Cetirizine Hydrochloride Tablets

DEFINITION

Cetirizine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount 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
Flow rate: 1 mL/min
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:

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

\[ r_0 = \text{peak response from the Sample solution} \]
\[ r_s = \text{peak response from the Standard solution} \]
\[ C_s = \text{concentration of USP Cetirizine Hydrochloride RS in the Standard solution (mg/mL)} \]
\[ L = \text{label claim (mg/Tablet)} \]
\[ V = \text{volume of Medium, 900 mL} \]

Tolerances: NLT 80% (Q) of the labeled amount of cetirizine hydrochloride (C21H25ClN2O3 · 2HCl) is dissolved.

• Test 2: If the product complies with this test, the labeling indicates that it meets USP Dissolution Test 2.

Medium: Water; 900 mL
Apparatus 2: 75 rpm
Time: 30 min
Buffer: 0.4 g/L of 1-heptane sulfonic acid sodium salt
Mobile phase: Acetonitrile and Buffer (50:50). Adjust with 0.1 N sulfuric acid to a pH of 3.5.
Standard solution: 11 µg/mL of USP Cetirizine Hydrochloride RS in Medium
Sample solution: Pass a 20-mL portion of the solution under test through a nylon filter of 0.45-µm pore size. Discard the first 10 mL of the filtrate.

Chromatographic system
(See Chromatography (621), System Suitability.) Mode: LC
Detector: UV 210 nm
Column: 3.9-mm × 30-cm; 10-µm packing L1
Flow rate: 1.5 mL/min
Injection volume: 50 µL
Run time: 1.6 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:

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

\[ r_0 = \text{peak response from the Sample solution} \]
\[ r_s = \text{peak response from the Standard solution} \]
\[ C_s = \text{concentration of USP Cetirizine Hydrochloride RS in the Standard solution (mg/mL)} \]

PERFORMANCE TESTS

Change to read:

• DISSOLUTION (711)

Test 1: (RB 1-Aug-2012)
Medium: Water; 900 mL, degassed
Apparatus 2: 50 rpm
Time: 30 min
Buffer: 2.9 mL/L of phosphoric acid in water
Mobile phase: Acetonitrile and Buffer (2:3)
Standard solution: 11 µg/mL of USP Cetirizine Hydrochloride RS in water. This solution can be stored for 48 h at room temperature.
L = label claim (mg/Tablet)
V = volume of Medium, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of cetirizine hydrochloride (C₂₁H₂₅ClN₂O₃·2HCl) 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 each impurity in the portion of Tablets taken:

\[
\text{Result} = \left( \frac{A_U}{A_S} \right) \times \left( \frac{C_S}{L} \right) \times \frac{V \times 100}{F}
\]

\[A_U\] = absorbance of the Sample solution
\[A_S\] = absorbance of 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 (C₂₁H₂₅ClN₂O₃·2HCl) is dissolved.

**IMPURITIES**

### 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

### Acceptance criteria:

<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 a</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 b</td>
<td>1.67</td>
<td>1.2</td>
<td>0.4 • (RB 1-Aug-2013)</td>
</tr>
<tr>
<td>Any unspecified degradation product</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total impurities</td>
<td>—</td>
<td>—</td>
<td>0.2</td>
</tr>
</tbody>
</table>

*6-O-[2-[(2-[(4-Chlorophenyl)(phenyl)methyl]piperazin-1-yl)ethoxy]acetyl]-β-D-galactopyranosyl-(1→4)β-D-glucopyranose.*
*2-[4-[(4-Chlorophenyl)phenylmethyl]pipersazin-1-yl]ethanol.*
ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, and store below 30°.

- **USP Reference Standards (11)**
  - USP Cetirizine Hydrochloride RS

**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.● (RB 1-Aug-2012)