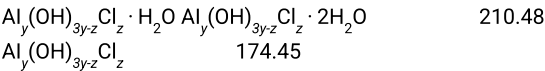


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# Aluminum Chlorohydrate



Aluminum chlorohydroxide, dihydrate;  
Aluminum hydroxychloride, dihydrate;  
Aluminum chlorohydroxide;  
Aluminum hydroxychloride;  
Dihydrate CAS RN®: 12359-72-7; UNII: HPN8MZW13M.  
Anhydrous CAS RN®: 12042-91-0; UNII: 407PSC3OC7.

## DEFINITION

Aluminum Chlorohydrate consists of complex basic aluminum chloride that is polymeric and loosely hydrated and encompasses a range of aluminum-to-chloride atomic ratios between 1.91:1 and 2.10:1. It contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of anhydrous aluminum chlorohydrate  $[\text{Al}_y(\text{OH})_{3y-z}\text{Cl}_z]$ .

## IDENTIFICATION

• **A. IDENTIFICATION TESTS—GENERAL, [Aluminum\(191\)](#) and [Chloride\(191\)](#).**

**Sample solution:** 100 mg/mL  
**Acceptance criteria:** Meets the requirements

## ASSAY

• **PROCEDURE 1: CONTENT OF CHLORIDE**

**Sample:** 700 mg  
**Titrimetric system**  
**Mode:** Direct titration  
**Titrant:** 0.1 N silver nitrate VS  
**Electrode system:** A glass silver–silver chloride 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 potentiometrically. 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 200 mg of Aluminum Chlorohydrate 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  $4.7 \pm 0.1$ . 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  $4.7 \pm 0.1$ . Titrate the excess edetate disodium with *Titrant* until the color changes from green-violet to rose-pink. Perform a blank titration, and make any necessary correction. 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 the test for *Content of Aluminum* and the percentage of chloride found in the test for *Content of Chloride*.  
Calculate the aluminum:chloride atomic ratio (X) as follows:

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

$P_{Al}$  = 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:** Between 1.91:1 and 2.10:1

• **PROCEDURE 4**

**Analysis:** Calculate the percentage of anhydrous aluminum chlorohydrate  $[Al_y(OH)_{3y-z}Cl_z]$  in the portion of Aluminum Chlorohydrate taken:

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

$P_{Al}$  = percentage of aluminum as obtained in the test for *Content of Aluminum*

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

$X$  = aluminum:chloride atomic ratio, as determined in the test for *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% on the anhydrous basis

**IMPURITIES**

**Change to read:**

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

**Change to read:**

• **LIMIT OF IRON**

**Standard solution:** Transfer 2.0 mL of *Standard Iron Solution*, prepared as directed in **Iron (241), Procedures, Procedure 1**▲ (CN 1-Jun-2023), to a 50-mL beaker.

**Sample solution:** Transfer 2.7 g of Aluminum Chlorohydrate to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 50-mL beaker.

**Analysis:** To each of the beakers containing the *Standard solution* and the *Sample solution*, 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:** 150 ppm; the color of the solution from the *Sample solution* is not darker than that of the solution from the *Standard solution*.

**SPECIFIC TESTS**

- **pH (791).**

**Sample solution:** 15 g of Aluminum Chlorohydrate in 100 g of water

**Acceptance criteria:** 3.0–5.0

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** The label states the content of anhydrous aluminum chlorohydrate.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ALUMINUM CHLOROHYDRATE	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3

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