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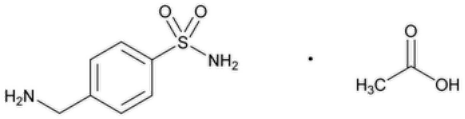
Mafenide Acetate



$C_7H_{10}N_2O_2S \cdot C_2H_4O_2$ 246.28

Benzenesulfonamide, 4-(aminomethyl)-, monoacetate;

α-Amino-*p*-toluenesulfonamide monoacetate CAS RN®: 13009-99-9; UNII: RQ6LP6Z0WY.

DEFINITION

Mafenide Acetate contains NLT 98.0% and NMT 102.0% of mafenide acetate ($C_7H_{10}N_2O_2S \cdot C_2H_4O_2$), calculated on the anhydrous basis.

IDENTIFICATION

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

• **B.** The R_F value of the principal spot of the *Identification solution* corresponds to that of *Standard solution A*, as obtained in the test for *Organic Impurities*.

ASSAY

Change to read:

• **Procedure**

Standard solution: 200 µg/mL of USP Mafenide Acetate RS in 0.01 N hydrochloric acid

Sample stock solution: 2 mg/mL of Mafenide Acetate

Sample solution: 200 µg/mL of Mafenide Acetate prepared as follows. Pipet 10 mL of the *Sample stock solution* into a 100-mL volumetric flask containing 1 mL of 1 N hydrochloric acid, and dilute with water to volume.

Instrumental conditions

▲(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)▲ (USP 1-Dec-2021)

Mode: UV

Analytical wavelength: 267 nm

Cell: 1 cm

Blank: 0.01 N hydrochloric acid

Analysis

Samples: *Standard solution* and *Sample solution*▲▲ (USP 1-Dec-2021)

Calculate the percentage of mafenide acetate ($C_7H_{10}N_2O_2S \cdot C_2H_4O_2$) in the portion of Mafenide Acetate taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Mafenide Acetate RS in the *Standard solution* (µg/mL)

C_U = concentration of Mafenide Acetate in the *Sample solution* (µg/mL)

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

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.2%

Delete the following:

▲• **Selenium ⟨291⟩**

Sample: 200 mg

Acceptance criteria: NMT 30 ppm▲ (USP 1-Dec-2021)

Change to read:

• **Organic Impurities**

Standard solution A: 500 µg/mL of USP Mafenide Acetate RS in methanol

Standard solution D: 500 µg/mL of USP Mafenide Related Compound A RS in methanol

▲▲ (USP 1-Dec-2021)

Standard solutions: Quantitatively dilute portions of *Standard solution A* with methanol to obtain *Standard solution B* and *Standard solution C*. Similarly, quantitatively dilute portions of *Standard solution D* with methanol to obtain *Standard solution E* and *Standard solution F*. The compositions are shown in *Table 1*.

Table 1

Standard Solution	Dilution	Concentration (µg/mL)	Percentage (%, for comparison with test specimen)
A	(undiluted)	500	1.0
B	5 in 10	250	0.5
C	1 in 5	100	0.2
D	(undiluted)	500	1.0
E	5 in 10	250	0.5
F	1 in 5	100	0.2

Sample solution: 50 mg/mL of Mafenide Acetate in methanol

Identification solution: 500 µg/mL from the *Sample solution* in methanol

Ninhydrin solution: 300 mg of ninhydrin in 100 mL of butyl alcohol. Add 3 mL of glacial acetic acid.

Chromatographic system

(See *Chromatography ⟨621⟩, General Procedures, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Ethyl acetate, methanol, and isopropylamine (77:20:3)

Spray reagent: *Ninhydrin solution*

Analysis

Samples: *Standard solutions*, *Sample solution*, and *Identification solution*

Apply the *Samples* separately to the chromatographic plate. Position the plate in a chromatographic chamber, and develop the chromatograms in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate in warm, circulating air. Examine the plate under short-wavelength UV light, and compare the intensities of any secondary spots observed in the chromatogram of the *Sample solution* at the R_F value corresponding to those of the principal spots in the chromatograms of *Standard solutions D*, *E*, and *F*. Spray the plate with *Spray reagent*, heat the plate at 105° for 5 min, and examine the plate. Compare the intensities of any secondary spots observed in the chromatogram of the *Sample solution* to those of the principal spots in the chromatograms of *Standard solutions A*, *B*, and *C*.

Acceptance criteria: No secondary spot, observed by both visualizations, from the chromatogram of the *Sample solution* is larger or more intense than the principal spots obtained from *Standard solution B* (0.5%) and *Standard solution E* (0.5%). The sum of the intensities of all secondary spots obtained from the *Sample solution* corresponds to NMT 1.0%.

SPECIFIC TESTS

• **Melting Range or Temperature ⟨741⟩:** Between 162° and 171°, but the range between the beginning and end of melting does not exceed 4°.

• **pH ⟨791⟩**

Sample solution: 100 mg/mL

Acceptance criteria: 6.4–6.8

• **Water Determination ⟨921⟩, *Method I*:** NMT 1.0%

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Mafenide Acetate RS

USP Mafenide Related Compound A RS

4-Formylbenzenesulfonamide.

$C_7H_7NO_3S$ 185.20

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

Topic/Question	Contact	Expert Committee
MAFENIDE ACETATE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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