

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-S05-0825-0064

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

Manufacturing Date: 08/13/25 Retest Date: 08/31/27
 Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360
 Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

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	$\leq 0.2000 \text{ a.u.}$	0.1008 a.u.
	260nm	$\leq 0.0300 \text{ a.u.}$	0.0089 a.u.
	275nm	$\leq 0.0300 \text{ a.u.}$	0.0037 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	185 - 187 °C
pH (6M)		4.5 - 6.0	5.1
Residue on Ignition (NF)		$\leq 0.05 \%$	$<0.05 \%$
Solubility (6M)		Passes Test	Passes Test

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ANALYSIS	SPECIFICATIONS	RESULT
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	<1.5 ppm
Chromium (Cr)	≤ 5 ppm	<1.5 ppm
Copper (Cu)	≤ 5 ppm	<1.5 ppm
Trace Metals Iron (Fe)	≤ 5 ppm	<1.5 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	33 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: S. J. Kew Date: 9/2/25 Job Title: QA Technician III

Reviewed by: A. Kuchmas Date: 9/2/25 Job Title: Senior Quality Manager