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Tamsulosin Hydrochloride Capsules

DEFINITION

Tamsulosin Hydrochloride Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$).

IDENTIFICATION

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

ASSAY

Change to read:

• PROCEDURE 1

Solution A: Dilute 20 mL of [hydrochloric acid](#) with [water](#) to 1000 mL.

Solution B: Dissolve 8.7 mL of [perchloric acid](#) 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 dilute with [water](#) to 2000 mL.

Mobile phase: [Acetonitrile](#) and *Solution B* (30:70)

Diluent: [Water](#) and [acetonitrile](#) (70:30)

Internal standard solution: 0.4 mg/mL of [propylparaben](#) in *Diluent*

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

Standard solution: 0.025 mg/mL of [USP Tamsulosin Hydrochloride RS](#) from the *Standard stock solution* and 0.05 mg/mL of propylparaben from the *Internal standard solution* in *Mobile phase*

Sample solution: Nominally 0.025 mg/mL of tamsulosin hydrochloride from Capsules and 0.05 mg/mL of propylparaben from the *Internal standard solution* prepared as follows. Transfer an amount equivalent to about 1 mg of tamsulosin hydrochloride, from a portion of the weighed and mixed contents of the Capsules (NLT 20), into a Teflon-lined, screw-capped centrifuge tube. Place approximately 100 glass balls with a diameter of about 5 mm into the tube, add 20 mL of 0.05 N [sodium hydroxide](#), heat at 50° for 10 min, and shake well for 30 min. Add 15 mL of a mixture of [acetonitrile](#) and *Solution A* (2:1), and shake well. Add 5.0 mL of the *Internal standard solution*, and shake well. Centrifuge at 1500 rpm for 10 min, and use the supernatant, passing it, if necessary, through a membrane filter of 0.5-µm or smaller pore size.

Chromatographic system

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

Mode: LC

Detector: UV 225 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.0-mm × 15-cm or 4.6-mm × 15-cm; 5-µm packing [L1](#)

Column temperature: 40°

Flow rate: 1.0 mL/min for the 4.0-mm column and 1.3 mL/min for the 4.6-mm column. [NOTE—The flow rate can be adjusted as needed to achieve a recommended retention time of approximately 6 min for tamsulosin.]

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 12 between tamsulosin and propylparaben. [NOTE—The elution order is tamsulosin hydrochloride followed by propylparaben.]

Relative standard deviation: NMT 2.0% for the ratios of the peak areas for tamsulosin and the internal standard

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak area ratio of tamsulosin to the internal standard from the *Sample solution*

R_S = peak area ratio of tamsulosin to the internal standard from the *Standard solution*

C_S = concentration of [USP Tamsulosin Hydrochloride RS](#) in the *Standard* ▲ (ERR 1-Dec-2024) *solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

- **PROCEDURE 2:** Use this procedure for Capsules labeled to meet the requirements of *Dissolution Test 2*.

Solution B and Mobile phase: Prepare as directed for *Procedure 1*.

Buffer: Dissolve 3.4 g of [monobasic potassium phosphate](#) in 1 L of [water](#). Adjust with [2 N sodium hydroxide](#) to a pH of 5.80 ± 0.05 .

Standard solution: 0.0032 mg/mL of [USP Tamsulosin Hydrochloride RS](#) prepared as follows. Dissolve 1.2 mg/mL of [USP Tamsulosin Hydrochloride RS](#) in [methanol](#). Further dilute this solution with *Buffer* to 3.2 µg/mL.

Sample solution: Nominally 0.0032 mg/mL of tamsulosin hydrochloride prepared as follows. Transfer an amount equivalent to 1.6 mg of tamsulosin hydrochloride, from a portion of the weighed and mixed contents of the Capsules (NLT 20), into a 100-mL volumetric flask. Add 20 mL of [methanol](#), stir for 30 min, sonicate for 30 min, and stir again for 30 min. Add 40 mL of [methanol](#), sonicate for another 30 min, and stir for another 60 min. Dilute with [methanol](#) to volume, mix well, and allow the solution to stand for 5 min. Dilute 5 mL of this solution with *Buffer* to 25 mL, and allow the solution to stand for 5 min. Pass through a PVDF filter of 0.45-µm pore size, discarding the first 5 mL of the filtrate.

Chromatographic system: Proceed as directed for *Procedure 1*, except for *Injection volume*.

Injection volume: 50 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 tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$) in the portion of Capsules 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](#) from the *Standard solution* (mg/mL)

C_U = nominal concentration of tamsulosin hydrochloride from the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

- **PROCEDURE 3:** Use this procedure for Capsules labeled to meet the requirements of *Dissolution Test 3*.

Solution B and Mobile phase: Prepare as directed for *Procedure 1*.

Buffer: 6.9 g/L of [monobasic sodium phosphate monohydrate](#) in [water](#). Adjust with [5 N sodium hydroxide](#) to a pH of 7.2 ± 0.05 .

Standard solution: 0.03 mg/mL of [USP Tamsulosin Hydrochloride RS](#) prepared as follows. Dissolve 0.5 mg/mL of [USP Tamsulosin Hydrochloride RS](#) in a mixture of [methanol](#) and [water](#) (50:50). Further dilute a portion of this solution with [methanol](#) to 0.03 mg/mL.

Sample solution: Nominally 0.03 mg/mL of tamsulosin hydrochloride from Capsules prepared as follows. Transfer an amount equivalent to 0.8 mg of tamsulosin hydrochloride, from a portion of the weighed and mixed contents of the Capsules (NLT 20), into a 25-mL volumetric flask. Add 5 mL of *Buffer*, shake for 15 min, add 10 mL of [methanol](#), shake for 1 h, and dilute with [methanol](#) to volume. Pass through a suitable filter of 0.45-µm pore size.

Chromatographic system: Proceed as directed for *Procedure 1*, except for *Injection volume*.

Injection volume: 20 µL

System suitability and Analysis: Proceed as directed for *Procedure 2*.

Acceptance criteria: 90.0%–110.0%

- **PROCEDURE 4:** For Capsules labeled to meet the requirements of *Dissolution Test 4*, proceed as directed for *Procedure 1*.

- **PROCEDURE 5:** Use this procedure for Capsules labeled to meet the requirements of *Dissolution Test 5*.

Solution B, Mobile phase, and Chromatographic system: Proceed as directed for *Procedure 1*.

Diluent: [Methanol](#) and [water](#) (75:25)

Standard solution: 0.016 mg/mL of [USP Tamsulosin Hydrochloride RS](#) in *Diluent*

Sample solution: Nominally 0.016 mg/mL of tamsulosin hydrochloride from Capsules prepared as follows. Transfer the contents of 10 Capsules (equivalent to 4 mg of tamsulosin hydrochloride) into a 250-mL volumetric flask. Add 200 mL of *Diluent*, stir, and sonicate simultaneously for at least 2 h. Cool, and dilute with *Diluent* to volume. Pass through a suitable filter.

System suitability and Analysis: Proceed as directed for *Procedure 2*.

Acceptance criteria: 90.0%–110.0%

- **PROCEDURE 6:** Use this procedure for Capsules labeled to meet the requirements of *Dissolution Test 6*.

Solution B and Mobile phase: Prepare as directed for *Procedure 1*.

Buffer: Dissolve 6.8 g/L of [monobasic potassium phosphate](#) and 0.9 g/L of [sodium hydroxide](#) in [water](#). Adjust with [sodium hydroxide](#) solution to a pH of 6.8.

Diluent 1: [Acetonitrile](#) and *Buffer* (50:50)

Diluent 2: [Acetonitrile](#) and *Solution B* (50:50)

Standard solution: 0.008 mg/mL of [USP Tamsulosin Hydrochloride RS](#) prepared as follows. Dissolve 0.4 mg/mL of [USP Tamsulosin Hydrochloride RS](#) in *Diluent 1*, using sonication as necessary. Further dilute the solution with *Diluent 2* to 0.008 mg/mL.

Sample solution: Nominally 0.008 mg/mL of tamsulosin hydrochloride from Capsules prepared as follows. Transfer an amount equivalent to 4 mg of tamsulosin hydrochloride, from a portion of the weighed and mixed contents of the Capsules (NLT 20), into a 100-mL volumetric flask. Add 60 mL of *Diluent 1*, and sonicate with intermittent shaking to disperse the pellets completely. Cool, and dilute with *Diluent 1* to volume. Centrifuge, transfer 5 mL of supernatant solution to a 25-mL volumetric flask, and dilute with *Diluent 2* to volume. Pass through a nylon membrane filter of 0.45-μm pore size.

Chromatographic system: Proceed as directed for *Procedure 1*, except for *Injection volume*.

Injection volume: 20 μL

System suitability and Analysis: Proceed as directed for *Procedure 2*.

Acceptance criteria: 90.0%–110.0%

- **PROCEDURE 7:** Use this procedure for Capsules labeled to meet the requirements of *Dissolution Test 7*.

Solution B and Mobile phase: Prepare as directed for *Procedure 1*.

Buffer: Dissolve 76 g/L of [tribasic sodium phosphate](#) in [water](#).

Diluent: [0.1 N hydrochloric acid](#) and *Buffer* (75:25), adjusted with diluted [hydrochloric acid](#) or [sodium hydroxide](#) solution to a pH of 7.0

Standard solution: 0.0016 mg/mL of [USP Tamsulosin Hydrochloride RS](#) in *Diluent*

Sample solution: Nominally 0.0016 mg/mL of tamsulosin hydrochloride from Capsules prepared as follows. Transfer an amount equivalent to 0.4 mg of tamsulosin hydrochloride, from a portion of the weighed and mixed contents of the Capsules (NLT 20), into a 250-mL volumetric flask, and dilute with *Diluent* to volume. Stir for 24 h by mechanical means at 40° protected from light. Pass through a suitable filter of 0.45-μm pore size.

Chromatographic system: Proceed as directed for *Procedure 1*, except for *Injection volume*.

Injection volume: 50 μL

System suitability and Analysis: Proceed as directed for *Procedure 2*.

Acceptance criteria: 90.0%–110.0%

- **PROCEDURE 8:** Use this procedure for Capsules labeled to meet the requirements of *Dissolution Test 8*.

Solution B, Mobile phase, and Chromatographic system: Proceed as directed for *Procedure 1*.

Standard solution: 0.025 mg/mL of [USP Tamsulosin Hydrochloride RS](#) prepared as follows. Dissolve 0.1 mg/mL of [USP Tamsulosin Hydrochloride RS](#) in [methanol](#). Further dilute the solution to 0.025 mg/mL of [USP Tamsulosin Hydrochloride RS](#) in *Mobile phase*.

Sample solution: Nominally 0.025 mg/mL of tamsulosin hydrochloride from Capsules prepared as follows. Transfer an amount equivalent to 2.5 mg of tamsulosin hydrochloride, from a portion of the weighed and mixed contents of the Capsules (NLT 20), into a 100-mL volumetric flask. Add 25 mL of [0.1 N sodium hydroxide](#), and sonicate for 30 min. Add 30 mL of *Mobile phase*, shake by mechanical means for 30 min, and dilute with *Mobile phase* to volume. Centrifuge, and pass through a PVDF membrane filter of 0.45-μm pore size, discarding the first few milliliters of the filtrate.

System suitability and Analysis: Proceed as directed for *Procedure 2*.

Acceptance criteria: 90.0%–110.0%

- **PROCEDURE 9:** For Capsules labeled to meet the requirements of *Dissolution Test 9*, proceed as directed for *Procedure 1*.

- **PROCEDURE 10:** Use this procedure for Capsules labeled to meet the requirements of *Dissolution Test 10*.

Solution A, Solution B, Mobile phase, and Diluent: Prepare as directed for *Procedure 1*.

Internal standard solution: 0.5 mg/mL of [propylparaben](#) in *Diluent*

Standard stock solution: 0.62 mg/mL of [USP Tamsulosin Hydrochloride RS](#) in *Diluent*

Standard solution: 0.025 mg/mL of [USP Tamsulosin Hydrochloride RS](#) from the *Standard stock solution* and 0.05 mg/mL of propylparaben from the *Internal standard solution* in *Mobile phase*.

Sample solution: Nominally 0.025 mg/mL of tamsulosin hydrochloride from Capsules and 0.05 mg/mL of propylparaben from the *Internal standard solution* prepared as follows. Transfer an amount equivalent to 1.2 mg of tamsulosin hydrochloride, from a portion of the weighed, mixed, and crushed contents of the Capsules (NLT 20), into a 50-mL volumetric flask. Add 25 mL of 0.05 N [sodium hydroxide](#) solution, heat at 50° for 15 min, and shake mechanically for 60 min. Sonicate for 30 min with intermittent shaking and add 15 mL of a mixture of *Solution A* and [acetonitrile](#) (1:2). Sonicate for another 15 min with intermittent shaking. Add 5 mL of *Internal standard solution*, dilute with a mixture of *Solution A* and [acetonitrile](#) (1:2) to volume, and mix well. Centrifuge the solution for 10 min and pass the solution through a suitable glass fiber filter.

Chromatographic system: Proceed as directed for *Procedure 1*.

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 12 between tamsulosin and propylparaben. [NOTE—The elution order is tamsulosin hydrochloride followed by propylparaben.]

Relative standard deviation: NMT 2.0% for each peak

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak area ratio of tamsulosin to the internal standard from the *Sample solution*

R_S = peak area ratio of tamsulosin to the internal standard from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

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

Test 1

Solution B, Mobile phase, Diluent, and Standard stock solution: Prepare as directed in the Assay, *Procedure 1*.

Acid stage medium: Dissolve 2.0 g of [sodium chloride](#) in 5.7 mL of [hydrochloric acid](#), and dilute to 1000 mL with [water](#). To 500 mL of this fluid, add 1 mL of [polysorbate 80](#) aqueous solution (3 g in 200 mL of [water](#)) just before the test; 500 mL.

Buffer stage medium: pH 7.2 phosphate buffer. Dissolve 6.8 g of [monobasic potassium phosphate](#) in 250 mL of [water](#), add 90 mL of [0.2 N sodium hydroxide](#) and 500 mL of [water](#), adjust with [0.2 N sodium hydroxide](#) or 0.2 N [hydrochloric acid](#) to a pH of 7.2 ± 0.05 , and dilute with [water](#) to 1000 mL; 500 mL.

Apparatus 2: 100 rpm, with sinker (see [Dissolution \(711\)](#), *Figure 2a*)

Times: 2, 3, and 8 h

Internal standard solution: 0.008 mg/mL of [propylparaben](#) in *Diluent*

Standard solution: 0.67 µg/mL of [USP Tamsulosin Hydrochloride RS](#) from the *Standard stock solution* and 1.3 µg/mL of propylparaben from the *Internal standard solution* in *Acid stage medium* prepared as follows. Transfer 4.0 mL of the *Standard stock solution* to a 100-mL volumetric flask, and dilute to volume with *Acid stage medium*. Transfer 4.0 mL of this dilution to another 100-mL volumetric flask, and dilute with *Acid stage medium* to volume. Transfer 10.0 mL of this last dilution to a test tube, and add 2.0 mL of the *Internal standard solution*.

Procedure: After 2 h in *Acid stage medium*, withdraw 10.0 mL of solution under test and immediately drain the *Acid stage medium* by suction through a tube capped with a 60-mesh stainless wire screen. Rinse the drain tube while adding *Buffer stage medium* previously warmed, and continue test. After 3 h (including the 2 h in the *Acid stage medium*), withdraw 10.0 mL of the solution under test and replace with the same volume of *Buffer stage medium*. After 8 h (including the 2 h in the *Acid stage medium*), withdraw 10.0 mL of the solution under test.

Sample solutions

Acid stage sample: Add 2.0 mL of the *Internal standard solution*, mix well, and pass through a suitable filter of 0.5-µm pore size, discarding the first 5 mL.

Buffer stage sample: Add 1.0 mL of [0.5 N hydrochloric acid](#) and 2.0 mL of the *Internal standard solution*, mix well, and pass through a suitable filter of 0.5-µm pore size, discarding the first 5 mL.

Chromatographic system: Proceed as directed in the *Assay, Procedure 1* except for *Injection volume*.

Injection volume: 250 µL

Analysis

Samples: *Standard solution* and *Sample solution* (either *Acid stage sample* or *Buffer stage sample* depending on time point)

Calculate the concentration (C_i) of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$) in the sample withdrawn at each time point (i):

$$\text{Result} = (R_U/R_S) \times C_S$$

R_U = peak area ratio of tamsulosin to the *Internal standard* from the *Sample solution*

R_S = peak area ratio of tamsulosin to the *Internal standard* from the *Standard solution*

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

Calculate the percentage of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$) dissolved at each time point (i):

$$\text{Result}_1 = C_1 \times V_1 \times (1/L) \times 100$$

$$\text{Result}_2 = [C_2 \times V_2 \times (1/L) \times 100] + \text{Result}_1$$

$$\text{Result}_3 = \{[(C_3 \times V_2) + (C_2 \times V_2) \times (V_S/V_2)] \times (1/L) \times 100\} + \text{Result}_1$$

C_i = concentration of tamsulosin hydrochloride in the portion of sample withdrawn at the specified time point (mg/mL)

V_1 = volume of *Acid stage medium*, 500 mL

L = label claim (mg/Capsule)

V_2 = volume of *Buffer stage medium*, 500 mL

V_S = volume of *Sample solution* withdrawn at each time point from the medium (mL)

Tolerances: See [Table 1](#).

Table 1

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	13–34
2	3	47–68
3	8	NLT 80

The percentages of the labeled amount of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$) dissolved at the times specified conform to [Dissolution \(711\)](#), [Acceptance Table 2](#).

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

Acid stage medium: 0.003% [Polysorbate 80](#), pH 1.2 prepared as follows. For each liter prepared, transfer 8.5 mL of [hydrochloric acid](#) to a suitable volumetric flask and add 900 mL of [water](#) and 0.03 mL of [polysorbate 80](#). Adjust with [0.2 N sodium hydroxide](#) or 0.2 N [hydrochloric acid](#) to a pH of 1.2 ± 0.05, and dilute with [water](#) to 1000 mL; 500 mL

Buffer stage medium: pH 7.2 phosphate buffer (proceed as directed for *Test 1*); 500 mL

Apparatus 2: 100 rpm, with sinkers¹

Times: 2 h in the *Acid stage medium* and 8 h in the *Buffer stage medium* (including the 2 h in the *Acid stage medium*).

Procedure: Perform the test using *Acid stage medium*. At 2 h after the start of the test, withdraw a sample of the solution under test. Carefully discard the *Acid stage medium* and replace it with the *Buffer stage medium* previously warmed, and continue the test. At 6 h after the replacement of the *Medium*, withdraw a sample of the solution under test.

Standard stock solution: 0.5 mg/mL of [USP Tamsulosin Hydrochloride RS](#) prepared as follows. Transfer about 25.0 mg of [USP Tamsulosin Hydrochloride RS](#) to a 50-mL volumetric flask. Add 25 mL of [methanol](#). Dilute with *Buffer stage medium* to volume. Sonicate until dissolved.

Standard solution: 0.8 µg/mL of [USP Tamsulosin Hydrochloride RS](#) from the *Standard stock solution* in *Buffer stage medium*

Sample solution: Pass a portion of the solution under test through a suitable filter.

Buffer: 3.4 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with [2 N sodium hydroxide](#) to a pH of 5.80 ± 0.05.

Mobile phase: *Buffer* and [acetonitrile](#) (3:1)

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

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

Flow rate: 1 mL/min

Injection volume: 50 µL

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 concentration (C_i) of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$) in the sample withdrawn at each time point (i):

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

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)

Calculate the percentage of the labeled amount of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$) dissolved at each time point (i):

$$\text{Result}_1 = C_1 \times V_1 \times (1/L) \times 100$$

$$\text{Result}_2 = [C_2 \times V_2 \times (1/L) \times 100] + \text{Result}_1$$

C_i = concentration of tamsulosin hydrochloride in the portion of sample withdrawn at the specified time point (mg/mL)

V_1 = volume of the *Acid stage medium*, 500 mL

L = label claim (mg/Capsule)

V_2 = volume of the *Buffer stage medium*, 500 mL

Tolerances: See [Table 2](#).

Table 2

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	NMT 25
2	8	NLT 85