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

Meloxicam Tablets

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Meloxicam Tablets contain Meloxicam.

The tablets comply with the requirements stated under Tablets 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) To a quantity of the powdered tablets containing 50 mg of Meloxicam, add 5 mL of 0.1M *methanolic sodium hydroxide* and 20 mL of *methanol*, stir for 15 minutes and filter.
(2) Dissolve 50 mg of *meloxicam BPCRS* in 5 mL of 0.1M *methanolic sodium hydroxide* and add sufficient *methanol* to produce 25 mL of solution.

CHROMATOGRAPHIC CONDITIONS

(a) Use a *silica gel F_{254} plate* (Merck HPTLC plates are suitable).
(b) Use the mobile phase described below.
(c) Apply 10 µL of each solution.
(d) Develop the plate to 15 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) is similar to that of the principal peak in the chromatogram obtained with solution (2).

TESTS

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia in the *dissolution test for tablets and capsules*, Appendix XII B1.

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 50 revolutions per minute.
(b) Use 900 mL of a buffer prepared by dissolving 13.61 g of *potassium dihydrogen orthophosphate* in 800 mL of *water*, adjusting the pH to 7.5 with 0.5M *sodium hydroxide*, adding sufficient *water* to produce 1000 mL, at a temperature of 37°, as the medium.

PROCEDURE

(1) After 45 minutes, withdraw a sample of the medium and filter. Measure the absorbance of the filtrate, Appendix II B, diluted with the dissolution medium if necessary, at 362 nm using dissolution medium in the reference cell.
(2) Measure the *absorbance* of a solution prepared by dissolving 30 mg of *meloxicam BPCRS* in 5 mL of *methanol*, adding 1 mL of 0.1M *sodium hydroxide* and adding sufficient dissolution medium to produce 100 mL. Dilute a volume of the resulting solution with sufficient dissolution medium to produce a solution containing 0.00075% w/v of Meloxicam.

DETERMINATION OF CONTENT

Calculate the total content of Meloxicam, $C_{14}H_{13}N_3O_4S_2$, in the medium from the absorbances obtained using the declared content of $C_{14}H_{13}N_3O_4S_2$ in *meloxicam BPCRS*.

Related substances

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

(1) Moisten a quantity of powdered tablets containing 30 mg of Meloxicam with 10 mL of 1M *sodium hydroxide*, add 40 mL of *methanol* and mix with the aid of ultrasound for 5 minutes. Add 40 mL of *methanol (40%)*, mix for 3 hours using a magnetic stirrer and then with the aid of ultrasound for 5 minutes. Cool, add sufficient *methanol (40%)* to produce 100 mL and filter.
(2) Dilute 1 volume of solution (1) to 100 volumes with *methanol (40%)*. Dilute 1 volume of the resulting solution to 10 volumes with *methanol (40%)*.
(3) Add 0.3 mL of 1M *sodium hydroxide* and 1 mL of *dimethylformamide* 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 (15 cm × 4.0 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Inertsil ODS 2 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 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 test is not valid unless, in the chromatogram obtained with solution (3):

the chromatogram closely resembles the chromatogram supplied with *meloxicam impurity standard BPCRS* at 260 nm and 350 nm;

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

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 A at 350 nm is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the area of any peak corresponding to impurity B at 260 nm is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.15%).

In both the chromatograms obtained with solution (1) at 350 nm and at 260 nm:

the area of any other *secondary peak* is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) at that wavelength (0.2%).

The nominal total content of all such impurities is not greater than 0.5%.

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (2) at the same wavelength (0.1%).

ASSAY

Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Moisten a quantity of the powdered tablets containing 30 mg of Meloxicam with 10 mL of 1M *sodium hydroxide*, add 40 mL of *methanol* and mix with the aid of ultrasound for 5 minutes. Add a further 40 mL of *methanol*, mix for 3 hours using a magnetic stirrer and then with the aid of ultrasound for 5 minutes. Cool, add sufficient *methanol* to produce 100 mL and filter.
(2) Dissolve 30 mg of *meloxicam BPCRS* in 10 mL of 1M *sodium hydroxide* and 40 mL of *methanol*, cool and add sufficient *methanol* to produce 100 mL.
(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 conditions described under Related substances may be used with a detection wavelength of 350 nm.

SYSTEM SUITABILITY

The Assay is not valid unless, in the chromatogram obtained with solution (3):

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

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

DETERMINATION OF CONTENT

Calculate the content of $C_{14}H_{13}N_3O_4S_2$ in the tablets 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.