Blank—Place 30.0 mL of chloroform and 60 mL of *Dilute hydrochloric acid* in a separator, shake for 30 seconds, and allow the phases to separate. Remove about 10 mL of the lower, organic layer to a screw-capped, 15-mL test tube containing 0.5 g of anhydrous sodium sulfate. Close the tube with a screw-cap having an inert liner, agitate vigorously, and centrifuge the mixture until a clear supernatant is obtained.

Procedure—Concomitantly determine the absorbances of the *Standard preparation* and the *Assay preparation* in 0.5-mm cells at the wavelength of maximum absorbance at about 7.9 µm, with a suitable IR spectrophotometer, using the *Blank* to set the instrument. Calculate the quantity, in mg, of $[–(CH_3)_2SiO–]_n$ in each Chewable Tablet taken by the formula:

$$(W/N)(A_U / A_S)$$

in which W is the weight, in mg, of USP Polydimethylsiloxane RS used to prepare the *Standard preparation; N* is the number of Chewable Tablets taken to prepare the *Assay preparation;* and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation,* respectively.

Alumina, Magnesia, and Simethicone Oral Suspension

» Alumina, Magnesia, and Simethicone Oral Suspension contains the equivalent of not less than 90.0 percent and not more than 115.0 per cent of the labeled amounts of aluminum hydroxide [$Al(OH)_3$] and magnesium hydroxide [$Mg(OH)_2$], and an amount of polydimethylsiloxane $[–(CH_3)_2SiO–]_n$ that is not less than 85.0 per cent and not more than 115.0 per cent of the labeled amount of simethicone.

Packaging and storage—Preserve in tight containers, and avoid freezing.

Labeling—Oral Suspension 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 $Al(OH)_3$. Label it to state the sodium content if it is greater than 1 mg per mL.

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

Identification—

A: *Infrared Absorption* ⟨197S⟩—

Cell: 0.5 mm.

Solution: prepared as directed in the *Assay for polydimethylsiloxane*.

B: To a solution of 5 g 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 just changes to deep yellow, then continue boiling for 2 minutes, and filter: the filtrate so obtained responds to the tests for *Magnesium* ⟨191⟩.

C: Wash the precipitate obtained in *Identification* test *B* with hot ammonium chloride solution (1 in 50), and dissolve the precipitate in hydrochloric acid. Divide this solution into two portions: the dropwise addition of 6 N ammonium hydroxide to one portion yields a gelatinous white precipitate, which does not dissolve in an excess of 6 N ammonium hydroxide. The dropwise addition of 1 N sodium hydroxide to the other portion yields a gelatinous white precipitate, which dissolves in an excess of 1 N sodium hydroxide, leaving some turbidity.

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⟩**—**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:

$$0.55(0.0385A) + 0.8(0.0343\ M)$$

in which 0.0385 and 0.0343 are the theoretical acid-neutralizing capacities, in mEq, of $Al(OH)_3$ and $Mg(OH)_2$, respectively, and A and M are the quantities, in mg, of $Al(OH)_3$ and $Mg(OH)_2$ in the specimen tested, based on the labeled quantities.

pH ⟨791⟩: between 7.0 and 8.6.

Sodium content—

Potassium chloride solution—Prepare a solution of potassium chloride in water containing 38 mg per mL.

Sodium chloride stock solution—Dissolve a suitable quantity of sodium chloride, previously dried at 105 ° for 2 hours and accurately weighed, in water, and dilute quantitatively and stepwise with water to obtain a solution containing 25.42 µg per mL (10 µg of sodium per mL).

Standard preparations—On the day of use, transfer 4.0 mL of 1 N hydrochloric acid and 10.0 mL of *Potassium chloride solution* to each of two 100-mL volumetric flasks. To the respective flasks add 5.0 mL and 10.0 mL of *Sodium chloride stock solution*. Dilute with water to volume, and mix. These solutions contain about 0.5 µg and 1.0 µg of sodium per mL, respectively.

Test preparation—Transfer 5.0 mL of Oral Suspension, previously well-shaken in its original container, to a 100-mL volumetric flask, add 50 mL of 1 N hydrochloric acid, boil for 15 minutes, cool to room temperature, dilute with water to volume, and mix. Filter, discarding the first few mL of the filtrate. Transfer 5.0 mL of the filtrate to a 100-mL volumetric flask containing 10.0 mL of *Potassium chloride solution*, dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard preparations* and the *Test preparation* at the sodium emission line at 589.0 nm with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-scattering* ⟨851⟩) equipped with a sodium hollow-cathode lamp and an air–acetylene flame, using as a blank a solution prepared by pipeting 4 mL of 1 N hydrochloric acid and 10.0 mL of *Potassium chloride solution* into a 100-mL volumetric flask, diluting with water to volume, and mixing. Plot the absorbances of the *Standard preparations* versus concentrations, in µg per mL, of sodium and draw a straight line between the plotted points. From the graph so obtained, determine the concentration, C, in µg per mL, of sodium in the *Test preparation*. Calculate the quantity, in mg, of sodium in each mL of Oral Suspension taken by the formula:

$$0.4C.$$

Assay for aluminum hydroxide—

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

Assay preparation—Transfer an accurately measured volume of Oral Suspension, previously well-shaken in its original container, equivalent to about 800 mg of aluminum hydroxide, to a suitable beaker. Add 20 mL of water, stir, and slowly add 10 mL of hydrochloric acid. Heat gently, if necessary, to aid solution, cool, and filter into a 200-mL volumetric flask. Wash the filter with water into the flask, add water to volume, and mix.

Procedure—Pipet 10 mL of the *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 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 making 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 hydroxide—

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

Procedure—Pipet a volume of the *Assay preparation*, equivalent to about 40 mg of magnesium hydroxide, into a 400-mL beaker, add 200 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 water for the *Assay preparation*, and make any necessary correction. Each mL of 0.05 M edetate disodium consumed is equivalent to 2.916 mg of $Mg(OH)_2$.

Assay for polydimethylsiloxane—Transfer an accurately measured volume of Oral Suspension, equivalent to about 50 mg of simethicone, to a suitable round, narrow-mouth, screw-capped, 120-mL bottle, add 40 mL of 0.1 N sodium hydroxide, and swirl to disperse. Add 25.0 mL of toluene, close the bottle securely with a cap having an inert liner, and shake for 15 minutes, accurately timed, on a reciprocating shaker (e.g., about 200 oscillations per minute and a stroke of 38 ± 2 mm). Transfer the mixture to a 125-mL separator. Remove about 5 mL of the upper, organic layer to a screw-capped, 15-mL test tube containing 0.5 g of anhydrous sodium sulfate. Close the tube with a screw-cap having an inert liner, agitate vigorously, and centrifuge the mixture until a clear supernatant (*Assay preparation*) is obtained. Prepare a *Standard preparation* similarly, except to dissolve about 50 mg of USP Polydimethylsiloxane RS, accurately weighed, in 25.0 mL of toluene, add 40 mL of 0.1 N sodium hydroxide, and add a volume of water equal to that of the specimen of Oral Suspension taken. Prepare a blank by mixing 10 mL of toluene with 0.5 g of anhydrous sodium sulfate and centrifuging to obtain a clear supernatant. Concomitantly determine the absorbances of the solutions in 0.5-mm cells at the wavelength of maximum absorbance at about 7.9 µm, with a suitable IR spectrophotometer, using the blank to set the instrument. Calculate the quantity, in mg, of $[–(CH_3)_2SiO–]_n$ in each mL of the Oral Suspension taken by the formula:

$$(W / V)(A_U / A_S)$$

in which W is the weight, in mg, of USP Polydimethylsiloxane RS used in preparing the *Standard preparation*; V is the volume, in mL, of Oral Suspension taken; and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation*, respectively.

Alumina, Magnesia, and Simethicone Chewable Tablets

Former Title: Alumina, Magnesia, and Simethicone Tablets

» Alumina, Magnesia, and Simethicone Chewable Tablets contain the equivalent of not less than 90.0 percent and not more than 115.0 per cent of the labeled amounts of aluminum hydroxide $[Al(OH)_3]$ and magnesium hydroxide $[Mg(OH)_2]$, and an amount of polydimethylsiloxane $[–(CH_3)_2SiO–]_n$ that is not less than 85.0 per cent and not more than 115.0 per cent 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. Label the Chewable Tablets to state the sodium content if it is greater than 5 mg per Tablet. The Chewable Tablets 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 $Al(OH)_3$.

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

Identification—

A: *Infrared Absorption* ⟨197S⟩—

Cell: 0.5 mm.

Solution: prepared as directed in the *Assay for polydimethylsiloxane.*

B: To a portion of finely powdered Chewable Tablets, equivalent to about 600 mg of magnesium hydroxide, add 25 mL of 3 N hydrochloric acid and 25 mL of water, and mix. Boil gently for 2 minutes. Allow to cool, and filter. Add 5 drops of methyl red TS, heat to boiling, and add 6 N ammonium hydroxide until the color of the solution just turns to deep yellow. Continue boiling for 2 minutes, and filter: the filtrate so obtained meets the requirements of 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 so obtained meets the requirements for *Identification* test *C* under *Alumina, Magnesia, and Simethicone Oral Suspension.*

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

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:

$$0.55(0.0385A) + 0.8(0.0343\ M)$$

in which 0.0385 and 0.0343 are the theoretical acid-neutralizing capacities, in mEq, of $Al(OH)_3$ and $Mg(OH)_2$, respectively, and A and M are the quantities, in mg, of $Al(OH)_3$ and $Mg(OH)_2$ in the specimen tested, based on the labeled quantities.

Sodium content—

Potassium chloride solution, Sodium chloride stock solution, and *Standard preparations*—Prepare as directed in the test for *Sodium content* under *Alumina, Magnesia, and Simethicone Oral Suspension.*

Test preparation—Weigh and finely powder not fewer than 20 Chewable Tablets. Transfer an accurately weighed portion of the powder, equivalent to the average weight of 1 Chewable Tablet, to a 100-mL volumetric flask. Add 50 mL of 1 N hydrochloric acid, boil for 15 minutes, cool to room temperature, dilute with water to volume, and mix. Filter, discarding the first few mL of the filtrate. Transfer 5.0 mL of the filtrate to a 100-mL volumetric flask containing 10.0 mL of *Potassium chloride solution,* dilute with water to volume, and mix.

Procedure—Proceed as directed in the test for *Sodium content* under *Alumina, Magnesia, and Simethicone Oral Suspension.* Calculate the quantity, in mg, of sodium per Chewable Tablet taken by the formula:

$$2C$$

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 fewer than 20 Chewable Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 800 mg of aluminum hydroxide, to a 150-mL beaker, add 20 mL of water, stir, and slowly add 30 mL of 3 N hydrochloric acid. Heat gently, if necessary, to aid solution, cool to room temperature, and filter into a 200-