Analysis: Proceed as directed in the chapter.
Acceptance criteria: NLT 5 mEq of acid is consumed by the minimum single dose recommended in the labeling, and NLT the number of mEq calculated as follows:

$$\text{Result} = (C \times A_{NC}) \times F$$

C = quantity of $CaCO_3$ in the sample tested (mg), based on the labeled amount
A_{NC} = theoretical acid-neutralizing capacity of $CaCO_3$, 0.02 mEq/mg
F = acceptance factor for the lower limit of the required acid-neutralizing capacity, 0.9

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** Label it to indicate whether it is for use as an antacid, or as a dietar y supplement, or both.

Calcium Carbonate and Magnesia Tablets

DEFINITION
Calcium Carbonate and Magnesia T ablets contain NLT 90.0% and NMT 110.0% of the labeled amount of calcium carbonate ($CaCO_3$) and NLT 90.0% and NMT 115.0% of the labeled amount of magnesium hydroxide [$Mg(OH)_2$].

IDENTIFICATION
- **A. IDENTIFICATION TESTS—GENERAL,** *Calcium* ⟨**191**⟩**:** The addition of 3 N hydrochloric acid to the T ablets produces effervescence. The resulting solution, after being boiled to expel carbon dioxide and neutralized with 6 N ammonium hydroxide, meets the requirements of the tests.
- **B. IDENTIFICATION TESTS—GENERAL,** *Magnesium* ⟨**191**⟩
  Sample solution: Heat 2 T ablets in 20 mL of 1 N sulfuric acid. Cool, add 20 mL of alcohol, mix, and allow to stand for 30 min. Filter this solution, and add 2 mL of 1 N hydrochloric acid to the filtrate.
  Acceptance criteria: The solution meets the requirements.

ASSAY
- **CALCIUM CARBONATE**
  Sample solution: Finely powder NLT 20 T ablets. Transfer a portion of the powder, equivalent to 400 mg of calcium carbonate, to a beaker with 25 mL of water. Add 40 mL of 1 N hydrochloric acid. Heat on a steam bath for 30 min, allow to cool, and transfer with the aid of water to a 100-mL volumetric flask. Dilute with water to volume, mix, filter, and use the filtrate. [NOTE—Reserve a portion of it for the test for *Magnesium Hydroxide*.]
  Analysis: Transfer 20.0 mL of the *Sample solution* to a suitable container, dilute with water to 100 mL, and add 30 mL of 1 N sodium hydroxide, 5 mL of triethanolamine, and 100 mg of hydroxy naphthol blue. T itrate with 0.05 M edetate disodium VS until the solution is deep blue in color. Each mL of 0.05 M edetate disodium is equivalent to 5.004 mg of $CaCO_3$.
  Acceptance criteria: 90.0%–110.0%
- **MAGNESIUM HYDROXIDE**
  Sample solution: Use the *Sample solution* from the test for *Calcium Carbonate*.
  Analysis: Transfer a portion of the *Sample solution*, equivalent to 120 mg of calcium carbonate and magnesium hydroxide combined, to a suitable container. Dilute with water to 100 mL, and add 10 mL of ammonia–ammonium chloride buffer TS, 5 mL of triethanolamine, and 0.3 mL of eriochrome black TS. T itrate with 0.05 M edetate disodium VS to a blue endpoint. The volume, in mL, of 0.05 M edetate disodium consumed, less the volume of 0.05 M edetate disodium corresponding to the content of calcium carbonate in the volume, in mL, of the *Sample solution* taken, represents the volume, in mL, of 0.05 M edetate disodium equivalent to the quantity of magnesium hydroxide present. Each mL of 0.05 M edetate disodium is equivalent to 2.916 mg of $Mg(OH)_2$.
  Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS
- **UNIFORMITY OF DOSAGE UNITS** ⟨**905**⟩**:** Meet the requirements for *Weight Variation* with respect to calcium carbonate and to magnesia

SPECIFIC TESTS
- **ACID-NEUTRALIZING CAPACITY** ⟨**301**⟩
  Analysis: NLT 5 mEq of acid is consumed by the minimum single dose recommended in the labeling, and NL T the number of mEq calculated by the formula:

$$\text{Result} = [0.8 \times (F_M \times M)] + [0.9 \times (F_C \times C)]$$

F_M = theoretical acid-neutralizing capacity of $Mg(OH)_2$, 0.0343 mEq
M = quantity of $Mg(OH)_2$ in the sample tested (mg), based on the labeled quantity
F_C = theoretical acid-neutralizing capacity of $CaCO_3$, 0.02 mEq
C = quantity of $CaCO_3$ in the sample tested (mg), based on the labeled quantity

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Calcium Carbonate and Magnesia Chewable Tablets

DEFINITION
Calcium Carbonate and Magnesia Chewable T ablets contain NLT 90.0% and NMT 110.0% of the labeled amount of calcium carbonate ($CaCO_3$) and NLT 90.0% and NMT 115.0% of the labeled amount of magnesium hydroxide [$Mg(OH)_2$].

IDENTIFICATION
- **A. IDENTIFICATION TESTS—GENERAL,** *Calcium* ⟨**191**⟩**:** The addition of 3 N hydrochloric acid to the Chewable T ablets produces effervescence. The resulting solution, after being boiled to expel carbon dioxide and neutralized with 6 N ammonium hydroxide, meets the requirements of the tests.
- **B. IDENTIFICATION TESTS—GENERAL,** *Magnesium* ⟨**191**⟩
  Sample solution: Heat 2 Chewable T ablets in 20 mL of 1 N sulfuric acid. Cool, add 20 mL of alcohol, mix, and allow to stand for 30 min. Filter this solution, and add 2 mL of 1 N hydrochloric acid to the filtrate.
  Acceptance criteria: The solution meets the requirements.

ASSAY
- **CALCIUM CARBONATE**
  Sample solution: Finely powder NLT 20 Chewable T ablets. Transfer a portion of the powder, equivalent to 400 mg of calcium carbonate, to a beaker with 25 mL of water. Add 40 mL of 1 N hydrochloric acid. Heat on a steam bath for 30 min, allow to cool, and transfer with the aid of water to a 100-mL volumetric flask. Dilute with water to volume, mix, filter, and use the filtrate. [NOTE—Reserve a portion of it for the test for *Magnesium Hydroxide*.]
  Analysis: Transfer 20.0 mL of the *Sample solution* to a suitable container, dilute with water to 100 mL, and add 30 mL of 1 N sodium hydroxide, 5 mL of triethanolamine, and 100 mg of hydroxy naphthol blue. T itrate with 0.05 M edetate disodium VS until the solution is deep blue in color. Each mL of 0.05 M edetate disodium is equivalent to 5.004 mg of $CaCO_3$.

Acceptance criteria: 90.0%–110.0%

- **MAGNESIUM HYDROXIDE**

Sample solution: Use the *Sample solution* from the test for *Calcium Carbonate*.

Analysis: Transfer a portion of the *Sample solution*, equivalent to 120 mg of calcium carbonate and magnesium hydroxide combined, to a suitable container. Dilute with water to 100 mL, and add 10 mL of ammonia–ammonium chloride buffer TS, 5 mL of triethanolamine, and 0.3 mL of eriochrome black TS. Titrate with 0.05 M edetate disodium VS to a blue endpoint. The volume, in mL, of 0.05 M edetate disodium consumed, less the volume of 0.05 M edetate disodium corresponding to the content of calcium carbonate in the volume, in mL, of the *Sample solution* taken, represents the volume, in mL, of 0.05 M edetate disodium equivalent to the quantity of magnesium hydroxide present. Each mL of 0.05 M edetate disodium is equivalent to 2.916 mg of $Mg(OH)_2$.

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meet the requirements for *Weight Variation* with respect to calcium carbonate and to magnesia

SPECIFIC TESTS

- **ACID-NEUTRALIZING CAPACITY ⟨301⟩**

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

$$\text{Result} = [0.8 \times (F_M \times M)] + [0.9 \times (F_C \times C)]$$

F_M = theoretical acid-neutralizing capacity of $Mg(OH)_2$, 0.0343 mEq

M = quantity of $Mg(OH)_2$ in the sample tested (mg), based on the labeled quantity

F_C = theoretical acid-neutralizing capacities of $CaCO_3$, 0.02 mEq

C = quantity of $CaCO_3$ in the sample tested (mg), based on the labeled quantity

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** Label the Chewable Tablets to indicate that they must be chewed before being swallowed.

Calcium Carbonate, Magnesia, and Simethicone Chewable Tablets

Former Title: Calcium Carbonate, Magnesia, and Simethicone Tablets

» Calcium Carbonate, Magnesia, and Simethicone Chewable Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of calcium carbonate ($CaCO_3$) and magnesium hydroxide [$Mg(OH)_2$], and an amount of polydimethylsiloxane [$–(CH_3)_2SiO–]_n$ that is not less than 85.0 percent and not more than 115.0 per cent of the labeled amount of simethicone.

Packaging and storage—Preserve in well-closed containers.

Labeling—Label it to indicate that the Chewable Tablets are to be chewed before swallowing. Label the Chewable Tablets to state the sodium content, in mg per Chewable Tablet, if it is greater than 5 mg per Chewable Tablet.

USP Reference standards ⟨11⟩—
USP Polydimethylsiloxane RS

Identification—

A: *Infrared Absorption ⟨197S⟩—*

Solution—Using Chewable Tablets, proceed to obtain IR absorption spectra as directed in the *Assay for polydimethylsiloxane* under *Alumina, Magnesia, and Simethicone Chewable Tablets.*

B: The addition of 1 N hydrochloric acid to a Chewable Tablet produces effervescence, and the resulting solution, after having been filtered, meets the requirements of the tests for *Calcium ⟨191⟩*.

C: Heat 2 Chewable Tablets in 20 mL of 1 N sulfuric acid. Cool, add 20 mL of alcohol, mix, and allow to stand for 30 minutes. Filter this solution, and to the filtrate add 2 mL of 1 N hydrochloric acid: this solution meets the requirements of the tests for *Magnesium ⟨191⟩*.

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

Acid-neutralizing capacity ⟨301⟩—Not less than 5 mEq of acid is consumed by the minimum single dose recommended in the labeling.

Content of sodium (if so labeled)—

Lanthanum chloride solution—Prepare as directed in the *Assay for calcium carbonate and magnesium hydroxide.*

Dilute hydrochloric acid—Prepare as directed in the *Assay for polydimethylsiloxane.*

Standard solution—Transfer 2.542 g of sodium chloride, previously dried at 105° for 2 hours, to a 1000-mL volumetric flask, dissolve in and dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 4.0 mL of this solution to a second 100-mL volumetric flask containing 6.0 mL of *Dilute hydrochloric acid* and 2.0 mL of *Lanthanum chloride solution,* dilute with water to volume, and mix. This solution contains 2.0 µg of sodium (Na) per mL.

Test solution—Transfer 3.0 mL of the aqueous layer retained from the preparation of the *Assay preparation* in the *Assay for polydimethylsiloxane* to a 50-mL volumetric flask containing 1.0 mL of *Lanthanum chloride solution,* dilute with water to volume, and mix.

Blank solution—Transfer 15.0 mL of *Dilute hydrochloric acid* and 5.0 mL of *Lanthanum chloride solution* to a 250-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard solution* and the *Test solution* 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 the *Blank solution* as the blank. Calculate the mg of sodium (Na) in each Chewable Tablet taken by the formula:

$$(5C/6)(A/W)(A_U / A_S)$$

in which C is the concentration, in µg per mL, of sodium in the *Standard solution; A* is the average weight, in mg, of each Chewable Tablet; *W* is the weight, in mg, of the portion of Chewable Tablets from the preparation of the *Assay preparation* in the *Assay for polydimethylsiloxane* used to prepare the *Test solution;* and A_U and A_S are the absorbances of the *Test solution* and the *Standard solution,* respectively. Each Chewable Tablet contains not more than the number of mg of sodium stated on the label.

Assay for polydimethylsiloxane—

Saccharin solution—Prepare a solution of saccharin in 4-methyl-2-pentanone containing 12.5 mg per mL.

Dilute hydrochloric acid—Mix 200 mL of hydrochloric acid with sufficient water to make 1000 mL.

Standard preparation—Dissolve a suitable quantity of USP Polydimethylsiloxane RS in 4-methyl-2-pentanone to obtain a stock solution having a known concentration of about 1 mg per mL. On the day of use, transfer 20.0 mL of this solution and