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Aluminum Sulfate and Calcium Acetate Tablets for Topical Solution

DEFINITION

Aluminum Sulfate and Calcium Acetate Tablets 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. [IDENTIFICATION TESTS—GENERAL, Aluminum\(191\)](#)

Sample solution: Suspend 2 g of ground Tablet powder in 50 mL of water, and filter. Use a portion in the *Analysis*, and retain the remaining filtrate for *Identification* test B.

Analysis: Mix 2 mL of the *Sample solution* with 2 mL of water and 2 drops of 3 N hydrochloric acid.

Acceptance criteria: Meets the requirements of test A

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

Sample solution: A portion of the filtrate retained from *Identification* test A

Acceptance criteria: Meets the requirements

ASSAY

• ALUMINUM SULFATE TETRADECAHYDRATE

Sample solution: Finely powder and mix NLT 20 Tablets. Weigh a portion of the powder, equivalent to 2.8 g of aluminum sulfate, and transfer to a 1000-mL volumetric flask. Add 100 mL of 1.2 N hydrochloric acid and 100 mL of water, and heat on a steam bath, with occasional swirling, to dissolve the powder. Allow the solution to 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

Back-titrant: 0.01 M edetate disodium VS

Endpoint detection: Visual

Analysis: Transfer 25.0 mL of the *Sample solution* to a 250-mL conical flask. Add, in the order named, 40.0 mL of *Back-titrant* 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 *Back-titrant* with *Titrant* until the color changes from green-violet to a clear rose-pink. Perform a blank determination. Each mL of 0.01 M edetate disodium is equivalent to 2.972 mg of the labeled amount of aluminum sulfate tetradecahydrate $[\text{Al}_2(\text{SO}_4)_3 \cdot 14\text{H}_2\text{O}]$.

Acceptance criteria: 90.0%–110.0%

• CALCIUM ACETATE MONOHYDRATE

Sample: Transfer 20.0 mL of the *Sample solution* retained from the Assay for Aluminum Sulfate Tetradecahydrate to a 125-mL conical flask.

Titrimetric system

Mode: Direct titration

Titrant: 0.01 M edetate disodium VS

Endpoint detection: Visual

Analysis: With constant stirring, add to the *Sample*, in the order named, 0.5 mL of trolamine, 10 mL of ammonia–ammonium chloride buffer TS, and 3 drops of a solution prepared by dissolving 500 mg of eriochrome black T titration in 10 mL of methanol. Titrate with *Titrant* to a violet endpoint. Each mL of 0.01 M edetate disodium is equivalent to 1.762 mg of the labeled amount of calcium acetate monohydrate $(\text{C}_4\text{H}_6\text{CaO}_4 \cdot \text{H}_2\text{O})$.

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISINTEGRATION \(701\)](#): 10 min

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meets the requirements for *Weight Variation*

SPECIFIC TESTS

• [pH \(791\)](#)

Sample solution: 2 g of ground Tablet powder in 500 mL of water

Acceptance criteria: 4.0–4.8

- [Loss on Drying \(731\)](#)

Analysis: Dry ground Tablet powder at 150° for 15 min.

Acceptance criteria: NMT 18%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and avoid 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 TABLETS FOR TOPICAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1

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