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Mefenamic Acid Capsules

DEFINITION

Mefenamic Acid Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of mefenamic acid ($C_{15}H_{15}NO_2$).

IDENTIFICATION

• **A.** The UV spectrum of the mefenamic acid peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

• **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**

Solution A: 50 mM solution of monobasic ammonium phosphate in water. Adjust with 3 M ammonium hydroxide to a pH of 5.0.

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

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

Sample solution: Nominally 0.2 mg/mL of mefenamic acid in *Mobile phase* prepared as follows. Transfer a suitable amount of mefenamic acid from the contents of NLT 20 Capsules to an adequate volumetric flask. Add 2% of final volume of tetrahydrofuran, and sonicate for about 5 min with occasional mixing. Dilute with *Mobile phase* to the final volume.

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.

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 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of mefenamic acid ($C_{15}H_{15}NO_2$) in the portion of Capsules 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 = nominal concentration of mefenamic acid in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution ⟨711⟩**

0.05 M tris buffer: Dissolve 60.5 g of tris(hydroxymethyl)aminomethane in 6 L of water, and dilute with water to 10 L. Adjust with phosphoric acid to a pH of 9.0 ± 0.05. To a second container, transfer about 6 L of this solution, add 100 g of sodium lauryl sulfate, and mix to dissolve the solid material. Transfer this solution back into the first container, and mix.

Medium: *0.05 M tris buffer*; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Solution A, Mobile phase, Standard solution, ▲▲ (ERR 1-Dec-2019) Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*, making any necessary volumetric adjustments.

▲Sample solution: Take a portion of the solution under test, and dilute if necessary.▲ (ERR 1-Dec-2019)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of mefenamic acid ($C_{15}H_{15}NO$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times D \times (1/L) \times 100$$

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)

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution*

L = label claim (mg/Capsule)

Tolerances: NLT 75% (Q) of the labeled amount of mefenamic acid ($C_{15}H_{15}NO$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

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

System suitability solution: 0.01 mg/mL of USP 2,3-Dimethylaniline RS and 1 mg/mL of USP Mefenamic Acid RS in *Mobile phase*

Sensitivity solution: 0.5 µg/mL of USP Mefenamic Acid RS in *Mobile phase*

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

Sample solution: Nominally 1 mg/mL of mefenamic acid in *Mobile phase* from the contents of NLT 20 Capsules. Sonicate to dissolve if necessary.

System suitability

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

Suitability requirements

Resolution: NLT 2 between 2,3-dimethylaniline and mefenamic acid, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak response of any individual degradation product 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 = nominal concentration of mefenamic acid in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*. The reporting threshold is 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
2,3-Dimethylaniline[a]	0.6	—
Mefenamic acid	1.0	—

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Any individual degradation product	—	0.16
Total degradation products	—	1.0

[a] This is a process impurity and is not included in the total degradation products.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store at 20°–25°, excursions permitted between 15° and 30°.
- **USP Reference Standards** ⟨11⟩

USP 2,3-Dimethylaniline RS

2,3-Dimethylaniline.

$C_{18}H_{11}N$ 121.18

USP Mefenamic Acid RS

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

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

Chromatographic Database Information: Chromatographic Database

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