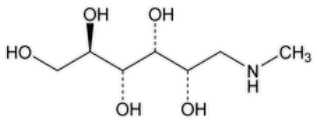
Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Jan-2018
Document Type: USP Monographs
DocId: GUID-2C4F2CFC-7787-40FC-AE46-A22FE495A8DF_4_en-US
DOI: https://doi.org/10.31003/USPNF_M48080_04_01
DOI Ref: 00e3t

Meglumine



$C_7H_{17}NO_5$ 195.21

D-Glucitol, 1-deoxy-1-(methylamino)-;

1-Deoxy-1-(methylamino)-D-glucitol CAS RN®: 6284-40-8.

DEFINITION

Meglumine contains NLT 99.0% and NMT 100.5% of meglumine ($C_7H_{17}NO_5$), calculated on the dried basis.

IDENTIFICATION

• **A.**

Sample solution: Transfer 250 mg to a dry, 50-mL centrifuge tube, add 500 mg of sodium metaperiodate, then add 5 mL of water rapidly in one portion. Allow to stand undisturbed.

Analysis: The solution instantly turns yellow, and heat is produced. The color then changes from deep yellow to orange-brown (rust), and after 20 min, the rust-colored solution is cloudy. Then add 2 mL of 2.5 N sodium hydroxide.

Acceptance criteria: The mixture turns bright yellow and becomes clear.

ASSAY

• **Procedure**

Sample: 500 mg

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N hydrochloric acid

Endpoint detection: Visual

Analysis: Transfer the *Sample* into a conical flask, dissolve in 40 mL of water, and add 2 drops of methyl red TS. Titrate with *Titrant*. Each mL of *Titrant* is equivalent to 19.52 mg of meglumine ($C_7H_{17}NO_5$).

Acceptance criteria: 99.0%–100.5% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

SPECIFIC TESTS

• **Absence of Reducing Substances**

Sample solution: 50 mg/mL

Analysis: To 5 mL of *Sample solution* add 5 mL of alkaline cupric tartrate TS, and heat to boiling.

Acceptance criteria: The color of the solution does not change.

• **Completeness and Color of Solution**

Sample solution: 200 mg/mL

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: Vis

Analytical wavelength: 420 nm

Cell: 1 cm

Blank: Water

Analysis

Sample: *Sample solution*

Acceptance criteria: Absorbance is NMT 0.030.

- **Loss on Drying ⟨731⟩**

Sample: 1 g

Analysis: Dry the *Sample* at 105° to constant weight.

Acceptance criteria: NMT 1.0%

- **Melting Range or Temperature ⟨741⟩:** 128°–132°
- **Optical Rotation,** *Specific Rotation*⟨781S⟩

Sample solution: 100 mg/mL, undried, in water

Acceptance criteria: −15.7° to −17.3°

ADDITIONAL REQUIREMENTS

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

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

Topic/Question	Contact	Expert Committee
MEGLUMINE	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-2C4F2CFC-7787-40FC-AE46-A22FE495A8DF_4_en-US
Previous DocID: GUID-2C4F2CFC-7787-40FC-AE46-A22FE495A8DF_2_en-US
Previous DocID: GUID-2C4F2CFC-7787-40FC-AE46-A22FE495A8DF_1_en-US
DOI: https://doi.org/10.31003/USPNF_M48080_04_01
DOI ref: 00e3t