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Captopril Tablets

General Notices

Details for the public consultation of this monograph are as follows:

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Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. Definition amended Dissolution final stage limit updated to Q value Related substances TLC method replaced by LC test & limits revised Assay LC method harmonised with new related substances test and SST criterion introduced. Impurities section added

Action and use

Angiotensin converting enzyme inhibitor.

DEFINITION

Captopril Tablets contain [Captopril](#).

The tablets comply with the requirements stated under [Tablets](#) and with the following requirements.

Content of captopril, C₉H₁₅NO₃S

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Dissolve a quantity of the powdered tablets containing 0.1 g of Captopril in 25 mL of [methanol](#) with the aid of ultrasound and filter. Mix 1 mL of the filtrate with 0.5 g of [potassium bromide](#), dry at room temperature at 2 kPa, grind to a uniform mixture and prepare a disc. The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of captopril ([RS 038](#)).

TESTS

Dissolution

Comply with the [dissolution test for tablets and capsules](#), [Appendix XII B1](#).

TEST CONDITIONS

- (a) Use Apparatus 1, rotating the basket at 50 revolutions per minute.
- (b) Use 900 mL of 0.01M *hydrochloric acid*, at a temperature of 37°, as the medium.

PROCEDURE

- (1) After 20 minutes withdraw a sample of the medium and measure the [absorbance](#) of the filtered sample, suitably diluted with the dissolution medium, if necessary, to produce a solution expected to contain of 0.0014% w/v of Captopril at the maximum at 205 nm, [Appendix II B](#), using dissolution medium in the reference cell.
- (2) Measure the [absorbance](#) of a 0.0014% w/v solution of [captopril BPCRS](#) in the dissolution medium using dissolution medium in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of captopril, $C_9H_{15}NO_3S$, in the medium from the absorbances obtained and using the declared content of $C_9H_{15}NO_3S$ in [captopril BPCRS](#).

LIMITS

The amount of captopril released is not less than 80% (Q) of the stated amount.

Related substances

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions prepared in the [methanol](#).

- (1) Transfer a quantity of the powdered tablets containing 25 mg of Captopril to a centrifuge tube, add 50 mL of [methanol](#), centrifuge and use the supernatant liquid.
- (2) Dilute 1 volume of solution (1) to 50 volumes.
- (3) Dissolve 5 mg of [captopril BPCRS](#) in 1 mL [methanol](#) and add 230 µL of 0.05M [iodine](#). If the solution is not colourless, add 0.1M [sodium thiosulfate](#) dropwise until it becomes colourless, and dilute

to 50 mL with [methanol](#) (impurity A generation). Further dilute 3 volumes to 20 volumes with [methanol](#).

(4) Dilute 1 volume of solution (2) to 10 volumes.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (25 cm × 4.6 mm) packed with [end-capped octadecylsilyl silica gel](#) (5 µm) (Ace C18 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 220 nm.
- (f) Inject 20 µL of each solution.
- (g) Allow the chromatography to proceed for 2.5 times the retention time of captopril.

MOBILE PHASE

0.5 volume of [orthophosphoric acid](#), 450 volumes of [water](#) and 550 volumes of [methanol](#).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the peaks due to captopril and impurity A is at least 2.0.

CALCULATION OF IMPURITIES

For impurity A, use the concentration of captopril in solution (2).

For each unspecified impurity, use the concentration of captopril in solution (4).

For the reporting threshold, use the concentration of captopril in solution (4).

For peak identification, use solution (3).

Captopril retention time: about 4 minutes.

Relative retention: impurity A, about 1.5.

LIMITS

- impurity A: not more than 2.0%;
- unspecified impurities: for each impurity, not more than 0.2%;
- total unspecified impurities: not more than 1.0%;
- reporting threshold: 0.1%.

ASSAY

Weigh and powder 20 tablets. Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

- (1) Transfer a quantity of the powdered tablets containing 25 mg of Captopril to a centrifuge tube, add 25 mL of the mobile phase, mix with the aid of ultrasound and centrifuge. Dilute 1 volume of the supernatant liquid to 10 volumes with the mobile phase.
- (2) 0.01% w/v of [captopril BPCRS](#) in the mobile phase.
- (3) Dissolve 5 mg of [captopril BPCRS](#) in 1 mL [methanol](#) and add 230 µL of 0.05M [iodine](#). If the solution is not colourless, add 0.1M [sodium thiosulfate](#) dropwise until it becomes colourless, and dilute to 50 mL with [methanol](#) (impurity A generation). Further dilute 3 volumes to 20 volumes with [methanol](#).

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used, excluding (g).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the peaks due to captopril and impurity A is at least 2.0.

DETERMINATION OF CONTENT

Calculate the content of captopril, $C_9H_{15}NO_3S$ in the tablets from the chromatograms obtained and using the declared content of $C_9H_{15}NO_3S$ in [captopril BPCRS](#).

IMPURITIES

The impurities limited by the requirements of this monograph include impurity A listed under [Captopril](#).