

BIOSPECTRA

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-S05-0125-0009

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

Manufacturing Date: 01/16/25 Retest Date: 01/31/27

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 01/31/25 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Acidity	$\leq 0.01\%$	$< 0.01\%$	
Appearance and Color	White / Crystals	White / Crystals	
Assay (Dried Basis)	99.5 - 101.0%	100.1%	
Cyanide	≤ 0.1 ppm	< 0.1 ppm	
Chloride and Sulfate, <i>Sulfate</i>	$\leq 0.005\%$	$< 0.005\%$	
Enzymes	DNase	None Detected	
	Protease	None Detected	
	RNase	None Detected	
Identification A, (<i>IR</i>)	Passes Test	Passes Test	
	230nm	≤ 0.2000 a.u.	0.0957 a.u.
	260nm	≤ 0.0300 a.u.	0.0078 a.u.
Identification B, <i>Absorbance</i>	275nm	≤ 0.0300 a.u.	
	275nm	≤ 0.0300 a.u.	0.0032 a.u.
Identification C, (<i>Chloride</i>)	Meets the Requirements of Test A	Meets the Requirements of Test A	
Limit of Nitrate	$\leq 0.005\%$	$< 0.005\%$	
Loss on Drying	$\leq 0.5\%$	0.1%	
Melting Range	184 – 188°C	186 - 187°C	
pH (5% solution)	4.5 – 6.0	5.5	
Residue on Ignition	$\leq 0.05\%$	$< 0.05\%$	
Solubility (6M)	Passes Test	Passes Test	

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ANALYSIS	SPECIFICATION	TEST RESULT	
	Arsenic (As)	≤ 0.5 ppm	< 0.45 ppm
	Antimony (Sb)	≤ 0.5 ppm	< 0.30 ppm
Trace Metals	Copper (Cu)	≤ 5 ppm	< 0.15 ppm
	Iron (Fe)	≤ 2 ppm	< 0.90 ppm
	Lead (Pb)	≤ 0.5 ppm	< 0.15 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: Anil McCall Date: 2/6/25 Job Title: QA Tech III

Reviewed by: John Boylan Date: 2/6/25 Job Title: QA Supervisor