

Manganese Sulfate Injection

Type of Posting	Revision Bulletin, Postponement
Posting Date	26-Jul-2019
Official Date	01-Aug-2019
Expert Committee	Chemical Medicines Monographs 3
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Chemical Medicines Monographs 3 Expert Committee has indefinitely postponed the omission of the Manganese Sulfate Injection monograph. Comments have been received and confirmed with the FDA noting the need for the monograph to support public health.

The Manganese Sulfate Injection Revision Bulletin postponement will supersede the monograph omission becoming official in the *First Supplement to USP42–NF37*.

Should you have any questions, please contact Morgan Puderbaugh, Senior Scientific Liaison (301-998-6833 or mxp@usp.org).

Change to read:

Manganese Sulfate Injection

▲The omission of this monograph has been postponed. As of August 1, 2019, this monograph remains official USP text. ▲ (RB 1-Aug-2019)

» Manganese Sulfate Injection is a sterile solution of Manganese Sulfate 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 2.0 and 3.5.

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, Manganese stock solution, and Standard preparations—Prepare as directed in the *Assay* under *Manganese Chloride Injection*.

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, dilute with water to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Manganese Chloride Injection*.