

BIOSPECTRA

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

Effective Date:	03-Feb-2025	03-Feb-2028	: Date of Next Review
Prepared By:	Taylor Yurick	BSI-COA-0242 v.1.1	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

CERTIFICATE OF ANALYSIS

GUANIDINE HYDROCHLORIDE

BIO EXCIPIENT GRADE / GHCL-3251

LOT#: GHCL-S05-0426-0020

NH₂C(NH)NH₂·HCl * F.W. 95.53 * CAS#: 50-01-1

Manufacturing Date: 04/25/26 Retest Date: 04/30/28

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

ANALYSIS	SPECIFICATIONS	RESULT
Acidity	≤0.01%	<0.01%
Appearance and Color	White / Crystals	White / Crystals
Assay (Dried Basis)	99.5 – 101.0%	100.0%
Chloride and Sulfate, <i>Sulfate</i>	≤ 0.005%	<0.005%
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identification A, <i>IR</i>	Passes Test	Passes Test
Identification B, <i>Absorbance</i>	275 nm	≤ 0.0300 a.u.
	260 nm	≤ 0.0300 a.u.
	230 nm	≤ 0.2000 a.u.
Identification C, <i>Chloride</i>	Meets the Requirements of test A	Meets the Requirements of test A
Limit of Nitrate	≤ 0.005%	<0.005%
Loss on Drying	≤ 0.5%	<0.5%
Melting Range	184-188°C	185 - 187°C
pH (6M)	4.5-6.0	5.3
Residue on Ignition	≤ 0.05%	0.03%
Solubility (6M)	Passes Test	Passes Test
TAMC	≤ 100 CFU/g	<10 CFU/g
TYMC	≤ 10 CFU/g	<10 CFU/g
Trace Metals	Arsenic (As)	≤ 5 ppm
	Copper (Cu)	≤ 5 ppm
	Iron (Fe)	≤ 5 ppm
	Lead (Pb)	≤ 5 ppm
Water Insoluble	≤0.05%	<0.05%

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0013

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.

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: S. Szymanski Date: 6/4/20 Job Title: QA Technician III

Reviewed by: Taylor Vanquay Date: 6/5/20 Job Title: QA SUPERVISOR