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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

Time (min)	Solution A (%)	Solution B (%)	Solution C (%)
55	70	15	15

Diluent: Methanol and water (90:10)

Standard solution: 0.002 mg/mL each of USP Desloratadine RS and USP Desloratadine Related Compound F RS in *Diluent*

Sensitivity solution: 0.1 µg/mL of USP Desloratadine RS in *Diluent*

Sample solution: Nominally 0.2 mg/mL of desloratadine, prepared as follows. Transfer NLT 20 Tablets into a suitable volumetric flask, add 10% of the flask volume of water, and allow the Tablets to disperse. Add methanol, about 50% of the flask volume, and stir for at least 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.

Chromatographic system

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

Mode: LC

Detector: UV 241 nm

Column: 4.6-mm × 15-cm; 3-µm packing L7

Column temperature: 35°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Column efficiency: NLT 1500 theoretical plates for desloratadine, *Standard solution*

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

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

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

Calculate the percentage of desloratadine related compound F in the portion of Tablets taken:

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

r_U = peak response of desloratadine related compound F from the *Sample solution*

r_S = peak response of desloratadine related compound F from the *Standard solution*

C_S = concentration of USP Desloratadine Related Compound F RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any unspecified degradation product in the portion of Tablets taken:

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

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

r_S = peak response of desloratadine 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: See *Table 2*. Disregard peaks less than 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Dechloro desloratadine[a]	0.37	—[b]
Desloratadine	1.00	—
Dehydro desloratadine[c]	1.4	—[b]
Desloratadine related compound F	1.8	0.30
Loratadine[d]	2.7	—[b]
Any unspecified degradation product	—	0.2
Total impurities	—	0.50

[a] 6,11-Dihydro-11-(piperidin-4-ylidene)-5*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridine.

[b] Process impurity controlled in the drug substance monograph. Provided for information only; the content is not calculated and not reported.

[c] 8-Chloro-11-(piperidin-4-ylidene)benzo[5,6]cyclohepta[1,2-*b*]pyridine.

[d] 8-Chloro-6,11-dihydro-11-(1-ethoxycarbonylpiperidin-4-ylidene)-5*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridine (loratadine).

ADDITIONAL REQUIREMENTS

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

USP Desloratadine RS

USP Desloratadine Related Compound F RS

8-Chloro-6,11-dihydro-11-(*N*-formyl-4-piperidinylidene)-5*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridine.

$C_{20}H_{19}ClN_2O$ 338.83

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

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

Chromatographic Database Information: Chromatographic Database

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