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Aluminum Chlorohydrate Solution

DEFINITION

Aluminum Chlorohydrate Solution consists of complex basic aluminum chloride that is polymeric and encompasses a range of aluminum-to-chloride ratios between 1.91:1 and 2.10:1. The following solvents may be used: water, propylene glycol, dipropylene glycol, or alcohol. It contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled concentration of anhydrous aluminum chlorohydrate ($Al_y(OH)_{3y-z}Cl_z$).

IDENTIFICATION

• **A. Identification Tests—General, *Aluminum*⟨191⟩and*Chloride*⟨191⟩**

Sample solution: Nominally equivalent to 100 mg/mL of anhydrous aluminum chlorohydrate

Acceptance criteria: Meets the requirements

• **B. Identification of Propylene Glycol**

Perform this test where propylene glycol is stated on the label.

Sample solution: 2 g of Solution in 10 mL of isopropyl alcohol. Mix, filter, and evaporate the filtrate to 1 mL on a steam bath.

Acceptance criteria: The IR spectrum of a film of the *Sample solution* on a silver chloride disk exhibits maxima only at the same wavelengths as that of a similar preparation of a film of propylene glycol.

• **C. Identification of Dipropylene Glycol**

Perform this test where dipropylene glycol is stated on the label.

Sample solution: 2 g of Solution in 10 mL of isopropyl alcohol. Mix, filter, and evaporate the filtrate to 1 mL on a steam bath.

Acceptance criteria: The IR spectrum of a film of the *Sample solution* on a silver chloride disk exhibits maxima only at the same wavelengths as that of a similar preparation of a film of dipropylene glycol.

• **D. Identification of Alcohol**

Perform this test where alcohol is stated on the label.

Analysis: Mix 5 drops of Solution in a small beaker with 1 mL of potassium permanganate solution (1 in 100) and 5 drops of 2 N sulfuric acid, and cover the beaker immediately with filter paper moistened with a freshly prepared solution of 0.1 g of sodium nitroferricyanide and 0.25 g of piperazine in 5 mL of water.

Acceptance criteria: An intense blue color is produced on the filter paper, the color becoming paler after a few min.

ASSAY

• **Procedure 1: Content of Chloride**

Sample: 1.4 g of Solution

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N silver nitrate VS

Electrode system: A silver–silver chloride glass electrode and a silver billet electrode system

Endpoint detection: Potentiometric

Analysis: Transfer the *Sample* to a 250-mL beaker, and add 100 mL of water and 10 mL of diluted nitric acid with stirring. Titrate with *Titrant*, and determine the endpoint.

Acceptance criteria: Each mL of 0.1 N silver nitrate is equivalent to 3.545 mg of chloride (Cl). Use the chloride content thus obtained to calculate the aluminum/chloride atomic ratio.

• **Procedure 2: Content of Aluminum**

Edetate disodium titrant: Prepare and standardize as directed in *Reagents*, *Volumetric Solutions*, *Edetate Disodium, Twentieth-Molar (0.05 M)*, except use 37.2 g of edetate disodium.

Sample solution: Transfer 400 mg of Solution to a 250-mL beaker, add 20 mL of water and 5 mL of hydrochloric acid, boil on a hot plate for NLT 5 min, and allow to cool.

Titrimetric system

Mode: Back titration

Titrant: 0.1 M zinc sulfate VS

Endpoint detection: Visual

Analysis: To the *Sample solution* add 25.0 mL of *Edetate disodium titrant*, and adjust with 2.5 N ammonium hydroxide or 1 N acetic acid to a pH of 4.7 ± 0.1. Add 20 mL of acetic acid–ammonium acetate buffer TS, 50 mL of alcohol, and 5 mL of dithizone TS. The pH of this solution should be 4.7 ± 0.1. Titrate excess edetate disodium with *Titrant* until the color changes from green-violet to rose-pink. Perform a blank titration, and make any necessary correction.

Acceptance criteria: Each mL of 0.1 M *Edetate disodium titrant* consumed is equivalent to 2.698 mg of aluminum (Al). Use the aluminum content thus obtained to calculate the aluminum/chloride atomic ratio.

- **Procedure 3: Aluminum/Chloride Atomic Ratio**

Analysis: Use the percentage of aluminum found in *Content of Aluminum* and the percentage of chloride found in *Content of Chloride*. Calculate the aluminum/chloride atomic ratio (*X*) as follows:

$$\text{Result} = (P_{Al}/P_{Cl}) \times (A_{Cl}/A_{Al})$$

P_{Al} = percentage of aluminum found in *Content of Aluminum*

P_{Cl} = percentage of chloride found in *Content of Chloride*

A_{Cl} = atomic weight of chlorine (Cl), 35.453

A_{Al} = atomic weight of aluminum (Al), 26.98

Acceptance criteria: 1.91:1 to 2.10:1

- **Procedure 4**

Analysis: Calculate the percentage of the labeled concentration of anhydrous aluminum chlorohydrate ($Al_y(OH)_{3y-z}Cl_z$) in the portion of Solution taken:

$$\text{Result} = P_{Al} \times \{[A_{Al}X + (M(3X - 1)) + A_{Cl}]/A_{Al}X\}$$

P_{Al} = percentage of aluminum found in *Content of Aluminum*

A_{Al} = atomic weight of aluminum (Al), 26.98

X = aluminum/chloride atomic ratio, as determined in *Aluminum/Chloride Atomic Ratio*

M = molecular weight of the hydroxide anion (OH), 17.01

A_{Cl} = atomic weight of chlorine (Cl), 35.453

Acceptance criteria: 90.0%–110.0%

IMPURITIES

Change to read:

- ▲Arsenic ⟨211⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023) : NMT 2 ppm

Change to read:

- **Limit of Iron**

Standard preparation: 2.0 mL of *Standard Iron Solution*, prepared as directed in ▲*Iron ⟨241⟩, Procedures, Procedure 1*▲ (CN 1-Jun-2023)

Test preparation: Transfer 5.3 g of Solution to a 100-mL volumetric flask, and dilute with water to volume.

Analysis: Transfer 2.0 mL of the *Standard preparation* into a 50-mL beaker. Transfer 5.0 mL of the *Test preparation* into a second 50-mL beaker. To each of the beakers add 5 mL of 6 N nitric acid, cover with a watch glass, and boil on a hot plate for 3–5 min. Allow to cool. Add 5 mL of *Ammonium Thiocyanate Solution*, prepared as directed in ▲*Iron ⟨241⟩, Procedures, Procedure 1*▲ (CN 1-Jun-2023) , transfer to separate 50-mL color-comparison tubes, and dilute with water to volume.

Acceptance criteria: 75 ppm; the color of the solution from the *Test preparation* is not darker than that from the *Standard preparation*.

SPECIFIC TESTS

- **pH ⟨791⟩**

Sample solution: Dilute 3 g of Solution with water to 10 mL.

Acceptance criteria: 3.0–5.0

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **Labeling:** Label Solution to state the solvent used and the claimed concentration of anhydrous aluminum chlorohydrate contained therein.

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

Topic/Question	Contact	Expert Committee
ALUMINUM CHLOROHYDRATE SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

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