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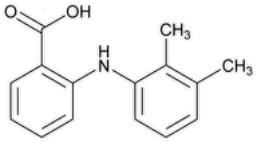
# Mefenamic Acid



$C_{15}H_{15}NO_2$ 241.29

Benzoic acid, 2-(2,3-dimethylphenyl)amino-;

*N*-2,3-Xylylanthranilic acid CAS RN®: 61-68-7; UNII: 367589PJ2C.

## DEFINITION

Mefenamic Acid contains NLT 98.0% and NMT 102.0% of mefenamic acid ($C_{15}H_{15}NO_2$), calculated on the dried basis.

## IDENTIFICATION

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K or 197A▲ (CN 1-May-2020)

• **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:** 50 mM monobasic ammonium phosphate. Adjust with 3 M ammonium hydroxide to a pH of 5.0.

**Mobile phase:** Acetonitrile, tetrahydrofuran, and *Buffer* (23:7:20)

**Standard solution:** 0.2 mg/mL of USP Mefenamic Acid RS in *Mobile phase*

**Sample solution:** 0.2 mg/mL of Mefenamic Acid in *Mobile phase*

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm × 25-cm; 5-µm packing L1

**Flow rate:** 1 mL/min

**Injection volume:** 10 µL

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Column efficiency:** NLT 8200 theoretical plates

**Tailing factor:** NMT 1.6

**Relative standard deviation:** NMT 0.73%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of mefenamic acid ($C_{15}H_{15}NO_2$) in the portion of Mefenamic Acid taken:

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

$r_U$ = peak response of mefenamic acid from the *Sample solution*

$r_S$ = peak response of mefenamic acid from the *Standard solution*

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

$C_U$ = concentration of Mefenamic Acid in 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**

**Buffer, Mobile phase,** and **Chromatographic system:** Proceed as directed in the *Assay*.

**Standard solution:** 0.01 mg/mL of USP Mefenamic Acid RS in *Mobile phase*

**Sensitivity solution:** 0.3 µg/mL of USP Mefenamic Acid RS in *Mobile phase* from the *Standard solution*

**Sample solution:** 1 mg/mL of Mefenamic Acid in *Mobile phase*

**System suitability**

**Samples:** *Standard solution* and *Sensitivity solution*

**Suitability requirements**

**Tailing factor:** NMT 1.6, *Standard solution*

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

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

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Mefenamic Acid taken:

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

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

$r_S$ = peak response of mefenamic acid from the *Standard solution*

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

$C_U$ = concentration of Mefenamic Acid in the *Sample solution* (mg/mL)

**Acceptance criteria:** The reporting threshold is 0.03%.

**Any impurity:** NMT 0.07%

**Total impurities:** NMT 0.5%

## SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

**Analysis:** Dry at 105° for 4 h.

**Acceptance criteria:** NMT 1.0%

## ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Mefenamic Acid RS

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| MEFENAMIC ACID | Documentary Standards Support | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
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