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 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⟩), 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.

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:

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