Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-May-2016
Document Type: USP Monographs
DocId: GUID-90976746-41A4-4F2C-B6AC-9E112DB68066_1_en-US
DOI: https://doi.org/10.31003/USPNF_M1370_01_01
DOI Ref: p8ara

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

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 [$Al_2(SO_4)_3 \cdot 14H_2O$] 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 [$Al_2(SO_4)_3 \cdot 14H_2O$]

- **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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 41(1)

Current DocID: GUID-90976746-41A4-4F2C-B6AC-9E112DB68066_1_en-US

DOI: https://doi.org/10.31003/USPNF_M1370_01_01

DOI ref: p8ara