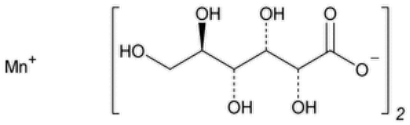
Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Jan-2018
Document Type: USP Monographs
DocId: GUID-5D003D77-418D-4AF8-B4A9-6B09AE01DA3D_3_en-US
DOI: https://doi.org/10.31003/USPNF_M47146_03_01
DOI Ref: 3vs92

Manganese Gluconate



$C_{12}H_{22}MnO_{14}$ 445.23
$C_{12}H_{22}MnO_{14} \cdot 2H_2O$ 481.26
Bis(D-gluconato-O^1,O^2) manganese;
Manganese D-gluconate (1:2).
Anhydrous CAS RN®: 6485-39-8.

DEFINITION

Manganese Gluconate is dried or contains two molecules of water of hydration. It contains NLT 98.0% and NMT 102.0% of manganese gluconate ($C_{12}H_{22}MnO_{14}$), calculated on the anhydrous basis.

IDENTIFICATION

- **A. Identification Tests—General, *Manganese* ⟨191⟩:** A 50-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 Manganese 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 *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: 700 mg of Manganese Gluconate

Blank: 50 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 50 mL of water. Add 1 g of ascorbic acid and 10 mL of ammonia–ammonium chloride buffer TS and 0.1 mL of eriochrome black TS. Titrate with the *Titrant* until the solution is deep blue in color. Perform the blank determination.

Calculate the percentage of manganese gluconate ($C_{12}H_{22}MnO_{14}$) 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 = actual molarity of the *Titrant* (mmol/mL)

F = equivalency factor, 445.2 mg/mmol

W = *Sample* weight (mg)

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

IMPURITIES

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

Standard: 0.70 mL of 0.020 N hydrochloric acid

Sample: 1.0 g of Manganese Gluconate

Acceptance criteria: NMT 0.05%

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

Standard: 4.0 mL of 0.020 N sulfuric acid

Sample: 2.0 g of Manganese Gluconate

Acceptance criteria: NMT 0.2%

• **Lead**

[Note—For the preparation of all aqueous solutions and for the rinsing of glassware before use, use water that has been passed through a strong-acid, strong-base, mixed-bed ion-exchange resin. Select all reagents to have as low a content of lead as practicable, and store all reagent solutions in containers of borosilicate glass. Cleanse glassware before use by soaking in warm 8 N nitric acid for 30 min and by rinsing with deionized water.]

Ascorbic acid–sodium iodide solution: 100 mg/mL of ascorbic acid and 192.5 mg/mL of sodium iodide

Trioctylphosphine oxide solution: 50 mg/mL of trioctylphosphine oxide in 4-methyl-2-pentanone.

[**Caution—**This solution causes irritation. Avoid contact with eyes, skin, and clothing. Take special precautions in disposing of unused portions of solutions to which this reagent is added.]

Standard solution: Transfer 5.0 mL of lead nitrate stock solution TS, to a 100-mL volumetric flask. Dilute with water to volume. Transfer 2.0 mL of the resulting solution to a 50-mL volumetric flask. Add 10 mL of 9 N hydrochloric acid and 10 mL of water. Add 20 mL of *Ascorbic acid–sodium iodide solution* and 5.0 mL of *Trioctylphosphine oxide solution*. Shake for 30 s, and allow to separate. Add water to bring the organic solvent layer into the neck of the flask, shake again, and allow to separate. The organic layer is the *Standard solution*, and it contains 2.0 µg/mL of lead.

Sample solution: To a 50-mL volumetric flask add 1.0 g of Manganese Gluconate, 10 mL of 9 N hydrochloric acid, 10 mL of water, 20 mL of *Ascorbic acid–sodium iodide solution*, and 5.0 mL of *Trioctylphosphine oxide solution*. Shake for 30 s, and allow to separate. Add water to bring the organic solvent layer into the neck of the flask, shake again, and allow to separate. The organic layer is the *Sample solution*.

Blank: To a 50-mL volumetric flask add 10 mL of 9 N hydrochloric acid, 10 mL of water, 20 mL of *Ascorbic acid–sodium iodide solution*, and 5.0 mL of *Trioctylphosphine oxide solution*. Shake for 30 s, and allow to separate. Add water to bring the organic solvent layer into the neck of the flask, shake again, and allow to separate. The organic layer is the *Blank*, and it contains 0 µg/mL of lead.

Instrumental conditions

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

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 283.3 nm

Lamp: Lead hollow-cathode

Flame: Air–acetylene

System suitability

Samples: *Standard solution* and *Blank*

Suitability requirements: The absorbance of the *Standard solution* and the absorbance of the *Blank* are significantly different.

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Concomitantly determine the absorbances of the *Blank*, *Standard solution*, and the *Sample solution*. Use the *Blank* to set the instrument to zero.

Acceptance criteria: The absorbance of the *Sample solution* does not exceed that of the *Standard solution* (NMT 10 ppm).

• **Reducing Substances**

Sample: 1.0 g of Manganese Gluconate

Blank: Proceed as directed in the *Analysis*, omitting the *Sample*.

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

• **Water Determination,** *Method I* ⟨921⟩

Analysis: Proceed as directed in the chapter. Maintain the mixture containing the *Test preparation* at 50°, and stir for 30 min before titrating with the *Reagent*.

Acceptance criteria

Where labeled as the dried form: 3.0%–9.0%

Where labeled as the dihydrate: 6.0%–9.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **Labeling:** The label indicates whether it is the dried or the dihydrate form.

• **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
MANGANESE 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(5)

Current DocID: GUID-5D003D77-418D-4AF8-B4A9-6B09AE01DA3D_3_en-US
Previous DocID: GUID-5D003D77-418D-4AF8-B4A9-6B09AE01DA3D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M47146_03_01
DOI ref: 3vs92