

# BIOSPECTRA

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

Effective Date:	12-Mar-2021	12-Mar-2024	: Date of Next Review
Prepared By:	Jared Lobb	21-003683 v.2.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Carissa McCollan	: Management Approval
Reason for Revision:	See Revision History in ensur		

## CERTIFICATE OF ANALYSIS

### SODIUM HYDROXIDE 1N

HIGH PURITY, LOW CHLORIDE, LOW IRON

MADE WITH WATER FOR INJECTION, STERILE FILTERED IN STERILE, SINGLE USE PACKAGING

### BIO EXCIPIENT GRADE / NEW CODE NAHY-3153-76

(HISTORICAL CODE NH3153-L1005)

LOT: NAHY-0121-0187

NaOH  $\Delta$  F.W. 40.00 g/mol.  $\Delta$  CAS# 1310-73-2

Manufacture Date: 3/19/21      Expiration Date: 3/31/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 3/20/21

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	Clear/Colorless Liquid	Clear/Colorless Liquid
Chloride	$\leq 5$ ppm	$\leq 5$ ppm
Endotoxins	$\leq 2.0$ EU/mL	$\leq 2.0$ EU/mL
Heavy Metals (as Pb)	$\leq 1$ ppm	$\leq 1$ ppm
Iron	$\leq 0.5$ ppm	$\leq 0.5$ ppm
Normality	0.9N – 1.1N	1.0 N
Sterile Filtered	StyLux ST 0.2 Ultra Cap HD Filter from Meissner	Pass
Sterile Filtered in Sterile BPC	Pass	Pass

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 19-003056

**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: Jaron Hughes      Date: 4/7/21      Job Title: QA Specialist

Reviewed by: Carissa McCollan      Date: 4/7/21      Job Title: QA Manager