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Magnesium Citrate Oral Solution

DEFINITION

Magnesium Citrate Oral Solution is a sterilized or pasteurized solution containing NLT 7.59 g of anhydrous citric acid ($C_6H_8O_7$) and an amount of magnesium citrate equivalent to NLT 1.55 g and NMT 1.9 g of magnesium oxide (MgO) in each 100 mL of Oral Solution.

Prepare Magnesium Citrate Oral Solution as follows.

Magnesium Carbonate	15 g
Anhydrous Citric Acid	27.4 g
Syrup	60 mL
Talc	5 g
Lemon Oil	0.1 mL
Potassium Bicarbonate	2.5 g
Purified Water, a sufficient quantity to make	350 mL

Dissolve the *Anhydrous Citric Acid* in 150 mL of hot *Purified Water* in a suitable dish, slowly add the *Magnesium Carbonate* previously mixed with 100 mL of *Purified Water*, and stir until it is dissolved. Add the *Syrup*, heat the mixed liquids to the boiling point, and immediately add the *Lemon Oil* previously triturated with *Talc*. Filter the mixture, while hot, into a strong bottle of suitable capacity previously rinsed with boiling *Purified Water*. Add boiled *Purified Water* to bring the preparation to final volume. Use Purified Cotton as a stopper for the bottle, and allow to cool. Add the *Potassium Bicarbonate*, and immediately insert the stopper in the bottle securely. Shake the solution occasionally until the *Potassium Bicarbonate* is dissolved, cap the bottle, and sterilize or pasteurize the solution.

Alternatively, 30 g of citric acid containing 1 molecule of water of hydration, equivalent to 27.4 g of *Anhydrous Citric Acid*, may be used in the foregoing formula. In this process, replace the 2.5 g of *Potassium Bicarbonate* with 2.1 g of sodium bicarbonate, preferably in tablet form. The Oral Solution may be further carbonated by the use of carbon dioxide under pressure.

IDENTIFICATION

- **A. Identification Tests—General, *Magnesium*⟨191⟩:** Meets the requirements
- **B.**

Sample: 5 mL

Analysis: To the *Sample* add 1 mL of potassium permanganate TS and 5 mL of mercuric sulfate TS, and heat the solution.

Acceptance criteria: A white precipitate is formed.

ASSAY

- **Citric Acid**

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

Assay preparation: Transfer 10 mL of Oral Solution that has been previously freed from excessive carbon dioxide by repeated pouring to a suitable volumetric flask, and proceed as directed in *Assay for Citric Acid/Citrate and Phosphate* ⟨345⟩, *Assay Preparation for Citric Acid/Citrate Assay*.

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

Calculate the quantity, g, of anhydrous citric acid ($C_6H_8O_7$) in 100 mL of Oral Solution:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times D \times (M_{r1}/M_{r2}) \times F$$

r_U = peak area of citrate from the *Assay preparation*

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

C_S = concentration of citrate in *Standard preparation 1* (µg/mL)

V = final volume of Oral Solution, 100 mL

D = dilution factor

M_{r1} = molecular weight of citric acid ($C_6H_8O_7$), 192.12

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

F = conversion factor, 10^{-6} g/µg

Acceptance criteria: NLT 7.59 g in 100 mL of Oral Solution

- **Magnesium Oxide**

Sample: 50.0 mL of Oral Solution that has been previously freed from excessive carbon dioxide by repeated pouring

Analysis: Transfer the *Sample* to a 100-mL volumetric flask, and dilute with water to volume. Transfer 5.0 mL of the resulting solution to a beaker containing 150 mL of water heated to 70°–80°, and add 1 mL of ammonium chloride TS and 3 mL of ammonium hydroxide. Mix, and slowly add 8 mL of 8-hydroxyquinoline TS with stirring. After standing for 30 min, filter through a sintered-glass crucible, previously dried and weighed, and wash the precipitate with ten 10-mL portions of water. Dry the crucible and contents at 105° for 3 h, cool, and weigh. Determine the equivalent of magnesium oxide (MgO) in 100 mL of Oral Solution by multiplying the weight of $C_{18}H_{12}MgN_2O_2 \cdot 2H_2O$ so obtained by 4.624.

Acceptance criteria: 1.55–1.9 g in 100 mL of Oral Solution

IMPURITIES

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

Sample: 2.0 mL

Acceptance criteria: 0.01%; it shows no more chloride than corresponds to 0.30 mL of 0.020 N hydrochloric acid.

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

Sample: 2.0 mL

Acceptance criteria: 0.015%; it shows no more sulfate than corresponds to 0.30 mL of 0.020 N sulfuric acid.

- **Tartaric Acid**

Sample: 10 mL

Analysis: Place the *Sample* 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.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in bottles NLT 200 mL in capacity. Store at controlled room temperature or in a cool place.

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

Topic/Question	Contact	Expert Committee
MAGNESIUM CITRATE COMPOUNDED ORAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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