

WATER FOR INJECTION

USP, EP, JPC, GMP, EXCIPIENT

CAS #: 7732-18-5

Formula: H₂O

F.W.: 18.02 g/mol

WAFI-3150

BIO EXCIPIENT GRADE

ANALYSIS	SPECIFICATIONS
Appearance	Clear, Colorless Liquid, No Odor
Aluminum (EP)	< = 10 ppb
Ammonium (EP)	< = 0.2 ppm
Endotoxin (USP/EP/JPC)	< = 0.25 EU/mL
Calcium and Magnesium (EP)	Passes Test
Chloride (EP)	Passes Test
Conductivity (USP/EP/JPC)	Meets the Requirements
Microbial Monitoring	< 10 CFU/100mL
Nitrates (EP)	< = 0.2 ppm
Oxidizable Substances (USP/EP)	Passes Test
Particulate Matter (USP/EP)	Meets the Requirements
Residue on Evaporation (EP)	< = 3mg (0.003%)
Total Organic Carbon (USP/EP/JPC)	< = 500 ppm

General Product Overview

Water for Injection, commonly referred to as WFI, is ultrapure water meeting compendial requirements, used as a solvent in critical pharmaceutical applications. It is commonly used as a cleaning agent for anything that comes into contact with the drug or for making high purity solutions. It can also be used in the manufacture of final drug products, where sterilization takes place later in production process. BioSpectra uses WFI in-house to manufacture high purity buffer solutions. BioSpectra Water for Injection should not be confused with **Sterile** Water for Injection, used to dissolve or dilute a drug substance (API), to be immediately administered via injection or infusion. Rather, BioSpectra WFI can only be used in parenteral drug manufacturing that requires further terminal sterilization and is itself not to be considered a sterile product.

Industry Application

BioSpectra WFI is an ICH Q7 cGMP manufactured product, at our FDA registered cGMP facility in Bangor PA, USA. It is suitable for use as an ultrapure cleaning agent, solvent or as an excipient in parenteral drug applications requiring further terminal sterilization. Though not a sterile finished product, BioSpectra WFI is 0.2 micron filtered into a sterile, single-use, bioprocessing container of 200L or 1,000L. It can also be packaged in non-sterile package options of 200L, 10L, 4x4L and 6x1L. Important: WFI quality specifications are designed for pharmaceutical manufacturing and related applications. This product is not intended for direct injection, ingestion or inhalation in humans or animals.

Key Product Features

- The manufacturing of Water for Injection is performed at BioSpectra's Bangor, PA facility.
- Appears as a clear, colorless liquid with no odor
- Manufactured in accordance with ICH Q7
- Manufactured in a hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: AQUA; Water, Distilled, Conductivity or of Similar Purity

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf-Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

200L, 1,000L, 10L, 4x4L, 6x1L

[Click here to view SDS, CoAs and other supporting regulatory documents on our website.](#)

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