BIOSPECTRA

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

Effective Date:	24-Aug-2023	24-Aug-2026	: Date of Next Review
Prepared By:	Amy Yencho	BSI-COA-0017 v.4.1	: Supersedes
QA/QC Approval:	Wayne Talamonti	Carissa Albert	: 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-S05-1224-0084

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

Manufacturing Date: 11/18/24 Retest Date: 11/30/26

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 12/12/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATIONS	RESULT
Acidity		≤ 0.01%	< 0.01%
Appearance and Color		White / Crystals	White / Crystals
Assay (Dried Basis)		99.5 – 101.0%	100.4%
Chloride and Sulfate, *Sulfate*		≤ 0.005%	< 0.005%
Enzymes	DNase	None Detected	None Detected
	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	0.1229 a.u.
	260nm	≤ 0.0300 a.u.	0.0133 a.u.
	275nm	≤0.0300 a.u.	0.0071 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 (6M)		4.5 - 6.0	5.0
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%

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.

RESIDUAL SOLVENTS 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: Amil McCall Date: 12/19/24 Job Title: QA Tech III

Reviewed by: Jason Bright Date: 12/19/24 Job Title: QA Supervisor