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Trazodone Hydrochloride Tablets

DEFINITION

Trazodone Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of trazodone hydrochloride ($C_{19}H_{22}ClN_5O \cdot HCl$).

IDENTIFICATION

- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **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

Change to read:

PROCEDURE

Buffer: 1.15 g/L of [monobasic ammonium phosphate](#), adjusted with [sodium hydroxide](#) to a pH of 6.0

Mobile phase: [Methanol](#) and *Buffer* (75:25)

Standard solution: 0.1 mg/mL of [USP Trazodone Hydrochloride RS](#) in [0.01 N hydrochloric acid TS](#)

Sample solution: Nominally 0.1 mg/mL of trazodone hydrochloride from finely powdered Tablets (NLT 20). Transfer a suitable quantity of the powder to a suitable volumetric flask. Dissolve in [0.01 N hydrochloric acid TS](#) and dilute with [0.01 N hydrochloric acid TS](#) to volume.

Sonicate for about 30 min, and pass through a suitable filter of 0.45-μm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 246 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 5-mm × 10-cm; 4-μm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 μL

Run time: NLT 4.5 times the retention time of trazodone

System suitability

Sample: *Standard solution*

Suitability requirements

▲ **Tailing factor:** NMT 2.5 ▲ (USP 1-May-2023)

Relative standard deviation: NMT ▲1.0% ▲ (USP 1-May-2023)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of trazodone hydrochloride ($C_{19}H_{22}ClN_5O \cdot HCl$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS**Change to read:**

- [DISSOLUTION \(711\)](#).

Test 1

Medium: [0.01 N hydrochloric acid TS](#); 900 mL

Apparatus 2: 50 rpm

Time: 60 min

Buffer, Mobile phase, Standard solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

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

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of the labeled amount of trazodone hydrochloride ($C_{19}H_{22}ClN_5O \cdot HCl$) dissolved:

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

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

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

C_S = concentration of [USP Trazodone Hydrochloride 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 trazodone hydrochloride ($C_{19}H_{22}ClN_5O \cdot HCl$) is dissolved.

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

Medium: [0.01 N hydrochloric acid TS](#); ▲500▲ (USP 1-May-2023) mL

Apparatus 2: ▲75▲ (USP 1-May-2023) rpm

Time: ▲15▲ (USP 1-May-2023) min

Buffer: To each liter of [water](#) add 5 mL of [triethylamine](#), and adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (25:75)

Standard solution: ▲(L/500)▲ (USP 1-May-2023) mg/mL of [USP Trazodone Hydrochloride RS](#) in *Medium*, ▲where L is the label claim, in mg/Tablet.▲ (USP 1-May-2023) Sonicate if necessary.

Sample solution: Pass the solution through a suitable filter of 0.45-μm pore size. Discard the first 5 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 246 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 45°

Flow rate: 1.5 mL/min

Injection volume: ▲5▲ (USP 1-May-2023) μL

Run time: NLT 1.6 times the retention time of trazodone

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 trazodone hydrochloride ($C_{19}H_{22}ClN_5O \cdot HCl$) dissolved:

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