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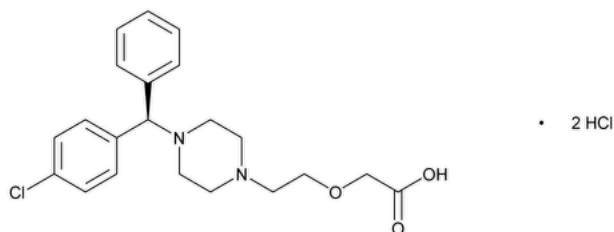
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Levocetirizine Dihydrochloride


 $C_{21}H_{25}ClN_2O_3 \cdot 2HCl$ 461.81

Acetic acid, [2-[4-[(R)-(4-chlorophenyl)phenylmethyl]-1-piperazinyl]ethoxy]-, dihydrochloride;

(2-[4-[(R)-(4-Chlorophenyl)phenylmethyl]piperazin-1-yl]ethoxy)acetic acid dihydrochloride CAS RN®: 130018-87-0.

Levocetirizine free base

 $C_{21}H_{25}ClN_2O_3$ 388.89 CAS RN®: 130018-77-8.

DEFINITION

Levocetirizine Dihydrochloride contains NLT 98.0% and NMT 102.0% of levocetirizine dihydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the levocetirizine peak of the *System suitability solution*, as obtained in the test for *Enantiomeric Purity*.
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\), Chloride](#): Meets the requirements

ASSAY

PROCEDURE

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

Standard solution: 0.05 mg/mL of [USP Levocetirizine Dihydrochloride RS](#) in *Mobile phase*

Sample solution: 0.05 mg/mL of Levocetirizine Dihydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L3](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak response of levocetirizine 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 = concentration of Levocetirizine Dihydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

• ORGANIC IMPURITIES

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

System suitability solution: 0.2 mg/mL of [USP Levocetirizine Dihydrochloride RS](#) and 0.2 µg/mL each of [USP Levocetirizine Amide RS](#) and [USP Chlorobenzhydryl Piperazine RS](#) in *Mobile phase*. Use the solution within 16 h.

Standard solution: 0.2 µg/mL each of [USP Levocetirizine Dihydrochloride RS](#), [USP Levocetirizine Amide RS](#), and [USP Chlorobenzhydryl Piperazine RS](#) in *Mobile phase*. Use the solution within 16 h.

Sample solution: 200 µg/mL of Levocetirizine Dihydrochloride in *Mobile phase*. Use the solution within 16 h.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L3](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 3 times the retention time of levocetirizine

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 1](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 3.0 between levocetirizine and chlorobenzhydryl piperazine, *System suitability solution*

Tailing factor: NMT 2.0 for levocetirizine, *System suitability solution*

Relative standard deviation: NMT 5.0% for levocetirizine, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of levocetirizine amide or chlorobenzhydryl piperazine in the portion of Levocetirizine Dihydrochloride taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

r_u = peak response of levocetirizine amide or chlorobenzhydryl piperazine from the *Sample solution*

r_s = peak response of levocetirizine amide or chlorobenzhydryl piperazine from the *Standard solution*

C_s = concentration of [USP Levocetirizine Amide RS](#) or [USP Chlorobenzhydryl Piperazine RS](#) in the *Standard solution* (µg/mL)

C_u = concentration of Levocetirizine Dihydrochloride in the *Sample solution* (µg/mL)

Calculate the percentage of any unspecified impurity in the portion of Levocetirizine Dihydrochloride taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

r_u = peak response of any unspecified 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* (µg/mL)

C_u = concentration of Levocetirizine Dihydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: See [Table 1](#).

Table 1