BIOSPECTRA

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

Effective Date:	8-Apr-2020	8-Apr-2023	: Date of Next Review
Prepared By:	Amy Saam	19-002978 v.3.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

GUANIDINE HYDROCHLORIDE

BIO EXCIPIENT GRADE / GH3250 – K001

LOT#: GH3250-006-0720

$NH_2C(NH)NH_2 \cdot HCl$ • F.W. 95.53 g /mol. • CAS# 50-01-1

Manufacturing Date: 7/5/20 Retest Date: 7/31/22

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 7/24/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATIONS	RESULT
Absorbance (6M)	230 nm	0.1500 a.u. max.	0.1288 a.u.
	260 nm	0.0300 a.u. max.	0.0086 a.u.
	275 nm	0.0300 a.u. max.	0.0027 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.5% min.	99.7%
Endotoxin		≤ 50 EU/g	<4 EU/g
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Identification (FTIR)		Passes Test	Passes Test
Identification (Chloride)		Passes Test	Passes Test
Insoluble Matter		0.15% max.	<0.15%
Loss on Drying		0.5% max.	<0.3%
Melting Range		184-188°C	186 - 187 °C
Microbial Content	TAMC	≤ 100 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
Nitrate		0.01% max.	<0.01%
pH (6M)		4.5-6.0	4.9
Residue on Ignition		0.05% max.	<0.05%
Solubility (6M)		Passes Test	Passes Test

ANALYSIS		SPECIFICATIONS	RESULT
Sulfate		0.01% max.	<0.01%
Trace Metals	Arsenic (As)	5 ppm max.	< 5 ppm
	Copper (Cu)	5 ppm max.	< 5 ppm
	Iron (Fe)	5 ppm max.	< 5 ppm
	Lead (Pb)	5 ppm max.	< 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.

Prepared by: _____ Date: 8/4/20 Job Title: QA Supervisor

Reviewed by: _____ Date: 08/04/20 Job Title: QA Manager