

BIOSPECTRA

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

Effective Date:	28-Jan-2025	28-Jan-2028	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0317 v. 1.0	: Supersedes
QA/QC Approval:	Krista Rehrig	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

GUANIDINE HYDROCHLORIDE

BIOTECH, MEETS NF, GMP

BIO PHARMA GRADE / GHCL-4223

LOT#: GHCL-S05-0325-0022

 $\text{NH}_2\text{C}(\text{NH})\text{NH}_2\cdot\text{HCl}$ * F.W. 95.53 g/mol. * CAS# 50-01-1

Manufacturing Date: 04/13/24

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATIONS	RESULT
Acidity (NF)		$\leq 0.01 \%$	$< 0.01 \%$
Appearance and Color		White / Crystals	White / Crystals
Assay, Dried Basis (NF)		99.5 - 101.0 %	100.0 %
Chloride and Sulfate, Sulfate (NF)		$\leq 50 \text{ ppm}$	$< 50 \text{ ppm}$
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Identification A, IR (NF)		Conforms to Reference Standard	Conforms to Reference Standard
Identification B, Absorbance (NF)	230nm	$\leq 0.2000 \text{ a.u.}$	0.1311 a.u.
	260nm	$\leq 0.0300 \text{ a.u.}$	0.0107 a.u.
	275nm	$\leq 0.0300 \text{ a.u.}$	0.0041 a.u.
Identification C, Chloride (NF)		Meets the Requirements of Test A	Meets the Requirements of Test A
Limit of Nitrate (NF)		$\leq 50 \text{ ppm}$	$< 50 \text{ ppm}$
Loss on Drying (NF)		$\leq 0.5 \%$	0.1 %
Melting Range (NF)		184 – 188 °C	187 - 188 °C
pH (6M)		4.5 - 6.0	5.0
Residue on Ignition (NF)		$\leq 0.05 \%$	0.01 %
Solubility (6M)		Passes Test	Passes Test

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ANALYSIS	SPECIFICATIONS	RESULT	
Trace Metals	Aluminum (Al)	≤ 5 ppm	< 1.5 ppm
	Arsenic (As)	≤ 5 ppm	< 0.45 ppm
	Barium (Ba)	≤ 5 ppm	< 1.5 ppm
	Bismuth (Bi)	≤ 5 ppm	< 3.0 ppm
	Calcium (Ca)	≤ 10 ppm	< 1.5 ppm
	Cadmium (Cd)	≤ 5 ppm	< 0.06 ppm
	Cobalt (Co)	≤ 5 ppm	< 0.15 ppm
	Chromium (Cr)	≤ 5 ppm	< 1.5 ppm
	Copper (Cu)	≤ 5 ppm	< 0.15 ppm
	Iron (Fe)	≤ 5 ppm	< 0.90 ppm
	Potassium (K)	≤ 50 ppm	< 15 ppm
	Lithium (Li)	≤ 5 ppm	< 1.5 ppm
	Magnesium (Mg)	≤ 5 ppm	< 1.5 ppm
	Manganese (Mn)	≤ 5 ppm	< 1.5 ppm
	Molybdenum (Mo)	≤ 5 ppm	< 3.0 ppm
	Sodium (Na)	≤ 150 ppm	< 15 ppm
	Nickel (Ni)	≤ 5 ppm	< 0.60 ppm
Lead (Pb)	≤ 5 ppm	< 0.15 ppm	
Strontium (Sr)	≤ 5 ppm	< 1.5 ppm	
Zinc (Zn)	≤ 5 ppm	< 1.5 ppm	
Water, KF	≤ 0.3 %	0.1%	
Water Insoluble (NF)	≤ 0.05 %	< 0.05%	

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: BSI-ATM-0013

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: David McCall Date: 3/7/25 Job Title: QA Tech III

Reviewed by: John Bergh Date: 3/7/25 Job Title: QA Supervisor