

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://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 Yenko	Carissa McCollian	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### GUANIDINE HYDROCHLORIDE

### BIO EXCIPIENT GRADE / NEW CODE GHCL-3220-51

### (HISTORICAL CODE GH3220 – K050)

### LOT#: GHCL-0222-00106

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

Manufacturing Date: 02/22/22      Expiration Date: 02/28/25

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 03/02/22      Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

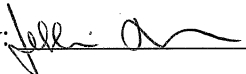
ANALYSIS	SPECIFICATIONS	RESULT
Absorbance (6M)	230 nm 260 nm 275 nm	0.2000 a.u. max. 0.0300 a.u. max. 0.0300 a.u. max.
Appearance and Color	White / Crystals	White / Crystals
Assay	99.5% min.	99.9%
Enzymes	DNase Protease RNase	None Detected None Detected None Detected
Identification (IR)	Passes Test	Passes Test
Insoluble Matter	0.15% max.	<0.15%
Loss on Drying	0.5% max.	0.1%
Melting Range	184-188°C	185 - 187°C
Nitrate	0.01% max.	<0.01%
pH (6M)	4.5-6.0	5.4 @ 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) Copper (Cu) Iron (Fe) Lead (Pb)	5 ppm max. 5 ppm max. 5 ppm max. 5 ppm max.
Water by Karl Fischer	NMT 0.3% w/w	0.1% w/w

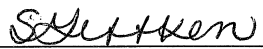
COUNTRY OF ORIGIN: U.S.A.

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: 4/24/24 Job Title: QA Manager

Reviewed by:  Date: 4/24/24 Job Title: QA technician II