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Aluminum Sulfate and Calcium Acetate for Topical Solution

DEFINITION

Aluminum Sulfate and Calcium Acetate for Topical Solution contains NLT 90.0% and NMT 110.0% of the labeled amounts of aluminum sulfate tetradecahydrate $[\text{Al}_2(\text{SO}_4)_3 \cdot 14\text{H}_2\text{O}]$ and calcium acetate monohydrate $(\text{C}_4\text{H}_6\text{CaO}_4 \cdot \text{H}_2\text{O})$.

IDENTIFICATION

• A.

Sample: 0.25 g of Aluminum Sulfate and Calcium Acetate for Topical Solution

Analysis: Place the *Sample* in a test tube. Add 10 mL of water and 0.25 g of calcium carbonate. Heat on a steam bath for 10 min, and filter.

Add 3–4 drops of ferric chloride TS to the filtrate. [NOTE—After the addition of the ferric chloride TS, the solution may be heated for 1 min to speed the reaction.]

Acceptance criteria: A reddish-brown color or precipitate indicates acetate.

• B. [IDENTIFICATION TESTS—GENERAL](#), [Sulfate\(191\)](#) and [Calcium\(191\)](#).

Sample solution: Suspend 2 g of sample in 50 mL of water and filter.

Acceptance criteria: Meets the requirements

ASSAY

• ALUMINUM SULFATE TETRADECAHYDRATE

Sample solution: Transfer 10 g of Aluminum Sulfate and Calcium Acetate for Topical Solution to a 1000-mL volumetric flask. Add 100 mL of 1.2 N hydrochloric acid and 250 mL of water. Heat on a steam bath or hot plate until dissolved. Cool, and dilute with water to volume.

Retain a portion of the *Sample solution* for the Assay for *Calcium Acetate Monohydrate*.

Blank: Water

Titrimetric system

Mode: Residual titration

Titrant: 0.02 M zinc sulfate VS

Endpoint detection: Visual

Analysis: Transfer a 5.0-mL aliquot of the *Sample solution* to a 250-mL conical flask. Add, in the order named, 40.0 mL of 0.01 M edetate disodium VS and 20 mL of acetic acid–ammonium acetate buffer TS, and mix by swirling. Add 50 mL of alcohol and 2 mL of dithizone TS, and titrate the excess 0.01 M edetate disodium VS with *Titrant* until the color changes from green-violet to a clear rose-pink. Perform a blank titration, substituting 5.0 mL of water for the *Sample solution*.

Calculate the percentage of aluminum sulfate tetradecahydrate $[\text{Al}_2(\text{SO}_4)_3 \cdot 14\text{H}_2\text{O}]$ in the portion of Aluminum Sulfate and Calcium Acetate for Topical Solution taken:

$$\text{Result} = \{[D \times (V_B - V_S) \times M \times F]/W\} \times 100$$

D = dilution factor, 1000/5.0

V_B = blank titration volume (mL)

V_S = sample titration volume (mL)

M = molarity of the *Titrant* (mmol/mL)

F = equivalency factor, 297.2 (mg/mmol)

W = weight of sample used (mg)

Acceptance criteria: 90.0%–110.0% of the labeled amount of aluminum sulfate tetradecahydrate $[\text{Al}_2(\text{SO}_4)_3 \cdot 14\text{H}_2\text{O}]$

• CALCIUM ACETATE MONOHYDRATE

Sample: Transfer a 5.0-mL aliquot of the *Sample solution* retained from the Assay for *Aluminum Sulfate Tetradecahydrate* to a 250-mL conical flask.

Titrimetric system

Mode: Direct titration

Titrant: 0.01 M edetate disodium VS

Endpoint detection: Visual

Analysis: Add 1–2 mL of 50% triethanolamine to mask the aluminum, and mix well. With constant stirring, add to the *Sample*, in the order named, 100 mL of water, 15 mL of 1 N sodium hydroxide, and 300 mg of hydroxy naphthol blue, and titrate with *Titrant*. The indicator will change from purple to a clear blue color at the endpoint.

Calculate the percentage of calcium acetate monohydrate ($C_4H_6CaO_4 \cdot H_2O$) in the portion of Aluminum Sulfate and Calcium Acetate for Topical Solution taken:

$$\text{Result} = [(D \times V \times M \times F)/W] \times 100$$

D = dilution factor, 1000/5.0

V = sample titration volume (mL)

M = molarity of the *Titrant* (mmol/mL)

F = equivalency factor, 176.2 (mg/mmol)

W = weight of sample used (mg)

Acceptance criteria: 90.0%–110.0% of the labeled amount of calcium acetate monohydrate ($C_4H_6CaO_4 \cdot H_2O$)

SPECIFIC TESTS

- [pH \(791\)](#)

Sample solution: 1 g of Aluminum Sulfate and Calcium Acetate for Topical Solution in 200 mL of water

Acceptance criteria: 4.0–4.8

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-unit containers, and protect from excessive heat.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ALUMINUM SULFATE AND CALCIUM ACETATE FOR TOPICAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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