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Tramadol Hydrochloride Tablets

DEFINITION

Tramadol Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of tramadol hydrochloride ($C_{16}H_{25}NO_2 \cdot HCl$).

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)▲ (CN 1-MAY-2020)

Sample solution: Transfer powdered Tablets, equivalent to 200 mg of tramadol hydrochloride, into a 50-mL volumetric flask, add 20 mL of dichloromethane, and sonicate. Filter, and transfer the clear supernatant to a separating funnel. Extract the dichloromethane layer with two 10-mL portions of 2 N sodium hydroxide, and discard the aqueous layer. Dry the dichloromethane layer over anhydrous sodium sulfate, and filter. Evaporate this solution to dryness under a stream of nitrogen.

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

Solution A: Dissolve 5 mL of perchloric acid in 950 mL of water in a 1-L volumetric flask. Add 4 mL of 25% ammonia water, dilute with water to volume, and mix. Adjust with 25% ammonia water to a pH of 2.2 ± 0.2 .

Mobile phase: Acetonitrile and *Solution A* (23:77)

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

Sample solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 50 mg of tramadol hydrochloride, into a 100-mL volumetric flask. Add 70 mL of 0.1 N hydrochloric acid, sonicate for 5 min, and shake for 10 min. Dilute with 0.1 N hydrochloric acid to volume, and mix. Pass a portion of this solution through a suitable filter, discarding the first 20 mL of the filtrate. Transfer 10 mL of the clear filtrate into a 50-mL volumetric flask, dilute with 0.1 N hydrochloric acid to volume, and mix.

Chromatographic system

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

Mode: LC

Detector: UV 273 nm

Column: 3.9-mm × 15-cm; packing L7

Flow rate: 2 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tramadol hydrochloride ($C_{16}H_{25}NO_2 \cdot HCl$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Solution A, Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Standard solution: 0.055 mg/mL of [USP Tramadol Hydrochloride RS](#) in *Medium*

Sample solution: Withdraw 9 mL from the dissolution vessel, and pass through a suitable filter. Discard the first 3 mL of the filtrate.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tramadol hydrochloride ($C_{16}H_{25}NO_2 \cdot HCl$) 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 Tramadol Hydrochloride RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of tramadol hydrochloride ($C_{16}H_{25}NO_2 \cdot HCl$) is dissolved.

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

Procedure for content uniformity

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

Sample solution: Transfer 1 whole Tablet to a 100-mL volumetric flask, add 70 mL of 0.1 N hydrochloric acid, sonicate until the Tablet is completely disintegrated, and shake for 10 min. Dilute with 0.1 N hydrochloric acid to volume, and mix. Pass a portion of this solution through a suitable filter, discarding the first 20 mL of the filtrate. Transfer 10 mL of the clear filtrate into a 50-mL volumetric flask, dilute with 0.1 N hydrochloric acid to volume, and mix.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tramadol hydrochloride ($C_{16}H_{25}NO_2 \cdot HCl$) in the Tablet 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 Tramadol Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

IMPURITIES

ORGANIC IMPURITIES

• PROCEDURE

Solution A and Mobile phase: Prepare as directed in the Assay.

System suitability solution: 0.2 mg/mL each of [USP Tramadol Hydrochloride RS](#) and [USP Tramadol Related Compound A RS](#) in *Mobile phase*

Standard solution: 6 µg/mL of [USP Tramadol Hydrochloride RS](#) in *Mobile phase*

System sensitivity solution: Transfer 5 mL of the *Standard solution* into a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.