

BIO SPECTRA

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

Effective Date:	18-AUG-2023	18-AUG-2026	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0247 v1.0	: Supersedes
QA/QC Approval:	Carissa Albert	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

GUANIDINE HYDROCHLORIDE

BIO EXCIPIENT GRADE / NEW CODE GHCL-3224-25

(HISTORICAL CODE GH3224-K025)

LOT: GHCL-0223-00078

NH₂C(NH)NH₂·HCl ▲ F.W. 95.53 g/mol. ▲ CAS# 50-01-1

Manufacturing Date: 09/14/23 Retest Date: 09/30/25

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 09/22/23 Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

ANALYSIS	SPECIFICATION	TEST RESULT
Acidity	≤ 0.01%	<0.01%
Appearance and Color	White / Crystals	White / Crystals
Assay (Dried Basis)	99.5 - 101.0%	99.7%
Cyanide	≤ 0.1 ppm	<0.1 ppm
Chloride and Sulfate, <i>Sulfate</i>	≤ 0.005 %	<0.005%
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identification A, (IR)	Passes Test	Passes Test
Identification B, <i>Absorbance</i>	230nm	≤ 0.2000 a.u.
	260nm	≤ 0.0300 a.u.
	275nm	≤ 0.0300 a.u.
Identification C, (Chloride)	Meets the Requirements of Test A	Meets the Requirements of Test A
Limit of Nitrate	≤ 0.005 %	<0.005%
Loss on Drying	≤ 0.5%	0.1%
Melting Range	184 – 188°C	186 - 187°C
pH (5% solution)	4.5 – 6.0	5.7 @ 25.0°C
Residue on Ignition	≤ 0.05%	0.02%
Solubility (6M)	Passes Test	Passes Test

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ANALYSIS	SPECIFICATION	TEST RESULT
Trace Metals	Arsenic (As)	≤ 0.5 ppm
	Antimony (Sb)	≤ 0.5 ppm
	Copper (Cu)	≤ 5 ppm
	Iron (Fe)	≤ 2 ppm
	Lead (Pb)	≤ 0.5 ppm
Water Insoluble	$\leq 0.05\%$	$<0.05\%$

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0013

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: Taylor Yunker Date: 10/16/23 Job Title: QA Tech III

Reviewed by: [Signature] Date: 10/16/23 Job Title: QA Manager