

## 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

#### Change to read:

- 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  
(IRA 1-Jul-2015)  
**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, (IRA 1-Jul-2015) 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, (IRA 1-Jul-2015) 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 Alu-

minum 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<sub>B</sub>* = blank titration volume (mL)
- V<sub>S</sub>* = sample titration volume (mL)
- M* = molarity of the *Titrant* (mmol/mL)
- F* = equivalency factor, 297.2 (mg/mmol)
- W* = weight of sample used (mg) (IRA 1-Jul-2015)

**Acceptance criteria:** 90.0%–110.0% of the labeled amount of aluminum sulfate tetradecahydrate  $[\text{Al}_2(\text{SO}_4)_3 \cdot 14\text{H}_2\text{O}]$  (IRA 1-Jul-2015)

#### Change to read:

### 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  $(\text{C}_4\text{H}_6\text{CaO}_4 \cdot \text{H}_2\text{O})$  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) (IRA 1-Jul-2015)

**Acceptance criteria:** 90.0%–110.0% of the labeled amount of calcium acetate monohydrate  $(\text{C}_4\text{H}_6\text{CaO}_4 \cdot \text{H}_2\text{O})$  (IRA 1-Jul-2015)

### 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.