

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 $\text{Al}(\text{OH})_3$ 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 $\text{Al}(\text{OH})_3$, 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 $\text{Al}(\text{OH})_3$ 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 $\text{Al}(\text{OH})_3$, 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 $\text{Al}(\text{OH})_3$ content].

Arsenic, Method 1 (211)—Prepare a *Standard Preparation* as directed in the test for *Arsenic* (211), 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 $\text{Al}(\text{OH})_3$, in 20 mL of 7 N sulfuric acid. The limit is 0.001%, based on the $\text{Al}(\text{OH})_3$ content.

Heavy metals (231)—Dissolve an accurately measured quantity of the Gel, equivalent to 0.24 g of $\text{Al}(\text{OH})_3$, in 10 mL of 3 N hydrochloric acid with the aid of heat, filter, if necessary, and dilute with water to 25 mL: the limit is 0.0083%, based on the $\text{Al}(\text{OH})_3$ 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 $\text{Al}(\text{OH})_3$, 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 $\text{Al}(\text{OH})_3$.

» Dried Aluminum Hydroxide Gel is an amorphous form of aluminum hydroxide in which there is a partial substitution of carbonate for hydroxide. It contains the equivalent of not less than 76.5 percent of $\text{Al}(\text{OH})_3$, and it may contain varying quantities of basic aluminum carbonate and bicarbonate.

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Labeling—Where the quantity of dried aluminum hydroxide gel equivalent is stated in the labeling of any preparation, this shall be understood to be on the basis that each mg of dried gel is equivalent to 0.765 mg of $\text{Al}(\text{OH})_3$.

USP Reference standards (11)—
USP Dried Aluminum Hydroxide Gel RS

Identification—

A: *Infrared Absorption* (197K).

B: Dissolve 500 mg in 10 mL of 3 N hydrochloric acid, with gentle warming: the solution responds to the tests for *Aluminum* (191).

Acid-neutralizing capacity (301): not less than 25.0 mEq per g, 400 mg being tested as directed for *Powders* under *Test Preparation*.

pH (791): not higher than 10.0, in an aqueous dispersion (1 in 25).

Chloride (221)—Dissolve 1.0 g in 30 mL of 2 N nitric acid, heat to boiling, add water to make 100 mL, and filter: a 5.0-mL portion of the filtrate, diluted with an equal volume of water, shows no more chloride than corresponds to 0.60 mL of 0.020 N hydrochloric acid (0.85%).

Sulfate (221)—Dissolve 330 mg in 15 mL of 3 N hydrochloric acid, heat to boiling, add water to make 250 mL, and filter: a 25-mL portion of the filtrate shows no more sulfate than corresponds to 0.20 mL of 0.020 N sulfuric acid (0.6%).

Arsenic, Method 1 (211)—Dissolve 1.5 g in 80 mL of 7 N sulfuric acid, and dilute with water to 220 mL: 55 mL of the resulting solution meets the requirements of the test, the addition of 20 mL of 7 N sulfuric acid specified under *Procedure* being omitted. The limit is 8 ppm.

Heavy metals (231)—Dissolve 330 mg in 10 mL of 3 N hydrochloric acid with the aid of heat, filter if necessary, and dilute with water to 25 mL: the limit is 0.006%.

Assay—

Edetate disodium titrant—Prepare and standardize as directed in the *Assay* under *Ammonium Alum*.

Procedure—Weigh accurately about 2 g of Gel, and dissolve in 15 mL of hydrochloric acid, with the aid of heat. 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 to a bright rose-pink color. Perform a blank determination, substituting 20 mL of water for the sample solution, and make any necessary correction. Each mL of 0.05 M *Edetate disodium titrant* is equivalent to 3.900 mg of $\text{Al}(\text{OH})_3$.

Dried Aluminum Hydroxide Gel

$\text{Al}(\text{OH})_3$ 78.00
Aluminum hydroxide [21645-51-2].

Dried Aluminum Hydroxide Gel Capsules

» Dried Aluminum Hydroxide Gel Capsules contain not less than 90.0 per cent and not more than 110.0 percent of the labeled amount of aluminum hydroxide [$\text{Al}(\text{OH})_3$].