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Loxapine Capsules

DEFINITION

Loxapine Capsules contain an amount of loxapine succinate ($C_{18}H_{18}ClN_3O \cdot C_4H_6O_4$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of loxapine ($C_{18}H_{18}ClN_3O$).

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.

Add the following:

▲ **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2022)

ASSAY

Change to read:

• PROCEDURE

Mobile phase: Dissolve 4 g of [tetramethylammonium chloride](#) in 800 mL of [water](#), and add 200 mL of [acetonitrile](#) and 1 mL of [phosphoric acid](#).

Standard solution: 0.136 mg/mL of [USP Loxapine Succinate RS](#) prepared as follows. Dissolve a suitable quantity of [USP Loxapine Succinate RS](#) in 0.01 N [hydrochloric acid](#) in a suitable volumetric flask, and dilute with *Mobile phase* to volume.

Sample solution: Nominally 0.1 mg/mL of loxapine prepared as follows. Weigh the contents of Capsules (NLT 20). Transfer a portion of the contents, nominally equivalent to NLT 50 mg of loxapine, to a suitable volumetric flask. Add 10% of the flask volume of 0.1 N [hydrochloric acid](#). Shake, and sonicate for 5 min. Dilute with *Mobile phase* to volume, and filter. Discard the first 8 mL of the filtrate.

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 220–400 nm.▲ (USP 1-Aug-2022)

Column: 4.6-mm × 15-cm; 5-μm packing [L10](#)

Flow rate: 1.6 mL/min

Injection volume: 20 μL

▲**Run time:** NLT 4 times the retention time of loxapine▲ (USP 1-Aug-2022)

System suitability

Sample: *Standard solution*

Suitability requirements

▲▲ (USP 1-Aug-2022)

Tailing factor: NMT 2.0

Relative standard deviation: NMT ▲1.0%▲ (USP 1-Aug-2022)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of loxapine ($C_{18}H_{18}ClN_3O$) in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak ▲response of loxapine▲ (USP 1-Aug-2022) from the *Sample solution*

r_S = peak ▲response of loxapine▲ (USP 1-Aug-2022) from the *Standard solution*

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

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

M_{r1} = molecular weight of loxapine, 327.81

M_{r2} = molecular weight of loxapine succinate, 445.90

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#).

Medium: [Water](#); 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Standard solution: [USP Loxapine Succinate RS](#) at a known concentration in *Medium*

Sample solution: Dilute with [water](#) as needed.

Instrumental conditions

▲(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)▲ (USP 1-Aug-2022)

Mode: UV

Analytical wavelength: 254 nm

Analysis

Samples: *Standard solution* and *Sample solution*

▲Calculate the percentage of the labeled amount of loxapine ($C_{18}H_{18}ClN_3O$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times (M_{r1}/M_{r2}) \times V \times D \times (1/L) \times 100$$

A_U = absorbance of loxapine from the *Sample solution*

A_S = absorbance of loxapine from the *Standard solution*

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

M_{r1} = molecular weight of loxapine, 327.81

M_{r2} = molecular weight of loxapine succinate, 445.90

V = volume of *Medium*, 900 mL

D = dilution factor of the *Sample solution*

L = label claim (mg/Capsule)▲ (USP 1-Aug-2022)

Tolerances: NLT 75% (Q) of the labeled amount of loxapine ($C_{18}H_{18}ClN_3O$) is dissolved.

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

Add the following:

▲IMPURITIES

• **ORGANIC IMPURITIES**

Buffer: 3.9 g/L of [ammonium acetate](#) in [water](#). Adjust with 20% [acetic acid](#) or [6 N ammonium hydroxide](#) to a pH of 7.3.

Solution A: *Buffer*

Solution B: [Acetonitrile](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
1	70	30
18	20	80
20	20	80
21	70	30
25	70	30



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