

# BIOSPECTRA

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

Effective Date:	22-Jan-2025	22-Jan-2028	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## SODIUM HYDROXIDE 10N

### CERTIFICATE OF ANALYSIS

#### BIOTECH, LOW CHLORIDE, GMP

#### BIO PHARMA GRADE / NAHY-4126

#### LOT: NAHY-M03-0125-0001

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

Manufacturing Date: 1/2/25      Expiration Date: 1/31/27

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance	260nm	$\leq 0.080$ a.u.	0.024 a.u.
	280nm	$\leq 0.050$ a.u.	0.014 a.u.
Appearance and Color	Clear / Colorless Liquid	Clear / Colorless Liquid	
Chloride	$\leq 5$ ppm	< 5 ppm	
Endotoxin	$\leq 2.0$ EU/mL	$\leq 0.5$ EU/mL	
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Normality	9.9 – 10.1 N	10.0 N	
Sodium Carbonate	$\leq 0.6$ %	0.1 %	
Trace Metals	Barium (Ba)	$\leq 1$ ppm	< 0.90 ppm
	Bismuth (Bi)	$\leq 1$ ppm	< 0.90 ppm
	Calcium (Ca)	$\leq 5$ ppm	< 0.90 ppm
	Cadmium (Cd)	$\leq 1$ ppm	< 0.90 ppm
	Cobalt (Co)	$\leq 1$ ppm	< 0.90 ppm
	Chromium (Cr)	$\leq 1$ ppm	< 0.90 ppm
	Copper (Cu)	$\leq 1$ ppm	< 0.90 ppm
	Iron (Fe)	$\leq 2$ ppm	< 0.90 ppm
	Magnesium (Mg)	$\leq 1$ ppm	< 0.90 ppm
	Manganese (Mn)	$\leq 1$ ppm	< 0.90 ppm
	Molybdenum (Mo)	$\leq 1$ ppm	< 0.90 ppm
	Nickel (Ni)	$\leq 1$ ppm	< 0.90 ppm


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ANALYSIS	SPECIFICATION	TEST RESULT
Trace Metals	Lead (Pb)	$\leq 1$ ppm
	Strontium (Sr)	$\leq 1$ ppm
	Zinc (Zn)	$\leq 1$ ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0039

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

Prepared by:  Date: 2/5/25 Job Title: QA Technician I

Reviewed by:  Date: 2/5/25 Job Title: Senior Quality Manager