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

Carprofen Tablets

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Carprofen Tablets contain Carprofen.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of carprofen, $C_{15}H_{12}ClNO_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake a quantity of powdered tablets containing 0.1 g of Carprofen with 30 mL of *water* and 3 drops of *hydrochloric acid*. Add 30 mL of *dichloromethane* and shake. Allow the layers to separate and filter the lower layer through *anhydrous sodium sulfate*. Evaporate the filtrate to dryness and dry the residue at 60° for 30 minutes. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of carprofen *(RSV 54)*.

TESTS

Dissolution

Carry out the following procedure protected from light. Comply with the *dissolution test for tablets and capsules*, Appendix XII B1.

TEST CONDITIONS

(a) Use Apparatus 2, and rotate the paddle at 50 revolutions per minute.
(b) Use 900 mL of *0.05M phosphate buffer solution pH 7.5*, at a temperature of 37°, as the dissolution medium.

PROCEDURE

(1) After 45 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 containing 0.002% w/v of Carprofen, at the maximum at 300 nm, Appendix II B using the dissolution medium in the reference cell.
(2) Slowly add 10 mL of *methanol* to 20 mg of *carprofen BPCRS*, and dilute to 100 mL with the medium. Dilute 1 volume of the resulting solution to 10 volumes with the medium. Measure the absorbance of this solution, and use the medium in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of carprofen, $C_{15}H_{12}ClNO_2$, in the medium from the absorbances obtained and using the declared content of $C_{15}H_{12}ClNO_2$ in *carprofen BPCRS*.

LIMITS

The amount of carprofen 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 protected from light.

(1) Shake a quantity of powdered tablets containing 50 mg of Carprofen with 75 mL of the mobile phase and dilute to 100 mL with the same solvent.
(2) Dilute 1 volume of solution (1) to 100 volumes with the mobile phase.
(3) 0.025% w/v of *carprofen for system suitability EPCRS* in the mobile phase.
(4) Dilute 1 volume of solution (2) to 10 volumes with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped polar-embedded octadecylsilyl amorphous organosilica polymer* (5 µm) (Waters C18 XTerra RP is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.3 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 235 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

300 volumes of a 0.01M *potassium dihydrogen orthophosphate* adjusted to pH 3.0 with *orthophosphoric acid*, and 700 volumes of *methanol*.

When the chromatograms are recorded under the prescribed conditions, the retention time of carprofen is about 10 minutes and the relative retention of impurity C is about 0.8.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to impurity C and carprofen is at least 3.5.

LIMITS

In the chromatogram obtained with solution (1):

the area of any *secondary peak* is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (1%);

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

Disregard any peak with an area less than 3 times the area of the principal peak in the chromatogram obtained with solution (4) (0.3%).

ASSAY

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

(1) Shake a quantity of the powdered tablets containing 25 mg of Carprofen in 30 mL of the mobile phase and dilute to 50 mL with the same solvent. Filter (a GMF filter is suitable) and dilute 1 volume of the filtrate to 100 volumes with the mobile phase.
(2) 0.0005% w/v of *carprofen BPCRS* in the mobile phase.
(3) 0.025% w/v of *carprofen for system suitability EPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to impurity C and carprofen is at least 3.5.

DETERMINATION OF CONTENT

Calculate the content of $C_{15}H_{12}ClNO_2$ in the tablets using the declared content of $C_{15}H_{12}ClNO_2$ in *carprofen BPCRS*.

STORAGE

Carprofen Tablets should be stored protected from light.

IMPURITIES

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