

Status: Currently Official on 14-Feb-2025

Official Date: Official as of 01-Aug-2024

Document Type: USP Monographs

DocId: GUID-B9F15412-107F-4DB8-A410-DD5F99020515_7_en-US

DOI: https://doi.org/10.31003/USPNF_M3711_07_01

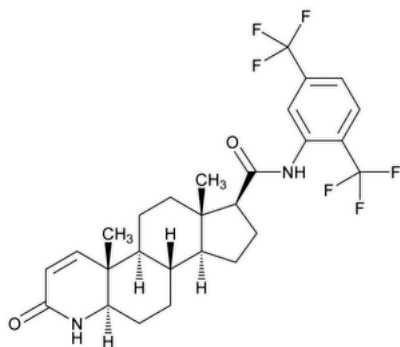
DOI Ref: 4lam9

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Dutasteride

Change to read:



$C_{27}H_{30}F_6N_2O_2$ $\Delta 528.54$ (CN 1-Aug-2024)

(5 α ,17 β)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-azaandrost-1-ene-17-carboxamide;

$\alpha,\alpha,\alpha,\alpha',\alpha'$ -Hexafluoro-3-oxo-4-aza-5 α -androst-1-ene-17 β -carboxy-2',5'-xylidide CAS RN[®]: 164656-23-9.

DEFINITION

Dutasteride contains NLT 97.0% and NMT 102.0% of dutasteride ($C_{27}H_{30}F_6N_2O_2$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A, 197K, or 197M
- **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

Diluent: [Acetonitrile](#) and [water](#) (60:40)

Mobile phase: [Acetonitrile](#), [water](#), and [trifluoroacetic acid](#) (52: 48: 0.025)

System suitability solution: 0.5 mg/mL of [USP Dutasteride Resolution Mixture RS](#) in *Diluent*. Sonicate to dissolve.

Standard solution: 0.5 mg/mL of [USP Dutasteride RS](#) in *Diluent*. Sonicate to dissolve.

Sample solution: 0.5 mg/mL of Dutasteride in *Diluent*. Sonicate to dissolve.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Column temperature: 35°

Flow rate: 1 mL/min

Injection volume: 10 μ L

Run time: NLT 1.5 times the retention time of dutasteride

System suitability

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

[NOTE—See [Table 3](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between dutasteride 17 α -epimer and dutasteride, *System suitability solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dutasteride ($C_{27}H_{30}F_6N_2O_2$) in the portion of Dutasteride 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 = concentration of Dutasteride in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

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

• LIMIT OF RESIDUAL SOLVENTS

Standard stock solution: 5 mg/mL each of [acetonitrile](#), [ethyl acetate](#), [pyridine](#), [toluene](#), [dioxane](#), and [n-heptane](#) in [dimethyl sulfoxide](#)

Standard solution: 10 µg/mL each of acetonitrile, ethyl acetate, pyridine, toluene, dioxane, and *n*-heptane in dimethyl sulfoxide from the *Standard stock solution*

Sample solution: 10 mg/mL of Dutasteride in [dimethyl sulfoxide](#)

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 30-m; capillary coated with 5-µm film of phase [G1](#)

Temperatures

Injection port: 180°

Detector: 260°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
50	—	50	3
50	10	200	2

Carrier gas: Helium

Flow rate: Head pressure at 12 psi

Split flow: 10 mL/min

Septum purge: 2 mL/min

Injector type: Headspace

Sample volume: 2 mL

Temperatures

Sample: 85°

Needle: 100°

Transfer line: 110°

Times

Equilibration: 1 min

Thermostating: 15 min

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 1.2 between *n*-heptane and dioxane peaks

Relative standard deviation: NMT 5% for each solvent

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each solvent in the portion of Dutasteride taken:

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

r_U = peak response of each solvent from the *Sample solution*