Official Monographs / Aluminum 169

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.

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• ARSENIC, Method I (211): NMT 2 ppm

Delete the following:

- HEAVY METALS, Method I (231): NMT 10 ppme (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.

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 ± 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:

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 dichlorohydrate contained therein.

Result = $(P_{AI}/P_{CI}) \times (A_{CI}/A_{AI})$

- = percentage of aluminum found in Content of P_{AI} Aluminum
- = percentage of chloride found in Content of P_{CI} Chloride
- = atomic weight of chlorine (Cl), 35.453 Acl
- = atomic weight of aluminum (Al), 26.98A_{AI} Acceptance criteria: 0.90: 1 to 1.25: 1

• PROCEDURE 4

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

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

- = percentage of aluminum found in *Content* of PAI Aluminum
- = atomic weight of aluminum (Al), 26.98 A_{AI} Χ
 - = aluminum/chloride atomic ratio, as determined in Aluminum/Chloride Atomic Ratio
- = molecular weight of the hydroxide anion Μ (OH), 17.01 = atomic weight of chlorine (Cl), 35.453 Ac

Aluminum Dichlorohydrex Polyethylene Glycol

 $Al_{y}(OH)_{3y-z}Cl_{z} \cdot nH_{2}O \cdot mH(OCH_{2}CH_{2})_{n}OH$ Aluminum chlorohydroxide polyethylene glycol complex. Aluminum hydroxýchloride polýethýlene glýcol complex.

» Aluminum Dichlorohydrex Polyethylene Glycol consists of aluminum dichlorohydrate 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 0.90:1 and 1.25:1. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of anhydrous aluminum dichlorohydrate.

Packaging and storage—Preserve in well-closed containers.

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

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