Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-F684CB94-8E26-4E85-A967-E57E5D41DCC1_3_en-US
DOI: https://doi.org/10.31003/USPNF_M46692_03_01
DOI Ref: 3j49w

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

DEFINITION

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 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 1.9 g of magnesium citrate to a 100-mL volumetric flask and dilute with water to volume.

Analysis: Transfer 10.0 mL of the *Sample solution* to a beaker. While stirring, 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, Chromatographic system, and **System suitability:** Proceed as directed in *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩.

Standard solution: 0.02 mg/mL of anhydrous citric acid, from USP Citric Acid RS in a freshly prepared 1 mM sodium hydroxide

Sample solution: Transfer a volume of constituted oral solution equivalent to 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 0.02 mg/mL of magnesium citrate, based on the label claim. Pass through a filter of 0.5-µm or finer pore size, and use the filtrate.

Analysis

Samples: *Standard solution* and *Sample solution*

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:

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

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

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

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

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

Acceptance criteria: 126.1%–154.4% of the labeled amount of magnesium citrate

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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⟩:** The total aerobic microbial count does not exceed 1000 cfu/g, and the total combined molds and yeasts count does not exceed 100 cfu/g. It meets the requirements of the test for absence of *Escherichia coli*.

• **pH ⟨791⟩**

Sample solution: Constitute as directed in the labeling.

Acceptance criteria: 3.3–4.3

ADDITIONAL REQUIREMENTS

• **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 ($C_{12}H_{10}Mg_3O_{14}$).

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

Topic/Question	Contact	Expert Committee
MAGNESIUM CARBONATE,CITRIC ACID, AND POTASSIUM 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 39(3)

Current DocID: GUID-F684CB94-8E26-4E85-A967-E57E5D41DCC1_3_en-US
Previous DocID: GUID-F684CB94-8E26-4E85-A967-E57E5D41DCC1_1_en-US
DOI: https://doi.org/10.31003/USPNF_M46692_03_01
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