

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-7FEFF24C-BB3C-4C6F-A478-18EA779DAADD_5_en-US
DOI: https://doi.org/10.31003/USPNF_M1407_05_01
DOI Ref: 19thw

© 2025 USPC
Do not distribute

Desloratadine Orally Disintegrating Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click <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)