

Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2014
Document Type: USP Monographs
DocId: GUID-019A57BA-8020-47C2-8A95-67161DC168DD_1_en-US
DOI: https://doi.org/10.31003/USPNF_M2585_01_01
DOI Ref: 4g97v

© 2025 USPC
Do not distribute

Loratadine Chewable Tablets

DEFINITION

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

IDENTIFICATION

• A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#)

Diluent: Chloroform and methanol (1:1)

Standard solution: 5 mg/mL of [USP Loratadine RS](#) in *Diluent*

Sample solution: Transfer a quantity of ground Chewable Tablets, equivalent to 25 mg of loratadine, to a centrifuge tube. Add 5 mL of *Diluent*, mix for 30 min, then centrifuge for 5 min. Use the clear supernatant.

Application volume: 5 μ L

Developing solvent system: Ethyl ether and diethylamine (40:1)

Acceptance criteria: Meet the requirements

• 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

Protect solutions containing loratadine from light.

Buffer A (phosphate buffer pH 7.2): Dissolve 4.35 g of dibasic potassium phosphate in 950 mL of water. Add 1 mL of triethylamine, adjust with 10% phosphoric acid or 10% potassium hydroxide to a pH of 7.2, and dilute with water to 1 L.

Buffer B (0.6 M dibasic potassium phosphate): 105 g/L of dibasic potassium phosphate in water

Diluent: Transfer 400 mL of 0.05 N hydrochloric acid and 80 mL of *Buffer B* to a 1-L volumetric flask. Dilute with a mixture of acetonitrile and methanol (1:1) to volume.

Mobile phase: Acetonitrile, methanol and *Buffer A* (40:10:50)

Standard solution: 0.4 mg/mL of [USP Loratadine RS](#) in *Diluent*

Sample solution: Nominally 0.4 mg/mL of loratadine in *Diluent*. Prepare by transferring 20 Chewable Tablets to a suitable volumetric flask. Add *Diluent* to 40% of the volume of the flask, and shake for 40 min. Dilute with *Diluent* to volume, and filter.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing L7

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 15 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.7

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 Chewable 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 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

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N hydrochloric acid; 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Buffer: 6.8 g/L of monobasic potassium phosphate in water. Adjust with 10% phosphoric acid to a pH of 2.80 ± 0.05 .

Mobile phase: Acetonitrile, methanol, and *Buffer* (40:30:35)

Standard solution: 10 µg/mL of [USP Loratadine RS](#) in *Medium*

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 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.7

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 from the *Sample solution*

r_S = peak response from the *Standard solution*

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

L = label claim (mg/Tablet)

V = volume of *Medium*, 500 mL

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

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

IMPURITIES

• ORGANIC IMPURITIES

Protect solutions containing loratadine from light.

Mobile phase, Diluent, and Sample solution: Prepare as directed in the Assay.

System suitability solution: 0.8 µg/mL each of [USP Loratadine Related Compound A RS](#), [USP Loratadine Related Compound B RS](#), and [USP Loratadine Related Compound C RS](#) in *Diluent*

Standard solution: 0.8 µg/mL of [USP Loratadine RS](#) in *Diluent*

Chromatographic system

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