Cetirizine Hydrochloride Tablets

DEFINITION
Cetirizine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of cetirizine hydrochloride (C₂₁H₂₅ClN₂O₃·2HCl).

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.

ASSAY

• PROCEDURE

Solution A: 2 N sulfuric acid and water (2:33)
Buffer: 2.9 mL/L of phosphoric acid in water
Mobile phase: Acetonitrile and Buffer (3:7)
Diluent: Acetonitrile, Solution A, and water (100:1:100)
Standard solution: 0.2 mg/mL of USP Cetirizine Hydrochloride RS in Diluent
Sample solution: 0.2 mg/mL of cetirizine hydrochloride in Diluent from NLT 20 powdered Tablets. [NOTE—Sonicate, if necessary.]

Chromatographic system
(See Chromatography (621), System Suitability.)
Mode: LC
Detector: UV 230 nm
Column: 4.6-mm × 25-cm; 5-µm packing L1
Injection volume: 10 µL
Run time: 1.3 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 (C₂₁H₂₅ClN₂O₃·2HCl) dissolved:

Result = \( \frac{r_0/r_s \times (C_s/C_0)}{V \times 100} \)

where

- \( r_0 \) = peak response from the Standard solution
- \( r_s \) = peak response from the Sample solution
- \( C_s \) = concentration of the Standard solution (mg/mL)
- \( C_0 \) = nominal concentration of cetirizine hydrochloride in the Sample solution (mg/mL)
- \( V \) = volume of Medium, 900 mL

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• DISSOLUTION (711)

  Test 1
  (See Chromatography (621), System Suitability.)
  Mode: LC
  Detector: UV 230 nm
  Column: 4.6-mm × 25-cm; 5-µm packing L1
  Flow rate: 1 mL/min
  Injection volume: 50 µL
  Run time: 1.3 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 (C₂₁H₂₅ClN₂O₃·2HCl) dissolved:

  Result = \( \frac{r_0/r_s \times (C_s/L)}{V \times 100} \)

  where

  - \( r_0 \) = peak response from the Standard solution
  - \( r_s \) = peak response from the Sample 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

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**Tolerances:** NLT 80% (Q) of the labeled amount of cetirizine hydrochloride (C_{21}H_{25}ClN_{2}O_{3} · 2HCl) is dissolved.

**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

**Time:** 30 min

**Standard solution:** (L/900) mg/mL of USP Cetirizine Hydrochloride RS in water, where L is the label claim of cetirizine hydrochloride, in mg/Tablet

**Sample solution:** Centrifuge a portion of the solution under test for NLT 15 min at 3000 rpm.

**Instrumental conditions**

(See Spectrophotometry and Light-Scattering (851).)

**Mode:** UV

**Analytical wavelength:** UV 231 nm

**Blank:** Medium

**Path length:** 1 cm

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of the labeled amount of cetirizine hydrochloride, in mg/Tablet, of cetirizine hydrochloride (C_{21}H_{25}ClN_{2}O_{3} · 2HCl) dissolved:

\[
\text{Result} = \frac{(A_d/A_0) \times (C_d/L)}{V} \times 100
\]

\(A_d\) = absorbance of the Sample solution

\(A_0\) = absorbance of the Standard solution

\(C_d\) = 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_{2}O_{3} · 2HCl) is dissolved.

**Organic Impurities**

**Solution A:** 2 N sulfuric acid and water (2:33)

**Buffer:** 3.4 g/L of tetrabutyl ammonium hydrogen sulfate in water

**Diluent:** Acetonitrile, Solution A, and water (910:27:63)

**Mobile phase:** Acetonitrile, Solution A, and Buffer (93:5:2)

**Standard solution:** 1.5 µg/mL of USP Cetirizine Hydrochloride RS in Diluent

**Sample solution:** 0.5 mg/mL of cetirizine hydrochloride in Diluent from NLT 20 powdered Tablets. [Note—Sonicate, if necessary.]

**Chromatographic system**

(See Chromatography (621), System Suitability.)

**Mode:** LC

**Detector:** UV 230 nm

**Column:** 4.0-mm × 25-cm; 5-µm packing L3

**Flow rate:** 0.8 mL/min

**Injection volume:** 20 µL

**Run time:** 2.5 times the retention time of cetirizine

**System suitability**

**Sample:** Standard solution

**Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 10.0%

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of each impurity in the portion of Tablets taken:

\[
\text{Result} = \frac{(r_d/r_0) \times (C_d/C_0) \times (1/F) \times 100}
\]

\(r_d\) = peak response of each impurity from the Sample solution

\(r_0\) = peak response of cetirizine from the Standard solution

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

\(C_0\) = nominal concentration of cetirizine hydrochloride in the Sample solution (mg/mL)

\(F\) = relative response factor (see Table 1)

**Acceptance criteria:** See Table 1.

### Table 1

<table>
<thead>
<tr>
<th>Name</th>
<th>Relative Retention Time</th>
<th>Relative Response Factor</th>
<th>Acceptance Criteria, NMT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cetirizine lactose ester</td>
<td>0.56</td>
<td>1.0</td>
<td>0.5 (RB 1-Feb-2013)</td>
</tr>
<tr>
<td>Cetirizine</td>
<td>1.0</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Cetirizine ethanol</td>
<td>1.67</td>
<td>1.2</td>
<td>0.2 (RB 1-Aug-2012)</td>
</tr>
<tr>
<td>Any unspecified degradation product</td>
<td>—</td>
<td>—</td>
<td>0.2</td>
</tr>
<tr>
<td>Total impurities</td>
<td>—</td>
<td>—</td>
<td>1.0 (RB 1-Feb-2013)</td>
</tr>
</tbody>
</table>


**ADDITIONAL REQUIREMENTS**

- **Packaging and Storage:** Preserve in well-closed containers, and store below 30°C.

**Add the following:**

- **LABELING:** When more than one Dissolution test is given, the labeling states the Dissolution test used only if Test 1 is not used.

- **USP Reference Standards**

  1. USP Cetirizine Hydrochloride RS

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