

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

$\text{NH}_2\text{C}(\text{NH})\text{NH}_2\cdot\text{HCl}$ Δ F.W. 95.53 g/mol. Δ 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

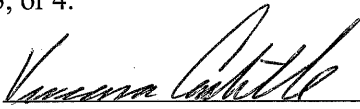
ANALYSIS	SPECIFICATIONS	RESULT	
Absorbance (6M)	230 nm	0.2000 a.u. max.	0.0393 a.u.
	260 nm	0.0300 a.u. max.	0.0044 a.u.
	275 nm	0.0300 a.u. max.	0.0023 a.u.
Appearance and Color	White / Crystals	White / Crystals	
Assay	99.5% min.	99.6%	
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	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:  Date: 11/31/23 Job Title: QA Technician

Reviewed by:  Date: 11/31/23 Job Title: QA Supervisor

BIOSPECTRA

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

Effective Date:	22-Mar-2022	25-Mar-2025	: Date of Next Review
Prepared By:	Wendy Santay	BSI-COA-0260 v.1.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

GUANIDINE HYDROCHLORIDE

BIO EXCIPIENT GRADE / GHCL-3253-25

LOT#: GHCL-0223-00008

NH₂C(NH)NH₂·HCl ^ F.W. 95.53 ^ 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	280 nm. 6mol/l, 1cm, water	≤0.10 a.u.	<0.10 a.u.
	275 nm. 6mol/l, 1cm, water	≤0.03 a.u.	<0.03 a.u.
	260 nm. 6mol/l, 1cm, water	≤0.03 a.u.	<0.03 a.u.
	235 nm. 6mol/l, 1cm, water	≤0.20 a.u.	0.03 a.u.
	230 nm. 6mol/l, 1cm, water	≤0.20 a.u.	0.04 a.u.
Appearance and Color	White / Crystals	White / Crystals	
Appearance of Solution (6mol/l; water)	Clear and Colorless	Clear and Colorless	
Assay	≥ 99.5%	99.6%	
Bacterial Endotoxins	≤ 2.5 IU/g	<2.0 IU/g	
Chloride (Cl) (argentometric)	36.5 – 37.5%	37.0%	
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals (as Pb)	≤ 10 ppm	<10 ppm	
Identification (IR)	Passes Test	Passes Test	
Insoluble Matter	≤ 0.15%	<0.15%	
Loss on Drying	≤ 0.5%	0.1%	
Melamine (HPLC)	≤ 0.01%	<0.01%	
Melting Range	184-188°C	186 - 187°C	
Nitrate	≤ 0.005%	<0.005%	
pH (6M)	4.5-6.0	5.1	
pH (0.5mol/l, water)	5.0 – 6.5	5.5	
Residue on Ignition	≤ 0.05%	<0.05%	
Solubility (6M)	Passes Test	Passes Test	

An original approved version of this document includes colored text. The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping, and the prevention of unauthorized appropriation, use, disclosure and copying.


ANALYSIS	SPECIFICATIONS	RESULT
Sulfate	≤ 0.01%	<0.01%
Sulfated ash (600°C)	≤ 0.05%	<0.05%
TAMC	≤ 100 CFU/g	<10 CFU/g
TYMC	≤ 10 CFU/g	< 10 CFU/g
Bile-Tolerant gram-negative bacteria (absent in 1g)	Passes Test	Passes Test
Candida albicans (absent in 1g)	Passes Test	Passes Test
Escherichia coli (absent in 1g)	Passes Test	Passes Test
Pseudomonas aeruginosa (absent in 1g)	Passes Test	Passes Test
Salmonella (absent in 10g)	Passes Test	Passes Test
Staphylococcus aureus (absent in 1g)	Passes Test	Passes Test
Trace Metals	Arsenic (As)	≤ 5 ppm
	Copper (Cu)	≤ 5 ppm
	Iron (Fe)	≤ 5 ppm
	Lead (Pb)	≤ 5 ppm
Water (according to Karl Fischer)	≤ 0.5%	0.1%

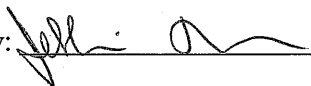
COUNTRY OF ORIGIN: U.S.A.

RESIDUAL SOLVENTS STATEMENT: Residual solvents (ICH (Q3C)) excluded by manufacturing process.

ELEMENTAL IMPURITY STATEMENT: Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

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:  Date: 1/31/23 Job Title: QA Technician

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