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Add the following:

▲Mannitol Compounded Injection

DEFINITION

Mannitol Compounded Injection contains NLT 95.0% and NMT 105.0% of the labeled amount of mannitol ($C_6H_{14}O_6$).

Prepare Mannitol Compounded Injection 250 mg/mL (1372 mOsmol/L or 25% w/v) as follows (see *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩).

Mannitol powder	25 g
Water for Injection, a sufficient quantity to make	100 mL

Dissolve the *Mannitol powder* in about 80% of the *Water for Injection* in an appropriate container. Gentle heating (to 40°–45°) may be applied to achieve complete dissolution. Allow to cool to room temperature. Add sufficient *Water for Injection* to bring to final volume and mix well. Pass through a filter of 0.45-µm or 1.2-µm pore size and then autoclave to achieve terminal sterilization (see *Moist Heat Sterilization of Aqueous Liquids*⟨1229.2⟩).

ASSAY

• **Procedure**

Standard solution: 2.5 mg/mL of USP Mannitol RS in water. Vortex, shake, and sonicate solution until completely dissolved.

Sample solution: Heat vial at 80° in a water bath for 30 min with occasional vigorous shaking to dissolve all crystals. Hold sample against a Tyndall beam to make sure there are no insoluble particles. Cool sample for 10 min. Shake vial for 30 s and transfer 2 mL of sample into a small polystyrene cup. Pipette 1 mL of sample into a 100-mL volumetric flask using a class A "To Contain" glass pipette. Rinse the pipette NLT 3 times using *Water* and add the contents into the same 100-mL volumetric flask. Bring the volumetric flask to volume with *Water*. Vortex and shake solution until well mixed.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: Refractive index

Column: 8.0-mm × 30-cm; 7-µm packing L22

Temperatures

Autosampler: 10°

Column: 80°

Flow rate: 1.0 mL/min

Injection volume: 80 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for mannitol is about 17.0 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of mannitol ($C_6H_{14}O_6$) in the portion of Injection taken:

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

r_U = peak response of mannitol from the *Sample solution*

r_S = peak response of mannitol from the *Standard solution*

C_S = concentration of USP Mannitol RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of mannitol in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.5–6.5

• **Appearance:** Clear, colorless solution with no particles

• **Sterility Tests** ⟨71⟩, *Test for Sterility of the Product to Be Examined, Membrane Filtration***:** It meets the requirements.

• **Bacterial Endotoxins Test** ⟨85⟩**:** It contains NMT 0.04 USP Endotoxin Unit/mg of mannitol where the labeled amount of mannitol in the Injection is 10% or less, and NMT 2.5 USP Endotoxin Units/g of mannitol where the labeled amount of mannitol in the Injection is greater than 10%.

• **Particulate Matter in Injections** ⟨788⟩**:** It meets the requirements.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in single-dose, sterile, amber, glass containers with bromobutyl stoppers and aluminum caps. Do not transfer into polyvinyl chloride (PVC) bags. Store at controlled room temperature.

• **Beyond-Use Date:** In the absence of passing a sterility test and endotoxins test, the beyond-use dates (BUDs) in ⟨797⟩ apply. If prepared as a Category 2 or Category 3 compounded sterile preparation (CSP) and the requirements of a sterility test and endotoxins test are met, NMT 90 days when stored at controlled room temperature.

• **Labeling:** Label to indicate the *Beyond-Use Date*. If crystals are present, warm to dissolve. Administer with a filter.

• **USP Reference Standards** ⟨11⟩
USP Mannitol RS▲ (USP 1-Dec-2024)

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

Topic/Question	Contact	Expert Committee
MANNITOL COMPOUNDED INJECTION	Blaine Groat Scientific Liaison	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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