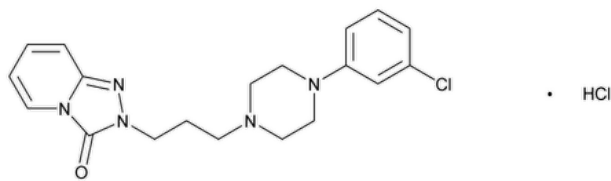


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Trazodone Hydrochloride



$C_{19}H_{22}ClN_5O \cdot HCl$ 408.32
1,2,4-Triazolo[4,3-a]pyridin-3(2H)-one, 2-[3-[4-(3-chlorophenyl)-1-piperazinyl]propyl]-, monohydrochloride;
2-[3-[4-(*m*-Chlorophenyl)-1-piperazinyl]propyl]-s-triazolo[4,3-a]-pyridin-3(2H)-one monohydrochloride CAS RN®: 25332-39-2; UNII: 6E8ZO8LRNM.

DEFINITION
Trazodone Hydrochloride contains NLT 98.0% and NMT 102.0% of trazodone hydrochloride ($C_{19}H_{22}ClN_5O \cdot HCl$), calculated on the dried basis.

IDENTIFICATION
Change to read:
• **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)
• **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: 0.01% (v/v) of triethylamine in water
Solution B: 0.01% (v/v) of triethylamine in acetonitrile
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
12	32	68
12.01	80	20
15	80	20

Diluent: *Solution A* and *Solution B* (80:20)
System suitability solution: 1 µg/mL each of [USP Trazodone Related Compound C RS](#) and [USP Trazodone Related Compound D RS](#), and 0.1 mg/mL of [USP Trazodone Hydrochloride RS](#) in *Diluent*
Standard solution: 1 mg/mL of [USP Trazodone Hydrochloride RS](#) in *Diluent*
Sample solution: 1 mg/mL of Trazodone Hydrochloride in *Diluent*
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC
Detector: UV 254 nm

Column: 4.6-mm × 7.5-cm; 3.5-μm packing L1

Flow rate: 2 mL/min

Injection volume: 10 μL

[NOTE—A mixture of acetonitrile, 2-propanol, acetone, and formic acid (400:300:300:2) is recommended for injector wash to minimize the sample carry-over.]

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between trazodone related compound C and trazodone; NLT 2.8 between trazodone and trazodone related compound D, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of trazodone hydrochloride ($C_{19}H_{22}ClN_5O \cdot HCl$) in the portion of Trazodone Hydrochloride 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 = concentration of Trazodone Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

• **ORGANIC IMPURITIES**

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

System suitability solution: 1 μg/mL each of [USP Trazodone Related Compound C RS](#) and [USP Trazodone Related Compound D RS](#) in the *Standard solution*

Standard solution: 1 μg/mL of [USP Trazodone Hydrochloride RS](#) in *Diluent*

Sample solution: 1 mg/mL of Trazodone Hydrochloride in *Diluent*

System suitability

Sample: *System suitability solution*

[NOTE—Refer to [Table 2](#) for the relative retention times.]

Suitability requirements

Relative standard deviation: NMT 5.0% for the trazodone peak

Resolution: NLT 1.5 between trazodone related compound C and trazodone; NLT 2.8 between trazodone and trazodone related compound D

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each individual impurity in the portion of Trazodone Hydrochloride taken:

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

r_U = peak response of each individual impurity 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 = concentration of Trazodone Hydrochloride in the *Sample solution* (mg/mL)

F = relative response factor (see [Table 2](#))