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Sterile Purified Water

[NOTE—For additional information, see [Water for Pharmaceutical Purposes \(1231\)](#).]
H₂O 18.02

DEFINITION
Sterile Purified Water is Purified Water sterilized and suitably packaged. It contains no antimicrobial agents.
[NOTE—Do not use Sterile Purified Water in preparations intended for parenteral administration. For such purposes use Water for Injection, Bacteriostatic Water for Injection, or Sterile Water for Injection.]

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 Purified Water in containers having a fill volume of 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
- [STERILITY TESTS \(71\)](#): Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in suitable tight containers.
- **LABELING:** Label it to indicate the method for preparation and to indicate that it is not for parenteral administration.

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

Topic/Question	Contact	Expert Committee
STERILE PURIFIED WATER	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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