

Status: Currently Official on 13-Feb-2025  
Official Date: Official as of 01-Jun-2023  
Document Type: USP Monographs  
DocId: GUID-E6A8A057-C16F-4602-A8B8-EBCE20008D26\_4\_en-US  
DOI: https://doi.org/10.31003/USPNF\_M2100\_04\_01  
DOI Ref: xe6ai

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# Aluminum Hydroxide Gel

Al(OH)<sub>3</sub> 78.00  
Aluminum hydroxide.

Aluminum hydroxide CAS RN®: 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)<sub>3</sub>]. 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 tight containers, and avoid freezing.

**Identification**—

**A:**Place about 1 g in a flask equipped with a stopper and glass tubing, the tip of which is immersed in calcium hydroxide TS in a test tube. Add 5 mL of 3 N hydrochloric acid to the flask, and immediately insert the stopper: gas evolves in the flask and a precipitate is formed in the test tube.

**B:**The solution remaining in the flask responds to the tests for [Aluminum \(191\)](#).

**MICROBIAL ENUMERATION TESTS (61) and TESTS FOR SPECIFIED MICROORGANISMS (62)**—Its total aerobic microbial count does not exceed 100 cfu per mL, and it meets the requirements of the test for the absence of *Escherichia coli*.

**ACID-NEUTRALIZING CAPACITY (301)**—Not less than 65.0% of the expected mEq value, calculated from the results of the Assay, is obtained. Each mg of Al(OH)<sub>3</sub> has an expected acid-neutralizing capacity value of 0.0385 mEq.

**pH (791)**: between 5.5 and 8.0, determined potentiometrically.

**Chloride**—Transfer an accurately measured quantity of the Gel, equivalent to 0.6 g of Al(OH)<sub>3</sub>, to a porcelain dish. Add 0.1 mL of potassium chromate TS and 25 mL of water. Stir, and add 0.10 N silver nitrate until a faint, persistent pink color is obtained: not more than 8.0 mL of 0.10 N silver nitrate is required [4.7%, based on the Al(OH)<sub>3</sub> content].

**SULFATE (221)**—Add 5.0 mL of 3 N hydrochloric acid to an accurately measured quantity of the Gel, equivalent to 0.3 g of Al(OH)<sub>3</sub>, and heat to dissolve the specimen under test. Cool, dilute with water to 250 mL, and filter if necessary: a 20-mL portion of the filtrate shows no more sulfate than corresponds to 0.20 mL of 0.020 N sulfuric acid [0.8%, based on the Al(OH)<sub>3</sub> content].

**Change to read:**

▲ **ARSENIC (211), Procedures, Procedure 1** ▲ (CN 1-Jun-2023) —Prepare a *Standard Preparation* as directed in the test for ▲ **Arsenic (211), Procedures, Procedure 1** ▲ (CN 1-Jun-2023), except to prepare it to contain 5 µg of arsenic instead of 3 µg. Prepare the *Test Preparation* as follows. Dissolve an accurately measured quantity of the Gel, equivalent to 0.5 g of Al(OH)<sub>3</sub>, in 20 mL of 7 N sulfuric acid. The limit is 0.001%, based on the Al(OH)<sub>3</sub> content.

**Assay**—

**Edetate disodium titrant**—Prepare and standardize as directed in the Assay under [Ammonium Alum](#).

**Procedure**—Transfer an accurately measured quantity of Gel, equivalent to about 1.5 g of Al(OH)<sub>3</sub>, to a beaker, add 15 mL of hydrochloric acid, and heat gently until solution is complete. Cool, transfer to a 500-mL volumetric flask, dilute with water to volume, and mix. Pipet 20 mL of this solution into a 250-mL beaker, and add, in the order named and with continuous stirring, 25.0 mL of *Edetate disodium titrant* and 20 mL of acetic acid–ammonium acetate buffer TS, then heat the solution near the boiling point for 5 minutes. Cool, and add 50 mL of alcohol and 2 mL of dithizone TS. Titrate the solution with 0.05 M zinc sulfate VS until the color changes from green-violet to rose-pink. Perform a blank determination, substituting 20 mL of water for the sample, and make any necessary correction. Each mL of 0.05 M *Edetate disodium titrant* consumed is equivalent to 3.900 mg of Al(OH)<sub>3</sub>.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ALUMINUM HYDROXIDE GEL	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3

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Pharmacopeial Forum: Volume No. Information currently unavailable

**Current DocID:** GUID-E6A8A057-C16F-4602-A8B8-EBCE20008D26\_4\_en-US

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