BIOSPECTRA

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

Effective Date:	2-May-2022	2-May-2025	: Date of Next Review
Prepared By:	Amy Hosein	BSI-COA-0017 v.4.0	: Supersedes
QA/QC Approval:	Amy Yencho	Carissa McCollian	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

GUANIDINE HYDROCHLORIDE

BIO EXCIPIENT GRADE / NEW CODE GHCL-3220-25

(HISTORICAL CODE GH3220 – K025)

LOT#: GHCL-0223-00009

$NH_2C(NH)NH_2 \cdot HCl$ ⅄ F.W. 95.53 g /mol. ⅄ CAS# 50-01-1

Manufacturing Date: 12/07/22 Retest Date: 12/31/24

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 12/14/22 Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

ANALYSIS		SPECIFICATIONS	RESULT
Absorbance (6M)	230 nm	0.2000 a.u. max.	0.0393 a.u.
	260 nm	0.0300 a.u. max.	0.0044 a.u.
	275 nm	0.0300 a.u. max.	0.0023 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.5% min.	99.6%
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		0.15% max.	<0.15%
Loss on Drying		0.5% max.	0.1%
Melting Range		184-188°C	186 - 187°C
Nitrate		0.01% max.	<0.01%
pH (6M)		4.5-6.0	5.1 @ 23.0°C
Residue on Ignition		0.05% max.	<0.05%
Solubility (6M)		Passes Test	Passes Test
Sulfate		0.01% max.	<0.01%
Trace Metals	Arsenic (As)	5 ppm max.	< 0.45 ppm
	Copper (Cu)	5 ppm max.	< 0.15 ppm
	Iron (Fe)	5 ppm max.	< 0.30 ppm
	Lead (Pb)	5 ppm max.	<0.30 ppm
Water by Karl Fischer		NMT 0.3% w/w	0.1% w/w

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.

OVI STATEMENT: 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: [signature] Date: 1/31/23 Job Title: QA Technician

Reviewed by: [signature] Date: 1/31/23 Job Title: QA Supervisor