W_U = nominal amount of simethicone in the portion of the Chewable Tablets taken to prepare the *Sample solution* (mg)

Acceptance criteria: 85.0%–115.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units** ⟨905⟩: Meet the requirements for *Weight Variation* with respect to aluminum hydroxide and to magnesium hydroxide

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:

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

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)

• **Sodium Content**

Potassium chloride solution: 38 mg/mL of potassium chloride

Sodium chloride stock solution: 25.42 µg/mL of sodium chloride (previously dried at 105° for 2 h) in water. The solution contains 10 µg/mL of sodium.

Standard solutions: 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 and 10.0 mL of *Sodium chloride stock solution*. Dilute with water to volume. The resulting *Standard solutions* contain 0.5 and 1.0 µg/mL of sodium (Na), respectively.

Sample solution: Weigh and finely powder NLT 20 Chewable Tablets. Transfer a 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 min, cool to room temperature, and dilute with water to volume. 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*, and dilute with water to volume.

Blank solution: Combine 4.0 mL of 1 N 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 a straight line between the 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:

$$\text{Result} = C \times D \times F$$

C = concentration of sodium in the *Sample solution* (µg/mL)

D = dilution factor for the *Sample solution*, 2000

F = conversion factor, 0.001 mg/µg

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. Label the Chewable Tablets to state the sodium content if it is greater than 5 mg/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 aluminum hydroxide [$Al(OH)_3$].

• **USP Reference Standards** ⟨11⟩

USP Polydimethylsiloxane RS

Alumina and Magnesium Carbonate Oral Suspension

» Alumina and Magnesium Carbonate Oral Suspension contains the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of aluminum hydroxide [$Al(OH)_3$] and magnesium carbonate ($MgCO_3$).

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

Identification—

A: Place about 1 g in a flask equipped with a stopper and glass tubing, the tip of which is immersed in calcium hydroxide TS in a test tube. Add 5 mL of 3 N hydrochloric acid to the flask, and immediately insert the stopper: gas evolves in the flask and a precipitate is formed in the test tube.

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 changes to deep yellow, then continue boiling for 2 minutes, and filter: the filtrate responds to 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 responds to the tests for *Aluminum* ⟨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*, *Salmonella* species, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*.

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:

$$0.55(0.0385A) + 0.8(0.024\,M)$$

in which 0.0385 and 0.024 are the theoretical acid-neutralizing capacities, in mEq, of $Al(OH)_3$ and $MgCO_3$, respectively; and A and M are the respective quantities, in mg, of $Al(OH)_3$ and $MgCO_3$ in the specimen tested, based on the labeled quantities.