

# BIO SPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

Effective Date:	10-Apr-2020	10-Apr-2023	: Date of Next Review
Prepared By:	Kyle Snyder	16-001146 v.2.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

## CERTIFICATE OF ANALYSIS

### GUANIDINE HYDROCHLORIDE

### BIO EXCIPIENT GRADE / GH3220 – K001

### LOT#: GH3220-005-1018

$\text{NH}_2\text{C}(\text{NH})\text{NH}_2\cdot\text{HCl}$  \* F.W. 95.53 g mol. \* CAS# 50-01-1

Manufacturing Date: 5/13/18      Retest Date: 5/31/21

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 10/9/18 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATIONS	RESULT
	230 nm	0.2000 a.u. max.
Absorbance (6M)	260 nm	0.0300 a.u. max.
	275 nm	0.0300 a.u. max.
Appearance and Color	White / Crystals	White / Crystals
Assay	99.5% min.	99.9%
	DNase	None Detected
Enzymes	Protease	None Detected
	RNase	None Detected
Identification (IR)	Passes Test	Passes Test
Insoluble Matter	0.15% max.	<0.15%
Loss on Drying	0.5% max.	<0.5%
Melting Range	184-188°C	185 - 187°C
Nitrate	0.01% max.	<0.01%
pH (6M)	4.5-6.0	5.0 @ 16.3°C
Residue on Ignition	0.05% max.	<0.01%
Solubility (6M)	Passes Test	Passes Test
Sulfate	0.01% max.	<0.01%
	Arsenic (As)	5 ppm max.
Trace Metals	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.


COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000493

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: 7/17/20 Job Title: QA Supervisor

Reviewed by:  Date: 7/17/20 Job Title: QA Specialist