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Manganese Chloride Injection

» Manganese Chloride Injection is a sterile solution of Manganese Chloride in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of manganese (Mn).

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I or Type II glass.

Labeling—Label the Injection to indicate that it is to be diluted to the appropriate strength with Sterile Water for Injection or other suitable fluid prior to administration.

Identification—The Assay preparation, prepared as directed in the Assay, exhibits an absorption maximum at about 279 nm when tested as directed for Procedure in the Assay.

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 0.45 USP Endotoxin Unit per μg of manganese.

pH (791): between 1.5 and 2.5.

PARTICULATE MATTER IN INJECTIONS (788): meets the requirements for small-volume injections.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products (1)*.

Assay—

Sodium chloride solution—Dissolve 1.8 g of sodium chloride in water, dilute with water to 2000 mL, and mix.

Manganese stock solution—Transfer 1.000 g of manganese to a 1000-mL volumetric flask, dissolve in 20 mL of nitric acid, dilute with 0.1 N hydrochloric acid to volume, and mix. This solution contains 1000 μg of manganese per mL. Store in a polyethylene bottle.

Standard preparations—Pipet 10 mL of the *Manganese stock solution* into a 500-mL volumetric flask, dilute with water to volume, and mix. Transfer 4.0, 5.0, and 6.0 mL, respectively, of this solution to separate 50-mL volumetric flasks, containing 10 mL of *Sodium chloride solution*, dilute the contents of each flask with water to volume, and mix. These *Standard preparations* contain, respectively, 1.6, 2.0, and 2.4 μg of manganese per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 1 mg of manganese, to a 100-mL volumetric flask, dilute with water to volume, and mix. Pipet 10 mL of this solution into a 50-mL volumetric flask. From the labeled amount of sodium chloride, if any, in the Injection, calculate the amount, in mg, of sodium chloride in the initial dilution, and add sufficient *Sodium chloride solution* to bring the total sodium chloride content in this flask to 9 mg. Dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard preparations* and the *Assay preparation* at the manganese emission line of 279 nm, with a suitable atomic absorption spectrophotometer (see *Atomic Absorption Spectroscopy (852)*) equipped with a manganese hollow-cathode lamp and an air–acetylene flame, using a dilution of *Sodium chloride solution* (1:5) as the blank. Plot the absorbances of the *Standard preparations* versus concentration, in μg per mL, of manganese, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, in μg per mL, of manganese in the *Assay preparation*. Calculate the quantity, in mg, of manganese in each mL of the Injection taken by the formula:

$$0.5C/V$$

in which C is the concentration, in μg per mL, of manganese in the *Assay preparation*; and V is the volume, in mL, of Injection taken.

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

Topic/Question	Contact	Expert Committee
MANGANESE CHLORIDE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

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