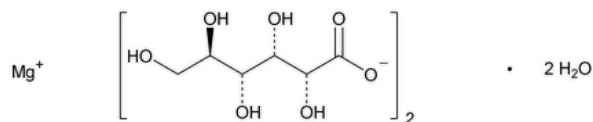


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Magnesium Gluconate



$C_{12}H_{22}MgO_{14}$ 414.60

$C_{12}H_{22}MgO_{14} \cdot 2H_2O$ 450.64

D-Gluconic acid, magnesium salt (2:1), hydrate;

Magnesium D-gluconate (1:2) hydrate;

Magnesium D-gluconate (1:2) dihydrate CAS RN®: 59625-89-7; UNII: T42NAD2KHC.

Anhydrous CAS RN®: 3632-91-5; UNII: TH52F4317B.

DEFINITION

Magnesium Gluconate contains NLT 98.0% and NMT 102.0% of anhydrous magnesium gluconate ($C_{12}H_{22}MgO_{14}$), calculated on the anhydrous basis.

IDENTIFICATION

• **A. IDENTIFICATION TESTS—GENERAL, [Magnesium\(191\)](#):** A 100-mg/mL solution meets the requirements.

• **B. THIN-LAYER CHROMATOGRAPHY**

Standard solution: 10 mg/mL of [USP Potassium Gluconate RS](#)

Sample solution: 10 mg/mL of Magnesium Gluconate, heating in a water bath at 60°, if necessary, to dissolve

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 5 µL

Developing solvent system: Alcohol, ethyl acetate, ammonium hydroxide, and water (50:10:10:30)

Spray reagent: Dissolve 2.5 g of ammonium molybdate in 50 mL of 2 N sulfuric acid in a 100-mL volumetric flask, add 1.0 g of ceric sulfate, swirl to dissolve, and dilute with 2 N sulfuric acid to volume.

Analysis

Samples: *Standard solution* and *Sample solution*

Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and dry at 110° for 20 min. Allow to cool, and spray with the *Spray reagent*. Heat the plate at 110° for about 10 min.

Acceptance criteria: The principal spot of the *Sample solution* corresponds in color, size, and R_f value to that of the *Standard solution*.

ASSAY

• **PROCEDURE**

Sample: 800 mg of Magnesium Gluconate

Blank: 20 mL of water

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in 20 mL of water. Add 5 mL of ammonia–ammonium chloride buffer TS and 0.1 mL of eriochrome black TS.

Titrate with *Titrant* to a blue endpoint. Perform the *Blank* determination.

Calculate the percentage of magnesium gluconate ($C_{12}H_{22}MgO_{14}$) in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times M \times F] / W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)

V_B = *Titrant* volume consumed by the *Blank* (mL)

M = *Titrant* molarity (mM/mL)

F = equivalency factor, 414.6 mg/mM

W = *Sample* weight (mg)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• [CHLORIDE AND SULFATE, Chloride\(221\)](#).

Standard solution: 0.7 mL of 0.020 N hydrochloric acid

Sample: 1.0 g

Acceptance criteria: NMT 0.05%

• [CHLORIDE AND SULFATE, Sulfate\(221\)](#).

Standard solution: 1.0 mL of 0.020 N sulfuric acid

Sample: 2.0 g

Acceptance criteria: NMT 0.05%

• REDUCING SUBSTANCES

Sample: 1.0 g of Magnesium Gluconate

Blank: 10 mL of water

Titrimetric system

(See [Titrimetry\(541\)](#).)

Mode: Residual titration

Titrant: 0.1 N iodine VS

Back titrant: 0.1 N sodium thiosulfate VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a 250-mL conical flask, dissolve in 10 mL of water, and add 25 mL of alkaline cupric citrate TS. Cover the flask, boil gently for 5 min, accurately timed, and cool rapidly to room temperature. Add 25 mL of 0.6 N acetic acid, 10.0 mL of *Titrant*, and 10 mL of 3 N hydrochloric acid, and titrate with *Back titrant*, adding 3 mL of starch TS as the endpoint is approached. Perform the *Blank* determination.

Calculate the percentage of reducing substances (as dextrose) in the *Sample* taken:

$$\text{Result} = \{[(V_B - V_S) \times N \times F] / W\} \times 100$$

V_B = *Back titrant* volume consumed by the *Blank* (mL)

V_S = *Back titrant* volume consumed by the *Sample* (mL)

N = *Back titrant* normality (mEq/mL)

F = equivalency factor, 27 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

• [pH\(791\)](#).

Sample solution: 50 mg/mL

Acceptance criteria: 6.0–7.8

• [WATER DETERMINATION, Method Ib\(921\)](#).

Test preparation: Proceed as directed in the chapter. Allow 30 min for solubilization of Magnesium Gluconate and for the reaction to reach completion.

Blank: Use the same volume of *Reagent* as that of the *Test preparation* but without the specimen.

Analysis

Samples: *Test preparation and Blank*

Calculate the water content, in mg, of the Magnesium Gluconate taken:

$$\text{Result} = F \times (X_B - X) \times R$$

X_B = volume of standardized *Water–Methanol Solution* required to neutralize the unconsumed *Reagent* in the *Blank* determination (mL)

The other terms are as defined in [Water Determination, Method Ib \(921\)](#).

Acceptance criteria: 3.0%–12.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS (11).**
[USP Potassium Gluconate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
MAGNESIUM GLUCONATE	Nagaphani Batchu Senior Scientist I, Documentary Standards	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

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