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Cetirizine Hydrochloride Orally Disintegrating Tablets

DEFINITION

Cetirizine Hydrochloride Orally Disintegrating Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$).

IDENTIFICATION

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

ASSAY

• **PROCEDURE**

- Buffer A:** Dissolve 13.2 g of sodium 1-decanesulfonate in 2760 mL of water. Add 5.5 g of monobasic sodium phosphate and 1.2 mL of phosphoric acid. Pass through a suitable filter.
- Buffer B:** Dissolve 13.2 g of sodium 1-decanesulfonate in 2000 mL of water. Add 5.5 g of monobasic sodium phosphate and 1.2 mL of phosphoric acid. Pass through a suitable filter.
- Solution A:** Acetonitrile and *Buffer A* (31:69)
- Solution B:** Acetonitrile and *Buffer B* (50:50)
- Mobile phase:** See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
35.0	0	100
35.1	100	0
45.0	100	0

- Diluent:** Acetonitrile and 0.01 N hydrochloric acid (20:80)
- System suitability stock solution:** 0.04 mg/mL of [USP Meclizine Related Compound A RS](#), prepared as follows. Transfer a quantity of the compound into a suitable volumetric flask. Add 5% of the flask volume of acetonitrile to dissolve the components. Sonicate if needed. Dilute with *Diluent* to volume.
- System suitability solution:** 0.4 mg/mL of [USP Cetirizine Hydrochloride RS](#) and 1.2 µg/mL of [USP Meclizine Related Compound A RS](#), prepared as follows. In a 100-mL volumetric flask, dissolve 40 mg of [USP Cetirizine Hydrochloride RS](#) in *Diluent*, and then pipet 3.0 mL of the *System suitability stock solution*. Dilute with *Diluent* to volume.
- Standard solution:** 0.4 mg/mL of [USP Cetirizine Hydrochloride RS](#) in *Diluent*
- Sample solution:** Nominally 0.4 mg/mL of cetirizine hydrochloride, prepared as follows. Transfer 20 Tablets into a 500-mL volumetric flask, add 375 mL of *Diluent*, and stir for at least 30 min. Dilute with *Diluent* to volume and pass a portion of this solution through a suitable filter (GHP or PVDF), discarding the first 1 mL of filtrate.
- Chromatographic system**
(See [Chromatography \(621\), System Suitability](#).)
- Mode:** LC
- Detector:** UV 230 nm. For *Identification test B*, use a diode array detector in the range of 210–300 nm.
- Column:** 4.6-mm × 15-cm; 3.5-µm packing L1
- Column temperature:** 30°
- Flow rate:** 1.5 mL/min
- Injection volume:** 20 µL
- System suitability**
Samples: *System suitability solution* and *Standard solution*

[NOTE—Identify the components on the basis of their relative retention times, as shown in [Table 2](#).]

Suitability requirements

Resolution: NLT 1.5 between cetirizine and meclizine related compound A, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount 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 from the *Sample solution*

r_S = peak response 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%

PERFORMANCE TESTS

• [DISINTEGRATION \(701\)](#): NMT 30 s

• [DISSOLUTION \(711\)](#)

Medium: pH 6.5 phosphate buffer (4.77 g/L monobasic potassium phosphate and 2.62 g/L of dibasic potassium phosphate); 900 mL, degassed by USP procedure

Apparatus 2: 50 rpm

Time: 15 min

Buffer: 2.7 g/L of monobasic potassium phosphate in water. Add 0.6 mL/L of phosphoric acid.

Mobile phase: Acetonitrile and *Buffer* (33:67)

Diluent: Acetonitrile and 0.01 N hydrochloric acid (20:80)

Standard stock solution: 0.1 mg/mL of [USP Cetirizine Hydrochloride RS](#) in *Diluent*

Standard solution: 0.01 mg/mL of [USP Cetirizine Hydrochloride RS](#) from *Standard stock solution*, in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size, discarding the first 1–2 mL.

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 7.5-cm; 3.5-μm packing L1

Column temperature: 40°

Flow rate: 2.5 mL/min

Injection volume: 100 μL

Run time: 2.7 times the retention time of cetirizine

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times 1/L \times V \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of cetirizine hydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements