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Mafenide Acetate Cream

DEFINITION

Mafenide Acetate Cream is Mafenide Acetate in a water-miscible, oil-in-water cream base, containing suitable preservatives. It contains NLT 90.0% and NMT 110.0% of mafenide acetate ($C_7H_{10}N_2O_2S \cdot C_2H_4O_2$), in terms of the labeled amount of mafenide ($C_7H_{10}N_2O_2S$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020)

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

Acceptance criteria: Meets the requirements

• **B.** **Identification Tests—General, *Acetate*⟨191⟩**

Sample solution: Place about 1 g in a 60-mL separatory funnel, and add 20 mL of chloroform to dissolve it. Add 20 mL of water, shake for 2 min, allow the layers to separate completely, and discard the lower chloroform layer. Repeat this washing with another 20-mL portion of chloroform, and discard the chloroform washing. Centrifuge the aqueous layer. Use a 1-mL aliquot of the supernatant with 2 mL of water for test *A* and a 3-mL aliquot of the supernatant test *B*.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

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

Sample solution: Nominally 200 µg/mL of mafenide acetate prepared as follows. Transfer a portion of Cream containing 100 mg of mafenide acetate to a 60-mL separator, and add 20 mL of chloroform to dissolve it. Add 20 mL of water, shake for 2 min, allow the layers to separate completely, and discard the lower chloroform layer. Repeat this washing with two separate 20-mL portions of chloroform, and discard the chloroform washings. Pass the aqueous phase through a dry filter into a 100-mL volumetric flask. Rinse the separator and the filter with water, passing all rinses through the filter, and add water to volume. Centrifuge 30 mL, then pipet 20 mL of the clear supernatant into a 100-mL volumetric flask. Add 1 mL of 1 N hydrochloric acid, and add water to volume.

Instrumental conditions

Mode: UV

Analytical wavelength: 267 nm

Cell: 1 cm

Blank: 0.01 N hydrochloric acid

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

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

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers, and avoid exposure to excessive heat.

• **USP Reference Standards ⟨11⟩**

USP Mafenide Acetate RS

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

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

Chromatographic Database Information: Chromatographic Database

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