yeasts count does not exceed 100 cfu per g. It meets the requirements of the test for absence of *Escherichia coli.*

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

pH ⟨791⟩**:** between 3.3 and 4.3, determined in a solution constituted as directed in the labeling.

Content of anhydrous citric acid—

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

Standard preparation—Dissolve USP Citric Acid RS in a freshly prepared 1 mM sodium hydroxide to obtain a solution having a known concentration of about 0.02 mg of anhydrous citric acid per mL.

Assay preparation—Constitute the Oral Solution as directed in the labeling. Transfer the amount of the constituted Oral Solution, equivalent to about 500 mg of magnesium citrate, to a suitable volumetric flask, and dilute quantitatively, and stepwise if necessary, with a freshly prepared 1 mM sodium hydroxide to obtain a solution having a concentration of about 0.02 mg of magnesium citrate per mL, based on the label claim. Pass the resulting solution through a filter having a 0.5-µm or finer porosity, and use the filtrate.

Procedure—Proceed as directed for *Procedure* under *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩, and calculate the content, in g, of anhydrous citric acid ($C_6H_8O_7$) by the formula:

$$0.001(C_S\,DV_T/V)(r_U/r_S)$$

in which 0.001 is the conversion factor from mg to g; C_S is the concentration, in mg per mL, of anhydrous citric acid in the *Standard preparation; D* is the dilution factor for the *Assay preparation;* V_T is the total volume of constituted Oral Solution, as measured, when constituted as directed; *V* is the volume, in mL, of the constituted Oral Solution taken to prepare the *Assay preparation;* and r_U and r_S are the citrate peak areas obtained from the *Assay preparation* and the *Standard preparation,* respectively. The content of anhydrous citric acid is between 126.1% and 154.4% of the labeled amount of magnesium citrate.

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

Assay—Transfer an accurately measured volume of the constituted Oral Solution, equivalent to about 0.5 g of magnesium oxide, to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 10.0 mL of this solution to a beaker. While stirring, 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 and Sodium Bicarbonate for Oral Suspension

» Magnesium Carbonate and Sodium Bicarbonate for Oral Suspension contains not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of $MgCO_3$ and $NaHCO_3$. It may contain suitable flavors.

Packaging and storage—Preserve in tight containers.

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: The solution remaining in the flask responds to the tests for *Magnesium* ⟨191⟩ and for *Sodium* ⟨191⟩.

Minimum fill ⟨755⟩: meets the requirements.

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:

$$0.8(0.024M) + 0.8(0.0119S)$$

in which 0.024 and 0.0119 are the theoretical acid-neutralizing capacities, in mEq, of $MgCO_3$ and $NaHCO_3$, respectively; and *M* and *S* are the quantities, in mg, of $MgCO_3$ and $NaHCO_3$ in the specimen tested, based on the labeled quantities.

Assay for magnesium carbonate—Transfer an accurately weighed portion of Magnesium Carbonate and Sodium Bicarbonate for Oral Suspension, equivalent to about 4.2 g of $MgCO_3$, to a 500-mL volumetric flask. Add 200 mL of 1 N hydrochloric acid, and mix. When dissolved, dilute with water to volume, and mix. Transfer 10.0 mL of this stock solution to a suitable container, dilute with water to 100 mL, add 10 mL of ammonia–ammonium chloride buffer TS, 5 mL of triethanolamine, and 0.3 mL of eriochrome black TS, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Each mL of 0.05 M edetate disodium consumed is equivalent to 4.216 mg of $MgCO_3$.

Assay for sodium bicarbonate—

Standard preparations—Dissolve a suitable quantity of sodium chloride, previously dried at 125° for 30 minutes and accurately weighed, in water, and dilute quantitatively with water to obtain a solution having a known concentration of about 600 µg per mL. On the day of use, further dilute this solution quantitatively with water to obtain three solutions containing 6.0, 12.0, and 18.0 µg of sodium chloride per mL, respectively.

Assay preparation—Transfer an accurately measured volume of the stock solution remaining from the *Assay for magnesium carbonate,* equivalent to about 180 mg of $NaHCO_3$, to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 10.0 mL of the resulting solution to a 1000-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard preparations* and the *Assay preparation* at the sodium emission line at about 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 water as the blank. Plot the absorbances of the *Standard preparations* versus concentration, in µg of sodium chloride per mL, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, in µg per mL, of sodium chloride equivalent in the *Assay preparation.* Calculate the quantity, in g, of $NaHCO_3$ in the portion of Magnesium Carbonate and Sodium Bicarbonate for Oral Suspension taken by the formula:

$$(84.01/58.44)(5C/V)$$

in which 84.01 and 58.44 are the molecular weights of sodium bicarbonate and sodium chloride, respectively; *C* is the concentration, in µg per mL, of sodium chloride equivalent in the *Assay preparation;* and *V* is the volume, in mL, of the stock solution remaining from the *Assay for magnesium carbonate* taken.

Magnesium Chloride

$MgCl_2 \cdot 6H_2O$ Magnesium chloride, hexahydrate [7791-18-6].	203.30
Anhydrous [7786-30-3].	95.21

DEFINITION
Magnesium Chloride contains NLT 98.0% and NMT 101.0% of $MgCl_2 \cdot 6H_2O$.

IDENTIFICATION
- **A. IDENTIFICATION TESTS—GENERAL,** *Magnesium* ⟨**191**⟩
  Sample solution: 50 mg/mL
- **B. IDENTIFICATION TESTS—GENERAL,** *Chloride* ⟨**191**⟩
  Sample solution: 50 mg/mL
  [NOTE—Acidify the *Sample solution* with diluted nitric acid before adding 6 N ammonium hydroxide.]

ASSAY
- **PROCEDURE**
  Sample: 450 mg
  Analysis: Dissolve the *Sample* in 25 mL of water, add 5 mL of ammonia–ammonium chloride buffer TS and 0.1 mL of eriochrome black TS, and titrate with 0.05 M edetate disodium VS to a blue endpoint. Each mL of 0.05 M disodium edetate is equivalent to 10.17 mg of $MgCl_2 \cdot 6H_2O$.
  Acceptance criteria: 98.0%–101.0%

IMPURITIES
- **INSOLUBLE MATTER**
  Sample: 20 g
  Analysis: Dissolve the *Sample* in 200 mL of water, heat to boiling, and digest in a covered beaker on a steam bath for 1 h. Filter through a tared filtering crucible, wash thoroughly, dry at 115°, and determine the weight of the residue.
  Acceptance criteria: NMT 0.005%
- **CHLORIDE AND SULFATE,** *Sulfate* ⟨**221**⟩
  Sample: 10 g
  Acceptance criteria: It shows no more sulfate than corresponds to 0.50 mL of 0.020 N sulfuric acid (0.005%).
- **BARIUM**
  Sample: 1 g
  Analysis: Dissolve the *Sample* in 10 mL of water, and add 1 mL of 2 N sulfuric acid.
  Acceptance criteria: No turbidity is produced within 2 h.
- **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 10.0 g of Magnesium Chloride to a 200-mL volumetric flask, and add water to dissolve. Add 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*.
  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 Chloride taken:

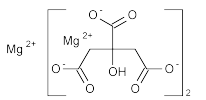
$$\text{Result} = (V/W \times C \times F) \times 100$$

  V = volume of the *Sample solution* (mL)
  W = weight of Magnesium Chloride taken (mg)
  C = as defined above
  F = conversion factor from µg/mL to mg/mL, 0.001
  Acceptance criteria: NMT 0.01%
- **POTASSIUM**
  Sample solution: 5 g
  Analysis: Dissolve the *Sample* in 5 mL of water, and add 0.2 mL of sodium bitartrate TS.
  Acceptance criteria: No turbidity is produced within 5 min.
- **ALUMINUM** ⟨**206**⟩ (where it is labeled as intended for use in hemodialysis)
  Test preparation: Prepare as directed in the chapter, using 2.0 g.
  Acceptance criteria: NMT 1 ppm
- **HEAVY METALS** ⟨**231**⟩
  Test preparation: Dissolve 2 g in water, and dilute with water to 25 mL.
  Acceptance criteria: NMT 10 ppm

SPECIFIC TESTS
- **pH** ⟨**791**⟩
  Sample solution: 50 mg/mL in carbon dioxide-free water
  Acceptance criteria: 4.5–7.0

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** Where Magnesium Chloride is intended for use in hemodialysis, it is so labeled.

Magnesium Citrate



$C_{12}H_{10}Mg_3O_{14}$ 451.11
1,2,3-Propanetricarboxylic acid, hydroxy-, magnesium salt (2:3); Magnesium citrate (3:2) [3344-18-1].

DEFINITION
Magnesium Citrate contains NLT 14.5% and NMT 16.4% of magnesium (Mg), calculated on the dried basis.

IDENTIFICATION
- **A. IDENTIFICATION TESTS—GENERAL,** *Magnesium* ⟨**191**⟩
  Sample: 10 mg/mL
  Acceptance criteria: Meets the requirements
- **B. IDENTIFICATION TESTS—GENERAL,** *Citrate* ⟨**191**⟩
  Sample: 80 mg/mL
  Acceptance criteria: Meets the requirements

ASSAY
- **PROCEDURE**
  Sample: 400 mg
  Analysis: Dissolve the *Sample* in 50 mL of water. Add 20 mL of ammonia–ammonium chloride buffer TS and 0.1 mL of