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Magnesium Gluconate Tablets

DEFINITION

Magnesium Gluconate Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of magnesium gluconate ($C_{12}H_{22}MgO_{14}$).

IDENTIFICATION

• **A. Identification Tests—General, *Magnesium*⟨191⟩**

Sample solution: A filtered solution in water from powdered Tablets, equivalent to 100 mg/mL of magnesium gluconate

Acceptance criteria: Meet the requirements

• **B. Thin-Layer Chromatographic Identification Test**

Standard solution: 10 mg/mL of USP Potassium Gluconate RS

Sample solution: Equivalent to 10 mg/mL of magnesium gluconate from a dilution of the *Sample solution* obtained for the *Identification* test *A*

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 *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: A portion of the powder from NLT 20 finely powdered Tablets, equivalent to 800 mg of magnesium gluconate

Blank: Proceed as directed in the *Analysis* without the *Sample*.

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to a crucible, and ignite, gently at first, until free from carbon. Cool the crucible, add 25 mL of water and 5 mL of hydrochloric acid, and stir. Heat on a steam bath for 5 min. Filter, rinsing the filter with several portions of water. Dilute the combined filtrate and washings with water to 150 mL. Add ammonia–ammonium chloride buffer TS until the solution is neutral to litmus. Add an excess of 5 mL of ammonia–ammonium chloride buffer TS and 0.1 mL of eriochrome black TS, and titrate with *Titrant* to a blue endpoint. Perform a *Blank* determination.

Calculate the percentage of the labeled amount of magnesium gluconate ($C_{12}H_{22}MgO_{14}$) in the portion of Tablets 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 = actual molarity of the *Titrant* (mM/mL)

F = equivalency factor, 414.6 mg/mM

W = nominal amount of magnesium gluconate in the *Sample* taken (mg)

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: Solution having a known concentration of magnesium in the *Medium*

Sample solution: Filtered portion of the solution under test, suitably diluted with the *Medium* if necessary

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 285.2 nm

Lamp: Magnesium hollow-cathode

Flame: Air–acetylene

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the concentration of magnesium (Mg) in the *Sample solution* in comparison with a *Standard solution*.

Calculate the percentage of the labeled amount of magnesium gluconate ($C_{12}H_{22}MgO_{14}$) dissolved:

$$\text{Result} = (C \times D \times V/L) \times (M_r/A_r) \times 100$$

C = determined concentration of magnesium in the *Sample solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label amount of magnesium gluconate (mg/Tablet)

M_r = molecular weight of magnesium gluconate, 414.60

A_r = atomic weight of magnesium, 24.31

Tolerances: NLT 80.0% (Q) of the labeled amount of magnesium gluconate ($C_{12}H_{22}MgO_{14}$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

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 TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable
Current DocID: GUID-F60BEC83-8689-4276-82E0-B56A3768D2C9_2_en-US
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