S = peak response of pseudoephedrine 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⟩**

Test 1

Medium: 0.1 N hydrochloric acid; 500 mL, deaerated

Apparatus 1: 100 rpm

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Time: 30 min for cetirizine hydrochloride and 30 min (used only for adjustments in the calculations); 1, 2, and 6 h for pseudoephedrine hydrochloride

Buffer: 0.77 g/L of ammonium acetate in water. To 1 L of the solution add 1.0 mL of triethylamine. Adjust with glacial acetic acid to a pH of 4.5 ± 0.05.

Mobile phase: Acetonitrile and *Buffer* (3:7)

Standard stock solution: 0.5 mg/mL of USP Cetirizine Hydrochloride RS in water

Standard solution: 0.24 mg/mL of USP Pseudoephedrine Hydrochloride RS and 0.01 mg/mL of USP Cetirizine Hydrochloride RS in *Medium* from the *Standard stock solution*

Sample solution: At the times specified, withdraw 5 mL of the solution under test, and pass through a suitable filter of 0.45-µm pore size, discarding the first few mL.

Chromatographic system

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

Mode: LC

Detector: UV, 230 nm for cetirizine hydrochloride, 254 nm for pseudoephedrine hydrochloride

Column: 4.6-mm × 15-cm; 5-µm packing L9

Flow rate: 1.5 mL/min

Injection volume: 25 µL

Run time: 2 times the retention time of pseudoephedrine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0 for both cetirizine and pseudoephedrine

Relative standard deviation: NMT 2.0% for both cetirizine and pseudoephedrine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cetirizine hydrochloride dissolved:

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

r_U = peak response of cetirizine from the *Sample solution*

r_S = peak response of cetirizine from the *Standard solution*

C_S = concentration of cetirizine hydrochloride in the *Standard solution* (mg/mL)

L = label claim for cetirizine hydrochloride (mg/Tablet)

V = volume of *Medium,* 500 mL

Calculate the percentage of pseudoephedrine hydrochloride dissolved at each time point:

$$Q_{30} = (r_U/r_S) \times (C_S/L) \times V \times 100$$

$$Q_1 = (Q_{30} \times 5/500) + [(r_U/r_S) \times (C_S/L) \times 495 \times 100]$$

$$Q_2 = (Q_{30} \times 5/500) + (Q_1 \times 5/495) + [(r_U/r_S) \times (C_S/L) \times 490 \times 100]$$

$$Q_6 = (Q_{30} \times 5/500) + (Q_1 \times 5/495) + (Q_2 \times 5/490) + [(r_U/r_S) \times (C_S/L) \times 485 \times 100]$$

r_U = peak response of pseudoephedrine from the *Sample solution*

r_S = peak response of pseudoephedrine from the *Standard solution*

C_S = concentration of pseudoephedrine hydrochloride in the *Standard solution* (mg/mL)

L = label claim for pseudoephedrine hydrochloride (mg/Tablet)

V = initial volume of *Medium*, 500 mL

Tolerances

Cetirizine hydrochloride: NLT 80% (Q) of the labeled amount of cetirizine hydrochloride is dissolved in 30 min.

Pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$): See *Table 2*.

Table 2

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