DCN: BSI-COA-0322 v.1.0



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

Effective Date:	22-Jan-2025	22-Jan-2028	: Date of Next Review
Prepared By:	Amy Yencho	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-M03-1224-0084

NaOH → 40.00 g/mol. → CAS# 1310-73-2

Manufacturing Date: 12/18/24 Expiration Date: 12/31/26 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Analysis		SPECIFICATION	TEST RESULT	
A 1 1	260nm	≤ 0.080 a.u.	0.023 a.u.	
Absorbance	280nm	$\leq 0.050 \text{ a.u.}$	0.016 a.u.	
Appearance and Color		Clear / Colorless Liquid	Clear / Colorless Liquid	
Chloride		≤ 5 ppm	< 5 ppm	
Endotoxin		\leq 2.0 EU/mL	≤ 0.5 EU/mL	
	DNase	None Detected	None Detected	
Enzymes	RNase	None Detected	None Detected	
	Protease	None Detected	None Detected	
Normality		9.9 - 10.1 N	10.1 N	
Sodium Carbonate		≤ 0.6 %	0.1 %	
F	Barium (Ba)	≤ 1 ppm	< 0.90 ppm	
В	ismuth (Bi)	≤ 1 ppm	< 0.90 ppm	
C	alcium (Ca)	≤ 5 ppm	< 0.90 ppm	
Cadmium (Cd)		≤ 1 ppm	< 0.90 ppm	
	Cobalt (Co)	≤ 1 ppm	< 0.90 ppm	
Trace Chr	omium (Cr)	≤ 1 ppm	< 0.90 ppm	
Metals (Copper (Cu)	≤ 1 ppm	< 0.90 ppm	
	Iron (Fe)	≤2 ppm	< 0.90 ppm	
Magn	esium (Mg)	≤ 1 ppm	< 0.90 ppm	
Mang	ganese (Mn)	≤ 1 ppm	< 0.90 ppm	
Molybdenum (Mo)		≤ 1 ppm	< 0.90 ppm	
	Nickel (Ni)	≤ 1 ppm	< 0.90 ppm	

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	Analysis	SPECIFICATION	TEST RESULT	
	Lead (Pb)	≤ 1 ppm	< 0.90 ppm	
Trace Metals	Strontium (Sr)	≤ 1 ppm	< 0.90 ppm	
	Zinc (Zn)	≤ 1 ppm	< 0.90 ppm	

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0039

<u>INTENDED USE:</u> 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: Euro	Date: 2/5/25	Job Title: QA Technician 1
Reviewed by:	Date: 2/5/25	Job Title: Senior Quality Manager