170 Aluminum / Official Monographs

USP 41

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 $\langle 791 \rangle$: between 3.0 and 5.0, in a solution [15 in 100 (w/w)].

Arsenic, *Method I* $\langle 211 \rangle$: 2 µg per g.

Delete the following: A the second a second second

*Heavy metals, Method I (231): 20 µg per g.a. (official 1-Jan-2018)

Limit of iron—Using Aluminum Dichlorohydrex 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.

Identification----

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

B: 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 \pm 0.05. Filter the suspension of precipitate thus obtained. Evaporate about 15 mL of the filtrate to about 1 mL on a hot plate: the IR absorption spectrum of a film of this 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.

pH $\langle 791 \rangle$: between 3.0 and 5.0, in a solution [15 in 100 (w/w)]. Arsenic, Method I $\langle 211 \rangle$: 2 µg per g.

Content of aluminum—Using Aluminum Dichlorohydrex 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 Dichlorohydrex 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 0.90:1 and 1.25:1.

Assay—Calculate the percentage of anhydrous aluminum dichlorohydrate in the Aluminum Dichlorohydrex Polyethylene Glycol by the formula:

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

Delete the following:

Heavy metals, *Method* / (231): 20 μg per g. (omcial 1-jan-2018)

Limit of iron—Using Aluminum Dichlorohydrex Propylene 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 Dichlorohydrex Propylene 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 Dichlorohydrex Propylene 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 0.90:1 and 1.25:1. **Assay**—Calculate the percentage of anhydrous aluminum dichlorohydrate in the Aluminum Dichlorohydrex Propylene Glycol by the formula:

in which *AI* is the percentage of aluminum found in the test for *Content of aluminum*, *x* is the aluminum-to-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 (CI).

Aluminum Dichlorohydrex Propylene Glycol

 $Al_{y}(OH)_{3y-z}Cl_{z} \cdot nH_{2}O \cdot mC_{3}H_{8}O_{2}$ Aluminum chlorohydroxide propylene glycol complex. Aluminum hydroxychloride propylene glycol complex.

» Aluminum Dichlorohydrex Propylene Glycol consists of aluminum dichlorohydrate in which some of the waters of hydration have been replaced by propylene 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. $AI({26.98x + [17.01(3x - 1)] + 35.453} / 26.98x)$

in which *AI* is the percentage of aluminum found in the test for *Content of aluminum*, *x* is the aluminum-to-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).

Aluminum Hydroxide Gel

Al(OH)₃ 78.00 Aluminum hydroxide. Aluminum hydroxide [21645-51-2].

» Aluminum Hydroxide Gel is a suspension of amorphous aluminum hydroxide in which there is a partial substitution of carbonate for hydroxide. It contains the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amount of aluminum hydroxide [Al(OH)₃]. It may contain Peppermint Oil, Glycerin, Sorbitol, Sucrose, Saccharin, or other suitable flavors, and it may contain suitable antimicrobial agents.

Packaging and storage—Preserve in well-closed containers.

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