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Meloxicam Oral Suspension

DEFINITION

Meloxicam Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of meloxicam ($C_{14}H_{13}N_3O_4S_2$).

IDENTIFICATION

• **A.** The UV absorption spectrum of the meloxicam peak of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the *Standard solution*, as obtained in the *Assay*.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: Dissolve 2 g of monohydrate citric acid and 2 g of boric acid in 1000 mL of water, and adjust with dihydrate trisodium citrate to a pH of 2.9.

Solution A: Acetonitrile, methanol, and *Buffer* (200:260:565)

Mobile phase: Dissolve 200 mg of sodium dodecyl sulfate in 1000 mL of *Solution A*.

Diluent: Dissolve 3 g of boric acid and 1.5 g of dihydrate trisodium citrate in 1000 mL of water, and adjust with 2 M sodium hydroxide to a pH of 8.3. Mix 420 mL of the resulting buffer with 420 mL of methanol and 160 mL of acetonitrile.

Related compound standard stock solution: 8.4 µg/mL of USP Meloxicam Related Compound B RS prepared as follows. Transfer 21 mg of USP Meloxicam Related Compound B RS into a 100-mL volumetric flask. Add 3.0 mL of dimethylformamide, 15 mL of methanol, and about 60 mL of *Diluent*. Sonicate, and mix until dissolved. Cool to room temperature. Dilute with *Diluent* to volume. Dilute further with *Diluent* to a concentration of 8.4 µg/mL.

System suitability solution: Transfer a volume of Oral Suspension, nominally equivalent to 15 mg of meloxicam, to a 50-mL volumetric flask. Add 3.0 mL of *Related compound standard stock solution*. Add 3.0 mL of dimethylformamide. Swirl the flask, and allow to stand for 5 min. Add 15 mL of methanol. Dilute with *Diluent* to just below volume. Sonicate for 30 min, mixing the flask vigorously about every 5 min. Cool to room temperature. Dilute with *Diluent* to volume. Mix, and allow particulates to settle. Pass through a 0.45-µm membrane filter with a fiberglass prefilter.

Standard stock solution: Transfer about 67 mg of USP Meloxicam RS into a 100-mL volumetric flask. Add 3.0 mL of dimethylformamide. Swirl the flask, and allow to stand for 5 min. Add 15 mL of methanol. Dilute with *Diluent* to just below volume. Sonicate for 30 min, and mix until dissolved. Cool to room temperature. Dilute with *Diluent* to volume.

Standard solution: 0.3 mg/mL of USP Meloxicam RS in *Diluent* from *Standard stock solution*

Sample solution: Nominally 0.3 mg/mL of meloxicam prepared as follows. Transfer a volume of Oral Suspension, nominally equivalent to 15 mg of meloxicam, to a 50-mL volumetric flask. Add 3.0 mL of dimethylformamide. Swirl the flask, and allow to stand for about 5 min. Add 15 mL of methanol. Dilute with *Diluent* to just below volume. Sonicate for 30 min, mixing the flask vigorously about every 5 min. Cool to room temperature. Dilute with *Diluent* to volume. Mix, and allow particulates to settle. Pass through a 0.45-µm membrane filter with a fiberglass prefilter.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 360 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4-mm × 12.5-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 1.0 mL/min

Run time: NLT 2 times the retention time of meloxicam

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between meloxicam and any other adjacent peak, *System suitability solution*

Tailing factor: NMT 2.0 for the meloxicam peak, *System suitability solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of meloxicam ($C_{14}H_{13}N_3O_4S_2$) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of meloxicam from the *Sample solution*

r_S = peak area of meloxicam from the *Standard solution*

C_S = concentration of USP Meloxicam RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of meloxicam in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

Medium: pH 7.5 phosphate buffer; 900 mL

Apparatus 2: 25 rpm

Time: 15 min

Standard solution: Transfer about 20.83 mg of USP Meloxicam RS into a 100-mL volumetric flask. Dissolve in 5 mL of methanol and 1 mL of 0.1 M sodium hydroxide, and dilute with *Medium* to volume. Dilute with *Medium* to a final concentration of 8.3 µg/mL of meloxicam.

Sample solution: Shake each sample for 15 min. Weigh six portions, equivalent to 7.5 mg of the Oral Suspension, into separate tared 10-mL beakers, and record each weight. Introduce each of the samples to the middle of the dissolution vessels, and rinse each beaker with 20 mL of the *Medium* withdrawn from the vessel. Carefully lower the paddle to the appropriate height and start the rotation. After completion of the dissolution, pass a 20-mL aliquot through a nylon filter having 0.45-µm porosity, discarding the first 3 mL of the filtrate.

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: At about 362 nm (wavelength of maximum absorbance)

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of meloxicam ($C_{14}H_{13}N_3O_4S_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times (1/W_U) \times (1/L) \times d \times V \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Meloxicam RS in the *Standard solution* (mg/mL)

W_U = weight of the Oral Suspension taken ▲(g)▲ (ERR 1-Aug-2022)

L = label claim (mg/mL)

d = density of the Oral Suspension (g/mL)

V = volume of *Medium*, 900 mL

Tolerances: NLT 75% (Q) of the labeled amount of meloxicam ($C_{14}H_{13}N_3O_4S_2$) is dissolved.

IMPURITIES

• **Organic Impurities**

Buffer, Solution A, Mobile phase, Diluent, Related compound standard stock solution, and **Sample solution:** Proceed as directed in the *Assay*.

Sensitivity solution: 0.08 µg/mL of USP Meloxicam Related Compound B RS in *Diluent* from *Related compound standard stock solution*

Standard solution: 0.5 µg/mL of USP Meloxicam Related Compound B RS in *Diluent* from *Related compound standard stock solution*

Chromatographic system: Proceed as directed in the *Assay*, except for the *Detector*.

Detector: UV 260 and 360 nm

System suitability

Samples: *Sensitivity solution* and *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0 for the meloxicam related compound B peak at 260 nm, *Standard solution*

Relative standard deviation: NMT 10% for meloxicam related compound B at 260 nm, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of meloxicam related compound B in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of meloxicam related compound B in the *Sample solution* at 260 nm

r_S = peak area of meloxicam related compound B in the *Standard solution* at 260 nm

C_S = concentration of USP Meloxicam Related Compound B RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of meloxicam in the *Sample solution* (mg/mL)

Calculate the percentage of each unknown degradation product in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area of any unknown degradation product in the *Sample solution* at 360 nm

r_T = sum of peak areas of meloxicam and all impurities in the *Sample solution* at 360 nm

Acceptance criteria

Meloxicam related compound B: NMT 0.15%

Any individual unknown degradation product: NMT 0.2%

Total degradation products: NMT 0.5%

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed 10^2 cfu/g or 10^2 cfu/mL. The total yeasts and molds count does not exceed 5×10^1 cfu/g or 5×10^1 cfu/mL. It meets the requirements of the test for the absence of *Escherichia coli*.

• **pH ⟨791⟩:** 3.5–4.5

• **Viscosity—Rotational Methods ⟨912⟩**

Analysis: Determine at 20° by using a shear rate programmable rotational viscometer.

Acceptance criteria: 40–100 centipoises

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.

• **USP Reference Standards ⟨11⟩**

USP Meloxicam RS

USP Meloxicam Related Compound B RS

5-Methylthiazol-2-amine.

$C_4H_6N_2S$ 114.175

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MELOXICAM ORAL SUSPENSION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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