Edition: BP 2025 (Ph. Eur. 11.6 update)

Tamsulosin Prolonged-release Tablets

General Notices

Prolonged-release Tamsulosin Tablets

Tamsulosin Prolonged-release Tablets 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 Tablets 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 tablets comply with the requirements stated under Tablets 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 a quantity of the powdered tablets containing 0.8 mg of Tamsulosin Hydrochloride for at least 15 minutes with the aid of ultrasound, and with intermittent shaking, 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 100 volumes with mobile phase. Dilute 1 volume to 5 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.

MOBILE PHASE

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

When the chromatograms are recorded under the prescribed conditions, the retention time of tamsulosin is about 6 minutes.

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

Identify any peak corresponding to impurity H in the chromatogram obtained with solution (1) using the chromatogram obtained with solution (3) and the chromatogram supplied with *tamsulosin hydrochloride impurity standard BPCRS*.

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 3.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.7%);

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

Tablets containing less than 2 mg and/or less than 2% w/w of Tamsulosin Hydrochloride 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.

(1) Intermittently shake 1 tablet with 10 mL of 1M *methanolic hydrochloric acid* for at least 15 minutes with the aid of ultrasound, 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 0.04% 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 tablet using the declared content of $C_{20}H_{28}N_2O_5S$,HCl in *tamsulosin hydrochloride BPCRS*.

ASSAY

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

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) To a quantity of the powdered tablets 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 tablets 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.