



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

Effective Date:	16-Jul-2025	16-Jul-2028	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0017 v.4.3	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS
GUANIDINE HYDROCHLORIDE
NF, GMP
BIO EXCIPIENT GRADE / GHCL-3220
LOT#: GHCL-S05-1125-0080

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

Manufacturing Date: 11/29/25 Retest Date: 11/30/27
 Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360
 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATIONS		RESULT
Acidity		≤ 0.01%	< 0.01%
Appearance and Color		White / Crystals	White / Crystals
Assay (Dried Basis)		99.5 – 101.0%	100.0%
Chloride and Sulfate, <i>Sulfate</i>		≤ 0.005%	< 0.005%
Enzymes	DNase Protease RNase	None Detected None Detected None Detected	None Detected None Detected None Detected
Identification A, (IR)		Passes Test	Passes Test
Identification B, <i>Absorbance</i>	230nm 260nm 275nm	≤ 0.2000 a.u. ≤ 0.0300 a.u. ≤ 0.0300 a.u.	0.0886 a.u. 0.0070 a.u. 0.0017 a.u.
Identification C, <i>Chloride</i>		Meets the Requirements of Test A	Meets the Requirements of Test A
Limit of Nitrate		≤ 0.005%	< 0.005%
Loss on Drying		≤ 0.5%	0.1%
Melting Range		184 - 188°C	186 - 187°C
pH (6M)		4.5 - 6.0	5.1
Residue on Ignition		≤ 0.05%	0.04%
Solubility (6M)		Passes Test	Passes Test
Trace Metals	Arsenic (As) Copper (Cu) Iron (Fe) Lead (Pb)	≤ 5 ppm ≤ 5 ppm ≤ 5 ppm ≤ 5 ppm	< 0.45 ppm < 0.15 ppm < 0.90 ppm < 0.15 ppm
Water by Karl Fischer		≤ 0.3% w/w	0.2% w/w
Water Insoluble		≤ 0.05%	0.01%

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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.

RESIDUAL SOLVENTS 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: April McDowell Date: 1/14/26 Job Title: QA Tech II

Reviewed by: John Blythe Date: 1/14/26 Job Title: QA Supervisor