

BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / 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 – G100

LOT#: GH3220-019-0720

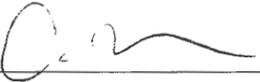
$\text{NH}_2\text{C}(\text{NH})\text{NH}_2\text{HCl}$ * F.W. 95.53 g/mol * CAS# 50-01-1
 Manufacturing Date: 6/8/20 Retest Date: 6/30/22
 Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360
 Packaging Date: 7/14/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013

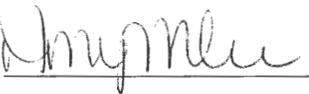
ANALYSIS	SPECIFICATIONS	RESULT
Absorbance (6M)	230 nm 260 nm 275 nm	0.2000 a.u. max. 0.0300 a.u. max. 0.0300 a.u. max.
Appearance and Color	White / Crystals	White / Crystals
Assay	99.5% min.	100.3%
Enzymes	DNase Protease RNase	None Detected None Detected None Detected
Identification (IR)	Passes Test	Passes Test
Insoluble Matter	0.15% max.	<0.15%
Loss on Drying	0.5% max.	0.1%
Melting Range	184-188°C	186 - 187°C
Nitrate	0.01% max.	<0.01%
pH (6M)	4.5-6.0	5.0 @ 25.0°C
Residue on Ignition	0.05% max.	<0.01%
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.
		< 5 ppm < 5 ppm < 5 ppm < 5 ppm

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: 7/15/20 Job Title: QA Supervisor

Reviewed by:  Date: 7/15/20 Job Title: QC Compliance Supervisor