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

Carprofen Injection

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Carprofen Injection is a sterile solution containing Carprofen. It is supplied as a ready-to-use solution.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

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

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) To a quantity of the injection containing 50 mg of Carprofen add 10 mL of a mixture of 1 volume of *methanol* and 9 volumes of *dichloromethane*, and shake. Centrifuge and separate the lower layer. Filter (a GF/C filter is suitable) and use the filtrate.
(2) 0.5% w/v of *carprofen BPCRS* in a mixture of 1 volume of *methanol* and 9 volumes of *dichloromethane*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel H*.
(b) Use the mobile phase described below.
(c) Apply 5 µL of each solution.
(d) Develop the plate to 10 cm.
(e) After removal of the plate, dry at 120° for 30 minutes, spray with a 1% w/v solution of *potassium permanganate*, heat at 105° for a further 20 minutes and examine under *ultraviolet light (365 nm)*.

MOBILE PHASE

1 volume of *glacial acetic acid*, 5 volumes of *ethyl acetate* and 15 volumes of *n-hexane*.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).
B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).

TESTS

Related substances

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

(1) Dilute a quantity of the injection, if necessary, with the mobile phase to produce a solution containing 0.05% w/v of Carprofen.
(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 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

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

(1) Dilute a weighed quantity of the injection containing 50 mg of Carprofen in 100 mL of the mobile phase. Dilute 1 volume of the resulting solution to 100 volumes with the mobile phase, and filter.
(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 carprofen impurity C and carprofen is at least 3.5.

DETERMINATION OF CONTENT

Determine the weight per mL of the injection, Appendix V G, and calculate the content of $C_{15}H_{12}ClNO_2$, weight in volume, in the injection using the declared content of $C_{15}H_{12}ClNO_2$ in *carprofen BPCRS*.

STORAGE

Carprofen Injection should be stored protected from light.

IMPURITIES

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