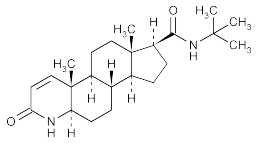
• **USP REFERENCE STANDARDS** ⟨11⟩
USP Endotoxin RS
USP Filgrastim RS

Finasteride



$C_{23}H_{36}N_2O_2$ 372.54
4-Azaandrost-1-ene-17-carboxamide, *N*-(1,1-dimethylethyl)-3-oxo-, (5α,17β)-.
N-*tert*-Butyl-3-oxo-4-aza-5α-androst-1-ene-17β-carboxamide [98319-26-7].

» Finasteride contains not less than 98.5 percent and not more than 101.0 percent of $C_{23}H_{36}N_2O_2$, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight containers, and store at controlled room temperature.

USP Reference standards ⟨11⟩**—**
USP Finasteride RS

Identification—

A: *Infrared Absorption* ⟨197M⟩.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Specific rotation ⟨781S⟩: between −56.0° and −60.0°, determined at 405 nm.

Test solution: 10 mg per mL, in methanol.

Water Determination, *Method I* ⟨921⟩: not more than 0.3%.

Residue on ignition ⟨281⟩: not more than 0.1%.

Delete the following:

•**Heavy metals,** *Method II* ⟨231⟩: 0.001%.• (Official 1-Jan-2018)

Chromatographic purity—

Mobile phase—Prepare a filtered and degassed mixture of water, tetrahydrofuran, and acetonitrile (8:1:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Diluting solution—Prepare a solution of water and acetonitrile (1:1).

Standard solution—Dissolve an accurately weighed quantity of USP Finasteride RS in *Diluting solution*, and dilute quantitatively, and stepwise if necessary, with *Diluting solution* to obtain a solution having a known concentration of about 1.0 mg per mL.

Test solution—Transfer about 100 mg of Finasteride, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with *Diluting solution* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 210-nm detector and a 4.6-mm × 30-cm column that contains 4-µm packing L1. The flow rate is about 1.5 mL per minute. The column temperature is maintained at 60°. Chromatograph the *Standard solution*, and record the peak responses as directed for *Procedure:* the column efficiency is not less than 10,000 theoretical plates; and the tailing factor is not more than 1.3.

Procedure—Inject a volume (about 15 µL) of the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the percentage of each impurity in the portion of Finasteride taken by the formula:

$$100(r_i / r_s)$$

in which r_i is the peak response for each impurity, and r_s is the sum of the responses of all peaks: not more than 0.5% of any individual impurity is found; and not more than 1.0% of total impurities is found.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of water and tetrahydrofuran (4:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Diluting solution—Prepare a solution of water and acetonitrile (1:1).

Standard preparation—Dissolve an accurately weighed quantity of USP Finasteride RS in *Diluting solution*, and dilute quantitatively, and stepwise if necessary, with *Diluting solution* to obtain a solution having a known concentration of about 200 µg per mL.

Assay preparation—Transfer about 20 mg of Finasteride, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with *Diluting solution* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 215-nm detector and a 3.0-mm × 3.0-cm column that contains 3-µm packing L7. The flow rate is about 3 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the column efficiency is not less than 1800 theoretical plates; the tailing factor is not more than 1.3; and the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{23}H_{36}N_2O_2$ in the portion of Finasteride taken by the formula:

$$100C(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of USP Finasteride RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Finasteride Tablets

» Finasteride Tablets contain not less than 95.0 percent and not more than 105.0 percent of finasteride ($C_{23}H_{36}N_2O_2$).

Packaging and storage—Preserve in tight, light-resistant containers, and store at controlled room temperature.

USP Reference standards ⟨11⟩**—**
USP Finasteride RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.