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Desloratadine Tablets

DEFINITION

Desloratadine Tablets contain NLT 93.0% and NMT 105.0% of the labeled amount of desloratadine ($C_{19}H_{19}ClN_2$).

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 absorption spectra of the desloratadine peak of the *Sample solution* exhibit maxima and minima at the same wavelengths as those of the corresponding peak of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Use amber, low-actinic glassware.

Buffer: Dissolve 4.35 g of dibasic potassium phosphate in 1 L of water. Adjust with phosphoric acid to a pH of 3.0.

Mobile phase: Methanol and *Buffer* (20:80)

Diluent: Methanol and water (90:10)

Standard solution: 0.02 mg/mL of [USP Desloratadine RS](#) in *Diluent*

Sample stock solution: Nominally 0.2 mg/mL of desloratadine, prepared as follows. Transfer NLT 20 Tablets into a suitable volumetric flask, add water to fill 10% of the flask volume, and allow the Tablets to disperse. Add methanol, about 50% of the flask volume, and stir for NLT 60 min. Allow the solution to cool to room temperature and dilute with methanol to volume. Centrifuge a portion of this solution and use the supernatant.

Sample solution: Nominally 0.02 mg/mL of desloratadine in *Diluent*, from *Sample stock solution*

Chromatographic system

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

Mode: LC

Detectors

Assay: UV 241 nm

Identification B: Diode array; UV 230–400 nm

Column: 4.6-mm × 15-cm; 5-μm packing L10

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 μL

Run time: NLT 4.2 times the retention time of desloratadine

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 desloratadine ($C_{19}H_{19}ClN_2$) 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 Desloratadine RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of desloratadine in the *Sample solution* (mg/mL)

Acceptance criteria: 93.0%–105.0%

PERFORMANCE TESTS

• [DISSOLUTION <711>](#)

Medium: 0.1 N hydrochloric acid; 500 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: 0.01 mg/mL of [USP Desloratadine RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Discard the first 5 mL of the filtrate.

Instrumental conditions

Mode: UV

Analytical wavelength: 282 nm

Cell: 1.0 cm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of desloratadine ($C_{19}H_{19}ClN_2$) 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 Desloratadine RS](#) in the *Standard solution* (mg/mL)

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of desloratadine ($C_{19}H_{19}ClN_2$) is dissolved.

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

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

▲ Protect all solutions containing desloratadine from light. ▲ (ERR 1-May-2018)

Solution A: Dissolve 4.35 g of dibasic potassium phosphate in 1 L of water. Adjust with phosphoric acid to a pH of 3.2.

Solution B: Acetonitrile

Solution C: Methanol

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)
0	70	15	15
12	70	15	15
30	40	30	30
45	40	30	30
47	70	15	15