BISPECTRA

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

Effective Date:	16-Jul-2025	16-Jul-2028	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0017 v.4.3	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

GUANIDINE HYDROCHLORIDE

NF, GMP

BIO EXCIPIENT GRADE / GHCL-3220

LOT#: GHCL-S05-0825-0064

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 Acidity		SPECIFICATIONS	RESULT <0.01% White / Crystals
		≤ 0.01%	
Appearance and Color		White / Crystals	
Assay (Dried Basis)		99.5 – 101.0%	100.0%
Chloride and Sulfate, Sulfate		≤ 0.005%	<0.005%
	DNase	None Detected	None Detected
Enzymes	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Identification A, (IR)		Passes Test	Passes Test
Identification B, Absorbance	230nm	≤ 0.2000 a.u	0.1008 a.u.
	260nm	≤ 0.0300 a.u.	0.0089 a.u.
	275nm	≤0.0300 a.u.	0.0037 a.u.
Identification C, Chloride		Meets the Requirements of Test A	Meets the Requirements of Test A
Limit of Nitrate		$\leq 0.005\%$	<0.005%
Loss on Drying		≤ 0.5%	0.1%
Melting Range		184 - 188°C	185 - 187°C
oH (6M)		4.5 - 6.0	5.1
Residue on Ignition		≤ 0.05%	<0.05%
Solubility (6M)		Passes Test	Passes Test
Trace Metals	Arsenic (As)	≤ 5 ppm	<0.45 ppm
	Copper (Cu)	≤ 5 ppm	<0.15 ppm
	Iron (Fe)	≤ 5 ppm	<0.90 ppm
	Lead (Pb)	≤ 5 ppm	<0.15 ppm
Water by Karl Fischer		≤0.3% w/w	0.1% w/w
Water Insoluble		≤ 0.05%	<0.05%

DCN: BSI-COA-0017 v.4.4

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0013

<u>INTENDED USE:</u> 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.

<u>RESIDUAL SOLVENTS STATEMENT:</u> Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

Prepared by: Syffiew	_ Date: <u>9 9 25</u>	Job Title: <u>QA Technician</u> 1	<u> </u>
Reviewed by: 1008 .	_ Date: <u>919125</u>	Job Title: <u>QA Managor</u>	