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Sterile Water for Injection

[NOTE—For additional information, see [Water for Pharmaceutical Purposes \(1231\)](#).]

H₂O 18.02

DEFINITION

Sterile Water for Injection is prepared from Water for Injection that is sterilized and suitably packaged. It contains no antimicrobial agent or other added substance.

SPECIFIC TESTS

Delete the following:

▲ • **OXIDIZABLE SUBSTANCES**

Sample: 100 mL

Analysis: Add 10 mL of 2 N sulfuric acid, and heat to a boil. For Sterile Water for Injection in containers having a fill volume less than 50 mL, add 0.4 mL of 0.02 M potassium permanganate, and boil for 5 min; where the fill volume is 50 mL or more, add 0.2 mL of 0.02 M potassium permanganate, and boil for 5 min. If a precipitate forms, cool in an ice bath to room temperature, and pass through a sintered-glass filter.

Acceptance criteria: The pink color does not completely disappear. Alternatively, perform the test for [Total Organic Carbon \(643\)](#), [Sterile Water](#). ▲ (USP 1-May-2021)

Change to read:

- [TOTAL ORGANIC CARBON \(643\)](#), [Procedures, Sterile Water](#): Meets the requirements ▲ (USP 1-May-2021)
- [WATER CONDUCTIVITY \(645\)](#), [Sterile Water](#): Meets the requirements
- [PARTICULATE MATTER IN INJECTIONS \(788\)](#): Meets the requirements
- [STERILITY TESTS \(71\)](#): Meets the requirements
- [BACTERIAL ENDOTOXINS TEST \(85\)](#): Less than 0.25 USP Endotoxin Units/mL

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose glass or plastic containers of not larger than 1-L size. Glass containers are preferably of Type I or Type II glass.
- **LABELING:** Label it to indicate that no antimicrobial or other substance has been added, and that it is not suitable for intravascular injection without first having been made approximately isotonic by the addition of a suitable solute.

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

Topic/Question	Contact	Expert Committee
STERILE WATER FOR INJECTION	Antonio Hernandez-Cardoso Senior Scientific Liaison	GCCA2020 General Chapters - Chemical Analysis 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	GCCA2020 General Chapters - Chemical Analysis 2020

Chromatographic Database Information: [Chromatographic Database](#)

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