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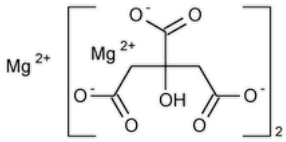
Magnesium Citrate



$C_{12}H_{10}Mg_3O_{14}$ 451.11

1,2,3-Propanetricarboxylic acid, hydroxy-, magnesium salt (2:3);

Magnesium citrate (3:2) CAS RN®: 3344-18-1.

DEFINITION

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

IDENTIFICATION

- **A.** The retention time of the magnesium peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Citrate*

Sample solution: 80 mg/mL of Magnesium Citrate in water

Acceptance criteria: Meets the requirements

ASSAY

- **Procedure**

Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.

Mobile phase: 48 mM methanesulfonic acid. [Note—It is recommended to use suitable cation trapping techniques to ensure the *Mobile phase* is free of all cationic impurities.]

Diluent: 0.02 N hydrochloric acid

System suitability solution: 120 µg/mL of USP Magnesium Citrate RS and 5 µg/mL of USP Calcium Carbonate RS in *Diluent*

Standard stock solution: 6 mg/mL of USP Magnesium Citrate RS prepared as follows. Transfer an appropriate portion of USP Magnesium Citrate RS to a suitable volumetric flask. Add about 20% of the final volume of 6 N hydrochloric acid, and dissolve. Dilute with water to volume.

Standard solution: 120 µg/mL of USP Magnesium Citrate RS in water from the *Standard stock solution*

Sample stock solution: 6 mg/mL of Magnesium Citrate from the previously dried Magnesium Citrate prepared as directed for the *Standard stock solution*

Sample solution: 120 µg/mL of Magnesium Citrate in water from the *Sample stock solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: Conductivity with suppression

Columns

Guard: 5-mm × 5-cm; 5.5-µm packing L84

Analytical: 5-mm × 25-cm; 5.5-µm packing L84

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

Run time: NLT 2 times the retention time of magnesium

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for the magnesium and calcium ions are 1.0 and 1.3, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the magnesium and calcium ions, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of magnesium (Mg) in the portion of Magnesium Citrate taken:

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

r_U = peak response of magnesium from the *Sample solution*

r_S = peak response of magnesium from the *Standard solution*

C_S = concentration of USP Magnesium Citrate RS in the *Standard solution* (µg/mL)

C_U = concentration of Magnesium Citrate in the *Sample solution* (µg/mL)

A_r = atomic weight of magnesium, 24.31

M_r = molecular weight of magnesium citrate, 451.11

F = number of magnesium ions in one mole of magnesium citrate, 3

Acceptance criteria: 14.5%–16.4% on the dried basis

IMPURITIES

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

Standard solution: 0.20 mL of 0.020 N hydrochloric acid VS

Sample: 300 mg of Magnesium Citrate

Acceptance criteria: The *Sample* shows no more chloride than the *Standard solution* (0.05%).

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

Standard solution: 0.20 mL of 0.020 N sulfuric acid VS

Sample: 100 mg of Magnesium Citrate

Acceptance criteria: The *Sample* shows no more sulfate than the *Standard solution* (0.2%).

Change to read:

• **▲Arsenic ⟨211⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023) :** NMT 3 ppm

Change to read:

• **▲Iron ⟨241⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023)**

Sample solution: Boil 50 mg of Magnesium Citrate with 5 mL of 2 N nitric acid for 1 min. Cool, dilute with water to 45 mL, and add 2 mL of hydrochloric acid.

Acceptance criteria: NMT 200 ppm

• **Limit of Calcium**

Mobile phase, Diluent, System suitability solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 3.0 µg/mL of USP Calcium Carbonate RS in *Diluent*

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for the magnesium and calcium ions are 1.0 and 1.3, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the magnesium and calcium ions, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5%, *Standard solution*

Analysis

Samples: *Sample solution* and *Standard solution*

Measure the response for the calcium peak.

Acceptance criteria: NMT 1.0% on the dried basis. The peak response of calcium from the *Sample solution* does not exceed that of the *Standard solution*.

SPECIFIC TESTS

• **pH ⟨791⟩**

Sample solution: 50 mg/mL of Magnesium Citrate suspension in water

Acceptance criteria: 5.0–9.0

• **Loss on Drying ⟨731⟩**

Sample: 1 g of Magnesium Citrate

Analysis: Dry the *Sample* in a mechanical convection oven at 135° for 16 h, then to constant weight.

Acceptance criteria: NMT 29% for Magnesium Citrate; NMT 2.0% for Magnesium Citrate where it is labeled as anhydrous

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** Magnesium Citrate that loses NMT 2.0% of its weight in the test for *Loss on Drying* may be labeled as Anhydrous Magnesium Citrate.

- **USP Reference Standards** ⟨11⟩

USP Calcium Carbonate RS
USP Magnesium Citrate RS

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

Topic/Question	Contact	Expert Committee
MAGNESIUM CITRATE	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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