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Finasteride Tablets

General Notices

Action and use

5-Alpha reductase inhibitor; treatment of benign prostatic hyperplasia.

DEFINITION

Finasteride Tablets contain Finasteride. They are coated.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of finasteride, $C_{23}H_{36}N_2O_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. In the test for Dissolution, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to finasteride in the chromatogram obtained with solution (2).
B. In the test for Uniformity of content, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to finasteride in the chromatogram obtained with solution (2).

TESTS

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia in the *dissolution test for tablets and capsules*, Appendix XII B1.

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 50 revolutions per minute.
(b) Use 900 mL of *water*, at a temperature of 37°, as the medium.

PROCEDURE

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) After 45 minutes withdraw a 10 mL sample of the medium and filter. Use the filtered medium.
(2) A suitable solution of *finasteride BPCRS* in a mixture of 3 volumes of *water* and 7 volumes of *acetonitrile*.

CHROMATOGRAPHIC CONDITIONS

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(a) Use a stainless steel column (5 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (3 µm) (Hypersil ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use a column temperature of 45°.
(e) Use a detection wavelength of 220 nm.
(f) Inject 200 µL of each solution.

MOBILE PHASE

21 volumes of *water* and 29 volumes of *acetonitrile*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the *symmetry factor* of the peak corresponding to finasteride is less than 2.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{23}H_{36}N_2O_2$ in the medium from the chromatograms obtained using the declared content of $C_{23}H_{36}N_2O_2$ in *finasteride BPCRS*.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Add 30 mL of a mixture of equal volumes of *acetonitrile* and *water* to a quantity of powdered tablets containing 100 mg of Finasteride, dilute to 50 mL with the same mixture of solvents, centrifuge and filter the supernatant liquid (0.2%).
(2) Dilute 2 volumes of solution (1) to 100 volumes with a mixture of equal volumes of *acetonitrile* and *water*, dilute 1 volume of this solution to 10 volumes with a mixture of equal volumes of *acetonitrile* and *water*.
(3) 0.2% w/v of *finasteride for peak identification EPCRS* in a mixture of equal volumes of *acetonitrile* and *water*.
(4) Dilute 25 volumes of solution (2) to 100 volumes with equal volumes of *acetonitrile* and *water*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.0 mm) packed with *base-deactivated, end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil BDS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use a column temperature of 60°.
(e) Use a detection wavelength of 210 nm.
(f) Inject 50 µL of each solution.

When the chromatograms are recorded using the prescribed conditions the retention time of finasteride is about 28 minutes. The retention times relative to finasteride are: impurity A, about 0.9; impurity B, about 1.2; impurity C, about 1.4. For solution (1) allow the chromatography to run for twice the retention time of the finasteride peak.

MOBILE PHASE

10 volumes of *acetonitrile*, 10 volumes of *tetrahydrofuran* and 80 volumes of *water*.

SYSTEM SUITABILITY

The test is not valid, unless in the chromatogram obtained with solution (3), the *peak-to-valley ratio* between finasteride impurity A and finasteride is at least 2.5.

LIMITS

In the chromatogram obtained with solution (1):

identify any peak due to finasteride impurity A and multiply the peak area by a correction factor of 2.4;

any peak corresponding to finasteride impurity A is not greater than 1.5 times the area of the principal peak in solution (2) (0.3%);

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the area of any peak corresponding to finasteride impurity B is not greater than 1.5 times the area of the principal peak in solution (2) (0.3%);

the area of any peak corresponding to finasteride impurity C is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.3%);

the area of any other *secondary peak* is not greater than 0.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.1%);

the sum of the areas of any *secondary peaks* is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (0.6%).

Disregard any peak with an area less than 0.25 times the area of the peak due to finasteride in the chromatogram obtained with solution (2) (0.05%).

Uniformity of content

Tablets containing less than 2 mg and/or less than 2% w/w of Finasteride comply with the requirements stated under Tablets using the following method of analysis. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in a mixture of 3 volumes of *water* and 7 volumes of *acetonitrile* (solvent A).

(1) Add 2.5 mL of *water* to one tablet, shake with the aid of ultrasound until the tablet is completely dispersed. Add 35 mL of solvent A mix with the aid of ultrasound for a further 30 minutes. Cool to room temperature, dilute to 50 mL with solvent A, centrifuge and use the clear supernatant liquid.
(2) A suitable solution of *finasteride BPCRS* in solvent A.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (10 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use a column temperature of 45°.
(e) Use a detection wavelength of 240 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

Equal volumes of *acetonitrile* and 0.0025M of *orthophosphoric acid*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the *symmetry factor* of the peak due to finasteride is less than 2.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{23}H_{36}N_2O_2$ in each tablet using the declared content of $C_{23}H_{36}N_2O_2$ in *finasteride BPCRS*.

ASSAY

For tablets containing less than 2 mg and/or less than 2% w/w of Finasteride

Use the average of the individual results determined in the test for Uniformity of content.

For tablets containing 2 mg or more and 2% w/w or more of Finasteride

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in a mixture of 3 volumes of *water* and 7 volumes of *acetonitrile* (solvent A).

(1) Add 25 mL of *water* to a quantity of the powdered tablets containing 50 mg of Finasteride, add 350 mL of solvent A, mix with the aid of ultrasound for 30 minutes. Allow to attain room temperature and dilute to 500 mL with solvent A, centrifuge and use the clear supernatant liquid.

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(2) 0.010% w/v of *finasteride BPCRS* in solvent A.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Uniformity of content may be used.

SYSTEM SUITABILITY

The assay is not valid unless, in the chromatogram obtained with solution (2), the *symmetry factor* of the peak due to finasteride is less than 2.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{23}H_{36}N_2O_2$ in the tablets from the chromatograms obtained and using the declared content of $C_{23}H_{36}N_2O_2$ in *finasteride BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed in the monograph for Finasteride.

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