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-L08-1224-0041

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

Manufacture Date: 12/13/24 Retest Date: 12/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 12/16/24

ANALYSIS		SPECIFICATION	TEST RESULT
Appearance and Color		Clear Colorless Solution	Clear Colorless Solution
Assay		4.9-5.1M	4.9M
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: Jason Bingham Date: 1/6/25 Job Title: QA Supervisor

Reviewed by: David McCall Date: 1/6/25 Job Title: QA Tech III