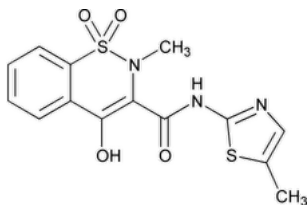


Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-1A58A07F-EF8F-48F7-A672-FCD33F0E4E27_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M48120_05_01
 DOI Ref: ekcmc

© 2025 USPC
 Do not distribute

Meloxicam



$C_{14}H_{13}N_3O_4S_2$ 351.40

4-Hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide 1,1-dioxide CAS RN®: 71125-38-7; UNII: VG2QF83CGL.

DEFINITION

Meloxicam contains NLT 98.0% and NMT 102.0% of meloxicam ($C_{14}H_{13}N_3O_4S_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)
- **B.** The retention time of the meloxicam peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Solution A: Mixture of a 0.1% (w/v) solution of ammonium acetate adjusted with 10% ammonia solution to a pH of 9.1

Mobile phase: Methanol and *Solution A* (21:29)

Diluent: Methanol and 1 N sodium hydroxide (250:1)

System suitability solution: 0.08 mg/mL each of [USP Meloxicam RS](#) and [USP Meloxicam Related Compound A RS](#) prepared as follows.

Dissolve [USP Meloxicam RS](#) and [USP Meloxicam Related Compound A RS](#) in 50% of the flask volume of *Diluent*, and dilute with water to volume.

Standard solution: 0.2 mg/mL of [USP Meloxicam RS](#) prepared as follows. Dissolve [USP Meloxicam RS](#) in 50% of the flask volume of *Diluent*, and dilute with water to volume.

Sample solution: 0.2 mg/mL of Meloxicam prepared as follows. Dissolve Meloxicam in 50% of the flask volume of *Diluent*, and dilute with water to volume.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 360 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

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

[NOTE—The relative retention times for meloxicam related compound A and meloxicam are 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between meloxicam related compound A and meloxicam, *System suitability solution*

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

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of meloxicam ($C_{14}H_{13}N_3O_4S_2$) in the portion of Meloxicam 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 = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES, PROCEDURE 1**

Perform either *Procedure 1* or *Procedure 2*, depending on the manufacturing process used.

Solution A: 0.1% (w/v) solution of monobasic potassium phosphate adjusted with 1 N sodium hydroxide to a pH of 6.0

Solution B: Methanol

Diluent: Methanol and 1 N sodium hydroxide (50:3)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	60	40
2	60	40
10	30	70
15	30	70
15.1	60	40
18	60	40

System suitability solution: 0.08 mg/mL each of [USP Meloxicam RS](#), [USP Meloxicam Related Compound A RS](#), and [USP Meloxicam Related Compound B RS](#) prepared as follows. Dissolve [USP Meloxicam RS](#), [USP Meloxicam Related Compound A RS](#), and [USP Meloxicam Related Compound B RS](#) in 10% of the flask volume of *Diluent*, and dilute with water to volume.

Standard stock solution: 0.6 mg/mL of [USP Meloxicam RS](#) prepared as follows. Dissolve [USP Meloxicam RS](#) in 25% of the flask volume of *Diluent*, and dilute with methanol to volume.

Standard solution: 0.012 mg/mL of [USP Meloxicam RS](#) in methanol from the *Standard stock solution*

Sample solution: 4 mg/mL of Meloxicam prepared as follows. Dissolve Meloxicam in 25% of the flask volume of *Diluent*, and dilute with methanol to volume.

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 260 and 350 nm (variable wavelength or multi-wavelength detector)

Column: 4.6-mm × 15-cm; 5-μm packing L1

Column temperature: 45°

Flow rate: 1 mL/min

Injection volume: 5 μL

System suitability

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

[NOTE—The relative retention times are listed in [Table 2](#).]

Suitability requirements

Resolution: NLT 3.0 between meloxicam related compound A and meloxicam at 350 nm; NLT 3.0 between meloxicam related compound B and meloxicam at 260 nm, *System suitability solution*

Relative standard deviation: NMT 10%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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