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Diclofenac Sodium Injection

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

EAG/Panel/Working Party	Medicinal Chemicals 2
Contact Details	helen.corns@mhra.gov.uk rachael.feltham@mhra.gov.uk sophie.cherrington@mhra.gov.uk bpcom@mhra.gov.uk
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Notes	New monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required.

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Diclofenac Sodium Injection is a sterile solution containing Diclofenac Sodium in a suitable vehicle.

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

Content of diclofenac sodium, $C_{14}H_{10}Cl_2NNaO_2$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. In the Assay, record the UV spectrum of the principal peak in the chromatograms obtained with solutions (1) and (2) with a diode array detector in the range of 190 to 400 nm.

The UV spectrum of the principal peak in the chromatogram obtained with solution (1) is concordant with that of the peak in the chromatogram obtained with solution (2);

the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2).

B. Yields the reactions characteristic of *sodium salts*, Appendix VI.

TESTS

Clarity and colour of solution

Dilute the injection, if necessary, to produce a solution containing 2.5% w/v of Diclofenac Sodium. The solution is *clear*, Appendix IV A, and not more intensely coloured than reference solution BY_4, Appendix IV B, Method I.

Related substances

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

(1) Dilute the injection to produce a solution containing 0.05% w/v of Diclofenac Sodium.
(2) Dilute 1 volume of solution (1) to 100 volumes.
(3) Dissolve the contents of a vial of *diclofenac for system suitability EPCRS* in 1 mL.
(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 for chromatography* (5 µm) (YMC Pack ODS-A is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.0 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) Allow the chromatography to proceed for 1.6 times the retention time of diclofenac.

MOBILE PHASE

34 volumes of a solution containing 0.05% w/v of *orthophosphoric acid* and 0.08% w/v of *sodium dihydrogen orthophosphate*, previously adjusted to pH 2.5 with *orthophosphoric acid*, and 66 volumes of *methanol*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks corresponding to impurity F and diclofenac is at least 4.0.

CALCULATION OF IMPURITIES

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

For other impurities, use the concentration of diclofenac sodium in solution (4).

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

For peak identification, use solution (3).

Diclofenac retention time: about 22 minutes.

Relative retention: impurity A, about 0.5; impurity F, about 0.8.

Correction factors: impurity A, multiply by 0.7; impurity F, multiply by 0.3.

LIMITS

— impurity A: not more than 1.5%;

— unspecified impurities: for each impurity, not more than 0.2%;

— total unspecified impurities: not more than 0.5%;

— reporting threshold: 0.1%.

ASSAY

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

(1) Dilute the injection to produce a solution containing 0.005% w/v of Diclofenac Sodium.
(2) 0.005% w/v of *diclofenac sodium BPCRS*.
(3) 0.0005% w/v each of *diclofenac sodium BPCRS* and *diclofenac impurity A BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped octylsilyl silica gel for chromatography* (5 µm) (Zorbax C8 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 254 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

20 volumes of a solution containing 0.05% w/v of *orthophosphoric acid* and 0.08% w/v of *sodium dihydrogen orthophosphate*, previously adjusted to pH 2.5 with *orthophosphoric acid*, and 80 volumes of *methanol*.

When the chromatograms are recorded under the prescribed conditions, the retention time of diclofenac is about 5 minutes.

SYSTEM SUITABILITY

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

DETERMINATION OF CONTENT

Calculate the content of diclofenac sodium, $C_{14}H_{10}Cl_2NNaO_2$, in the injection from the chromatograms obtained and using the declared content of $C_{14}H_{10}Cl_2NNaO_2$ in *diclofenac sodium BPCRS*.

Supporting information for Assay

Geometric scaling of column dimensions and chromatographic parameters to the validated Assay method conditions have been explored in order to reduce the solvent needed and the environmental impact. The "More resources" tab, available in the BP online monograph, provides additional information on the investigations carried out. Visit https://www.pharmacopoeia.com/guidance/environmentalhub for more information.

STORAGE

Diclofenac Sodium Injection should be protected from light.

IMPURITIES

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