Magnesium hydroxide content—

Test preparation—Transfer an accurately measured quantity of Oral Suspension, equivalent to about 1 g of magaldrate, to a 100-mL volumetric flask, add 30 mL of dilute hydrochloric acid (1 in 10), shake to dissolve, dilute with water to volume, and mix.

Procedure—Transfer 10.0 mL of *Test preparation* to a 400-mL beaker, and proceed as directed in the test for *Magnesium hydroxide content* under *Magaldrate*, beginning with "and dilute with water to about 200 mL." Not less than 492 mg and not more than 666 mg of magnesium hydroxide [$Mg(OH)_2$] per g of the labeled amount of magaldrate is found.

Aluminum hydroxide content—

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

Test preparation—Prepare as directed in the test for *Magnesium hydroxide content*.

Procedure—Transfer 10.0 mL of *Test preparation* and 20 mL of water to a 250-mL beaker, and proceed as directed for *Procedure* in the test for *Aluminum hydroxide content* under *Magaldrate*, beginning with "Add, with stirring, 25.0 mL of *Edetate disodium titrant*." Not less than 321 mg and not more than 459 mg of aluminum hydroxide [$Al(OH)_3$] per g of the labeled amount of magaldrate is found.

Other requirements—Evaporate a volume of Oral Suspension, equivalent to about 5 g of magaldrate, on a steam bath to dryness: the residue so obtained meets the requirements of the tests for *Arsenic* and *Heavy metals* under *Magaldrate*.

Assay for magaldrate—Transfer an accurately measured quantity of Oral Suspension, equivalent to about 3 g of magaldrate, to a beaker. Add 100.0 mL of 1 N hydrochloric acid VS, and mix, using a magnetic stirrer to achieve dissolution. Titrate the excess acid with 1 N sodium hydroxide VS to a pH of 3.0, determined potentiometrically. Perform a blank determination (see *Residual Titrations* under *Titrimetry* ⟨541⟩). Each mL of 1 N hydrochloric acid is equivalent to 35.40 mg of magaldrate [$Al_5Mg_{10}(OH)_{31}(SO_4)_2$].

Assay for polydimethylsiloxane—Transfer an accurately measured quantity of Oral Suspension, equivalent to about 250 mg of simethicone, to a 200-mL centrifuge bottle. Add an equal volume of hydrochloric acid, swirl to dissolve the Oral Suspension, add 25.0 mL of hexanes, and immediately close the bottle securely with a cap having an inert liner. Shake the bottle for 30 minutes, and centrifuge the mixture until a clear supernatant layer is obtained (*Assay preparation*). Prepare a *Standard preparation* of USP Polydimethylsiloxane RS in hexanes having a known concentration of about 10 mg per mL. Concomitantly determine the absorbances of the *Assay preparation* and the *Standard preparation* in 0.1-mm cells at the wavelength of maximum absorbance at about 7.9 μm and at the wavelengths of minimum absorbance at about 7.5 μm and 8.3 μm, with a suitable IR spectrophotometer, using hexanes as the blank. Draw a linear baseline between the two minima, and determine the absorbances for the *Standard preparation* and the *Assay preparation* with respect to the baseline, making any necessary correction for the blank. Calculate the quantity, in mg, of $[–(CH_3)_2SiO–]_n$ in the portion of Oral Suspension taken by the formula:

$$25C(A_U / A_S)$$

in which C is the concentration, in mg per mL, of USP Polydimethylsiloxane RS in the *Standard preparation;* and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation,* respectively.

Magaldrate and Simethicone Chewable Tablets

Former Title: Magaldrate and Simethicone Tablets

» Magaldrate and Simethicone Chewable Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of magaldrate [$Al_5Mg_{10}(OH)_{31}(SO_4)_2$], and an amount of polydimethylsiloxane $[–(CH_3)_2SiO–]_n$ that is not less than 85.0 percent and not more than 115.0 percent of the labeled amount of simethicone.

Packaging and storage—Preserve in well-closed containers.

Labeling—Label the Chewable Tablets to indicate that they are to be chewed before being swallowed.

USP Reference standards ⟨11⟩**—**
USP Magaldrate RS
USP Polydimethylsiloxane RS

Identification—

A: Transfer a quantity of powdered Chewable Tablets, equivalent to about 2 g of magaldrate, to a 100-mL centrifuge tube. Add about 60 mL of water, cap, and shake for 3 minutes. Centrifuge the suspension, and discard the supernatant. Repeat the washing with three more 60-mL portions of water. Transfer the residue to a 250-mL beaker, and heat on a steam bath to dryness: the residue so obtained meets the requirements of the *Identification* tests under *Magaldrate*.

B: The IR absorption spectrum, in the 7- to 11-μm region, determined in a 0.5-mm cell, of the *Assay preparation* prepared as directed in the *Assay for polydimethylsiloxane,* exhibits maxima only at the same wavelengths as that of the *Standard preparation* containing about 2 mg of USP Polydimethylsiloxane RS per mL prepared as directed in the *Assay for polydimethylsiloxane.*

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩**—**Chewable Tablets meet the requirements of the test for absence of *Escherichia coli.*

Uniformity of dosage units ⟨905⟩**:** meet the requirements for *Weight Variation* with respect to magaldrate.

Acid-neutralizing capacity—Proceed as directed under *Acid-neutralizing Capacity* ⟨301⟩. The acid consumed by the minimum single dose recommended in the labeling is not less than 5 mEq, and not less than the number of mEq calculated by the formula:

$$0.8(0.0282\ M)$$

in which 0.0282 is the theoretical acid-neutralizing capacity, in mEq per mg, of magaldrate, and M is the quantity, in mg, of the labeled amount of magaldrate.

Magnesium hydroxide content—

Test preparation—Weigh and finely powder not fewer than 20 Chewable Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 1 g of magaldrate, to a 100-mL volumetric flask, add 30 mL of dilute hydrochloric acid (1 in 10), shake for 15 minutes, dilute with water to volume, and mix.

Procedure—Transfer 10.0 mL of the *Test preparation* to a 400-mL beaker, and proceed as directed in the test for *Magnesium hydroxide content* under *Magaldrate,* beginning with "and dilute with water to about 200 mL." Not less than 492 mg and not more than 666 mg of magnesium hydroxide [$Mg(OH)_2$] per g of the labeled amount of magaldrate is found.

Aluminum hydroxide content—

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

Test preparation—Prepare as directed in the test for *Magnesium hydroxide content*.

Procedure—Transfer 10.0 mL of *Test preparation* and 20 mL of water to a 250-mL beaker, and proceed as directed for *Procedure* in the test for *Aluminum hydroxide content* under *Magaldrate*, beginning with "Add, with stirring, 25.0 mL of *Edetate disodium*." Not less than 321 mg and not more than 459 mg of aluminum hydroxide [$Al(OH)_3$] per g of the labeled amount of magaldrate is found.

Assay for magaldrate—Weigh and finely powder not fewer than 20 Chewable Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 6 g of magaldrate, to a 200-mL volumetric flask. Add 100.0 mL of 2 N hydrochloric acid VS, and swirl by mechanical means for 30 minutes. Dilute with water to volume, mix, and filter. Transfer 100.0 mL of the filtrate to a beaker. Titrate the excess acid with 1 N sodium hydroxide VS to a pH of 3.0, determined potentiometrically. Perform a blank determination (see *Residual Titrations* under *Titrimetry* ⟨541⟩). Each mL of 2 N hydrochloric acid is equivalent to 70.80 mg of $Al_5Mg_{10}(OH)_{31}(SO_4)_2$.

Assay for polydimethylsiloxane—Weigh and finely powder not fewer than 20 Chewable Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 20 mg of simethicone, to a 60-mL separator. Add 10.0 mL of hexanes and 25 mL of 6 N hydrochloric acid, cap the separator, and shake by mechanical means for not less than 2 hours. Allow to stand for about 10 minutes, and drain off as much of the lower, aqueous layer as possible without removing any of the unseparated interphase. Add 25 mL of 4 N sodium hydroxide to the separator, cap it, and shake by mechanical means for 1 hour. Transfer the mixture from the separator to a 50-mL centrifuge tube, cap, and centrifuge to obtain clear layers. Transfer not less than 5 mL of the clear upper hexanes layer to a test tube containing about 0.5 g of anhydrous sodium sulfate. Cap the tube, shake vigorously, and allow to stand to obtain a clear supernatant (*Assay preparation*). Prepare three *Standard preparations* in hexanes having known concentrations of about 1.6, 2.0, and 2.4 mg of USP Polydimethylsiloxane RS per mL, respectively. Concomitantly determine the absorbances of the *Assay preparation* and the *Standard preparations* in a 0.5-mm cell at the wavelength of maximum absorbance at about 1260 cm^{-1} with an IR spectrophotometer, using hexanes as the blank. [NOTE—Between each measurement, rinse the cell with heptane, empty, and dry it.] Plot the absorbances for the *Standard preparations* versus concentration, in mg per mL, of USP Polydimethylsiloxane RS, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, *C*, in mg per mL, of polydimethylsiloxane in the *Assay preparation.* Calculate the quantity, in mg, of $[–(CH_3)_2SiO–]_n$ in the portion of Chewable Tablets taken by multiplying *C* by 10.

Milk of Magnesia

$Mg(OH)_2$ 58.32
Magnesium hydroxide.
Magnesium hydroxide [1309-42-8].

» Milk of Magnesia is a suspension of Magnesium Hydroxide. Milk of Magnesia, Double-Strength Milk of Magnesia, and Triple-Strength Milk of Magnesia contain not less than 90.0 percent and not more than 115.0 percent of the labeled amount of $Mg(OH)_2$, the labeled amount being 80, 160, and 240 mg of $Mg(OH)_2$ per mL, respectively. It may contain not more than 0.05 percent of a volatile oil or a blend of volatile oils, suitable for flavoring purposes.

Packaging and storage—Preserve in tight containers, preferably at a temperature not exceeding 35°. Avoid freezing.

Labeling—Double- or Triple-Strength Milk of Magnesia is so labeled, or may be labeled as 2× or 3× Concentrated Milk of Magnesia, respectively.

Identification—A solution of the equivalent of 1 g of regular-strength Milk of Magnesia in 2 mL of 3 N hydrochloric acid meets the requirements of the tests for *Magnesium* ⟨191⟩.

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩**—**Its total aerobic microbial count does not exceed 100 cfu per mL, and it meets the requirements of the test for absence of *Escherichia coli.*

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 the number of mEq calculated by the formula:

$$0.8(0.0343M)$$

in which 0.0343 is the theoretical acid-neutralizing capacity, in mEq, of $Mg(OH)_2$; and *M* is the quantity, in mg, of $Mg(OH)_2$ in the specimen tested, based on the labeled quantity.

Soluble alkalies—Centrifuge about 50 mL of Milk of Magnesia. Dilute 5.0 mL of the clear supernatant with 40 mL of water. Add 1 drop of methyl red TS, and titrate the solution with 0.10 N sulfuric acid to the production of a persistent pink color: not more than 1.0 mL of the acid is required. Where the specimen is Double- or Triple-Strength Milk of Magnesia, not more than 2.0 or 3.0 mL of the acid is required, respectively.

Carbonate and acid-insoluble matter—To the equivalent of 1 g of regular-strength Milk of Magnesia add 2 mL of 3 N hydrochloric acid: not more than a slight effervescence occurs, and the solution is not more than slightly turbid.

Assay—Transfer an accurately measured quantity of Milk of Magnesia, previously shaken in its original container, equivalent to about 800 mg of magnesium hydroxide, to a 250-mL volumetric flask. Dissolve in 30 mL of 3 N hydrochloric acid, dilute with water to volume, and mix. Filter, if necessary, and transfer 25.0 mL of the filtrate to a beaker containing 75 mL of water, and mix. Adjust the reaction of the solution with 1 N sodium hydroxide to a pH of 7 (using pH indicator paper; see *Indicator and Test Papers* under *Reagents*, in the section *Reagents, Indicators, and Solutions*), add 5 mL of ammonia–ammonium chloride buffer TS and 0.15 mL of eriochrome black TS, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 2.916 mg of $Mg(OH)_2$.

Magnesia Tablets

DEFINITION
Magnesia Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of magnesium hydroxide [$Mg(OH)_2$].

IDENTIFICATION
• **A. IDENTIFICATION TESTS—GENERAL,** *Magnesium* ⟨**191**⟩
Sample solution: Crush several Tablets, and dissolve 1 g of the powder in 20 mL of 3 N hydrochloric acid.
Acceptance criteria: Meet the requirements

ASSAY
• **PROCEDURE**
Sample solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 250 mg of magnesium hydroxide, to a 100-mL volumetric flask. Dissolve in 10 mL of 3 N hydrochloric acid, and dilute with water to volume. Filter, if necessary, and transfer 25.0 mL of the filtrate to a beaker containing 75 mL of water.
Analysis: Adjust the reaction of the solution with 1 N sodium hydroxide to a pH of 7 (using pH indicator paper; see *Reagents, Indicators, and Solutions—Indicator and Test Pa-*