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Aluminum Acetate Topical Solution

DEFINITION

Aluminum Acetate Topical Solution yields NLT 1.20 g and NMT 1.45 g of aluminum oxide (Al_2O_3) and NLT 4.24 g and NMT 5.12 g of acetic acid ($C_2H_4O_2$), corresponding to NLT 4.8 g and NMT 5.8 g of aluminum acetate ($C_6H_9AlO_6$) in each 100 mL. Aluminum Acetate Topical Solution may be stabilized by the addition of NMT 0.6% of boric acid (H_3BO_3).

Aluminum Subacetate Topical Solution	545 mL
Glacial Acetic Acid	15 mL
Purified Water, a sufficient quantity to make	1000 mL

Add the *Glacial Acetic Acid* to the *Aluminum Subacetate Topical Solution* and sufficient *Purified Water* to bring to final volume. Mix, and filter if necessary. Dispense only clear Aluminum Acetate Topical Solution.

IDENTIFICATION

• **A. Identification Tests—General ⟨191⟩:** It meets the requirements of the test for *Aluminum* and for the test *B* under *Acetate*. Ferric chloride TS produces a deep red color that is destroyed by the addition of a mineral acid.

ASSAY

• **Aluminum Oxide**

Edetate disodium titrant: Prepare and standardize 0.05 M edetate disodium titrant as directed in *Reagents, Volumetric Solutions, Edetate Disodium, Twentieth-Molar (0.05 M)*.

Sample: 25 mL

Blank: 25 mL of water

Titrimetric system

Mode: Residual titration

Back-titrant: 0.05 M zinc sulfate VS

Endpoint detection: Visual

Analysis: Pipet the *Sample* into a 250-mL volumetric flask, add 5 mL of hydrochloric acid, and dilute with water to volume. Pipet 25 mL of this solution into a 250-mL beaker, and add, in the order named and with continuous stirring, 25.0 mL of *Edetate disodium titrant* and 20 mL of acetic acid–ammonium acetate buffer TS, then heat the solution near the boiling point for 5 min. Cool, and add 50 mL of alcohol and 2 mL of dithizone TS. Titrate the solution with *Back-titrant* to a bright rose-pink color. Perform a blank determination, and make any necessary correction. Each mL of *Edetate disodium titrant* is equivalent to 2.549 mg of aluminum oxide (Al_2O_3).

Acceptance criteria: 1.20–1.45 g of aluminum oxide (Al_2O_3) in 100 mL

• **Acetic Acid**

Sample: 20 mL

Titrimetric system

Mode: Residual titration

Titrant: 0.5 N sodium hydroxide VS

Back-titrant: 0.5 N sulfuric acid VS

Endpoint detection: Visual

Analysis: Pipet the *Sample* into a Kjeldahl flask containing a mixture of 20 mL of phosphoric acid and 150 mL of water. Connect the flask to a condenser, the delivery tube from which dips beneath the surface of 50.0 mL of *Titrant* contained in a receiving flask. Distill about 160 mL, then remove the delivery tube from below the surface of the liquid. Allow the distilling flask to cool, add 50 mL of water, and distill an additional 40–45 mL into the receiving flask. Add phenolphthalein TS to the distillate, and titrate the excess *Titrant* with *Back-titrant*. Each mL of *Titrant* is equivalent to 30.03 mg of acetic acid ($C_2H_4O_2$).

Acceptance criteria: 4.24–5.12 g of acetic acid ($C_2H_4O_2$) in 100 mL

OTHER COMPONENTS

• **Limit of Boric Acid**

Sample: 25 mL

Titrimetric system

Mode: Direct titration

Titrant: 0.5 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Pipet the *Sample* into 75 mL of water in a conical flask. Add 3 mL of phenolphthalein TS, and add *Titrant* from a buret until a faint pink color is obtained. Heat to boiling, and again neutralize. Add 150 mL of glycerin to the neutralized solution, and titrate with *Titrant*. Perform a blank determination in a similar manner. Subtract the volume of *Titrant* used in the blank from the volume of *Titrant* used after the addition of the glycerin. Each mL of *Titrant* is equivalent to 30.92 mg of boric acid (H_3BO_3).

Acceptance criteria: NMT 0.6% of boric acid (H_3BO_3)

IMPURITIES

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.6–4.4

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight containers.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ALUMINUM ACETATE TOPICAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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