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Diclofenac Prolonged-release Capsules

[General Notices](#)

Prolonged-release Diclofenac Capsules

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

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Target Publication Date (subject to change)	BP 2028
Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. Identification B new test added. Related substances test procedure revised, quantitative limits introduced & limits revised. Assay non-specific test replaced with LC method.

Diclofenac Prolonged-release Capsules from different manufacturers, whilst complying with the requirements of the monograph, are not interchangeable unless otherwise justified and authorised.

DEFINITION

Diclofenac Prolonged-release Capsules contain [Diclofenac Sodium](#). They are formulated so that the active substance is released over a period of several hours.

The capsules comply with the requirements stated under [Capsules](#) and with the following requirements.

PRODUCTION

A suitable dissolution test is carried out to demonstrate the appropriate release of Diclofenac Sodium. The dissolution profile reflects the *in vivo* performance which in turn is compatible with the dosage schedule recommended by the manufacturer.

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

95.0 to 105.0% of the stated amount.

IDENTIFICATION

- A. Add 0.5 mL of *glacial acetic acid* and 15 mL of *methanol* to a quantity of the powdered capsule contents containing 0.15 g of Diclofenac Sodium and mix with the aid of ultrasound for 40 minutes. Shake gently for 1 minute, filter and collect the filtrate in 15 mL of *water*. Filter the precipitate (Whatman GF/C is suitable) under reduced pressure, wash with four 5-mL quantities of *water* and dry at 105° for 2 to 3 hours. The *infrared absorption spectrum* of the dried precipitate, [Appendix II A](#), is concordant with the *reference spectrum* of diclofenac ([RS 096](#)).
- B. Yields the reactions characteristic of *sodium salts*, [Appendix VI](#).

TESTS**Related substances**

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

- (1) Shake a quantity of the capsule contents containing 50 mg of Diclofenac Sodium with 70 mL, add sufficient of the mobile phase to produce 100 mL, mix, centrifuge an aliquot and filter the supernatant liquid (a 0.45- μ m nylon filter is suitable).
- (2) Dilute 1 volume of solution (1) to 100 volumes and further dilute 1 volume of this solution to 5 volumes.
- (3) Dissolve the contents of a vial of *diclofenac for system suitability* [EPCRS](#) in 1 mL.

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (25 cm \times 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 μ m) (YMC Pack-pro C18 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 μ L 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 each impurity, use the concentration of diclofenac sodium in solution (2).

For the reporting threshold, use the concentration of diclofenac sodium in solution (2).

For peak identification, use solution (3).

Diclofenac retention time: about 25 minutes.

Relative retention: impurity A, about 0.4; impurity F, about 0.8.

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

LIMITS

- unspecified impurities: for each impurity, not more than 0.2%;
- total unspecified impurities: not more than 0.5%;
- reporting threshold: 0.1%.

ASSAY

Weigh the contents of 20 capsules. Mix and powder if necessary. Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions prepared in the mobile phase.

- (1) Shake a quantity of the capsule contents containing 50 mg of Diclofenac Sodium with 70 mL, add sufficient of the mobile phase to produce 100 mL and filter. Dilute 1 volume to 10 volumes.
- (2) 0.005% w/v of [diclofenac sodium 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.

DETERMINATION OF CONTENT

Calculate the content of diclofenac sodium, $C_{14}H_{10}Cl_2NNaO_2$, in the capsules 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 Prolonged-release Capsules should be protected from moisture.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed in the monograph for [Diclofenac Sodium](#).

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SUBJECT TO CHANGE