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Meclofenamate Sodium Capsules

DEFINITION

Meclofenamate Sodium Capsules contain an amount of meclofenamate sodium ($C_{14}H_{10}Cl_2NNaO_2$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of meclofenamic acid ($C_{14}H_{11}Cl_2NO_2$).

IDENTIFICATION

Delete the following:

▲• **Thin-Layer Chromatographic Identification Test ⟨201⟩**

Sample solution: 20 mg/mL of meclofenamate sodium, from Capsule contents in methanol; filter

Developing solvent system: Methylene chloride, methyl ethyl ketone, and glacial acetic acid (50:48:2)

Acceptance criteria: The filtrate meets the requirements.▲ (USP 1-May-2022)

Add the following:

▲• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2022)

Add the following:

▲• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2022)

ASSAY

Change to read:

• **Procedure**

▲**Solution A:** 0.63 g/L of ammonium formate in water. Adjust with formic acid to a pH of 3.0.

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	30	70
1	30	70
12	5	95
13	5	95
14	30	70
18	30	70

Diluent: Methanol and water (50:50)

Standard solution: 0.3 mg/mL of USP Meclofenamate Sodium RS in *Diluent*

Sample solution: Nominally 0.28 mg/mL of meclofenamic acid, equivalent to 0.3 mg/mL of meclofenamate sodium (anhydrous) in *Diluent*, prepared as follows. Mix the contents of Capsules (NLT 10) and transfer a suitable portion to a suitable volumetric flask. Add *Diluent* to about 80% of the volume, vortex, and sonicate for NLT 5 min. Dilute with *Diluent* to volume. Pass through a suitable filter of 0.45-µm pore size and use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 270 nm. For *Identification B*, use a diode array detector in the range of 190–400 nm.

Column: 4.6-mm × 15-cm; 3.5-µm packing L1

Column temperature: 35°

Flow rate: 0.8 mL/min

Injection volume: 10 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 meclofenamic acid ($C_{14}H_{11}Cl_2NO_2$) in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

r_S = peak response of meclofenamate from the *Standard solution*

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

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

M_{r1} = molecular weight of meclofenamic acid, 296.15

M_{r2} = molecular weight of meclofenamate sodium (anhydrous), 318.13▲ (USP 1-May-2022)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

Medium: 0.05 M pH 7.5 phosphate buffer (See *Reagents, Indicators, and Solutions, Solutions, Buffer Solutions*); 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: A known concentration of USP Meclofenamate Sodium RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary.

Instrumental conditions

Analytical wavelength: 279 nm (maximum absorbance)

Mode: UV

▲**Analysis**

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of meclofenamic acid ($C_{14}H_{11}Cl_2NO_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

D = dilution factor of the *Sample solution* if needed

L = label claim (mg/Capsule)

M_{r1} = molecular weight of meclofenamic acid, 296.15

M_{r2} = molecular weight of meclofenamate sodium (anhydrous), 318.13▲ (USP 1-May-2022)

Tolerances: NLT 75% (*Q*) of the labeled amount of meclofenamic acid ($C_{14}H_{11}Cl_2NO_2$) is dissolved.

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

IMPURITIES

Add the following:

▲• **Organic Impurities**

Solution A, Mobile phase, Diluent, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.6 µg/mL of USP Meclofenamate Sodium RS in *Diluent*

Sensitivity solution: 0.3 µg/mL of USP Meclofenamate Sodium RS in *Diluent* from *Standard solution*

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of any degradation product in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of any degradation product from the *Sample solution*

r_S = peak response of meclofenamate from the *Standard solution*

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

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

M_{r1} = molecular weight of meclofenamic acid, 296.15

M_{r2} = molecular weight of meclofenamate sodium (anhydrous), 318.13

Acceptance criteria: See *Table 2*. The reporting threshold is 0.1%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Meclofenamate	1.0	—
Any degradation product	—	0.2
Total degradation products	—	1.0

▲ (USP 1-May-2022)

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight, light-resistant containers ▲at controlled room temperature.▲ (USP 1-May-2022)

• **USP Reference Standards** ⟨11⟩

USP Meclofenamate Sodium RS

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

Topic/Question	Contact	Expert Committee
MECLOFENAMATE SODIUM CAPSULES	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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