Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-E1C83646-EFE1-4C02-AFF7-85B27C0CE725_3_en-US
DOI: https://doi.org/10.31003/USPNF_M2353_03_01
DOI Ref: q69ty

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 [$Al_2(SO_4)_3 \cdot 14H_2O$] and calcium acetate monohydrate ($C_4H_6CaO_4 \cdot H_2O$).

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⟩ and *Calcium*⟨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 [$Al_2(SO_4)_3 \cdot 14H_2O$].

  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 trituration 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 ($C_4H_6CaO_4 \cdot H_2O$).

  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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-E1C83646-EFE1-4C02-AFF7-85B27C0CE725_3_en-US
Previous DocID: GUID-E1C83646-EFE1-4C02-AFF7-85B27C0CE725_1_en-US
DOI: https://doi.org/10.31003/USPNF_M2353_03_01
DOI ref: q69ty