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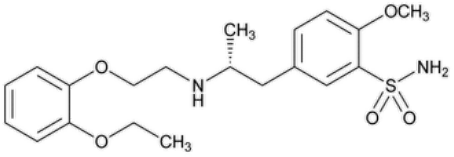
Tamsulosin Hydrochloride



• HCl

$C_{20}H_{28}N_2O_5S \cdot HCl$ 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-[(2*R*)-2-[(2-phenoxyethyl)amino]propyl]benzenesulfonamide, and methoxy impurity is 2-methoxy-5-[(2*R*)-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*.)

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

[NOTE—Record the chromatogram for NLT 5 times the retention time of tamsulosin.]

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: Use a column that meets the resolution requirements in *Procedure 1*.

Relative standard deviation: NMT 4% for six replicate injections

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of any individual impurity eluting after 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 after 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%

Total impurities: NMT 0.2%, including all impurities in *Procedure 1* and *Procedure 2*

- **ENANTIOMERIC PURITY**

Mobile phase: Hexane, dehydrated alcohol, methanol, and diethylamine (650:200:150:1)

System suitability solution: 40 µg/mL of USP Racemic Tamsulosin Hydrochloride RS in methanol

Sample solution: 2.0 mg/mL of Tamsulosin Hydrochloride in methanol

Standard solution: 2 µg/mL of Tamsulosin Hydrochloride from the *Sample solution* in methanol

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 25-cm; packing L51

Column temperature: 40°

Flow rate: 0.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for the *S*-enantiomer and tamsulosin are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2 between the *S*-enantiomer and tamsulosin

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of the *S*-enantiomer 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 the *S*-enantiomer 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: NMT 0.3% of the *S*-enantiomer

SPECIFIC TESTS

- **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

USP Tamsulosin Hydrochloride RS

USP Racemic Tamsulosin Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TAMSULOSIN HYDROCHLORIDE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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