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Magnesium Citrate for Oral Solution

DEFINITION

Magnesium Citrate for Oral Solution, when constituted as directed in the labeling, yields a solution that contains NLT 90.0% and NMT 110.0% of the labeled amount of magnesium citrate ($C_{12}H_{10}Mg_3O_{14}$).

IDENTIFICATION

• **A. Identification Tests—General,** *Magnesium* ⟨191⟩

Sample solution: Constitute as directed in the labeling.

Acceptance criteria: Meets the requirements

• **B.** The retention time of the citrate peak of the *Sample solution* corresponds to that of *Standard solution 1*, as obtained in the test for *Content of Anhydrous Citric Acid*.

ASSAY

• **Procedure**

Sample solution: Transfer a volume of constituted oral solution, equivalent to 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 10 min. Dilute with water to volume. Stir by mechanical means for about 30 min.

Analysis: Transfer 10.0 mL of the *Sample solution* to a 250-mL beaker. 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 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 ($C_{12}H_{10}Mg_3O_{14}$).

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

• **Content of Anhydrous Citric Acid**

Mobile phase, Standard solution 1, Chromatographic system, and **System suitability:** Proceed as directed in *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩.

Sample solution: Transfer an appropriate volume of the constituted oral solution into a suitable volumetric flask, and proceed as directed for the *Sample solution* in *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩, *Sample solution (for the assay of citric acid/citrate)*.

Analysis

Samples: *Standard solution 1* and *Sample solution*

Proceed as directed for *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩, *Procedure*.

Calculate the percentage of anhydrous citric acid ($C_6H_8O_7$) in relation to the labeled amount of magnesium citrate in the volume of constituted oral solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak area of citrate from the *Sample solution*

r_S = peak area of citrate from *Standard solution 1*

C_S = concentration of citrate in *Standard solution 1* (mg/mL)

C_U = nominal concentration of magnesium citrate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of anhydrous citric acid, 192.12

M_{r2} = molecular weight of citrate ($C_6H_5O_7$), 189.10

Acceptance criteria: 76.6%–93.7% of the labeled amount of magnesium citrate

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

IMPURITIES

• **Chloride and Sulfate,** *Chloride* ⟨221⟩

Sample solution: Constitute as directed in the labeling.

Acceptance criteria: A 2.0-mL portion of *Sample solution* shows no more chloride than corresponds to 0.30 mL of 0.020 N hydrochloric acid (NMT 0.01%).

• **Chloride and Sulfate,** *Sulfate* ⟨221⟩

Sample solution: Constitute as directed in the labeling.

Acceptance criteria: A 2.0-mL portion of *Sample solution* shows no more sulfate than corresponds to 0.30 mL of 0.020 N sulfuric acid (NMT 0.015%).

• **Tartaric Acid**

Sample solution: Constitute as directed in the labeling.

Analysis: To 10 mL of *Sample solution* in a test tube, add 1 mL of glacial acetic acid and 3 mL of a solution of potassium acetate (1 in 2). Shake the mixture vigorously, then gently rub the inner wall of the test tube with a glass rod for a few min, and allow to stand for 1 h.

Acceptance criteria: No white, crystalline precipitate soluble in 6 N ammonium hydroxide is formed.

SPECIFIC TESTS

• **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.

ADDITIONAL REQUIREMENTS

• **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.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MAGNESIUM CITRATE FOR ORAL SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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