each Tablet, as determined in the *Assay for magnesium carbonate*.

Alumina and Magnesium Trisilicate Oral Suspension

» Alumina and Magnesium Trisilicate Oral Suspension contains the equivalent of not less than 90.0 percent and not more than 110.0 per cent of the labeled amounts of aluminum hydroxide [$Al(OH)_3$] and magnesium trisilicate ($Mg_2Si_3O_8$).

Packaging and storage—Preserve in tight containers.

Identification—

A: To a mixture of 5 mL in 10 mL of 3 N hydrochloric acid add 5 drops of methyl red TS, heat to boiling, add 6 N ammonium hydroxide until the color of the solution changes to deep yellow, then continue boiling for 2 minutes, and filter: the filtrate responds to the tests for *Magnesium* ⟨191⟩.

B: Wash the solids on the filter obtained in *Identification* test *A* with hot ammonium chloride solution (1 in 50), add 10 mL of 3 N hydrochloric acid, and filter: the filtrate responds to the tests for *Aluminum* ⟨191⟩.

C: Transfer the filter paper and contents from *Identification* test *B* to a small platinum dish, ignite, cool in a desiccator, and weigh. Moisten the residue with water and add 6 mL of hydrofluoric acid. Evaporate to dr yness, ignite for 5 minutes, cool in a desiccator, and weigh: a loss of more than 10% in relation to the weight of the residue from the initial ignition indicates SiO_2.

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

pH ⟨791⟩: between 7.5 and 8.5.

Assay for aluminum hydroxide—

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

Assay preparation—Transfer about 10 g of well-shaken Oral Suspension to a tared beaker, and weigh accurately. Add 50 mL of water and 10 mL of hydrochloric acid, and digest on a steam bath for 1 hour. Cool, and filter into a 200-mL volumetric flask, washing the filter with water into the flask. Dilute with water to volume, and mix.

Procedure—Pipet 20 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 *Edetate disodium titrant* and 20 mL of acetic acid–ammonium acetate buffer TS, and heat near the boiling point for 5 minutes. Cool, add 50 mL of alcohol and 2 mL of dithizone TS, and mix. T itrate 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 *Assay preparation*, and make any necessar y 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—

Assay preparation—Prepare as directed in the *Assay for aluminum hydroxide*.

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. Per form a blank determination, substituting 20 mL of water for the *Assay preparation*, and make any necessar y 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 T risilicate Tablets contain not less than 90.0 per cent and not more than 110.0 per cent 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 temporar y relief of heartburn (acid indigestion) due to acid reflux are exempt from this requirement.]

Foam [where Tablets are labeled for the temporar y relief of heartburn (acid indigestion) due to acid reflux]— Finely powder a number of T ablets, 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 temporar y 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 necessar y, to aid solution, cool, and transfer to a 200-mL volumetric flask. W ash 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. Per form a blank determination,