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Levocetirizine Dihydrochloride Tablets

DEFINITION

Levocetirizine Dihydrochloride Tablets contain NLT 90% and NMT 110% of the labeled amount of levocetirizine dihydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020)

Medium: Water

Sample solution: Nominally 0.1 mg/mL of levocetirizine dihydrochloride from Tablets in water prepared as follows. Transfer 1 Tablet to a suitable volumetric flask, and add 40% of the flask volume of water. Shake for NLT 5 min to promote the disintegration of the Tablet. Dilute with water to volume. Pass a 10-mL portion of the resulting solution through a suitable filter, and discard the first mL. Use the filtrate.

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**

Solution A: 1 M sulfuric acid and water (5.7:94.3)

Mobile phase: Acetonitrile, water, and 1 M sulfuric acid (93:6.6:0.4)

System suitability solution: 0.2 mg/mL of USP Levocetirizine Dihydrochloride RS and 0.2 µg/mL of USP Chlorobenzhydryl Piperazine RS in *Mobile phase*

Standard solution: 0.2 mg/mL of USP Levocetirizine Dihydrochloride RS in *Mobile phase*

Sample solution: Nominally 0.2 mg/mL of levocetirizine dihydrochloride prepared as follows. Transfer a number of Tablets (NLT 10), equivalent to 50 mg of levocetirizine dihydrochloride, to a 250-mL volumetric flask. Add 20 mL of *Solution A*, and put the flask on a mechanical shaker for 15 min. Add 150 mL of acetonitrile, and place the flask in an ultrasonic bath for 10 min. Allow the contents to cool to room temperature, if necessary, and dilute with acetonitrile to final volume. Homogenize the solution, and centrifuge a 10-mL portion for 5 min. Use the supernatant solution.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Columns

Guard: 4-mm × 0.3-cm; 5-µm packing L3

Analytical: 4.6-mm × 25-cm; 5-µm packing L3

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

[Note—See *Table 1* for relative retention times.]

Suitability requirements

Resolution: NLT 3.0 between levocetirizine and chlorobenzhydryl piperazine

Tailing factor: NMT 1.5 for levocetirizine

Relative standard deviation: NMT 1.0% for levocetirizine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of levocetirizine dihydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) in the portion of Tablets taken:

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

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

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

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

C_U = nominal concentration of levocetirizine dihydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90%–110%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: (*L*/900) mg/mL of USP Levocetirizine Dihydrochloride RS in *Medium*, where *L* is the label claim in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV-Vis

Analytical wavelength: 230 or 231 nm; use a suitable wavelength for background correction

Cell: 1 or 2 cm

Blank: *Medium*

Analysis

Samples: *Standard solution*,*Sample solution*, and *Blank*

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

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (*Q*) of levocetirizine dihydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Solution A, Mobile phase, System suitability solution, and **Sample solution:** Prepare as directed in the *Assay*.

Standard solution: 0.002 mg/mL of USP Levocetirizine Dihydrochloride RS in *Mobile phase*

Chromatographic system: Proceed as directed in the *Assay*, except for the *Run time*.

Run time: 2.3 times the retention time of levocetirizine

System suitability

Sample: *System suitability solution*

[Note—See *Table 1* for relative retention times.]

Suitability requirements

Resolution: NLT 3.0 between levocetirizine and chlorobenzhydryl piperazine

Tailing factor: NMT 1.5 for levocetirizine

Relative standard deviation: NMT 1.0% for levocetirizine; NMT 5.0% for chlorobenzhydryl piperazine

Analysis

Samples: *Sample solution* and *Standard solution*

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

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

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

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

C_U = nominal concentration of levocetirizine dihydrochloride in the *Sample solution* (mg/mL)

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M_{r1} = molecular weight of levocetirizine (free base), 388.89

M_{r2} = molecular weight of levocetirizine dihydrochloride, 461.81

Acceptance criteria: See *Table 1*. Disregard peaks less than 0.1%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Levocetirizine	1.0	—
Chlorobenzhydryl piperazine[a]	1.4	—
Levocetirizine amide[a,b]	2.1	—
Any individual unspecified degradation product	—	0.30
Total impurities	—	1.0

[a] This is a process impurity that is included in this table for identification only. This impurity is controlled in the drug substance. This impurity is not to be reported for the drug product and is not to be included in the total impurities.

[b] (*R*)-2-(2-{4-[(4-Chlorophenyl)phenylmethyl]piperazin-1-yl}ethoxy)acetamide.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, and store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

USP Chlorobenzhydryl Piperazine RS

(*R*)-1-[(4-Chlorophenyl)phenylmethyl]piperazine.

$C_{17}H_{19}ClN_2$ 286.80

USP Levocetirizine Dihydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
LEVOCETIRIZINE DIHYDROCHLORIDE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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