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

Meloxicam Oral Suspension

General Notices

Action and use

Cyclo-oxygenase inhibitor; analgesic; anti-inflammatory.

DEFINITION

Meloxicam Oral Suspension is a suspension of Meloxicam in a suitable vehicle.

The oral suspension complies with the requirements stated under Oral Liquids 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 quantity of the oral suspension containing 3 mg of Meloxicam to 10 mL with *acetone*, stir for 10 minutes, filter and use the filtrate.
(2) Dissolve 3 mg of *meloxicam BPCRS* in about 5 mL of *acetone*, add 0.5 mL of *water* and dilute to 10 mL with *acetone*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating high-performance *silica gel* F_{254} (Merck silica gel 60 F_{254} HPTLC plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 5 µL of each solution.
(d) Develop the plate to 8 cm.
(e) After removal of the plate, allow it to dry in air and examine under *ultraviolet light (254* and *365 nm)*.

MOBILE PHASE

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

CONFIRMATION

By each method of visualisation the principal spot in the chromatogram obtained with solution (1) is similar in position, colour and size to that in the chromatogram obtained with solution (2).

B. Disperse a quantity of the oral suspension containing 1.5 mg of Meloxicam in 5 mL of 0.1M *sodium hydroxide*, dilute to 100 mL with *methanol* and filter. The *light absorption* of the filtrate, Appendix II B, in the range 340 to 450 nm exhibits a maximum at 362 nm.

ASSAY

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

(1) Mix a quantity of the oral suspension containing 15 mg of Meloxicam with sufficient of the mobile phase to produce 200 mL, mix with the aid of ultrasound for 30 minutes and filter.
(2) 0.0075% w/v of *meloxicam BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (10 cm × 4 mm) packed with *octadecylsilyl silica gel for chromatography* (10 µm) (Nucleosil C18 is suitable) and a pre-column 1-cm long packed with the same material.
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 0.8 mL per minute.
(d) Use a column temperature of 40°.
(e) Use a detection wavelength of 254 nm.
(f) Inject 20 µL of each solution and continue the chromatography for twice the retention time of the principal peak.

MOBILE PHASE

35 volumes of a mixture containing 10 parts of *propan-2-ol* and 65 parts of *methanol* and 65 volumes of a 0.2% w/v solution of *diammonium hydrogen orthophosphate* previously adjusted to pH 7.0 with *orthophosphoric acid*.

DETERMINATION OF CONTENT

Determine the *weight per mL* of the oral suspension, Appendix V G, and calculate the content of $C_{14}H_{13}N_3O_4S_2$, weight in volume, from the declared content of $C_{14}H_{13}N_3O_4S_2$ in *meloxicam BPCRS*.