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

Alfuzosin Prolonged-release Tablets

General Notices

Prolonged-release Alfuzosin Tablets

Alfuzosin 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

Alfuzosin Prolonged-release Tablets contain Alfuzosin 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 alfuzosin 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 alfuzosin hydrochloride, $C_{19}H_{27}N_5O_4$,HCl

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing 30 mg of Alfuzosin Hydrochloride with 250 mL of *water* for 5 minutes and filter. Adjust the pH of the filtrate to pH 12.5 with 18M *ammonia*, extract with two 25-mL quantities of *dichloromethane*, wash the combined extracts with 10 mL of *water*, dry over *sodium sulfate* and evaporate to dryness. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of alfuzosin *(RS 446)*.

TESTS

Related substances

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

(1) Shake a quantity of powdered tablets containing 15 mg of Alfuzosin Hydrochloride in 70 mL of *methanol* for 30 minutes, add 10 mL of 0.01M *hydrochloric acid*, cool, dilute to 100 mL with *methanol* and filter. Dilute 1 volume of the solution to 5 volumes with the mobile phase.
(2) Dilute 1 volume of solution (1) to 200 volumes with the mobile phase.
(3) Dilute 2 volumes of solution (2) to 5 volumes with the mobile phase.

(4) Dilute 1 volume of solution (2) to 5 volumes with the mobile phase.
(5) 0.01% w/v of *alfuzosin impurity standard BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Inertsil ODS 2 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 an ambient column temperature.
(e) Use a detection wavelength of 254 nm.
(f) Inject 20 µL of each solution.
(g) For solution (1), allow the chromatography to proceed for twice the retention time of the principal peak.

MOBILE PHASE

1 volume of *tetrahydrofuran*, 20 volumes of *acetonitrile* and 80 volumes of *sodium perchlorate solution* prepared in the following manner. Add 5 mL of *perchloric acid* to 900 mL of *water*, adjust to pH 3.5 with 2M *sodium hydroxide* and add sufficient *water* to produce 1000 mL.

SYSTEM SUITABILITY

The test is not valid unless:

the chromatogram obtained with solution (5) closely resembles the reference chromatogram supplied with *alfuzosin impurity standard BPCRS*;

the *resolution* between the peaks due to impurity D and impurity E is at least 2.0;

the *resolution* between the peaks due to alfuzosin and impurity A is at least 2.0.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurity D (the first eluting peak in the chromatogram obtained with solution (5)) is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.5%);

the area of any peak corresponding to impurity E (the second eluting peak in the chromatogram obtained with solution (5)) is not greater than 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 (3) (0.2%);

the sum of the areas of any other *secondary peaks* is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (1.0%).

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.1%).

ASSAY

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

(1) Weigh and powder 20 tablets. Shake a quantity of powdered tablets containing 10 mg of Alfuzosin Hydrochloride in 70 mL of *methanol* for 30 minutes, add 10 mL of 0.01M *hydrochloric acid*, cool, dilute to 100 mL with *methanol* and filter. Dilute 1 volume of the resulting solution to 10 volumes with the mobile phase.
(2) 0.001% w/v of *alfuzosin hydrochloride BPCRS*.
(3) 0.01% w/v of *alfuzosin impurity standard BPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The Assay is not valid unless:

the chromatogram obtained with solution (3) closely resembles the reference chromatogram supplied with *alfuzosin impurity standard BPCRS*;

the *resolution* between the peaks due to impurity D and impurity E is at least 2.0;

the *resolution* between the peaks due to alfuzosin and impurity A is at least 2.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{19}H_{27}N_5O_4$,HCl in the tablets from the chromatograms obtained and using the declared content of $C_{19}H_{27}N_5O_4$,HCl in *alfuzosin hydrochloride BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Alfuzosin Hydrochloride.