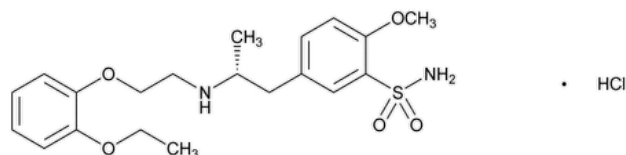


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Tamsulosin Hydrochloride



$C_{20}H_{28}N_2O_5S \cdot HCl$ 444.97

Benzenesulfonamide, 5-[2-[[2-(2-ethoxyphenoxy)ethyl] amino]propyl]-2-methoxy-, monohydrochloride, (R)-;

(-)-(R)-5-[2-[[2-(o-Ethoxyphenoxy)ethyl]amino]propyl]-2-methoxybenzenesulfonamide monohydrochloride CAS RN®: 106463-17-6; UNII: 11SV1951MR.

DEFINITION

Tamsulosin Hydrochloride contains NLT 98.0% and NMT 102.0% of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

• **B.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chloride](#)

Sample solution: 7.5 mg/mL in [water](#), using heat to dissolve the sample. In an ice bath, cool 5 mL of the solution. Add 3 mL of diluted [nitric acid](#), and shake until mixed thoroughly. Allow to stand for 30 min at room temperature, and filter.

• **C.** 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

Buffer: Transfer 0.1 g of [octanesulfonic acid sodium salt](#) and 1.0 mL of [phosphoric acid](#) into 1 L of [water](#), and mix.

Mobile phase: Acetonitrile and *Buffer* (20:80)

Diluent: Acetonitrile and [water](#) (20:80)

Standard solution: 0.5 mg/mL of [USP Tamsulosin Hydrochloride RS](#) in *Diluent*

Sample solution: 0.5 mg/mL of Tamsulosin Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing [L1](#)

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 0.85% for six replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$) in the portion of Tamsulosin Hydrochloride taken:

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

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

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

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

C_U = concentration of Tamsulosin Hydrochloride in the *Sample solution* (mg/mL)

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

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

- **ORGANIC IMPURITIES, PROCEDURE 1:** Use for impurities eluting before tamsulosin

Buffer: Dissolve 8.7 mL of [perchloric acid \(70%\)](#) and 3.0 g of [sodium hydroxide](#) in 1900 mL of [water](#). Adjust with [1 N sodium hydroxide](#) to a pH of 2.0, and add sufficient [water](#) to make 2000 mL.

Mobile phase: Acetonitrile and *Buffer* (3:7)

System suitability solution: 25 µg/mL of Tamsulosin Hydrochloride and 50 µg/mL of [propylparaben](#) in *Mobile phase*

Sample solution: 5.0 mg/mL of Tamsulosin Hydrochloride in *Mobile phase*

Standard solution: 10 µg/mL of Tamsulosin Hydrochloride from the *Sample solution* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

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

Column temperature: 40°

Flow rate: 1.3 mL/min

Injection volume: 10 µL

[NOTE—Record the chromatogram for NLT 1.5 times the retention time of tamsulosin.]

System suitability

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

Suitability requirements

Resolution: NLT 12 between tamsulosin and propylparaben, *System suitability solution*. [NOTE—The elution order is tamsulosin followed by propylparaben.]

Relative standard deviation: NMT 4% for six replicate injections, *Standard solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of any individual impurity eluting before the tamsulosin peak in the portion of Tamsulosin Hydrochloride taken:

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

r_U = peak response of each impurity eluting before tamsulosin from the *Sample solution*

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

C_S = concentration of the *Standard solution* (mg/mL)

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

Acceptance criteria: The reporting level for impurities is 0.05%.

Any individual impurity: NMT 0.10%. [NOTE—If present, the des-ethoxy and methoxy impurities eluting at the relative retention time of about 0.8 are not separated by this method, and should be integrated together to determine conformance. (Des-ethoxy impurity is 2-methoxy-5-[(2R)-2-[(2-phenoxyethyl)amino]propyl]benzenesulfonamide, and methoxy impurity is 2-methoxy-5-[(2R)-2-[[2-(2-methoxyphenoxy)ethyl]amino]propyl]benzenesulfonamide.) NMT 0.15% of the sum of des-ethoxy and methoxy impurities is found.]

- **ORGANIC IMPURITIES, PROCEDURE 2:** Use for impurities eluting after tamsulosin

Buffer, Sample solution, and Standard solution: Prepare as directed in *Procedure 1*.

[NOTE—Use the *Mobile phase* in *Procedure 1* to prepare the *Sample solution* and *Standard solution*.]

Mobile phase: Acetonitrile and *Buffer* (1:1)

Chromatographic system

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