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Citric Acid, Magnesium Oxide, and Sodium Carbonate Irrigation

DEFINITION

Citric Acid, Magnesium Oxide, and Sodium Carbonate Irrigation is a sterile solution of Citric Acid, Magnesium Oxide, and Sodium Carbonate in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amounts of citric acid ($C_6H_8O_7 \cdot H_2O$), magnesium oxide (MgO), and sodium carbonate (Na_2CO_3).

IDENTIFICATION

- **A. Identification Tests—General, *Sodium*⟨191⟩and*Magnesium*⟨191⟩**
- **B.**

Sample solution: 10 mL of Irrigation

Analysis: Add 1 mL of mercuric sulfate TS to the *Sample solution*, heat to boiling, and add a few drops of potassium permanganate TS.

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 for citric acid/citrate assay: Nominally 20 µg/mL of citrate from Irrigation in 1 mM of sodium hydroxide prepared as follows. Transfer a suitable volume of Irrigation to an appropriately sized volumetric flask, and proceed as directed in *Assay for Citric Acid/Citrate and Phosphate ⟨345⟩,Sample solution (for the assay of citric acid/citrate)*.

Analysis

Samples: *Standard preparation 1* and *Assay preparation for citric acid/citrate assay*

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

Calculate the percentage of the labeled amount of citric acid monohydrate ($C_6H_8O_7 \cdot H_2O$) in the portion of Irrigation taken:

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

r_U = peak response of citrate from the *Assay preparation for citric acid/citrate assay*

r_S = peak response of citrate from *Standard preparation 1*

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

C_U = nominal concentration of citric acid monohydrate in the *Assay preparation for citric acid/citrate assay* (µg/mL)

M_{r1} = molecular weight of citric acid monohydrate, 210.14

M_{r2} = molecular weight of citrate, 189.10

Acceptance criteria: 95.0%–105.0%

- **Magnesium Oxide**

Sample solution: A volume of Irrigation, nominally equivalent to 40 mg of magnesium oxide

Analysis: Transfer the *Sample solution* to a beaker containing 130 mL of water heated to 75° ± 5°, and add 4 mL of ammonium chloride TS and then 5 mL of ammonium hydroxide. Mix, and add slowly, with stirring, 8 mL of 8-hydroxyquinoline TS. After allowing to stand for 30 min at 75°, filter through a sintered-glass crucible, previously dried and weighed. Wash the precipitate with 50 mL of a warm mixture of water and 6 N ammonium hydroxide (45:5), followed by 50 mL of cool water. Dry the crucible and contents at 105° for 3 h, cool, and weigh. Determine the equivalent of magnesium oxide (MgO) in the portion of Irrigation taken by multiplying the weight of the $C_{18}H_{12}MgN_2O_2 \cdot 2H_2O$ so obtained by 0.1156 (mg of MgO).

Calculate the percentage of the labeled amount of magnesium oxide (MgO) in the portion of Irrigation taken.

Acceptance criteria: 95.0%–105.0%

- **Sodium Carbonate**

Sodium chloride stock solution: 4.75 mg/mL of sodium chloride, previously dried at 105° for 2 h, in water

Internal standard solution: 0.636 mg/mL of lithium chloride in water

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Standard solution: 0.0475 mg/mL of sodium chloride and 0.6296 mg/mL of lithium chloride prepared from an appropriate mixture of *Sodium chloride stock solution* and *Internal standard solution*

Sample stock solution: Nominally equivalent to 4.4 mg/mL of sodium carbonate from Irrigation diluted with water

Sample solution: 0.044 mg/mL of sodium carbonate and 0.6296 mg/mL of lithium chloride prepared from an appropriate mixture of *Sample stock solution* and *Internal standard solution*

Instrumental conditions

Mode: Flame photometer

Analytical wavelengths: 591 and 671 nm

Analysis

Samples: *Internal standard solution*, *Standard solution*, and *Sample solution*

Concomitantly determine the emittances of the *Standard solution* and the *Sample solution*, adjusting the instrument with *Internal standard solution* to zero emittance.

Calculate the percentage of the labeled amount of sodium carbonate (Na_2CO_3) in the portion of Irrigation taken:

$$\text{Result} = (r_{U,591}/r_{U,671}) \times (r_{S,671}/r_{S,591}) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

$r_{U,591}$ = emittance reading from the *Sample solution* at 591 nm

$r_{U,671}$ = emittance reading from the *Sample solution* at 671 nm

$r_{S,671}$ = emittance reading from the *Standard solution* at 671 nm

$r_{S,591}$ = emittance reading from the *Standard solution* at 591 nm

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

C_U = nominal concentration of sodium carbonate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of sodium carbonate, 105.99

M_{r2} = two times the molecular weight of sodium chloride, 116.88

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.8–4.2

• **Bacterial Endotoxins Test** ⟨85⟩**:** It contains not more than 2.80 USP Endotoxin Units per mL.

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩, except that the container may be designed to empty rapidly and may exceed 1000 mL in capacity.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose containers, preferably of Type I or Type II glass.

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

Topic/Question	Contact	Expert Committee
CITRIC ACID, MAGNESIUM OXIDE, AND SODIUM CARBONATE IRRIGATION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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