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

Captopril Tablets

General Notices

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, $C_9H_{15}NO_3S$

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

Captopril disulfide

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 50 mL of *methanol*, centrifuge for 15 minutes and use the supernatant liquid.
(2) Dilute 1 volume of solution (1) to 100 volumes with *methanol*.
(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* (generation of captopril disulfide). Further dilute 3 volumes to 20 volumes with *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (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.

MOBILE PHASE

0.5 volume of *orthophosphoric acid*, 450 volumes of *water* and 550 volumes of *methanol*.

When the chromatograms are recorded under the prescribed conditions, the relative retention of captopril disulfide (impurity A) with reference to captopril (retention time about 4 minutes) is 1.5.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to captopril and captopril disulfide is at least 2.0.

LIMITS

In the chromatogram obtained with solution (1), the area of any peak corresponding to captopril disulfide is not greater than three times the area of the peak in the chromatogram obtained with solution (2) (3%).

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 for 15 minutes 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.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Captopril disulfide may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_9H_{15}NO_3S$ in the tablets using the declared content of $C_9H_{15}NO_3S$ in *captopril BPCRS*.