Acceptance criteria

Individual impurities: See *Table 8*.

Total impurities: The combined total impurities from *Procedure 3* and *Procedure 4* is NMT 0.3%.

Table 8

Name	Relative Retention Time	Relative Response Factor[a]	Acceptance Criteria, NMT(%)
Benzaldehyde	0.43	0.40	0.1
Benzoic acid	0.55	1.0	0.1
Ephedrone[b]	0.97	—	—
Pseudoephedrine	1.0	0.52	—
Individual unspecified impurity	—	0.52[c]	0.1

[a] Response factors relative to benzoic acid.

[b] Ephedrone is not quantitated in this method. A separate method is used for the quantitation of this impurity.

[c] The response factor of pseudoephedrine relative to that of benzoic acid is used in the calculation of individual unspecified impurities.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, and store at controlled room temperature.
- **LABELING:** When more than one *Dissolution Test* is given, the labeling states the test used only if *Test 1* is not used. If a test for *Organic Impurities* other than *Procedure 1* is used, the labeling states with which *Procedures* the article complies.
- **USP REFERENCE STANDARDS** ⟨11⟩

USP Benzoic Acid RS

USP Fexofenadine Hydrochloride RS

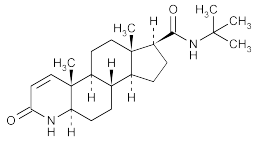
USP Fexofenadine Related Compound A RS

Benzeneacetic acid, 4-[1-oxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]butyl]-α,α-dimethyl.

$C_{32}H_{37}NO_4$ 499.65

USP Pseudoephedrine Hydrochloride RS

Finasteride



$C_{23}H_{36}N_2O_2$ 372.55

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 per cent and not more than 101.0 per cent 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, *Method I* ⟨921⟩: not more than 0.3%.

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

Heavy metals, *Method II* ⟨231⟩: 0.001%.

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 per cent 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*.

Dissolution ⟨711⟩**—**

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

FOR PRODUCTS LABELED AS 5-MG TABLETS—

Time: 45 minutes.

Determine the amount of $C_{23}H_{36}N_2O_2$ dissolved by employing the following method.

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile and water (29:21). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Diluting solution—Prepare a solution of acetonitrile and water (7:3).

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 approximately equivalent to the sample under test.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 220-nm detector and a 4.6-mm × 5-cm column that contains packing L1. The column temperature is maintained at 45 °. The flow rate is about 2 mL per minute. Chromatograph the *Standard solution,* and record the peak responses as directed for *Procedure:* the capacity factor, *k′*, is not less than 2.0; the column efficiency is greater than 1000 theoretical plates; the tailing factor is less than 2; and the relative standard deviation for replicate injections is less than 2.0%.

Procedure—Separately inject equal volumes (about 200 µL) of the solution under test and the *Standard solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity of $C_{23}H_{36}N_2O_2$ dissolved.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{23}H_{36}N_2O_2$ is dissolved in 45 minutes.

FOR PRODUCTS LABELED AS 1-MG TABLETS—

Time: 30 minutes.

Mobile phase—Prepare a degassed mixture of acetonitrile and water (11:9). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Diluting solution—Prepare a solution of water and acetonitrile (7:3).

Standard solution—Dissolve an accurately weighed quantity of USP Finasteride RS in *Diluting solution,* to obtain a solution having a known concentration of 0.1 mg per mL. Dilute this solution quantitatively, and stepwise if necessary, in 0.5% sodium lauryl sulfate to obtain a solution containing 0.001 mg of finasteride per mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 220-nm detector and a 4.6-mm × 15-cm column that contains 5- µm packing L11. The column temperature is maintained at 45 °. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard solution,* and record the peak responses as directed for *Procedure:* the column efficiency is not less than 5000 theoretical plates; the tailing factor is not more than 2; and the relative standard deviation for replicate injections is not more than 2%.

Procedure—Separately inject equal volumes (about 100 µL) of the solution under test and the *Standard solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity of finasteride ($C_{23}H_{36}N_2O_2$) dissolved.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{23}H_{36}N_2O_2$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩**:** meet the requirements.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of 2.5 mM phosphoric acid and acetonitrile (1:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Diluting solution—Prepare a solution of acetonitrile and water (7:3).

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 100 µg per mL.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an amount of powder equivalent to about 10 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 240-nm detector and a 4.6-mm × 10.0-cm column that contains packing L1. The column temperature is maintained at 45 °. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the capacity factor, *k′*, is not less than 2.0; the column efficiency is not less than 1000 theoretical plates; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 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 finasteride ($C_{23}H_{36}N_2O_2$) in the portion of Tablets 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.