

# BIOSPECTRA

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

|                      |  |                    |                       |
|----------------------|--|--------------------|-----------------------|
| Effective Date:      | 4-Apr-2024                             | 4-Apr-2027         | : Date of Next Review |
| Prepared By:         | Carissa Albert                         | BSI-COA-0142 v.2.0 | : Supersedes          |
| QA/QC Approval:      | Jaron Hughes                           | Wayne Talamonti    | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. |                    |                       |

## CERTIFICATE OF ANALYSIS

### SODIUM CHLORIDE 5M SOLUTION

cGMP, STERILE FILTERED, MADE WITH MULTI-COMPENDIAL NaCl AND WFI 1025L

BPC WITH SATELLITE SAMPLES

### BIO EXCIPIENT GRADE / NaCl-3150-76

LOT: NaCl-0124-00025

NaCl \* F.W. 58.44 g/mol \* CAS# 7647-14-5

Manufacture Date: 08/27/24 Retest Date: 08/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 08/28/24

| ANALYSIS             |                    | SPECIFICATION            | TEST RESULT              |
|----------------------|--------------------|--------------------------|--------------------------|
| Appearance and Color |                    | Clear Colorless Solution | Clear Colorless Solution |
| Assay                |                    | 4.9-5.1M                 | 5.0M                     |
| Endotoxin            |                    | ≤ 2.5 EU/mL              | < 0.3 EU/mL              |
| Identification       | Chloride USP <191> | Meets Requirements       | Meets Requirements       |
|                      | Sodium USP <191>   | Meets Requirements       | Meets Requirements       |
| Microbial Content    | TAMC               | ≤ 50 CFU/g               | < 10 CFU/g               |
|                      | TYMC               | ≤ 150 CFU/g              | < 10 CFU/g               |
| Trace Metals         | Arsenic (As)       | ≤ 2 ppm                  | < 0.45 ppm               |
|                      | Copper (Cu)        | ≤ 2 ppm                  | < 1.5 ppm                |
|                      | Iron (Fe)          | ≤ 2 ppm                  | < 1.5 ppm                |
|                      | Lead (Pb)          | ≤ 2 ppm                  | < 0.15 ppm               |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0048

**MANUFACTURING STATEMENT:** Material represented by this Certification of Analysis was manufactured using Sodium Chloride Multi-Compendia Raw Material and USP Water for Injection.

**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: Tril McDall Date: 9/17/24 Job Title: QA Tech I

Reviewed by: Jason Bligh Date: 9/17/24 Job Title: QA Supervisor