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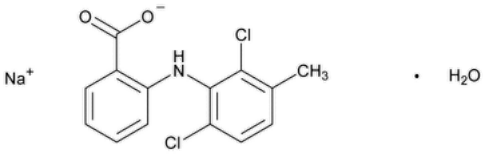
Meclofenamate Sodium

Change to read:



$C_{14}H_{10}Cl_2NNaO_2 \cdot H_2O$ 336.14

Benzoic acid, 2-[(2,6-dichloro-3-methylphenyl)amino]-, monosodium salt, monohydrate;

Monosodium *N*-(2,6-dichloro-*m*-tolyl)anthranilate monohydrate;

▲Sodium 2-[(2,6-dichloro-3-methylphenyl)amino]benzoate monohydrate▲ (USP 1-May-2023) CAS RN®: 67254-91-5; UNII: 94NJ818U2W.

Anhydrous CAS RN®: ▲6385-02-0.▲ (USP 1-May-2023) 318.13

DEFINITION

Meclofenamate Sodium contains NLT 97.0% and NMT 103.0% of meclofenamate sodium ($C_{14}H_{10}Cl_2NNaO_2$), calculated on the anhydrous basis.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K

Delete the following:

▲• **B. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*▲** (USP 1-May-2023)

Delete the following:

▲• **C. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*▲** (USP 1-May-2023)

Add the following:

▲• **B.** 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-2023)

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: 0.3 mg/mL of Meclofenamate Sodium in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 270 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 1.10%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of meclofenamate sodium, anhydrous ($C_{14}H_{10}Cl_2NNaO_2$) in the portion of Meclofenamate Sodium taken:

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

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 = concentration of Meclofenamate Sodium in the *Sample solution* (mg/mL)▲ (USP 1-May-2023)

Acceptance criteria: 97.0%–103.0% on the anhydrous basis

IMPURITIES

Delete the following:

▲• **Limit of Copper**▲ (USP 1-May-2023)

Change to read:

• **Organic Impurities**

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

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

Sensitivity solution: 0.15 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 impurity in the portion of Meclofenamate Sodium taken:

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

r_U = peak response of any impurity 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 = concentration of Meclofenamate Sodium in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 2*. The reporting threshold is 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Meclofenamate	1.0	—
Any impurity	—	0.10
Total impurities	—	1.0▲ (USP 1-May-2023)

SPECIFIC TESTS

• **Water Determination** ⟨921⟩, *Method I*: 4.8%–5.8%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **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	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(4)

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