

BIOSPECTRA

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

Effective Date:	5-Mar-2021	5-Mar-2024	: Date of Next Review
Prepared By:	Shana Geffken	16-001146 v.3.0	: Supersedes
QA/QC Approval:	Jess DeMaio	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS
GUANIDINE HYDROCHLORIDE
BIO EXCIPIENT GRADE / NEW CODE GHCL-3220-25
(HISTORICAL CODE GH3220 – K025)
LOT#: GHCL-0121-00073

NH₂C(NH)NH₂·HCl ▲ F.W. 95.53 g /mol. ▲ CAS# 50-01-1
 Manufacturing Date: 11/09/20 Retest Date: 11/30/22
 Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360
 Packaging Date: 09/04/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATIONS	RESULT	
Absorbance (6M)	230 nm	0.2000 a.u. max.	0.0707 a.u.
	260 nm	0.0300 a.u. max.	0.0085 a.u.
	275 nm	0.0300 a.u. max.	0.0045 a.u.
Appearance and Color	White / Crystals	White / Crystals	
Assay	99.5% min.	100.0%	
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	4.9 @ 23.3°C	
Residue on Ignition	0.05% max.	0.03%	
Solubility (6M)	Passes Test	Passes Test	
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

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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: Ad S. L. Date: 09/09/21 Job Title: CAPA specialist

Reviewed by: Jason Hughes Date: 9/9/21 Job Title: QA Specialist