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Alumina and Magnesium Carbonate Tablets

» Alumina and Magnesium Carbonate Tablets contain the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of aluminum hydroxide [$Al(OH)_3$] and magnesium carbonate ($MgCO_3$).

Packaging and storage—Preserve in tight containers.

Identification—

A: Place about 1 g of finely powdered Tablets 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: To a 7-g portion of finely powdered Tablets add 10 mL of 3 N hydrochloric acid and 5 drops of methyl red TS, heat to boiling, and add 6 N ammonium hydroxide until the color of the solution changes to deep yellow. Continue boiling for 2 minutes, and filter: the filtrate responds to the tests for *Magnesium* ⟨191⟩.

C: Wash the precipitate obtained in *Identification* test *B* with a hot solution of ammonium chloride (1 in 50), and dissolve the precipitate in hydrochloric acid: the solution 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 for *Weight Variation* with respect to aluminum hydroxide and to magnesium carbonate.

Acid-neutralizing capacity ⟨301⟩—Not less than 5 mEq of acid is consumed by the minimum single dose recommended in the labeling.

Assay for aluminum hydroxide—

Potassium chloride solution—Prepare a solution containing 38.1 g of potassium chloride in each 1000 mL.

Digestion fluid—Mix 5 mL of hydrochloric acid, 10 mL of nitric acid, and 10 mL of water, and use promptly.

Aluminum stock solution—Transfer 1.000 g of aluminum metal to a 1000-mL volumetric flask, and add 50 mL of 6 N hydrochloric acid. Swirl to ensure contact of the aluminum and the acid, and allow the reaction to proceed until all of the aluminum has dissolved. Dilute with water to volume, and mix.

Standard preparations—To separate 100-mL volumetric flasks transfer 3.0 mL, 4.0 mL, and 5.0 mL of *Aluminum stock solution*, respectively. To each flask add 10 mL of *Potassium chloride solution* and 7.5 mL of *Digestion fluid*, dilute with water to volume, and mix. These *Standard preparations* contain 30, 40, and 50 µg of aluminum per mL, respectively.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 30 mg of aluminum hydroxide, to a 100-mL volumetric flask, add 25-mL of *Digestion fluid*, and heat on a steam bath for 30 minutes or on a hot plate until the volume is reduced by about one-half. Cool, dilute with water to volume, and mix. Filter, discarding the first 20 mL of the filtrate. Transfer 15.0 mL of the filtrate to a 50-mL volumetric flask, add 5.0 mL of *Potassium chloride solution*, dilute with water to volume, and mix. [Note—Reserve a portion of the filtrate for use in the *Assay for magnesium carbonate*.]

Procedure—Concomitantly determine the absorbances of the *Standard preparations* and the *Assay preparation* at the aluminum emission line at 309.3 nm, with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with an aluminum hollow-cathode lamp and a nitrous oxide–acetylene flame, using water as the blank. Plot the absorbances of the *Standard preparations* versus concentration, in µg per mL, of aluminum, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, *C*, in µg per mL, of aluminum in each mL of the *Assay preparation*. Calculate the quantity, in mg, of aluminum hydroxide [$Al(OH)_3$] in the portion of Tablets taken by the formula:

$$(78.00/26.98)(C/3)$$

in which 78.00 is the molecular weight of aluminum hydroxide, and 26.98 is the atomic weight of aluminum.

Assay for magnesium carbonate—

Lanthanum chloride solution—Transfer 17.6 g of lanthanum chloride to a 1000-mL volumetric flask, add 500 mL of water, and carefully add 50 mL of hydrochloric acid. Mix, and allow to cool. Dilute with water to volume, and mix.

Digestion fluid—Mix 5 mL of hydrochloric acid, 10 mL of nitric acid, and 10 mL of water, and use promptly.

Magnesium stock solution—Transfer 1.000 g of magnesium metal to a 1000-mL volumetric flask containing 50 mL of water, and slowly add 10 mL of hydrochloric acid. Dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 500-mL volumetric flask, dilute with water to volume, and mix.

Standard preparations—To separate 100-mL volumetric flasks transfer 4.0, 6.0, and 8.0 mL of *Magnesium stock solution*, respectively. To each flask add 0.5 mL of *Digestion fluid* and 10 mL of *Lanthanum chloride solution*, dilute with water to volume, and mix. These *Standard preparations* contain 0.40, 0.60, and 0.80 µg of magnesium per mL, respectively.

Assay preparation—Transfer an accurately measured volume of the filtrate used to prepare the *Assay preparation* in the *Assay for aluminum hydroxide*, equivalent to about 0.4 mg of magnesium carbonate, to a 200-mL volumetric flask, add 20 mL of *Lanthanum chloride solution*, dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard preparations* and the *Assay preparation* at the magnesium emission line at 285.2 nm, with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with a magnesium hollow-cathode lamp and an air–acetylene flame, using water as the blank. Plot the absorbances of the *Standard preparations* versus concentration, in µg per mL, of magnesium, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, *C*, in µg per mL, of magnesium in each mL of the *Assay preparation*. Calculate the quantity, in mg, of magnesium carbonate ($MgCO_3$) in the portion of Tablets taken by the formula:

$$(84.31/24.31)(20C/V)$$

in which 84.31 is the molecular weight of magnesium carbonate; 24.31 is the atomic weight of magnesium; and *V* is the volume taken, in mL, of the *Assay preparation* prepared as directed in the *Assay for aluminum hydroxide*.

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

Topic/Question	Contact	Expert Committee
ALUMINA AND MAGNESIUM CARBONATE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3
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