

BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

Effective Date:	16-Feb-2024	16-Feb-2027	: Date of Next Review
Prepared By:	Amy Yenko	BSI-COA-0184 v.1.1	: Supersedes
QA/QC Approval:	Hannah Kuchmas	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

WATER FOR INJECTION

USP, EP, JP, GMP, EXCIPIENT GRADE

BIO EXCIPIENT GRADE / WAFI-3150-XX

LOT: WAFI-0124-00000

H_2O \wedge F.W. 18.02 g/mol. \wedge CAS #: 7732-18-5

Manufacture Date: MM/DD/YY Retest Date: MM/DD/YY

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: MM/DD/YY Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP, EP and JP Specifications

ANALYSIS	SPECIFICATION	TEST RESULT
Acidity or Alkalinity (EP)	Passes Test	Passes Test
Appearance	Clear, Colorless Liquid, no odor	Clear, Colorless Liquid, no odor
Aluminum (EP)	≤ 10 ppb	<7.5 ppb
Ammonium (EP)	≤ 0.2 ppm	<0.2 ppm
Bacterial Endotoxins (USP/EP/JP)	< 0.25 EU/mL	<0.01 EU/mL
Calcium and Magnesium (EP)	Passes Test	Passes Test
Chlorides (EP)	Passes Test	Passes Test
¹ Conductivity (USP/EP/JP)	Meets the Requirements	Meets the requirements
Microbial Monitoring	< 10 CFU/100mL	<1 CFU/100mL
Nitrates (EP)	≤ 0.2 ppm	<0.2 ppm
Oxidizable Substances (USP/EP)	Passes Test	Passes Test
Particulate Matter (USP/EP)	Meets the Requirements	Meets the requirements
pH	5.0 – 7.0	5.2
Residue on Evaporation (EP)	≤ 3 mg (0.003 %)	<3 %
¹ Total Organic Carbon (USP/EP/JP)	≤ 500 ppb	<500 ppb

¹Meets specification at the time of packaging.

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0037

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Prepared by: David McCall Date: 5/16/24 Job Title: QA Tech I

Reviewed by: James Bligh Date: 5/16/24 Job Title: QA Supervisor