

Table 4

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Dutasteride	1.0	—	—
Dihydrodutasteride <sup>a</sup>	1.19	1.0	0.15
Dutasteride α-dimer	3.7	3.7	0.3
Dutasteride β-dimer	3.7	3.7	0.3
Any other individual impurity	1.0	1.0	0.1
Total impurities <sup>b</sup>	—	—	—

<sup>a</sup> (5α,17β)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-azaandrostane-17-carboxamide.  
<sup>b</sup> Sum of impurities from Table 3 and Table 4.

SPECIFIC TESTS

- **WATER DETERMINATION** (921), Method I, Method Ic  
Sample: 100 mg  
Analysis: The Sample is heated in a tube at 180° for 4 min in a stream of dry inert gas.  
Acceptance criteria  
For the anhydrous form: NMT 0.50%  
For the hydrate form: NMT 1.5%
- **OPTICAL ROTATION** (781S), Procedures, Specific Rotation  
Sample solution: 10 mg/mL in chloroform and alcohol (98:2)  
Acceptance criteria: +15.0° to +25.0°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store below 30°.
- **LABELING:** Where it is the hydrate form, the label so indicates.
- **USP REFERENCE STANDARDS** (11)  
USP Dutasteride RS  
USP Dutasteride Resolution Mixture RS  
The mixture contains Dutasteride and the following impurities (other impurities may also be present):  
Dutasteride 17α-epimer: (5α,17α)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-azaandrost-1-ene-17-carboxamide.  
C<sub>27</sub>H<sub>30</sub>F<sub>6</sub>N<sub>2</sub>O<sub>2</sub> 528.53  
Dutasteride α-dimer: [(5α,17β)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-azaandrost-1-ene-17-carboxamide-]4-yl][(5α,17α)-3-oxo-4-azaandrost-1-ene]-17-yl)methanone.  
C<sub>46</sub>H<sub>55</sub>F<sub>6</sub>N<sub>3</sub>O<sub>4</sub> 827.94  
Dutasteride β-dimer: [(5α,17β)-N-[2,5-Bis(trifluoromethyl)phenyl]-3-oxo-4-azaandrost-1-ene-17-carboxamide-]4-yl][(5α,17β)-3-oxo-4-azaandrost-1-ene]-17-yl)methanone.  
C<sub>46</sub>H<sub>55</sub>F<sub>6</sub>N<sub>3</sub>O<sub>4</sub> 827.94

Absorbable Dusting Powder

» Absorbable Dusting Powder is an absorbable powder prepared by processing cornstarch and intended for use as a lubricant for surgical gloves. It contains not more than 2.0 percent of magnesium oxide.

**Packaging and storage**—Preserve in well-closed containers. It may be preserved in sealed paper packets.

**Identification**—A 1 in 10 suspension is colored purplish blue to deep blue by iodine TS.

**Stability to autoclaving**—Transfer about 2 g to a suitable paper packet, and seal or close the packet with a double fold. Wrap the paper packet in muslin, transfer to an autoclave, heat to 121° for 30 minutes, and cool: the powder is not caked, and any lumps are easily crushed between the fingers.

**Sedimentation**—Boil 100 mL of a 1 in 10 suspension in water for 20 minutes. Cool, transfer to a 100-mL graduated cylinder, dilute with water to volume, and allow to stand undisturbed for 24 hours: the volume occupied by the settled Powder is between 45 mL and 75 mL.

**pH** (791): between 10.0 and 10.8, in a 1 in 10 suspension.

**Loss on drying** (731)—Dry about 2 g, accurately weighed, at 105° to constant weight: it loses not more than 12% of its weight.

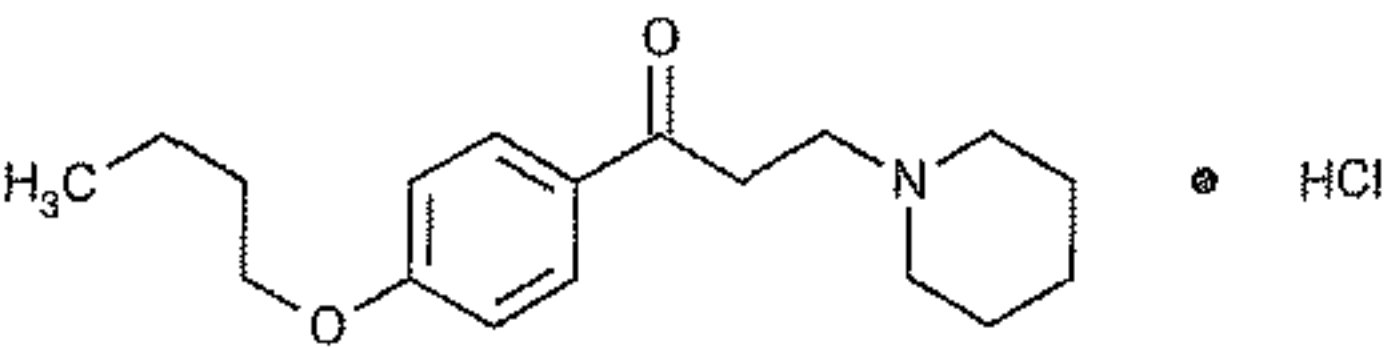
**Residue on ignition** (281)—Heat about 1 g, accurately weighed, in a covered platinum crucible until most of the carbon is burned away, but do not ignite the sample. Remove the cover, and ignite to constant weight: not more than 3.0% of residue remains.

Delete the following:

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

**Assay for magnesium oxide**—Weigh accurately about 2.5 g, and transfer to a beaker. Add 25 mL of water and 2 mL of 3 N hydrochloric acid, and stir the mixture for 5 minutes. Add 5 mL of hydroxylamine hydrochloride solution (1 in 10), 15 mL of ammonia-ammonium chloride TS, 5 mL of potassium cyanide solution (1 in 10), and 5 drops of eriochrome black TS, mix, and titrate with 0.05 M edetate disodium VS until the solution becomes distinctly blue in color. Each mL of 0.05 M edetate disodium is equivalent to 2.015 mg of MgO.

Dyclonine Hydrochloride



C<sub>18</sub>H<sub>27</sub>NO<sub>2</sub> · HCl 325.87  
1-Propanone, 1-(4-butoxyphenyl)-3-(1-piperidinyl)-hydrochloride.  
4'-Butoxy-3-piperidinopropiophenone hydrochloride [536-43-6].

» Dyclonine Hydrochloride contains not less than 98.0 percent and not more than 102.0 percent of C<sub>18</sub>H<sub>27</sub>NO<sub>2</sub> · HCl, calculated on the dried basis.

**Packaging and storage**—Preserve in tight, light-resistant containers.

**USP Reference standards** (11)—  
USP Dyclonine Hydrochloride 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.  
C: Add 2 mL of silver nitrate TS to 10 mL of Dyclonine Hydrochloride solution (1 in 100): a white precipitate is formed. Add 2 mL of nitric acid, centrifuge, and discard the supernatant. Wash the precipitate twice by adding 10 mL of 2 N nitric acid, centrifuging, and discarding the supernatant: