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Desloratadine Orally Disintegrating Tablets

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<https://www.uspnf.com/rb-desloratadine-odt-20181130>

DEFINITION

Desloratadine Orally Disintegrating Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of desloratadine ($C_{19}H_{19}ClN_2$).

IDENTIFICATION

Change to read:

- **A.**  [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Ultraviolet-Visible Spectroscopy*: **197U**  (CN 1-MAY-2020)

Standard solution and **Sample solution**: Proceed as directed in the Assay.

Instrumental conditions

Mode: UV

Wavelength range: 230–330 nm

[NOTE—Alternatively, a diode array detector may be used in the Assay to obtain the spectra.]

Acceptance criteria: The UV spectrum of the *Sample solution* corresponds to that of the *Standard solution*.

- **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

Buffer: 6.8 g/L of [monobasic potassium phosphate](#). Adjust with phosphoric acid to a pH of 3.0.

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer* (28:7:65)

Diluent: [Methanol](#) and [0.1 N hydrochloric acid](#) (40:60)

Standard solution: 0.05 mg/mL of [USP Desloratadine RS](#) in *Diluent*. Sonication may be used to aid dissolution.

Sample stock solution: Nominally 0.25 mg/mL of desloratadine, prepared as follows. Transfer 10 Tablets to a suitable volumetric flask, add water to 15% of the flask volume, and shake until the Tablets disintegrate completely. Add 75% of the flask volume of *Diluent* and sonicate for 30 min with intermittent shaking, and dilute with *Diluent* to volume. Centrifuge a portion of this solution. Use the supernatant.

Sample solution: Nominally 0.05 mg/mL of desloratadine from the *Sample stock solution* in *Diluent*; centrifugate

Chromatographic system

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

Mode: LC

Detector: UV 258 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

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 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: 95.0%–105.0%

PERFORMANCE TESTS

• [DISINTEGRATION \(701\)](#): NMT 30 s

• [DISSOLUTION \(711\)](#)

Medium: [0.1 N hydrochloric acid](#) (degassed); 900 mL

Apparatus 2: 50 rpm

Time: 10 min

Buffer: 6.8 g/L of [monobasic potassium phosphate](#)

Solution A: [Acetonitrile](#) and [methanol](#) (80:20)

Mobile phase: *Solution A* and *Buffer* (40:60)

Standard stock solution: 0.28 mg/mL of [USP Desloratadine RS](#) in [methanol](#). Sonication may be used to aid dissolution.

Standard solution: (L/900) mg/mL of [USP Desloratadine RS](#) from the *Standard stock solution* in *Medium*, where L is the label claim (mg/Tablet)

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

Chromatographic system

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

Mode: LC

Detector: UV 258 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 40 μL

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 ($C_{19}H_{19}ClN_2$) dissolved:

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

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)

V = volume of *Medium*, 900 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**

Buffer: Add 10 mL/L of [triethylamine](#) to a 1.36 g/L solution of [monobasic potassium phosphate](#). Adjust with phosphoric acid to a pH of 2.5.

Solution A: [Methanol](#), [acetonitrile](#), and *Buffer* (15:5:80)

Solution B: [Acetonitrile](#), [tetrahydrofuran](#), and *Buffer* (70:5:30)

Solution C: Dilute 8.5 mL of [hydrochloric acid](#) with [methanol](#) to 1 L.

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
10	100	0
40	50	50
50	50	50
52	100	0
65	100	0

Diluent: *Solution C* and *Buffer* (30:70)

System suitability stock solution: 0.05 mg/mL each of [USP Desloratadine Related Compound A RS](#) and [USP Desloratadine Related Compound F RS](#) in [methanol](#).

System suitability solution: 0.5 mg/mL of [USP Desloratadine RS](#), 1.0 µg/mL each of [USP Desloratadine Related Compound A RS](#) and [USP Desloratadine Related Compound F RS](#), prepared as follows. Transfer 50 mg of [USP Desloratadine RS](#) into a 100-mL volumetric flask, add 70 mL of *Diluent*, and sonicate to dissolve. Add 2 mL of the *System suitability stock solution* and dilute with *Diluent* to volume.

Standard solution: 0.0025 mg/mL of [USP Desloratadine RS](#) and 0.001 mg/mL of [USP Desloratadine Related Compound F RS](#) in *Diluent*

Sample solution: Nominally 0.5 mg/mL of desloratadine from NLT 40 Tablets, prepared as follows. Transfer an amount of powder to a suitable volumetric flask to obtain the nominal concentration of desloratadine. Add 70% of the flask volume of *Diluent* and sonicate for 20 min with intermittent shaking. Dilute with *Diluent* to volume. Centrifuge a portion of the solution and use the supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L7](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 40 µL

System suitability

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

[NOTE—Relative retention times are given in [Table 2](#).]

Suitability requirements

Resolution: NLT 2.0 between desloratadine and desloratadine related compound A, *System suitability solution*

Tailing factor: NMT 2.0 for desloratadine and desloratadine related compound F, *Standard solution*

Relative standard deviation: NMT 10.0% desloratadine related compound F, *Standard solution*

Signal-to-noise ratio: NLT 10 for desloratadine peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Identify the impurities using the relative retention times given in [Table 2](#).

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* (µg/mL)

C_U = nominal concentration of desloratadine in the *Sample solution* (µg/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 any unspecified degradation product 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* (µg/mL)

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

Acceptance criteria: See [Table 2](#).

Table 2

Compound	Relative Retention Time	Acceptance Criteria, NMT (%)
Dechloro desloratadine ^{a,b}	0.42	—
Desloratadine	1.00	—
Desloratadine related compound A ^b	1.09	—
Dehydro desloratadine ^{b,c}	1.33	—
Desloratadine related compound F	1.37	0.2
Loratadine ^{b,d}	1.89	—
Any other individual unspecified degradation product	—	▲0.2▲ (RB 1-Dec-2018)
Total degradation products	—	0.5

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

^b This is a process impurity and is included in the table for identification only. This impurity is controlled in the drug substance. It is not to be reported for the drug product and should not be included in the total impurities.

^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)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers. Store at controlled room temperature.

• **USP REFERENCE STANDARDS (11).**

[USP Desloratadine RS](#)

[USP Desloratadine Related Compound A RS](#)

8-Bromo-6,11-dihydro-11-(piperidin-4-ylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine.

$C_{19}H_{19}BrN_2$ 355.27

[USP Desloratadine Related Compound F RS](#)

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

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

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

Chromatographic Database Information: [Chromatographic Database](#)

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