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Water for Injection

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

H₂O 18.02

DEFINITION

Water for Injection is water purified by distillation or a purification process that is equivalent or superior to distillation in the removal of chemicals and microorganisms. 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—Water for Injection, whether it is available in bulk or packaged forms, is intended for use in the preparation of parenteral solutions. Where used for the preparation of parenteral solutions subject to final sterilization, use suitable means to minimize microbial growth, or first render the Water for Injection sterile and, thereafter, protect it from microbial contamination. For parenteral solutions that are prepared under aseptic conditions and are not sterilized by appropriate filtration or in the final container, first render the Water for Injection sterile and, thereafter, protect it from microbial contamination. In addition to the *Specific Tests*, Water for Injection that is packaged for commercial use elsewhere meets the additional requirements for *Packaging and Storage* and *Labeling* as indicated under *Additional Requirements*.]

SPECIFIC TESTS

[NOTE—Required for bulk and packaged forms of [Water for Injection](#).]

- [BACTERIAL ENDOTOXINS TEST \(85\)](#): Less than 0.25 USP Endotoxin Unit/mL
- [WATER CONDUCTIVITY, Bulk Water \(645\)](#): Meets the requirements
- [TOTAL ORGANIC CARBON \(643\)](#): Meets the requirements

ADDITIONAL REQUIREMENTS

[NOTE—Required for packaged forms of *Water for Injection*.]

- **PACKAGING AND STORAGE:** Where packaged, preserve in unreactive storage containers that are designed to prevent microbial entry.
- **LABELING:** Where packaged, label the article to state that it contains no antimicrobial or other substance, and that it is not intended for direct parenteral administration.

Delete the following:

- ▲ [USP REFERENCE STANDARDS \(11\)](#)

[USP 1,4-Benzoquinone RS](#) ▲ (ERR 1-Nov-2018)

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

Topic/Question	Contact	Expert Committee
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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