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

Tenoxicam Injection

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Tenoxicam Injection is a sterile solution of Tenoxicam in Water for Injections. It is prepared by dissolving Tenoxicam for Injection in the requisite amount of Water for Injections immediately before use.

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

STORAGE

Tenoxicam Injection should be used immediately after preparation.

TENOXICAM FOR INJECTION

DEFINITION

Tenoxicam for Injection is a sterile material consisting of Tenoxicam with or without excipients. It is supplied in a sealed container.

The contents of the sealed container comply with the requirements for Powders for Injections or Infusions stated under Parenteral Preparations and with the following requirements.

Content of tenoxicam, $C_{13}H_{11}N_3O_4S_2$

104.5 to 115.5% of the stated amount.

IDENTIFICATION

A. In the test for Related substances, the principal peak in the chromatogram obtained with solution (1) has the same retention time as the peak in the chromatogram obtained with solution (4).
B. The *light absorption*, Appendix II B, in the range 230 to 400 nm of the solution prepared in the Assay exhibits three maxima at 257 nm, 285 nm and 368 nm.
C. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Shake a quantity of the contents of the sealed container containing 20 mg of Tenoxicam with 10 mL of a mixture containing equal volumes of *dichloromethane* and *methanol* for 5 minutes, centrifuge and use the supernatant liquid.
(2) 0.2% w/v of *tenoxicam BPCRS* in a mixture of equal volumes of *dichloromethane* and *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel* F_{254} (Merck silica gel 60 F_{254} plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 10 µL of each solution.
(d) Develop the plate to 10 cm.
(e) After removal of the plate, dry in air and examine under *ultraviolet light (254 nm)*. Spray the plate with *acid potassium iodobismuthate solution* and examine again.

MOBILE PHASE

2 volumes of *glacial acetic acid*, 45 volumes of *acetone* and 55 volumes of *toluene*.

CONFIRMATION

Using each method of visualisation the principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).

TESTS

Alkalinity

pH of the injection when constituted in accordance with the manufacturer's instructions, 9.0 to 10.0, Appendix V L.

Clarity of solution

The injection, constituted in accordance with the manufacturer's instructions, is *clear*, Appendix IV A.

Related substances

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

(1) Dissolve a quantity of the contents of the sealed container containing 20 mg of Tenoxicam in 20 mL of *acetonitrile* (*50%*) and dilute 1 volume of the resulting solution to 4 volumes with the mobile phase.
(2) Dilute 1 volume of solution (1) to 200 volumes with the mobile phase.
(3) 0.0000625% w/v of *2-pyridylamine* (impurity A) in *acetonitrile* (*50%*).
(4) Dilute 5 mL of a 0.1% w/v solution of *tenoxicam BPCRS* to 20 mL with the mobile phase.
(5) Dilute 1 volume of a 0.1% w/v solution of *tenoxicam degradation impurity standard BPCRS* in *acetonitrile* (*50%*) to 4 volumes with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4 mm) packed with *octylsilyl silica gel for chromatography* (5 µm) (Nucleosil C8 is suitable) and a pre-column packed with *octylsilyl silica gel for chromatography* (10 µm) (Spheri-10 RP8, RP-GU pre-column is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 0.7 mL per minute.
(d) Use an ambient column temperature.
(e) Use detection wavelengths of 254 nm and 290 nm.
(f) Inject 20 µL of each solution.
(g) Condition the column with the mobile phase for 3 hours.

MOBILE PHASE

Dissolve 0.12 g of *sodium dodecyl sulfate* in 700 mL of *methanol*, mix with 1000 mL of 0.05M *potassium dihydrogen orthophosphate* and adjust the pH to 2.8 with *orthophosphoric acid*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (5) closely resembles the reference chromatogram provided with *tenoxicam degradation impurity standard BPCRS*.

LIMITS

At a detection wavelength of 290 nm In the chromatogram obtained with solution (1):

the area of any peak corresponding to 2-pyridylamine (impurity A) is not greater than the area of the peak in the chromatogram obtained with solution (3) (0.25%).

At a detection wavelength of 254 nm 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) (0.5%);

the sum of the areas of any such peaks is not greater than four times the area of the principal peak in the chromatogram obtained with solution (2) (2%).

Water

Not more than 4.0% w/w, Appendix IX C. Use 0.3 g.

ASSAY

Determine the weight of the contents of 10 containers as described in the test for *uniformity of weight*, Appendix XII C1, Powders for Parenteral Use.

Dissolve the contents of 10 containers in 0.1M *sodium hydroxide* and dilute to 1000 mL with 0.1M *sodium hydroxide*. Dilute the resulting solution with 0.1M *sodium hydroxide* to contain 0.0016% of Tenoxicam. Mix well, filter and measure the *absorbance* of the resulting solution at the maximum at 368 nm, Appendix II B.

Calculate the total content of $C_{13}H_{11}N_3O_4S_2$ in a container of average content weight in the injection from the *absorbance* of a 0.0016% w/v solution of *tenoxicam BPCRS* in 0.1M *sodium hydroxide* using the declared content of $C_{13}H_{11}N_3O_4S_2$ in *tenoxicam BPCRS*.

STORAGE

Where the sealed container is supplied with an ampoule of Water for Injections, this should not be allowed to freeze.

IMPURITIES

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