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Meloxicam Tablets

DEFINITION

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

IDENTIFICATION

Change to read:

• **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*.▲2S *(USP41)*

• **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

Change to read:

• **Procedure**

Solution A: Dissolve 2.0 g of dibasic ammonium phosphate in 1 L of water. Adjust with phosphoric acid to a pH of 7.0 ± 0.1.

Solution B: Methanol and isopropyl alcohol (65:10)

Mobile phase: *Solution B* and *Solution A* (37:63)

▲**Standard stock solution 1**

For Tablets labeled to contain 7.5 mg/Tablet: 0.75 mg/mL of USP Meloxicam RS, prepared as follows. Transfer a quantity of USP Meloxicam RS to a suitable volumetric flask, dissolve with 2% of the final volume of 1 N sodium hydroxide and 60% of the final volume of methanol, and dilute with methanol to volume.

For Tablets labeled to contain 15 mg/Tablet: 1.5 mg/mL of USP Meloxicam RS, prepared as follows. Transfer a quantity of USP Meloxicam RS to a suitable volumetric flask, dissolve with 2% of the final volume of 1 N sodium hydroxide and 60% of the final volume of methanol, and dilute with methanol to volume.

Standard stock solution 2

For Tablets labeled to contain 7.5 mg/Tablet: 0.075 mg/mL of USP Meloxicam RS, prepared as follows. Transfer a suitable volume of *Standard stock solution 1* to an adequate volumetric flask, add 10% of the final volume of 1 N sodium hydroxide, and dilute with methanol to volume.

For Tablets labeled to contain 15 mg/Tablet: 0.15 mg/mL of USP Meloxicam RS, prepared as follows. Transfer a suitable volume of *Standard stock solution 1* to a suitable volumetric flask, add 10% of the final volume of 1 N sodium hydroxide, and dilute with methanol to volume.▲2S *(USP41)*

Standard solution

▲**For Tablets labeled to contain 7.5 mg/Tablet:** 0.045 mg/mL of USP Meloxicam RS in water from *Standard stock solution 2*

For Tablets labeled to contain 15 mg/Tablet: 0.09 mg/mL of USP Meloxicam RS in water from *Standard stock solution 2*▲2S *(USP41)*

Sample stock solution: Transfer 10 Tablets to a 1000-mL volumetric flask, add about 100 mL of 1 N sodium hydroxide, shake to disperse the Tablets, and add 800 mL of methanol. Sonicate the solution for 15 min, then stir for 30 min. Dilute with methanol to volume. Filter the resulting solution, and use the filtrate. ▲The nominal concentration of this solution is 0.075 mg/mL of meloxicam for Tablets labeled to contain 7.5 mg/Tablet and 0.15 mg/mL of meloxicam for Tablets labeled to contain 15 mg/Tablet.▲2S *(USP41)*

Sample solution

▲**For Tablets labeled to contain 7.5 mg/Tablet:** Nominally 0.045 mg/mL of meloxicam in water from the *Sample stock solution*

For Tablets labeled to contain 15 mg/Tablet: Nominally 0.09 mg/mL of meloxicam in water from the *Sample stock solution*▲2S *(USP41)*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. ▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲2S *(USP41)*

Columns

Guard: ▲4-mm × 1-cm; 10-µm▲2S *(USP41)* packing L1

Analytical: 4-mm × 10-cm; ▲10-µm▲2S *(USP41)* packing L1

Column temperature: 40°

Flow rate: 0.8 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

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 Tablets taken:

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

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

r_S = peak response 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 (dissolve 6.81 g of monobasic potassium phosphate in 800 mL of water, adjust with 0.5 N sodium hydroxide to a pH of 7.5, and dilute with water to 1 L); 900 mL

Time: 30 min

Apparatus 2: 75 rpm

▲**Standard stock solution:** 0.333 mg/mL of USP Meloxicam RS, prepared as follows. Transfer a quantity of USP Meloxicam RS to a suitable volumetric flask. Add 5% of the total volume of methanol, 1% of the total volume of 0.1 N sodium hydroxide, and dilute with *Medium* to volume.

Standard solution

For Tablets labeled to contain 7.5 mg/Tablet: 0.008325 mg/mL of USP Meloxicam RS in *Medium* from the *Standard stock solution*

For Tablets labeled to contain 15 mg/Tablet: 0.01665 mg/mL of USP Meloxicam RS in *Medium* from the *Standard stock solution* ▲2S *(USP41)*

Sample solution: Pass portions of the solution under test through a suitable filter of 10-µm pore size. Discard the first few milliliters.

Instrumental conditions

Mode: UV

Analytical wavelength: 362 nm (maximum absorbance)

Cell: 1 cm

Blank: *Medium*

Analysis

Samples: ▲*Standard solution* ▲2S *(USP41)* and *Sample solution*

Calculate the percentage of the labeled amount of meloxicam dissolved:

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

A_U = absorbance from the *Sample solution*

A_S = absorbance from the ▲*Standard solution* ▲2S *(USP41)*

C_S = concentration of USP Meloxicam RS in the ▲*Standard solution* ▲2S *(USP41)* (mg/mL)

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 70% (Q) of the labeled amount of meloxicam is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

IMPURITIES

Change to read:

• **Organic Impurities**

Solution A, Solution B, Mobile phase, ▲**Standard stock solution 1, Standard stock solution 2,**▲2S *(USP41)* **Standard solution,** ▲**Sample stock solution,**▲2S *(USP41)* **Sample solution,** and **Chromatographic system:** Proceed as directed in the *Assay*.

▲**Diluent:** Methanol, water, and 1 N sodium hydroxide (54:40:6)

Sensitivity solution: 0.000045 mg/mL of USP Meloxicam RS in *Diluent* from the *Standard solution*▲2S *(USP41)*

System suitability

Samples: *Standard solution* and ▲*Sensitivity solution*▲2S *(USP41)*

Suitability requirements

Tailing factor: NMT 2.0, ▲*Standard solution*▲2S *(USP41)*

Relative standard deviation: NMT 2.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, ▲*Sensitivity solution*▲2S *(USP41)*

Analysis

Samples: *Standard solution* and *Sample solution*

▲▲2S *(USP41)*

Calculate the percentage of each impurity in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response 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)

F = relative response factor ▲(see *Table 1*)▲2S *(USP41)*

Acceptance criteria: ▲See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
5-Methylthiazol-2-amine (meloxicam related compound B)	0.5	2.7	0.15
Meloxicam	1.0	—	—
Individual unknown impurity	—	1.0	0.2
Total impurities	—	—	0.5▲2S *(USP41)*

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in well-closed containers ▲in a dry place.▲2S *(USP41)* Store at ▲controlled room temperature.▲2S *(USP41)*

• **USP Reference standards** ⟨11⟩

USP Meloxicam RS

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

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

Chromatographic Database Information: Chromatographic Database

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