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 [$Al(OH)_3$], 0.0385 mEq
A = amount of aluminum hydroxide [$Al(OH)_3$] in the specimen tested, based on the labeled quantity (mg)
F_M = theoretical acid-neutralizing capacity of magnesium hydroxide [$Mg(OH)_2$], 0.0343 mEq
M = amount of magnesium hydroxide [$Mg(OH)_2$] 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)

- **Sodium Content**

Potassium chloride solution: 30 mg/mL of potassium chloride

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

Standard stock solution: Transfer 2.5420 g of sodium chloride, previously dried at 105° for 2 h, to a 1000-mL volumetric flask, and dissolve in and dilute with water to volume. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, and dilute with water to volume. Transfer 10.0 mL of this solution to a second 100-mL volumetric flask, and dilute with water to volume.

Standard solutions: To three separate 100-mL volumetric flasks, each containing 10.0 mL of *Potassium chloride solution* and 3.0 mL of *Dilute hydrochloric acid*, add 10.0, 20.0, and 30.0 mL, respectively, of the *Standard stock solution*. The resulting *Standard solutions* contain 1.0, 2.0, and 3.0 µg/mL of sodium (Na), respectively.

Sample stock solution: Weigh 10 Chewable Tablets, and determine the average weight, *A*, in mg. Cut 4 Chewable Tablets into pieces, combine the pieces, and weigh them. Transfer the combined pieces to a 500-mL volumetric flask, add 150 mL of *Dilute hydrochloric acid*, and swirl gently to dissolve the pieces. Dilute with water to volume.

Sample solution: Transfer 10.0 mL of the *Sample stock solution* to a 100-mL volumetric flask, add 10.0 mL of *Potassium chloride solution*, and dilute with water to volume.

Blank solution: Combine 3.0 mL of *Dilute hydrochloric acid* and 10.0 mL of *Potassium chloride solution* in a 100-mL volumetric flask, and dilute with water to volume.

Analysis

Samples: *Standard solution* and *Sample solution*

Concomitantly determine the absorbances of the *Standard solutions* and the *Sample solution* at the sodium emission line at 589.0 nm with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy* ⟨852⟩) equipped with a sodium hollow–cathode lamp and an air–acetylene flame, using the *Blank solution* as the blank. Plot the absorbances of the *Standard solutions* versus concentration, in µg/mL, of sodium, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, *C*, in µg/mL, of sodium in the *Sample solution*.

Calculate the quantity, in mg, of sodium (Na) in each Chewable Tablet taken:

$$\text{Result} = (A/W) \times C \times D \times F$$

A = average weight of each Tablet (mg)
W = weight of the portion of Chewable Tablets taken to prepare the *Sample solution* (mg)
C = concentration of sodium in the *Sample solution* (µg/mL)
D = dilution factor for the *Sample solution*, 5000
F = conversion factor, 0.001 mg/µg

Acceptance criteria: Chewable Tablets contain NMT 5 mg/Tablet of sodium, except when labeled as containing more than 5 mg/Tablet of sodium; then they contain NMT 110% of the labeled amount.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **Labeling:** The labeling indicates that the Chewable Tablets are to be chewed before swallowing. Label the Chewable Tablets to state the sodium content, if it is greater than 5 mg/Chewable Tablet.
- **USP Reference Standards** ⟨11⟩

USP Polydimethylsiloxane RS

Alumina, Magnesia, and Simethicone Oral Suspension

DEFINITION

Alumina, Magnesia, and Simethicone Oral Suspension contains the equivalent of NLT 90.0% and NMT 115.0% of the labeled amounts of aluminum hydroxide [$Al(OH)_3$] and magnesium hydroxide [$Mg(OH)_2$], and an amount of polydimethylsiloxane ([$–(CH_3)_2 SiO–]_n$) that is NLT 85.0% and NMT 115.0% of the labeled amount of simethicone.

IDENTIFICATION

- **A. 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: Meets the requirements

- **B. Identification Tests—General,** *Magnesium* ⟨191⟩

Sample solution: Add 5 g of Oral Suspension to 10 mL of 3 N hydrochloric acid, then 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 min, and filter.

Acceptance criteria: Meets the requirements

- **C. Identification Tests—General,** *Aluminum* ⟨191⟩

Sample solution: Wash the precipitate from *Identification* test *B* with hot ammonium chloride solution (1 in 50), and dissolve the precipitate in hydrochloric acid. Divide this solution into two portions.

Analysis 1: Add, dropwise, 6 N ammonium hydroxide to one portion of the *Sample solution*.

Acceptance criteria 1: A gelatinous white precipitate, which does not dissolve in an excess of 6 N ammonium hydroxide, is obtained.

Analysis 2: Add, dropwise, 1 N sodium hydroxide to the second portion of the *Sample solution*.

Acceptance criteria 2: A gelatinous white precipitate, which dissolves in an excess of 1 N sodium hydroxide, leaving some turbidity, is obtained.

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 measured amount of Oral Suspension, previously well shaken in its original container, equivalent to 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 volu-