Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: USP Monographs
Docld: GUID-91A9DEB9-D2E3-48C2-8AE4-4625A4AAA22D\_4\_en-US
DOI: https://doi.org/10.31003/USPNF\_M2068\_04\_01
DOI Ref: x3pn3

© 2025 USPC Do not distribute

## **Aluminum Dichlorohydrex Propylene Glycol**

 $AI_{v}(OH)_{3v-z}CI_{z} \cdot nH_{2}O \cdot mC_{3}H_{8}O_{2}$ 

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Dichlorohydrex Propylene Glycol consists of aluminum dichlorohydrate in which some of the waters of hydration have been replaced by propylene glycol.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.

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

## Change to read:

**ARSENIC** <u>⟨211⟩</u>, <u>Procedures, Procedure 1</u> (CN 1-Jun-2023): 2 μg per g.

**Limit of iron**—Using Aluminum Dichlorohydrex Propylene Glycol instead of Aluminum Chlorohydrate, proceed as directed in the test for <u>Limit of iron</u> under <u>Aluminum Chlorohydrate</u>. 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 <u>Aluminum Chlorohydrate</u>*. 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 <u>Aluminum Chlorohydrate</u>. Use the result obtained to calculate the <u>Aluminum/chloride</u> 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:

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

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

**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ALUMINUM DICHLOROHYDREX PROPYLENE GLYCOL	<u>Documentary Standards Support</u>	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-91A9DEB9-D2E3-48C2-8AE4-4625A4AAA22D\_4\_en-US

DOI: https://doi.org/10.31003/USPNF\_M2068\_04\_01

DOI ref: x3pn3