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Sterile Water for Inhalation

[Note—For additional information, see Water for Pharmaceutical Purposes ⟨1231⟩.]

H_2O 18.02

DEFINITION

Sterile Water for Inhalation is prepared from Water for Injection that is sterilized and suitably packaged. It contains no added antimicrobial agents. [Note—Do not use Sterile Water for Inhalation for parenteral administration or for other sterile compendial dosage forms.]

SPECIFIC TESTS

Delete the following:

▲• **Oxidizable Substances**

Sample: 100 mL

Analysis: Add 10 mL of 2 N sulfuric acid, and heat to boiling. For Sterile Water for Inhalation 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

• **Bacterial Endotoxins Test ⟨85⟩:** Less than 0.5 USP Endotoxin Units/mL

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in glass or plastic containers. Glass containers are preferably of Type I or Type II glass.

• **Labeling:** Label it to indicate that it is for inhalation therapy only and 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 WATER FOR INHALATION	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

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