

BIOSPECTRA

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

Effective Date:	29-Sep-2021	29-Sep-2024	: Date of Next Review
Prepared By:	Amy Hosein	Not Applicable	: Supersedes
QA/QC Approval:	Carissa McCollan	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

GUANIDINE HYDROCHLORIDE

BIO EXCIPIENT GRADE / NEW CODE GHCL-3224-25

(HISTORICAL CODE GH3224-K025)

LOT: GHCL-0222-00185

NH₂C(NH)NH₂·HCl ^ F.W. 95.53 g/mol. ^ CAS# 50-01-1

Manufacturing Date: 12/07/22 Retest Date: 12/31/24

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 12/14/22 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Absorbance (6M)	230nm ≤ 0.2000 a.u.	0.0393 a.u.
	260nm ≤ 0.0300 a.u.	0.0044 a.u.
	275nm ≤ 0.0300 a.u.	0.0023 a.u.
Acidity (HCl)	≤ 0.01%	<0.01%
Appearance and Color	White / Crystals	White / Crystals
Assay (Dried Basis)	≥ 99.5%	99.6%
Cyanide	≤ 0.1 ppm	<0.1 ppm
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%	<0.15%
Loss on Drying	≤ 0.5%	0.1%
Melting Range	184 – 188°C	186 - 187°C
Nitrate	< 0.005 %	<0.005%
pH (5% solution)	4.5 – 6.0	5.4
Residue on Ignition	≤ 0.05%	<0.05%
Solubility (6M)	Passes Test	Passes Test
Sulfate	< 0.005 %	<0.005%

ANALYSIS	SPECIFICATION	TEST RESULT
Trace Metals	Arsenic (As)	≤ 0.5 ppm
	Antimony (Sb)	≤ 0.5 ppm
	Copper (Cu)	≤ 5 ppm
	Iron (Fe)	≤ 2 ppm
	Lead (Pb)	≤ 0.5 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: Steph Date: 12/29/22 Job Title: QA support Technician

Reviewed by: H. Kuchmas Date: 12/29/22 Job Title: Assoc. Director of Quality