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Tamsulosin Prolonged-release Capsules

General Notices

Prolonged-release Tamsulosin Capsules

Tamsulosin Prolonged-release Capsules from different manufacturers, whilst complying with the requirements of the monograph, are not interchangeable unless otherwise justified and authorised.

Action and use

Alpha$_1$-adrenoceptor antagonist.

DEFINITION

Tamsulosin Prolonged-release Capsules contain Tamsulosin Hydrochloride. They are formulated so that the medicament is released over a period of several hours.

PRODUCTION

A suitable dissolution test is carried out to demonstrate the appropriate release of Tamsulosin Hydrochloride. The dissolution profile reflects the *in vivo* performance which in turn is compatible with the dosage schedule recommended by the manufacturer.

The capsules comply with the requirements stated under Capsules and with the following requirements.

Content of tamsulosin hydrochloride, $C_{20}H_{28}N_2O_5S,HCl$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. The *light absorption*, Appendix II B, in the range 210 to 400 nm of the solution prepared in the Assay exhibits a single maximum at 225 nm.
B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2).

TESTS

Related substances

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

(1) Mix for at least 15 minutes with the aid of ultrasound and with intermittent shaking a quantity of the capsules containing 0.8 mg of Tamsulosin Hydrochloride with 10 mL of 1M *methanolic hydrochloric acid* and filter through a 0.7-µm glass fibre filter. To 1 volume of the filtrate add 4 volumes of 1M *methanolic hydrochloric acid*.
(2) Dilute 1 volume of solution (1) to 500 volumes with mobile phase.
(3) 0.0032% w/v of *tamsulosin hydrochloride impurity standard BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Nucleosil C18 100Å 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 40°.
(e) Use a detection wavelength of 225 nm.
(f) Inject 20 µL of each solution.
(g) Allow the chromatography to proceed for 7 times the retention time of tamsulosin (retention time about 6 minutes).

MOBILE PHASE

300 volumes of *acetonitrile* and 700 volumes of *water* containing 0.44% v/v *perchloric acid* and 0.15% w/v *sodium hydroxide* previously adjusted to pH 2.0 with 1M *sodium hydroxide*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3) closely resembles the chromatogram supplied with *tamsulosin hydrochloride impurity standard BPCRS*.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurity H is not greater than 2.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.5%);

the area of any other *secondary peak* is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the sum of the areas of all the *secondary peaks* is not greater than 7.5 times the area of the principal peak in the chromatogram obtained with solution (2) (1.5%).

Disregard any peak with an area less than half the area of the principal peak in the chromatogram obtained with solution (2) (0.1%).

Uniformity of content

Capsules containing less than 2 mg and/or less than 2% w/w of Tamsulosin Hydrochloride comply with the requirements stated under Capsules using the following method of analysis.

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

(1) Mix the contents of 1 capsule with 10 mL of 1M *methanolic hydrochloric acid* for at least 15 minutes with the aid of ultrasound and with intermittent shaking, filter through a 0.7-µm glass fibre filter, dilute 1 volume of the filtrate to 10 volumes with 1M *methanolic hydrochloric acid* and filter through a 0.7-µm glass fibre filter.
(2) Prepare a 0.040% w/v solution of *tamsulosin hydrochloride BPCRS* in *methanol* with the aid of ultrasound, cool and dilute 1 volume to 100 volumes with 1M *methanolic hydrochloric acid*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{20}H_{28}N_2O_5S$,HCl in each capsule using the declared content of $C_{20}H_{28}N_2O_5S$,HCl in *tamsulosin hydrochloride BPCRS*.

ASSAY

For capsules containing less than 2 mg and/or less than 2% w/w of tamsulosin hydrochloride

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

For capsules containing 2 mg or more and 2% w/w or more of tamsulosin hydrochloride

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

(1) To a quantity of the powdered mixed contents of 20 capsules containing 1.6 mg of Tamsulosin Hydrochloride add 50 mL of 1M *methanolic hydrochloric acid*, mix for at least 15 minutes with the aid of ultrasound, cool and add sufficient 1M *methanolic hydrochloric acid* to produce 100 mL. Filter using a 0.7-µm glass fibre filter and dilute 1 volume of the filtrate to 4 volumes with 1M *methanolic hydrochloric acid*.
(2) Prepare a 0.040% w/v solution of *tamsulosin hydrochloride BPCRS* in *methanol* with the aid of ultrasound, cool and dilute 1 volume to 100 volumes with 1M *methanolic hydrochloric acid*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{20}H_{28}N_2O_5S,HCl$ in the capsules using the declared content of $C_{20}H_{28}N_2O_5S,HCl$ in *tamsulosin hydrochloride BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities B, E, F and H listed under Tamsulosin Hydrochloride.