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

Alfuzosin Tablets

General Notices

Action and use

Alpha$_1$-adrenoceptor antagonist.

DEFINITION

Alfuzosin Tablets contain Alfuzosin Hydrochloride.

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 50 mL of *water* for 5 minutes and filter. Adjust the pH of the filtrate to 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

Dissolution

Comply with 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 in the mobile phase.

(1) After 45 minutes withdraw a sample of the medium and filter. Use the filtered medium, diluted with mobile phase if necessary, to produce a solution expected to contain 0.0001% w/v of Alfuzosin Hydrochloride.
(2) 0.0001% 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. Inject 100 µL of each solution.

SYSTEM SUITABILITY

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

LIMITS

The amount of alfuzosin hydrochloride released is not less than 75% (Q) of the stated amount.

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 ODS2 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.

(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* in the mobile phase.
(3) 0.01% w/v of *alfuzosin impurity standard BPCRS* in the mobile phase.

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.