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Dutasteride and Tamsulosin Hydrochloride Capsules

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<https://www.uspnf.com/rb-dutasteride-tamsulosin-hcl-caps-20240426>.

DEFINITION

Dutasteride and Tamsulosin Hydrochloride Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of dutasteride ($C_{27}H_{30}F_6N_2O_2$) and NLT 90.0% and NMT 110.0% of the labeled amount of tamsulosin hydrochloride ($C_{20}H_{28}N_2O_5S \cdot HCl$). They may contain butylated hydroxytoluene or another suitable antioxidant.

IDENTIFICATION

- **A.** The retention time of the dutasteride peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay, *Procedure 1: Dutasteride*.
- **B.** The UV spectrum of the dutasteride peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay, *Procedure 1: Dutasteride*.
- **C.** The retention time of the tamsulosin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay, *Procedure 2: Tamsulosin Hydrochloride*.
- **D.** The UV spectrum of the tamsulosin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay, *Procedure 2: Tamsulosin Hydrochloride*.

ASSAY

PROCEDURE 1: DUTASTERIDE

Buffer: 1.37 g/L of [potassium dihydrogen phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (65:35)

Diluent A: [Acetonitrile](#) and [water](#) (90:10)

Diluent B: [Acetonitrile](#) and [water](#) (50:50)

Standard solution: 0.02 mg/mL of [USP Dutasteride RS](#) in *Diluent A*. Sonicate to dissolve, if necessary.

Sample solution: Nominally 0.02 mg/mL of dutasteride prepared as follows. Take Capsules (NLT 20) and remove the contents, separating the pellets and the soft gelatin capsules. Weigh and transfer the intact soft gelatin capsules into a 500-mL volumetric flask. Add *Diluent B* to 20% of the total volume, and sonicate with shaking until the capsules completely rupture. Add [acetonitrile](#) to 50% of the total volume and sonicate for NLT 10 min with shaking at every 3 min for a period of 30 s. Dilute with [acetonitrile](#) to volume and mix. Pass the solution through a suitable filter of 0.22-μm pore size. Discard the first few milliliters of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

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

Flow rate: 2 mL/min

Injection volume: 100 μL

Run time: NLT 2.5 times the retention time of dutasteride

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 percentage of the labeled amount of dutasteride ($C_{27}H_{30}F_6N_2O_2$) in the portion of Capsules taken:

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

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

r_s = peak response of dutasteride from the *Standard solution*

C_s = concentration of [USP Dutasteride RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of dutasteride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

• **PROCEDURE 2: TAMUSULOSIN HYDROCHLORIDE**

Buffer: 2.554 g/L of [anhydrous disodium hydrogen phosphate](#) and 0.272 g/L of [potassium dihydrogen phosphate](#) in [water](#). Adjust with dilute [phosphoric acid](#) to a pH of 7.0.

Mobile phase: [Methanol](#) and *Buffer* (55:45)

Standard stock solution: 160 µg/mL of [USP Tamsulosin Hydrochloride RS](#) in [methanol](#). Sonicate to dissolve, if necessary.

Standard solution: 8 µg/mL of [USP Tamsulosin Hydrochloride RS](#) from *Standard stock solution* in *Mobile phase*

Sample solution: Nominally 8 µg/mL of tamsulosin hydrochloride prepared as follows. Weigh Capsules (NLT 20) and determine the average net content. Open the capsules and remove pellets, and determine weight of the capsules with the soft gelatin capsules. Calculate the average net content of pellets. Accurately weigh and transfer a quantity of pellets equivalent to about 2 mg of tamsulosin hydrochloride to a 250-mL volumetric flask. Add 1 N [sodium hydroxide](#) solution to 12% of the total volume and sonicate for NLT 30 min. Add [methanol](#) to 28% of the total volume and sonicate for NLT 15 min. Dilute with *Mobile phase* to volume and mix. Pass a portion of the solution through a suitable filter of 0.45-µm pore size. Discard the first few milliliters of the filtrate.

Chromatographic system

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

Mode: LC

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

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 35°

Flow rate: 1 mL/min

Injection volume: 50 µL

Run time: NLT 1.5 times the retention time of tamsulosin

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 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](#) in the *Standard solution* (µg/mL)

C_u = nominal concentration of tamsulosin in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

• **CONTENT OF BUTYLATED HYDROXYTOLUENE (IF PRESENT IN THE PRODUCT)**

Buffer, Mobile phase, and Diluent A: Prepare as directed in the *Assay, Procedure 1: Dutasteride*.

Standard solution: 7 µg/mL of [USP Butylated Hydroxytoluene RS](#) in *Diluent A*. Sonicate to dissolve.

Sample solution: Nominally 7 µg/mL of butylated hydroxytoluene in *Diluent A* prepared as follows. Remove the contents of the Capsules (NLT 20) separating the pellets and soft gelatin capsules. Remove as completely as possible the content of the soft gelatin capsules. Mix the contents, and determine the average net content of the soft gelatin capsules. Accurately weigh and transfer a quantity of the contents of the soft gelatin capsules equivalent to about 0.175 mg of butylated hydroxytoluene to a 25-mL volumetric flask. Add *Diluent A* to 60% of the total volume and sonicate to dissolve. Dilute with *Diluent A* to volume and mix.

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

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of butylated hydroxytoluene ($C_{15}H_{24}O$) in the portion of Capsules taken:

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

r_U = peak response of butylated hydroxytoluene from the *Sample solution*

r_S = peak response of butylated hydroxytoluene from the *Standard solution*

C_S = concentration of [USP Butylated Hydroxytoluene RS](#) in the *Standard solution* ($\mu\text{g/mL}$)

C_U = nominal concentration of butylated hydroxytoluene in the *Sample solution* ($\mu\text{g/mL}$)

Acceptance criteria: 85.0%–110.0% of the labeled amount of butylated hydroxytoluene ($C_{15}H_{24}O$)

PERFORMANCE TESTS

Change to read:

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

▲Test 1▲ (RB 1-May-2024)

Test for dutasteride

Tier 1

Medium: 10 g/L of [cetyltrimethylammonium bromide](#) in 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 75 rpm with a suitable sinker

Time: 45 min

Tier 2

Medium: Dissolve 10 g of [cetyltrimethylammonium bromide](#) and 1.6 g of [pepsin, purified](#) in 1000 mL of 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 75 rpm with a suitable sinker

Time: 45 min

Buffer and Mobile phase: Prepare as directed in the Assay, *Procedure 1: Dutasteride*.

Standard stock solution: 0.22 mg/mL of [USP Dutasteride RS](#) in [methanol](#). Sonicate to dissolve.

Standard solution: 0.55 $\mu\text{g/mL}$ of [USP Dutasteride RS](#) from *Standard stock solution* in *Medium*

Sample solution: Withdraw and pass about 10 mL of the solution under test through a suitable filter of 0.45- μm pore size, discarding the first few milliliters of the filtrate.

Dissolution procedure: Perform the test using the conditions under *Tier 1*. In the presence of cross-linking repeat the test with new Capsules using the conditions under *Tier 2*.

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

Detector: UV 240 nm

Injection volume: 500 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 percentage of the labeled amount of dutasteride ($C_{27}H_{30}F_6N_2O_2$) dissolved:

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

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

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

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Capsule)

Tolerances: NLT 80% (Q) of the labeled amount dutasteride ($C_{27}H_{30}F_6N_2O_2$) is dissolved.

Test for tamsulosin hydrochloride

Acid stage medium: 0.1 N [hydrochloric acid](#); 750 mL