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

Meloxicam Injection

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Meloxicam Injection is a sterile solution of Meloxicam in Water for Injections.

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

Content of meloxicam, $C_{14}H_{13}N_3O_4S_2$

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) Dilute a volume of the injection containing 10 mg of Meloxicam to 20 mL with *acetone*, stir for 15 minutes, filter and use the filtrate.
(2) Dissolve 10 mg of *meloxicam BPCRS* in 10 mL of *acetone*, add 2 mL of *water* and dilute to 20 mL with *acetone*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a *silica gel F_{254} plate* (Merck HPTLC plates are suitable).
(b) Use the mobile phase described below.
(c) Apply 20 µL of each solution.
(d) Develop the plate to 8 cm.
(e) After removal of the plate, dry in air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

1 volume of 13.5M *ammonia*, 20 volumes of *methanol* and 80 volumes of *dichloromethane*.

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) corresponds to that of the principal peak in the chromatogram obtained with solution (2).

TESTS

Alkalinity

pH, 7.5 to 9.1, Appendix V L.

Related substances

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

(1) Add 0.3 mL of 0.4M *sodium hydroxide* to a volume of the injection containing 40 mg of Meloxicam and dilute with *methanol (40%)* to produce 10 mL.
(2) Dilute 1 mL of solution (1) to 100 mL with *methanol (40%)*.
(3) Add 0.3 mL of 0.4M *sodium hydroxide* to 40 mg of *meloxicam impurity standard BPCRS* and dilute with *methanol (40%)* to produce 10 mL.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (10 cm × 4.0 mm) packed with *octadecylsilyl silica gel for chromatography* (10 µm) (Kromasil 100 C18 is suitable).
(b) Use gradient 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 detection wavelengths of 260 nm and 350 nm.
(f) Inject 10 µL of each solution.

MOBILE PHASE

Mobile phase A 0.1% w/v solution of *potassium dihydrogen orthophosphate* adjusted to pH 6.0 with 2M *sodium hydroxide*.

Mobile phase B *methanol*.

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-2.5	60	40	isocratic
2.5-12	60→30	40→70	linear gradient
12-25	30	70	isocratic
25-26	30→60	70→40	linear gradient
26-30	60	40	re-equilibration

SYSTEM SUITABILITY

The chromatogram obtained with solution (3):

resembles that supplied with *meloxicam impurity standard BPCRS* at 260 nm and 350 nm and;

the *resolution* between the peaks due to meloxicam and impurity A at 350 nm is at least 3.0;

the *resolution* between the peaks due to impurity B and meloxicam at 260 nm is at least 3.0.

LIMITS

Identify any peaks in the chromatogram obtained with solution (1) corresponding to impurity A and impurity B using the chromatogram obtained with solution (3) and the chromatogram supplied with *meloxicam impurity standard BPCRS*.

In the chromatogram obtained with solution (1):

identify any peak corresponding to impurity A at 350 nm and multiply the area of this peak by a correction factor of 2.0;

the area of any peak corresponding to impurity B at 260 nm is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) at 350 nm (2.0%);

the area of any peak corresponding to impurity A at 350 nm is not greater than the area of the principal peak in the chromatogram obtained with solution (2) at 350 nm (1.0%).

the area of any other *secondary peak*, at the wavelength giving the higher value for the impurity, is not greater than the area of the peak in the chromatogram obtained with solution (2) at the same wavelength (1.0%).

The nominal total content of any such impurities is not greater than 3.5%.

Disregard any peak with an area less than 0.3 times the area of the principal peak in the chromatogram obtained with solution (2) at the same wavelength (0.3%).

ASSAY

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

(1) To a volume of the injection containing 40 mg of Meloxicam add 0.3 mL of 0.4M *sodium hydroxide* and add sufficient *methanol (40%)* to produce 10 mL. Dilute 1 mL of the resulting solution to 10 mL with *methanol (40%)*.
(2) 0.04% w/v of *meloxicam BPCRS* in *methanol (40%)*.
(3) Add 0.3 mL of 0.4M *sodium hydroxide* to 40 mg of *meloxicam impurity standard BPCRS* and dilute with *methanol (40%)* to produce 10 mL.

CHROMATOGRAPHIC CONDITIONS

The chromatographic procedure described under Related substances may be used but with a detection wavelength of 350 nm.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3):

closely resembles the chromatogram supplied with *meloxicam impurity standard BPCRS* at 350 nm;

the *resolution* between the peaks due to meloxicam and impurity A at 350 nm is at least 3.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{14}H_{13}N_3O_4S_2$ using the declared content of $C_{14}H_{13}N_3O_4S_2$ in *meloxicam BPCRS*.

IMPURITIES

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