

Procedure—Pipet 20 mL of *Assay preparation* into a 400-mL beaker, add 180 mL of water and 20 mL of triethanolamine, and stir. Add 10 mL of ammonia–ammonium chloride buffer TS and 3 drops of an eriochrome black indicator solution prepared by dissolving 200 mg of eriochrome black T in a mixture of 15 mL of triethanolamine and 5 mL of dehydrated alcohol, and mix. Cool the solution to between 3° and 4° by immersion of the beaker in an ice bath, then remove and titrate with 0.05 M edetate disodium VS to a blue endpoint. Perform a blank determination, substituting 20 mL of water for the *Assay preparation*, and make any necessary correction. Each mL of 0.05 M edetate disodium consumed is equivalent to 6.521 mg of $Mg_2Si_3O_8$.

Alumina and Magnesium Trisilicate Tablets

» Alumina and Magnesium Trisilicate Tablets contain 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 trisilicate ($Mg_2Si_3O_8$).

Packaging and storage—Preserve in well-closed containers.

Labeling—Tablets prepared with the use of *Dried Aluminum Hydroxide Gel* 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 $Al(OH)_3$. Tablets intended for the temporary relief of heartburn (acid indigestion) due to acid reflux are so labeled. Tablets that must be chewed before swallowing are so labeled.

Identification—One powdered Tablet responds to the *Identification tests* under *Alumina and Magnesium Trisilicate Oral Suspension*.

Disintegration (701): 10 minutes, simulated gastric fluid TS being substituted for water in the test. [NOTE—Tablets that must be chewed before swallowing are exempt from this requirement.]

Uniformity of dosage units (905): meet the requirements for *Weight Variation* with respect to aluminum hydroxide and to magnesium trisilicate.

Acid-neutralizing capacity (301)—Not less than 5 mEq of acid is consumed by the minimum single dose recommended in the labeling. [NOTE—Tablets labeled for the temporary relief of heartburn (acid indigestion) due to acid reflux are exempt from this requirement.]

Foam [where Tablets are labeled for the temporary relief of heartburn (acid indigestion) due to acid reflux]—Finely powder a number of Tablets, accurately counted, equivalent to the minimum single dose recommended in the labeling, and transfer the powder to a 100-mL beaker having an inside diameter of 45 mm. Add 5 mL of alcohol and sufficient water to make 40 mL. Mix at 300 rpm for 60 seconds, using a magnetic stirrer and a 9.5- × 38-mm polytef-coated stirring bar. Stop the stirrer, and carefully add 10 mL of 0.5 N hydrochloric acid down the side of the beaker. Stir for 30 seconds at 300 rpm. Allow to stand for 10 minutes, and measure the thickness of the foam layer above the liquid in the beaker: the thickness of the foam is not less than 10 mm.

pH (791) [where Tablets are labeled for the temporary relief of heartburn (acid indigestion) due to acid reflux]: not less than 4.5, determined on the foam layer obtained in the *Foam* test. [NOTE—Take care that the electrodes do not touch the liquid beneath the foam.]

Assay for aluminum hydroxide—

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

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 600 mg of aluminum hydroxide, to a beaker, add 20 mL of water, stir, and slowly add 40 mL of 3 N hydrochloric acid. Heat gently, if necessary, to aid solution, cool, and transfer to a 200-mL volumetric flask. Wash the beaker with water, adding the washings to the flask, add water to volume, and mix.

Procedure—Pipet 10 mL of *Assay preparation* into a 250-mL beaker, add 20 mL of water, then add, in the order named and with continuous stirring, 25.0 mL of 0.05 M *Edetate disodium titrant* and 20 mL of acetic acid–ammonium acetate buffer TS, and heat the solution near the boiling temperature for 5 minutes. Cool, add 50 mL of alcohol and 2 mL of dithizone TS, and mix. Titrate with 0.05 M zinc sulfate VS until the color changes from green-violet to rose-pink. Perform a blank determination, substituting 10 mL of water for the *Assay preparation*, and make any necessary correction. Each mL of 0.05 M *Edetate disodium titrant* consumed is equivalent to 3.900 mg of $Al(OH)_3$.

Assay for magnesium trisilicate—

Potassium chloride solution—Prepare a solution in water containing 5 g of potassium chloride per 100 mL.

Magnesium standard 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—Transfer 16.0 mL, 18.0 mL, and 20.0 mL of *Magnesium standard solution* to separate 100-mL volumetric flasks, add 2.0 mL of *Potassium chloride solution* to each flask, dilute with water to volume, and mix. These *Standard preparations* contain 1.6, 1.8, and 2.0 µg of magnesium per mL, respectively. [NOTE—Prepare these solutions on the day of use.]

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 5 mg of magnesium trisilicate, to a 100-mL volumetric flask, and add 10 mL of 18 N sulfuric acid. Heat on a steam bath for 30 minutes with occasional swirling. Allow to cool, dilute with water to volume, and mix. Filter this solution, discarding the first 20 mL of the filtrate. Transfer 20.0 mL of the filtrate to a second 100-mL volumetric flask, add 2.0 mL of *Potassium chloride solution*, dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbance of the *Standard preparations* and the *Assay preparation* at the magnesium emission line at 285.2 nm, with an atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* (852)), equipped with a magnesium hollow-cathode lamp and a nitrous oxide–acetylene flame, using water as the blank. Plot the absorbances of the *Standard preparations*, in µg per mL, of magnesium, and draw the line best fitting the three plotted points. From the graph so obtained determine the concentration, *C*, in µg per mL, of magnesium in the *Assay preparation*. Calculate the quantity, in mg, of magnesium trisilicate ($Mg_2Si_3O_8$) in the portion of Tablets taken by the formula:

$$0.5C(260.86 / 48.62)$$

in which 260.86 is the molecular weight of anhydrous magnesium trisilicate and 48.62 is twice the atomic weight of magnesium.