

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 *Eдетate 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 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 *Eдетate 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:

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

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: Between 0.90:1 and 1.25:1

• **PROCEDURE 4**

Analysis: Calculate the percentage of anhydrous aluminum dichlorohydrate [$Al_x(OH)_{3y-z}Cl_z$] in the portion of Aluminum Dichlorohydrate taken:

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

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

- **ARSENIC, Method I (211):** NMT 2 ppm

Delete the following:

- **HEAVY METALS, Method I (231):** NMT 20 ppm (Official 1, Jan-2018)

- **LIMIT OF IRON**

Standard solution: Transfer 2.0 mL of *Standard Iron Solution*, prepared as directed in *Iron (241)*, to a 50-mL beaker.

Sample solution: Transfer 2.7 g of Aluminum Dichlorohydrate 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)*), 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 Dichlorohydrate 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 dichlorohydrate.

Aluminum Dichlorohydrate Solution

DEFINITION

Aluminum Dichlorohydrate Solution consists of complex basic aluminum chloride that is polymeric and encompasses a range of aluminum-to-chloride atomic ratios between 0.90:1 and 1.25:1. 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 dichlorohydrate ($Al_x(OH)_{3y-z}Cl_z$).

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, Aluminum (191) and Chloride (191)**

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

Acceptance criteria: Meets the requirements

- **B. INFRARED ABSORPTION (197F):** (where propylene glycol is indicated on the label)

Sample solution: Add 10 mL of isopropyl alcohol to 2 g of Solution, and filter. Evaporate the filtrate to 1 mL on a steam bath. Deposit this solution on a silver chloride disk.

Standard solution: A similar preparation of propylene glycol

Acceptance criteria: Meets the requirements

- **C. INFRARED ABSORPTION (197F):** (where dipropylene glycol is indicated on the label)

Sample solution: Add 10 mL of isopropyl alcohol to 2 g of Solution, and filter. Evaporate the filtrate to 1 mL on a steam bath. Deposit this solution on a silver chloride disk.

Standard solution: A similar preparation of dipropylene glycol

Acceptance criteria: Meets the requirements

- **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