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Dried Aluminum Hydroxide Gel Capsules

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

Packaging and storage—Preserve in well-closed containers.

Labeling—The Capsules may be labeled to state the aluminum hydroxide content in terms of the equivalent amount of dried aluminum hydroxide gel, on the basis that each mg of dried gel is equivalent to 0.765 mg of $Al(OH)_3$.

Identification—

A: Place a portion of Capsule contents, equivalent to about 500 mg of aluminum hydroxide, 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 10 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⟩.

Disintegration ⟨701⟩: 10 minutes, simulated gastric fluid TS being substituted for water in the test.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Acid-neutralizing capacity ⟨301⟩—Not less than 5 mEq of acid is consumed by the minimum single dose recommended in the labeling, and not less than 55.0% of the expected mEq value, calculated from the labeled quantity of $Al(OH)_3$, is obtained. Each mg of $Al(OH)_3$ has an expected acid-neutralizing capacity value of 0.0385 mEq.

Assay—

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

Procedure—Weigh accurately the contents of not fewer than 20 Capsules, and mix. Transfer an accurately weighed portion of the powder, equivalent to about 1.2 g of aluminum hydroxide, to a beaker, add 15 mL of hydrochloric acid, and heat until dissolved. Dilute with water to about 100 mL, mix, and filter quantitatively into a 500-mL volumetric flask, washing the filter with water. Proceed as directed in the *Assay* under *Dried Aluminum Hydroxide Gel*, beginning with "dilute with water to volume." Each mL of 0.05 M *Edetate disodium titrant* is equivalent to 3.900 mg of $Al(OH)_3$.

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

Topic/Question	Contact	Expert Committee
DRIED ALUMINUM HYDROXIDE GEL CAPSULES	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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