pers), and add 5 mL of ammonia–ammonium chloride buffer TS and 0.15 mL of eriochrome black TS. 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 $Mg(OH)_2$.
Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS
- **DISINTEGRATION** ⟨**701**⟩
  Time: NMT 10 min, simulated gastric fluid TS being substituted for water in the test
- **UNIFORMITY OF DOSAGE UNITS** ⟨**905**⟩**:** Meet the requirements

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:

$$\text{Result} = (F_M \times M) \times 0.8$$

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

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

Magnesium Carbonate

Carbonic acid, magnesium salt, basic; or, Carbonic acid, magnesium salt (1:1), hydrate;
Magnesium carbonate, basic; or, Magnesium carbonate (1:1) hydrate [23389-33-5].
Anhydrous 84.31
[546-93-0].

DEFINITION
Magnesium Carbonate is a basic hydrated magnesium carbonate or a normal hydrated magnesium carbonate. It contains the equivalent of NLT 40.0% and NMT 43.5% of magnesium oxide (MgO).

IDENTIFICATION
- **A. IDENTIFICATION TESTS—GENERAL,** *Magnesium* ⟨**191**⟩**:** When treated with 3 N hydrochloric acid, it dissolves with effervescence, and the resulting solution meets the requirements.

ASSAY
- **PROCEDURE**
  Sample: 1 g
  Analysis: Dissolve the *Sample* in 30.0 mL of 1 N sulfuric acid VS, add methyl orange TS, and titrate the excess acid with 1 N sodium hydroxide VS. Perform the blank determination. Calculate the volume, V_S, of 1 N sulfuric acid, in mL, consumed by the *Sample*:

$$\text{Result} = (V_B - V_A) \times N_{NaOH}$$

V_B = volume of 1 N sodium hydroxide consumed by the blank determination (mL)
V_A = volume of 1 N sodium hydroxide consumed by the *Sample* (mL)
N_{NaOH} = exact normality of the sodium hydroxide solution
Calculate the volume of 1 N sulfuric acid, V_{Ca}, in mL, consumed by calcium, which is present in the portion of Magnesium Carbonate taken for the *Assay*:

$$\text{Result} = (W \times L_{Ca})/(F_{Ca} \times 100)$$

W = weight of Magnesium Carbonate taken (mg)
L_{Ca} = content of calcium as determined in the test for *Limit of Calcium* (%)
F_{Ca} = weight of Ca that is equivalent to each mL of 1 N sulfuric acid, 20.04 mg

Calculate the percentage of magnesium oxide (MgO) in the portion of Magnesium Carbonate taken:

$$\text{Result} = (V_S - V_{Ca}) \times F_{MgO}/W \times 100$$

V_S = volume of 1 N sulfuric acid consumed by the *Sample*, as calculated above (mL)
V_{Ca} = volume of 1 N sulfuric acid consumed by calcium, as calculated above (mL)
F_{MgO} = weight of MgO that is equivalent to each mL of 1 N sulfuric acid, 20.15 mg
W = weight of Magnesium Carbonate taken (mg)
Acceptance criteria: 40.0%–43.5% of MgO

IMPURITIES
- **SOLUBLE SALTS**
  Sample: 2.0 g
  Analysis: Mix the *Sample* with 100 mL of a mixture of equal volumes of *n*-propyl alcohol and water. Heat the mixture to the boiling point with constant stirring, cool to room temperature, dilute with water to 100 mL, and filter. Evaporate 50 mL of the filtrate on a steam bath to dryness, and dry at 105° for 1 h.
  Acceptance criteria: The weight of the residue does not exceed 10 mg (NMT 1.0%).
- **ACID-INSOLUBLE SUBSTANCES**
  Sample: 5.0 g
  Analysis: Mix the *Sample* with 75 mL of water, add hydrochloric acid in small portions, with agitation, until no more of the magnesium carbonate dissolves, and boil for 5 min. If an insoluble residue remains, filter, wash well with water until the last washing is free from chloride, and ignite.
  Acceptance criteria: The weight of the ignited residue does not exceed 2.5 mg (NMT 0.05%).
- **ARSENIC,** *Method I* ⟨**211**⟩
  Test preparation: 750 mg in 25 mL of 3 N hydrochloric acid
  Acceptance criteria: NMT 4 ppm
- **LIMIT OF CALCIUM**
  [NOTE—A commercially available atomic absorption standard solution for calcium may be used where preparation of a calcium standard stock solution is described below. Concentrations of the *Standard solutions* and the *Sample solution* may be modified to fit the linear or working range of the instrument.]
  Dilute hydrochloric acid: Dilute 100 mL of hydrochloric acid with water to 1000 mL.
  Lanthanum solution: To 58.65 g of lanthanum oxide add 400 mL of water, and add, gradually with stirring, 250 mL of hydrochloric acid. Stir until dissolved, and dilute with water to 1000 mL.
  Standard solutions: Transfer 249.7 mg of calcium carbonate, previously dried at 300° for 3 h and cooled in a desiccator for 2 h, to a 100-mL volumetric flask. Dissolve in a minimum amount of hydrochloric acid, and dilute with water to volume. Transfer 1.0, 5.0, 10.0, and 15.0 mL of this stock solution to separate 1000-mL volumetric flasks, each containing 20 mL of *Lanthanum solution* and 40 mL of *Dilute hydrochloric acid*. Dilute with water to volume. These *Standard solutions* contain 1.0, 5.0, 10.0, and 15.0 µg/mL of calcium, respectively.
  Blank solution: Transfer 4 mL *of Lanthanum solution* and 10 mL of *Dilute hydrochloric acid* to a 200-mL volumetric flask, and dilute with water to volume.
  Sample solution: Transfer 250 mg of Magnesium Carbonate to a beaker, add 30 mL of *Dilute hydrochloric acid*, and stir until dissolved, heating if necessary. Transfer the solution so obtained to a 200-mL volumetric flask containing 4 mL of *Lanthanum solution*, and dilute with water to volume.
  Instrumental conditions
  (See *Spectrophotometry and Light-Scattering* ⟨851⟩.)

Mode: Atomic absorption spectrophotometry
Lamp: Calcium hollow-cathode
Flame: Nitrous oxide–acetylene
Analytical wavelength: Calcium emission line at 422.7 nm
Analysis
Samples: *Standard solutions*, *Blank solution*, and *Sample solution*
Using the *Blank solution* as blank, determine the concentration, *C*, in µg/mL, of calcium in the *Sample solution* using the calibration graph.
Calculate the percentage of calcium in the portion of Magnesium Carbonate taken:

$$\text{Result} = (V/W \times C \times F) \times 100$$

V = volume of the *Sample solution* (mL)
W = weight of Magnesium Carbonate taken (mg)
C = as defined above
F = conversion factor from µg/mL to mg/mL, 0.001
Acceptance criteria: NMT 0.45%

- **HEAVY METALS,** *Method I* ⟨**231**⟩
Test preparation: Dissolve 0.67 g in 10 mL of 3 N hydrochloric acid in a suitable crucible, and evaporate the solution on a steam bath to dryness. Ignite at 550 ± 25° until all carbonaceous material is consumed. Dissolve the residue in 15 mL of water and 5 mL of hydrochloric acid, and evaporate to dryness. Toward the end of the evaporation, stir frequently to disintegrate the residue so that finally a dry powder is obtained. Dissolve the residue in 20 mL of water, and evaporate in the same manner as before to dryness. Redissolve the residue in 20 mL of water, filter, if necessary, and add to the filtrate 2 mL of 1 N acetic acid and water to make 25 mL.
Acceptance criteria: NMT 30 ppm
- **IRON** ⟨**241**⟩
Test preparation: Boil 50 mg with 5 mL of 2 N nitric acid for 1 min. Cool, dilute with water to 45 mL, add 2 mL of hydrochloric acid, and mix.
Acceptance criteria: NMT 200 ppm

SPECIFIC TESTS

- **MICROBIAL ENUMERATION TESTS** ⟨**61**⟩ and **TESTS FOR SPECIFIED MICROORGANISMS** ⟨**62**⟩**:** It meets the requirements of the test for absence of *Escherichia coli*.

ADDITIONAL REQUIREMENTS

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

Magnesium Carbonate and Citric Acid for Oral Solution

» Magnesium Carbonate and Citric Acid for Oral Solution contains a dry mixture of Magnesium Carbonate and Citric Acid that when constituted as directed in the labeling yields a solution that contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of magnesium citrate ($C_{12}H_{10}Mg_3O_{14}$).

Packaging and storage—Preserve in tight containers.

Labeling—The label contains directions for constitution of the powder and states the equivalent amount of magnesium citrate ($C_{12}H_{10}Mg_3O_{14}$) in a given volume of the Oral Solution obtained after constitution.

USP Reference standards ⟨11⟩**—**
USP Citric Acid RS

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩**—**It meets the requirements of the test for absence of *Escherichia coli* and *Salmonella* species.

Uniformity of dosage units ⟨905⟩: meets the requirements.

Content of anhydrous citric acid—

Mobile Phase, Standard Preparation 1, and *Chromatographic System*—Proceed as directed under *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩.

Assay preparation—Transfer an accurately measured volume of the constituted Oral Solution, equivalent to about 9 g of anhydrous citric acid into a suitable volumetric flask, and proceed as directed for *Assay Preparation for Citric Acid/Citrate Assay* under *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩.

Procedure—Proceed as directed for *Procedure* under ⟨345⟩, and calculate the quantity, in mg, of anhydrous citric acid ($C_6H_8O_7$) in the volume of constituted Oral Solution taken by the formula:

$$0.001(192.12/189.10)C_S\,D(r_U / r_S)$$

in which 192.12 is the molecular weight of anhydrous citric acid; 189.10 is the molecular weight of citrate ($C_6H_5O_7$); C_S is the concentration, in µg per mL, of citrate in *Standard Preparation 1; D* is the dilution factor; and r_U and r_S are the citrate peak areas obtained from the *Assay preparation* and *Standard Preparation 1,* respectively. The content of anhydrous citric acid is between 76.6% and 107.8% of the labeled amount of magnesium citrate.

Other requirements—Constitute Magnesium Carbonate and Citric Acid for Oral Solution as directed in the labeling: it responds to the *Identification* tests and meets the requirements for *Chloride, Sulfate,* and *Tartaric acid* under *Magnesium Citrate Oral Solution*.

Assay—Transfer an accurately measured volume of constituted Oral Solution, equivalent to about 18.7 g of magnesium citrate ($C_{12}H_{10}Mg_3O_{14}$), to a 1000-mL volumetric flask. Add 200 mL of 1 N hydrochloric acid, swirl, and allow to stand for about 10 minutes. Dilute with water to volume, and mix. Stir by mechanical means for about 30 minutes. Transfer 10.0 mL of this solution to a 250-mL beaker. Add 10 mL of ammonia–ammonium chloride buffer TS, 5 mL of triethanolamine, 0.3 mL of eriochrome black TS, and titrate with 0.05 M edetate disodium VS until the last hint of violet disappears (blue endpoint). Each mL of 0.05 M edetate disodium is equivalent to 7.520 mg of magnesium citrate ($C_{12}H_{10}Mg_3O_{14}$).

Magnesium Carbonate, Citric Acid, and Potassium Citrate for Oral Solution

» Magnesium Carbonate, Citric Acid, and Potassium Citrate for Oral Solution contains a dry mixture of Magnesium Carbonate, Citric Acid, and Potassium Citrate that when constituted as directed in the labeling yields a solution that contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of magnesium citrate ($C_{12}H_{10}Mg_3O_{14}$).

Packaging and storage—Preserve in tight, single-dose containers. Store at controlled room temperature.

Labeling—The label specifies the directions for the constitution of the powder and states the equivalent amount of magnesium citrate ($C_{12}H_{10}Mg_3O_{14}$).

USP Reference standards ⟨11⟩**—**
USP Citric Acid RS

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩**—**The total aerobic microbial count does not exceed 1000 cfu per g, and the total combined molds and