BIOSPECTRA

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

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|---|---|---|---|
| Effective Date: | 03-Feb-2025 | 03-Feb-2028 | : Date of Next Review |
| Prepared By: | Taylor Yurick | BSI-COA-0184 v.1.2 | : Supersedes |
| QA/QC Approval: | Jaron Hughes | Carissa Albert | : 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

## LOT: WAFI-L05-0625-0001

$H_2O$ ▲ F.W. 18.02 g/mol. ▲ CAS #: 7732-18-5

Manufacture Date: 06/26/25
Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
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 | 5.6 |
| Residue on Evaporation (EP) | ≤ 3mg (0.003 %) | < 0.003 % |
| [1]Total Organic Carbon (USP/EP/JP) | ≤ 500 ppb | < 500 ppb |

[1]Meets 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: Amil McCall Date: 7/16/25 Job Title: QA Tech III

Reviewed by: Jamie Bingham Date: 7/16/25 Job Title: QA Supervisor