BIOSPECTRA
Premium Pharmaceutical Ingredients

GMP Solution
ICH-Q7 GMP Manufactured Product

Water for Injection (WFI), USP, EP, JP, GMP Excipient Grade

Sterile Filtered* into Bio-Compatible Sterile Single Use Pkg.

INTENDED FOR CRITICAL BIOPHARMA APPLICATIONS

Intended for use as a critical GMP Solution and Excipient for further parenteral manufacturing. *Intended for use in further parenteral manufacturing that requires terminal sterilization. Not intended for use as a sterile product.

Formula: H_2O
F.W.: 18.02 g/mol
CAS #: 7732-18-5
pH @ 25°C: 6.0 – 8.0
Boiling Point: 100°C
Melting Point: 0°C
Density: 1.00 g/cm^3 @ 3.98°C
Storage Temp: 5°C to 30°C

H_2O

BIO EXCIPIENT GRADE | Product Code: WAFI-3150 | Previously: WI3150

H_2O • F.W. 18.02 g/mol. • CAS# 7732-18-5

Made in the USA

These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

USP Compendia

ANALYSIS	SPECIFICATIONS
Bacterial Endotoxins Test USP <85>	Less than 0.25 EU/mL
Oxidizable Substances	Solution Remains Faintly pink
Particulate Matter	Meets USP/EP Requirements
pH	5.0 – 7.0
Total Organic Carbon <643> ◆	Meets USP/EP Requirements
pH	Meets USP/EP Requirements

EP Compendia

ANALYSIS	SPECIFICATIONS
Acidity-Alkalinity	Conforms
Appearance	Clear and Colorless Liquid
Aluminum	10 ppb max.
Ammonium	≤ 0.2 ppm
Bacterial Endotoxins	Less than 0.25 EU/mL
Calcium and Magnesium	A Blue Color is Produced
Chlorides	No Change in Appearance
Conductivity ◆	Meets the Requirements
Microbial Monitoring	<10 CFU/100mL
Nitrates	0.2 ppm max.
Oxidizable Substances	Solution Remains Faintly pink
Particulate Matter	Meets USP/EP Requirements
pH	5.0 – 7.0
Residue on Evaporation	≤ 3.0 mg (0.003%)
Total Organic Carbon ◆	0.5 mg/L max.

JP Compendia

ANALYSIS	SPECIFICATIONS
Description	Clear, colorless liquid, no odor
Bacterial Endotoxins <4.01>	Less than 0.25 EU/mL
Conductivity <2.51> ◆	Not more than 2.1μS/cm^{-1}
Total Organic Carbon <2.59> ◆	Not more than 0.50mg/L

◆ MEETS STATED VALUE AT THE TIME OF PACKAGING

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400

BIOSPECTRA **Key Compliance Attributes of BioSpectra Grades**	**Bio Excipient Grade** **ICH-Q7 Compliant Manufactured**
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Excipient Grade: Intended for use as ICH-Q7 Compliant Excipient

LBLE: LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).
LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

Lead Time: 3-months
Minimum Order Quantity: 800 liters

General Product Description:

The manufacturing of Bio Excipient Grade GMP WFI, WAFI-3150 is performed at BioSpectra's Bangor, PA, US FDA registered, GMP facility and is conducted in a dedicated processing area using only dedicated equipment.

- Molecular Formula: H2O
- Molecular Weight: 18.02 g/mol
- CAS #: 7732-18-5
- GMP WFI is a clear, colorless liquid.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all GMP WFI, WAFI-3150 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- GMP WFI manufactured at BioSpectra and any raw materials used in the manufacture of GMP WFI at BioSpectra are not subject to genetic modification.

GMP Compliance:

Bio Excipient Grade GMP WFI, WAFI-3150 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of GMP WFI is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

The recommended retest period for GMP WFI is two years from the date of manufacture.

Storage and Shipping Conditions:

Ship and store at 5°C to 30°C

Package Sizes:

Sterile, Single use 1000L totes, 200L drums, 4L and 1L bottles.