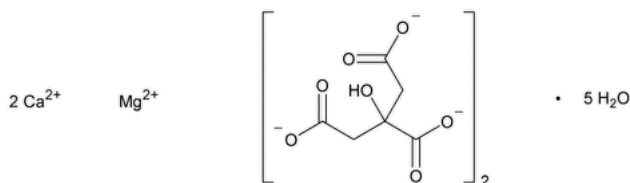


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Add the following:

▲ Calcium Magnesium Citrate



$C_{12}H_{10}Ca_2MgO_{14} \cdot 5H_2O$ 572.72

Calcium magnesium citrate pentahydrate. CAS RN[®]: 1370511-52-6.

DEFINITION

Calcium Magnesium Citrate is a salt of citric acid with calcium and magnesium and may contain up to 5 molecules of water of hydration. It contains NLT 15.4% and NMT 17.8% of calcium (Ca), NLT 4.7% and NMT 5.4% of magnesium (Mg), and NLT 76.0% and NMT 80.7% of citrate, all calculated on the dried basis. It contains NLT 97.0% of calcium magnesium citrate ($Ca_2MgC_{12}H_{10}O_{14}$), calculated on the dried basis.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Calcium, Citrate, and Magnesium:** Meets the requirements
- **B.** The retention times of the magnesium peak and the calcium peak of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the test for *Content of Calcium and Magnesium*. The retention time of the citrate peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the test for *Content of Citrate*.

ASSAY

• CONTENT OF CALCIUM AND MAGNESIUM

Mobile phase: 20 mM [methanesulfonic acid](#) in [water](#)

Calcium standard stock solution: Accurately transfer 200 mg of [USP Calcium Carbonate RS](#) to 10-mL volumetric flask, add 5 mL of [water](#), and slowly add 1.5 mL of [hydrochloric acid](#). Cool the solution to room temperature while mixing it intermittently. Dilute with [water](#) to volume and mix. This solution contains 8.0 mg/mL of calcium.

Magnesium standard stock solution: Accurately transfer 30 mg of magnesium metal to a 10-mL volumetric flask, add 5 mL of [water](#), and slowly add 1.5 mL of [hydrochloric acid](#) under a well-ventilated fume hood. Cool the solution to room temperature while mixing it intermittently. Dilute with [water](#) to volume and mix. This solution contains 3.0 mg/mL of magnesium.

Standard solution: Transfer 10.0 mL of [water](#) to a 100-mL volumetric flask and transfer 1.0 mL each of *Calcium standard stock solution* and *Magnesium standard stock solution*. Dilute with [water](#) to volume and mix. This solution contains 0.08 mg/mL of calcium and 0.03 mg/mL of magnesium. [NOTE—Commercially available standard solutions of calcium and magnesium may be used to prepare the *Standard solution*.]

Sample solution: Transfer 50 mg of Calcium Magnesium Citrate, previously dried, to a 100-mL volumetric flask, add 5 mL of [water](#) and 0.5 mL of [methanesulfonic acid](#), sonicate to dissolve, and mix. Dilute with [water](#) to volume and mix. Pass 2 mL of this solution through a 0.45-μm nylon filter into a polypropylene vial for chromatographic analysis.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: Ion chromatography

Detector: Conductivity with cation suppressor

Columns

Guard: 4-mm × 5-cm; 8.5-μm packing L106

Analytical: 4-mm × 25-cm; 8.5-μm packing L106

Cation suppressor: Use self-regenerating cation suppressor. Set the current to 60 milliamperes or optimize according to manufacturer's recommendations to achieve optimal signal-to-noise ratio.

Column temperature: 35°

Flow rate: 1.0 mL/min

Injection volume: 25 μL

Run time: NLT 2 times the retention time of calcium

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for magnesium and calcium are 0.81 and 1.00, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the magnesium and calcium peaks

Tailing factor: NMT 2 each for the magnesium and calcium peaks

Relative standard deviation: NMT 2.0% each for the magnesium and calcium peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate separately the percentages of calcium and magnesium in the portion of Calcium Magnesium Citrate taken:

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

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

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

C_S = concentration of [USP Calcium Carbonate RS](#) or magnesium in the *Standard solution* (mg/mL)

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

Acceptance criteria

Calcium: 15.4%–17.8% on the dried basis

Magnesium: 4.7%–5.4% on the dried basis

• CONTENT OF CITRATE

Diluent: 0.2 N [hydrochloric acid](#)

Mobile phase: 50 mM [monobasic potassium phosphate](#) in [water](#), adjusted with [phosphoric acid](#) to a pH of 2.5

Standard solution: 1.8 mg/mL of [USP Citric Acid RS](#) in *Diluent*

Sample solution: 2.5 mg/mL of Calcium Magnesium Citrate in *Diluent*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 226 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 35°

Flow rate: 1.0 mL/min

Injection volume: 10 μL

Run time: NLT 3 times the retention time of citrate

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 6000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of citrate in the portion of Calcium Magnesium Citrate taken:

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

r_U = peak response of citrate in the *Sample solution*

r_S = peak response citrate in the *Standard solution*

C_S = concentration of [USP Citric Acid RS](#) in the *Standard solution* (mg/mL)

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

F = factor to convert molecular weight of citric acid to that of citrate, 0.98

Acceptance criteria: 76.0%–80.7% on the dried basis

• CONTENT OF CALCIUM MAGNESIUM CITRATE

Analysis: Calculate the total content of calcium, magnesium, and citrate by adding the individual percentages on the dried basis, as obtained in the tests for *Content of Calcium and Magnesium* and *Content of Citrate*.

Acceptance criteria: NLT 97.0% on the dried basis

IMPURITIES