

Status: Currently Official on 18-Feb-2025
 Official Date: Official as of 01-Jun-2022
 Document Type: USP Monographs
 DocId: GUID-DA9464A9-561F-4FAA-9638-172677DA75F4_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M5958_04_01
 DOI Ref: 26kbo

© 2025 USPC
 Do not distribute

Loratadine Capsules

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-loratadine-capsules-20220527.

DEFINITION

Loratadine Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of loratadine ($C_{22}H_{23}ClN_2O_2$).

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 spectrum of the major peak of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: 1.74 g/L of [potassium phosphate dibasic](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 7.2.

Solution A: [Acetonitrile](#) and [methanol](#) (50:50)

Mobile phase: *Solution A* and *Buffer* (75:25)

Diluent: [Acetonitrile](#), [methanol](#), 0.05 N [hydrochloric acid](#), and 0.6 M [potassium phosphate dibasic](#) (26:26:40:8)

Standard solution: 0.1 mg/mL of [USP Loratadine RS](#) in *Diluent*

Sample solution: Nominally 0.1 mg/mL of loratadine in *Diluent*, prepared as follows. Transfer NLT 10 Capsules into a suitable volumetric flask. Add *Diluent* to about 50% of the total flask volume. Sonicate for about 30 min. Dilute with *Diluent* to volume. Transfer an appropriate volume of this solution into a suitable volumetric flask. Dilute with *Diluent* to volume. Pass a portion of the solution through a suitable filter of 0.45- μ m pore size.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm $\times$ 15-cm; 5- μ m packing [L1](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 20 μ L

Run time: NLT 2 times the retention time of loratadine

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 loratadine ($C_{22}H_{23}ClN_2O_2$) in the portion of Capsules taken:

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

r_U = peak response of loratadine from the *Sample solution*

r_S = peak response of loratadine from the *Standard solution*

C_S = concentration of [USP Loratadine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS**Change to read:**• **[DISSOLUTION \(711\)](#)**

Perform the test using the conditions under *Tier 1*. In the presence of cross-linking, repeat the test with new Capsules using the conditions under *Tier 2*.

▲Test 1▲ (RB 1-Jun-2022)**Tier 1**

Solution A: 1 g/L of [polysorbate 20](#) in 0.1 N [hydrochloric acid](#), prepared as follows. Mix 8.5 mL of [hydrochloric acid](#) in 1 L of [water](#). Add 1 g of [polysorbate 20](#).

Medium: *Solution A*; 900 mL

Apparatus 2: 75 rpm with sinker

Time: 20 min

Tier 2

Solution B: 1 g/L of [polysorbate 20](#) and 1.2 g/L of [pepsin](#) in 0.1 N [hydrochloric acid](#), prepared as follows. Mix 8.5 mL of [hydrochloric acid](#) in 1 L of [water](#). Add 1.0 g of [polysorbate 20](#) and 1.16 g of [pepsin](#).

Medium: *Solution B*; 900 mL

Apparatus 2: 75 rpm with sinker

Time: 20 min

Determine the amount of loratadine ($C_{22}H_{23}ClN_2O_2$) dissolved using the following method.

Mobile phase: Prepare as directed in the Assay.

Standard stock solution: 0.1 mg/mL of [USP Loratadine RS](#), prepared as follows. Transfer an appropriate amount of [USP Loratadine RS](#) to a suitable volumetric flask. Add about 20% of the total flask volume of [methanol](#). Sonicate to dissolve. Dilute with *Medium* to volume.

Standard solution: 0.01 mg/mL of [USP Loratadine RS](#) in *Medium*, from *Standard stock solution*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

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

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 50 μL

Run time: NLT 2 times the retention time of loratadine

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 loratadine ($C_{22}H_{23}ClN_2O_2$) dissolved:

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

r_U = peak response of loratadine from the *Sample solution*

r_S = peak response of loratadine from the *Standard solution*

C_S = concentration of [USP Loratadine RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Capsule)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of loratadine ($C_{22}H_{23}ClN_2O_2$) is dissolved.

▲Test 2

If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N [hydrochloric acid](#) containing 0.1% [polysorbate 20](#); 900 mL

Apparatus 2: 75 rpm, with sinkers

Time: 30 min

Buffer: 6.8 g/L of [potassium phosphate monobasic](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.8.

Mobile phase: [Acetonitrile](#) and *Buffer* (50:50)