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Mafenide Acetate for Topical Solution

DEFINITION

Mafenide Acetate for Topical Solution 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 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: Dissolve 6.8 g of monobasic potassium phosphate and 1.0 g of sodium 1-hexanesulfonate in 800 mL of water. Adjust with phosphoric acid to a pH of 2.5, and dilute to 1000 mL.

Mobile phase: Acetonitrile and *Solution A* (1:9)

Standard solution: 1 mg/mL of USP Mafenide Acetate RS in *Mobile phase*. Sonicate to dissolve if necessary.

Sample solution: Nominally 1 mg/mL of mafenide acetate prepared as follows. Constitute the Topical Solution as directed in the labeling. Transfer a volume of the constituted Topical Solution, equivalent to 25 mg of mafenide acetate, to a 25-mL volumetric flask. Using sonication, dissolve in 12 mL of *Mobile phase*. Dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 267 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of mafenide acetate ($C_7H_{10}N_2O_2S \cdot C_2H_4O_2$) in the portion of the constituted Topical Solution taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = nominal concentration of mafenide acetate in the *Sample solution* (mg/mL)

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

OTHER COMPONENTS

- **Content of Acetic Acid**

Internal standard solution: 0.5% (v/v) of propionic acid in water

Standard stock solution: Transfer 50 mL of water to a 100-mL volumetric flask, insert a stopper, and weigh. Add 0.5 mL of glacial acetic acid to the flask, insert the stopper, weigh, and calculate, by difference, the amount of acetic acid added. Dilute with water to volume.

Standard solution: 530 µg/mL of acetic acid prepared as follows. Add 10.0 mL of *Standard stock solution* and 10.0 mL of *Internal standard solution* to a 100-mL volumetric flask containing 200 mg of oxalic acid. Dilute with water to volume.

Sample solution: Nominally 2 mg/mL of mafenide acetate prepared as follows. Constitute the Topical Solution as directed in the labeling. Transfer a volume of the constituted Topical Solution, equivalent to 200 mg of mafenide acetate, to a 100-mL volumetric flask containing 200 mg of oxalic acid. Pipet 10.0 mL of *Internal standard solution* into the flask, and dilute with water to volume.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.25-mm × 60-m fused-silica capillary column coated with a 0.5-µm layer of acid-deactivated phase G35

Temperatures

Injection: 250°

Detector: 250°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
150	0	150	11
150	25	240	10
240	25	150	1

Carrier gas: Helium

Flow rate: 40 cm/s

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between acetic acid and propionic acid

Relative standard deviation: NMT 6.0% for peak response ratios

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of acetic acid in the portion of the constituted Topical Solution taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of acetic acid to propionic acid from the *Sample solution*

R_S = peak response ratio of acetic acid to propionic acid from the *Standard solution*

C_S = concentration of acetic acid in the *Standard solution* (mg/mL)

C_U = nominal concentration of mafenide acetate in the *Sample solution* (mg/mL)

Acceptance criteria: 22.0%–26.8%

IMPURITIES

Change to read:

• **Organic Impurities**

Solution A: Dissolve 6.8 g of monobasic potassium phosphate and 1.0 g of sodium 1-hexanesulfonate in 800 mL of water. Adjust with phosphoric acid to a pH of 2.5, and dilute to 1000 mL.

Mobile phase: Acetonitrile and *Solution A* (1:9)

Standard stock solution: 25 µg/mL of USP Mafenide Related Compound A RS in *Mobile phase*

[Note—USP Mafenide Related Compound A RS is 4-formylbenzenesulfonamide.]

System suitability solution: 1.0 mg/mL of USP Mafenide Acetate RS and 10 µg/mL of USP Mafenide Related Compound A RS from *Standard stock solution* in *Mobile phase*. Initially dissolve the USP Mafenide Acetate RS using 20% of the final volume by sonication in 2 mL of *Mobile phase*, add the appropriate volume of USP Mafenide Related Compound A RS, and dilute to final volume.

Standard solution A: 5 µg/mL of USP Mafenide Related Compound A RS from *Standard stock solution* in *Mobile phase*

Standard solution B: 1 µg/mL of USP Mafenide Related Compound A RS from *Standard solution A* in *Mobile phase*

Sample solution: Proceed as directed in the *Assay*.

Chromatographic system

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

Mode: LC

Detector: UV 267 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: 3 times the retention time of mafenide

System suitability

Samples: *System suitability solution* ▲and▲ (ERR 1-Jan-2023) *Standard solution A* ▲▲ (ERR 1-Jan-2023)

Suitability requirements

Resolution: NLT 3.0 between mafenide acetate and mafenide related compound A, *System suitability solution*

Tailing factor: NMT 2.0, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution A*

Analysis

Samples: *Mobile phase*, *Standard solution A*, ▲*Standard solution B*,▲ (ERR 1-Jan-2023) and *Sample solution*

Chromatograph ▲*Standard solution B*▲ (ERR 1-Jan-2023) and adjust the integration parameters so that the response is 5%–15% of full-scale deflection. Disregard the peaks corresponding to those obtained from the *Mobile phase*.

Calculate the percentage of each impurity in the portion of the constituted Topical Solution taken:

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

r_U = peak response for each impurity from the *Sample solution*

r_S = peak response of mafenide related compound A from *Standard solution A*

C_S = concentration of USP Mafenide Related Compound A RS in *Standard solution A* (µg/mL)

C_U = nominal concentration of mafenide acetate in the *Sample solution* (µg/mL)

Acceptance criteria

Individual impurity: NMT 0.5%

Total impurities: NMT 1.0%

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: Nominally 100 mg/mL

Acceptance criteria: 6.4–6.8

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers, at controlled room temperature. For prepared solutions, use within 48 h of preparation.

• **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 FOR TOPICAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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