

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 ($Al_x(OH)_{3y-z}Cl_z$) 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

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

~~Delete the following:~~

- ~~**HEAVY METALS, Method I (231):** NMT 10 ppm~~ (Official 1-

Jan-2018)

• **LIMIT OF IRON**

Standard preparation: 2.0 mL of *Standard Iron Solution*, prepared as directed in *Iron (241)*

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)*, 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.

Aluminum Chlorohydrate Polyethylene Glycol

$Al_x(OH)_{3y-z}Cl_z \cdot nH_2O \cdot mH(OCH_2CH_2)_nOH$

Aluminum chlorohydroxide polyethylene glycol complex.

Aluminum hydroxychloride polyethylene glycol complex.

» Aluminum Chlorohydrate Polyethylene Glycol consists of aluminum chlorohydrate in which some of the waters of hydration have been replaced by polyethylene glycol. It encompasses a range of aluminum-to-chloride atomic ratios between 1.91:1 and 2.10:1. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of anhydrous aluminum chlorohydrate.

Packaging and storage—Preserve in well-closed containers.

Labeling—The label states the content of anhydrous aluminum chlorohydrate.

Identification—

A: A solution (1 in 10) responds to the tests for *Aluminum (191)* and for *Chloride (191)*.

B: *Infrared Absorption (197F)—*

Test specimen—Dissolve 0.5 g in about 40 mL of water, and while mixing adjust with 2.5 N sodium hydroxide to a pH of 9.55 ± 0.05 . Filter the suspension of precipitate thus obtained. Evaporate about 15 mL of the filtrate to about 1 mL on a hot plate. Deposit this solution on a silver chloride disk.

Standard specimen: a similar preparation of polyethylene glycol.

pH (791): between 3.0 and 5.0, in a solution [15 in 100 (w/w)].

Arsenic, Method I (211): 2 µg per g.

~~Delete the following:~~

- ~~**Heavy metals, Method I (231):** 20 µg per g~~ (Official 1-Jan-

2018)

Limit of iron—Using Aluminum Chlorohydrate Polyethylene Glycol instead of Aluminum Chlorohydrate, proceed as directed in the test for *Limit of iron* under *Aluminum Chlorohydrate*. The limit is 150 µg per g.

Content of aluminum—Using Aluminum Chlorohydrate Polyethylene Glycol instead of Aluminum Chlorohydrate, proceed as directed in the test for *Content of aluminum* under *Aluminum Chlorohydrate*. Use the result obtained to calculate the *Aluminum/chloride atomic ratio*.

Content of chloride—Using Aluminum Chlorohydrate Polyethylene Glycol instead of Aluminum Chlorohydrate, proceed as directed in the test for *Content of chloride* under *Aluminum Chlorohydrate*. Use the result obtained to calculate the *Aluminum/chloride atomic ratio*.

Aluminum/chloride atomic ratio—Divide the percentage of aluminum found in the test for *Content of aluminum* by the percentage of chloride found in the test for *Content of chloride*, and multiply by 35.453/26.98, in which 35.453 and 26.98 are the atomic weights of chlorine and aluminum, respectively: the ratio is between 1.91:1 and 2.10:1.

Assay—Calculate the percentage of anhydrous aluminum chlorohydrate in the Aluminum Chlorohydrate Polyethylene Glycol by the formula:

$$Al\{26.98x + [17.01(3x - 1)] + 35.453\} / 26.98x$$

in which *Al* is the percentage of aluminum found in the test for *Content of aluminum*, *x* is the aluminum/chloride atomic ratio found in the test for *Aluminum/chloride atomic ratio*, 26.98 is the atomic weight of aluminum, 17.01 is the molecular weight of the hydroxide anion (OH), and 35.453 is the atomic weight of chlorine (Cl).