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Bacteriostatic Water for Injection

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

DEFINITION

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 particular medicinal substance that is to be dissolved or diluted.]

SPECIFIC TESTS

• **CALCIUM**

- Sample:** 100 mL
Analysis: Add 2 mL of ammonium oxalate TS to the *Sample*.
Acceptance criteria: No turbidity is produced.

• **CARBON DIOXIDE**

- Sample:** 25 mL
Analysis: Add 25 mL of calcium hydroxide TS to the *Sample*.
Acceptance criteria: The mixture remains clear.

• **SULFATE**

- Sample:** 100 mL
Analysis: Add 1 mL of barium chloride TS to the *Sample*.
Acceptance criteria: No turbidity is produced.

• **pH (791)**

- Sample:** To 100 mL of Bacteriostatic Water for Injection add 0.3 mL of saturated potassium chloride solution.
Acceptance criteria: 4.5–7.0

• **ANTIMICROBIAL AGENT(S):** Meets the requirements in [Antimicrobial Effectiveness Testing \(51\)](#), and meets the labeled claim for content of the antimicrobial agent(s), as determined by the method set forth in [Antimicrobial Agents—Content \(341\)](#).

- **STERILITY TESTS (71):** Meets the requirements
• **PARTICULATE MATTER IN INJECTIONS (788):** Meets the requirements
• **BACTERIAL ENDOTOXINS TEST (85):** Less than 0.5 USP Endotoxin Unit/mL

ADDITIONAL REQUIREMENTS

- **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, of not larger than 30-mL size.
- **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 Newborns”, 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.

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

Topic/Question	Contact	Expert Committee
BACTERIOSTATIC WATER FOR INJECTION	Antonio Hernandez-Cardoso Senior Scientific Liaison	GCCA2020 General Chapters - Chemical Analysis 2020

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	GCCA2020 General Chapters - Chemical Analysis 2020

Chromatographic Database Information: [Chromatographic Database](#)

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