

thol blue. Stir with a magnetic stirrer, and titrate immediately with 0.05 M edetate disodium VS until the solution is distinctly blue. Each mL of 0.05 M edetate disodium is equivalent to 5.004 mg of calcium carbonate (CaCO_3).

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• DISINTEGRATION (701)

Time: 45 min

Acceptance criteria: Meet the requirements

- **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements for *Weight Variation* with respect to aluminum hydroxide, to magnesium hydroxide, and to calcium carbonate.

SPECIFIC TESTS

• ACID-NEUTRALIZING CAPACITY (301)

Acceptance criteria: The acid consumed by the minimum single dose recommended in the labeling is NLT 5 mEq, and NLT the number of mEq calculated by the formula:

$$\text{Result} = 0.55 \times (F_A \times A) + 0.8 \times (F_M \times M) + 0.9 \times (F_C \times C)$$

- F_A = theoretical acid-neutralizing capacity of aluminum hydroxide [$\text{Al}(\text{OH})_3$], 0.0385 mEq
- A = amount of aluminum hydroxide [$\text{Al}(\text{OH})_3$] in the specimen tested, based on the labeled quantity (mg)
- F_M = theoretical acid-neutralizing capacity of magnesium hydroxide [$\text{Mg}(\text{OH})_2$], 0.0343 mEq
- M = amount of magnesium hydroxide [$\text{Mg}(\text{OH})_2$] in the specimen tested, based on the labeled quantity (mg)
- F_C = theoretical acid-neutralizing capacity of calcium carbonate (CaCO_3), 0.02 mEq
- C = amount of calcium carbonate (CaCO_3) in the specimen tested, based on the labeled quantity (mg)

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** Label the Chewable Tablets to indicate that they are to be chewed before being swallowed. Chewable Tablets prepared using 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 aluminum hydroxide [$\text{Al}(\text{OH})_3$].

Alumina, Magnesia, Calcium Carbonate, and Simethicone Chewable Tablets

DEFINITION

Alumina, Magnesia, Calcium Carbonate, and Simethicone Chewable Tablets contain NLT 90.0% and NMT 110.0% of the labeled amounts of aluminum hydroxide [$\text{Al}(\text{OH})_3$], magnesium hydroxide [$\text{Mg}(\text{OH})_2$], and calcium carbonate (CaCO_3), and an amount of polydimethylsiloxane [$[-(\text{CH}_3)_2\text{SiO}-]_n$] that is NLT 85.0% and NMT 115.0% of the labeled amount of simethicone.

IDENTIFICATION

• A. IDENTIFICATION TESTS—GENERAL, Calcium (191)

Sample solution: Cut a Chewable Tablet into pieces, add 50 mL of 1 N sulfuric acid, stir until the pieces disintegrate, and heat on a steam bath for 10 min. Cool, add 50 mL of alcohol, and stir. Place in an ice bath for

30 min. Filter while cold, retaining the filtrate for *Identification* test B. Wash the precipitate with 50 mL of 0.75 N sulfuric acid, and discard the washings. Dissolve the precipitate in 3 N hydrochloric acid, filter, and use the filtrate.

Acceptance criteria: Meet the requirements

• B. IDENTIFICATION TESTS—GENERAL, Aluminum (191)

Sample solution: To the filtrate obtained in *Identification* test A, add 5 drops of methyl red TS, and heat to boiling. Add 6 N ammonium hydroxide until the color of the solution changes to deep yellow, continue boiling for 2 min, and filter through hardened filter paper. (Retain the filtrate for *Identification* test C.) Wash the precipitate with 350 mL of a hot solution containing 20 mg/mL of ammonium chloride, discarding the washings. Dissolve the precipitate so obtained in 3 N hydrochloric acid.

Acceptance criteria: Meet the requirements

• C. IDENTIFICATION TESTS—GENERAL, Magnesium (191)

Sample solution: The filtrate obtained in *Identification* test B

Acceptance criteria: Meet the requirements

• D. INFRARED ABSORPTION (197S)

Sample solution: Prepare as directed in the Assay for *Polydimethylsiloxane*.

Analysis: Proceed as directed using a 0.5-mm cell.

Acceptance criteria: Meet the requirements

ASSAY

• ALUMINUM HYDROXIDE

Edetate disodium titrant: Prepare and standardize as directed in *Reagents, Volumetric Solutions, Edetate Disodium, Twentieth-Molar (0.05 M)*.

Sample solution: Transfer a number of Chewable Tablets, equivalent of about 665 mg of aluminum hydroxide, to a suitable beaker. Add 15 mL of hydrochloric acid, and swirl to dissolve the Chewable Tablets. Add 80 mL of water, and filter into a 200-mL volumetric flask. Wash the filter with water into the flask, and add water to volume.

Analysis: Pipet 20 mL of the *Sample solution* into a 250-mL beaker, 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 the solution near the boiling temperature for 5 min. Cool, add 50 mL of alcohol and 2 mL of dithizone TS. Titrate the excess edetate disodium 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 solution*, and make any necessary correction. Each mL of *Edetate disodium titrant* consumed is equivalent to 3.900 mg of $\text{Al}(\text{OH})_3$.

Acceptance criteria: 90.0%–110.0%

• MAGNESIUM HYDROXIDE

Lanthanum chloride solution: Transfer 17.6 g of lanthanum chloride to a 200-mL volumetric flask, add 100 mL of water, and carefully add 50 mL of hydrochloric acid. Allow to cool, and dilute with water to volume.

Dilute hydrochloric acid: Dilute 226 mL of hydrochloric acid to 1000 mL with water.

Potassium chloride solution: 30 mg/mL in water

Magnesium stock solution: Transfer 1.000 g of magnesium metal to a 1000-mL volumetric flask containing 10 mL of water, slowly add 10 mL of hydrochloric acid, and swirl to dissolve the metal. Dilute with water to volume. Transfer 1.0 mL of this solution to a 100-mL volumetric flask to obtain a solution containing 10 μg /mL of magnesium (Mg).

Standard solutions: To three separate 100-mL volumetric flasks each containing 5.0 mL of *Lanthanum chloride solution*, add 1.0, 2.0, and 3.0 mL, respectively, of the *Magnesium stock solution*. Dilute each with water to volume. These solutions contain 0.1, 0.2, and 0.3 μg /mL of magnesium (Mg), respectively.