Sterile Water for Inhalation

[NOTE—For microbiological guidance, see Water for Pharmaceutical Purposes (1231).]

**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**

- **OXIDIZABLE SUBSTANCES**
  
  **Sample:** 100 mL
  
  **Analysis:** Add 10 mL of N sulfuric acid, and heat to boiling. For Sterile Water for Inhalation 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.

- **WATER CONDUCTIVITY, Sterile Water (645):** Meets the requirements

- **STERILITY TESTS (71):** Meets the requirements

- **BACTERIAL ENDOTOXINS TEST (85):** Less than 0.5 USP Endotoxin Unit/mL

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in glass or plastic containers. Glass containers are preferably 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.

- **USP REFERENCE STANDARDS (11)**
  
  **USP Endotoxin RS**

Sterile Water for Injection

[NOTE—For microbiological guidance, see Water for Pharmaceutical Purposes (1231).]

**DEFINITION**
Sterile Water for Injection is prepared from Water for Injection that is sterilized and suitably packaged. It contains no added antimicrobial agents.

- **USP REFERENCE STANDARDS**
  
  **USP 1,4-Benzquinone RS**
  
  **USP Endotoxin RS**
  
  **USP Sucrose RS**

**Bacteriostatic Water for Injection**

[NOTE—For microbiological guidance, see general information chapter Water for Pharmaceutical Purposes (1231).]

> Bacteriostatic Water for Injection is prepared from Water for Injection that is sterilized and suitably packaged, containing one or more suitable antimicrobial agents.

**NOTE**—Use Bacteriostatic Water for Injection with due regard for the compatibility of the antimicrobial agent or agents it contains with the particulate medicinal substance that is to be dissolved or diluted.

- **Packaging and storage:** Preserve in single-dose or multiple-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass.

- **Labeling:** Label it to indicate the name(s) and proportion(s) of the added antimicrobial agent(s). Label it also to include the statement “NOT FOR USE IN NEWBORN” in boldface capital letters on the label immediately under the official name, printed in a contrasting color, preferably red. Alternatively, the statement may be placed prominently elsewhere on the label if the statement is enclosed within a box.

- **Sterility (71):** meets the requirements

- **USP Reference standards (11):**
  
  **USP Endotoxin RS**

- **Antimicrobial agent(s):**—It meets the requirements under Antimicrobial Effectiveness Testing (51), and meets the labeled claim for content of the antimicrobial agent(s), as determined by the method set forth under Antimicrobial Agents—Content (341).

- **Bacterial endotoxins (85):**—It contains less than 0.5 USP Endotoxin Unit per mL.

- **Particulate matter (788):** meets the requirements.

- **pH (791):** between 4.5 and 7.0, in a solution containing 0.3 mL of saturated potassium chloride solution per 100 mL of test specimen.

- **Calcium:** To 100 mL add 2 mL of ammonium oxalate TS: no turbidity is produced.

- **Carbon dioxide:** To 25 mL add 25 mL of calcium hydroxide TS: the mixture remains clear.

- **Sulfate:** To 100 mL add 1 mL of barium chloride TS: no turbidity is produced.

- **Water conductivity:**

  **Sample:** 100 mL
  
  **Analysis:** Add 10 mL of N sulfuric acid, and heat to boiling. 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.
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.

• USP Reference Standards (11)
  USP Endotoxin RS

Sterile Water for Irrigation

[NOTE—For microbiological guidance, see Water for Pharmaceutical Purposes (1231).]

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

SPECIFIC TESTS

• Oxidizable Substances
  Sample: 100 mL
  Analysis: Add 10 mL of 2 N sulfuric acid, and heat to boiling. For Sterile Water for Irrigation 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.

• Water Conductivity, Sterile Water (645): Meets the requirements

• Sterility Tests (71): Meets the requirements

• Bacterial Endotoxins Test (85): Less than 0.25 USP Endotoxin Unit/mL

ADDITIONAL REQUIREMENTS

• Packaging and Storage: Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass. The container may contain a volume of more than 1 L, and may be designed to empty rapidly.

• Labeling: Label it to indicate that no antimicrobial or other substance has been added. The designations “For irrigation only” and “Not for injection” appear prominently on the label.

• USP Reference Standards (11)
  USP Endotoxin RS

Purified Water

[NOTE—For microbiological guidance, see general information chapter Water for Pharmaceutical Purposes (1231).]

H₂O 18.02

DEFINITION
Purified Water is water obtained by a suitable process. It is prepared from water complying with the U. S. Environmental Protection Agency National Primary Drinking Water Regulations or with the drinking water regulations of the European Union or of Japan, or with the World Health Organization’s Guidelines for Drinking Water Quality. It contains no added substance.

[NOTE—Purified Water whether it is available in bulk or packaged forms, is intended for use as an ingredient of official preparations and in tests and assays unless otherwise specified (see 8.230. Water under 8. Terms and Definitions in the General Notices and Requirements). Where used for sterile dosage forms, other than for parenteral administration, process the article to meet the requirements under Sterility Tests (71), or first render the Purified Water sterile and thereafter protect it from microbial contamination. Do not use Purified Water in preparations intended for parenteral administration. For such purposes use Water for Injection, Bacteriostatic Water for Injection, or Sterile Water for Injection. In addition to the Specific Tests, Purified Water that is packaged for commercial use elsewhere meets the additional requirements for Packaging and Storage and Labeling as indicated under Additional Requirements.]

SPECIFIC TESTS

• Oxidizable Substances
  Sample: 100 mL
  Analysis: Add 10 mL of 2 N sulfuric acid, and heat to boiling. 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.

• Water Conductivity, Sterile Water (645): 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.

Sterile Purified Water

[NOTE—For microbiological guidance, 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

• Oxidizable Substances
  Sample: 100 mL
  Analysis: Add 10 mL of 2 N sulfuric acid, and heat to boiling. 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.

• Water Conductivity, Sterile Water (645): 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.