



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-0140 v.4.2	: 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-3250**  
**LOT#: GHCL-S05-0325-0024**

$\text{NH}_2\text{C}(\text{NH})\text{NH}_2\cdot\text{HCl}$   $\Delta$  F.W. 95.53 g/mol.  $\Delta$  CAS# 50-01-1

Manufacturing Date: 3/9/25      Retest Date: 3/31/27

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATIONS	RESULT
Acidity		$\leq 0.01\%$	$<0.01\%$
Appearance and Color		White / Crystals	White / Crystals
Assay (Dried Basis)		99.5 – 101.0%	99.8%
Chloride and Sulfate, Sulfate		$\leq 0.005\%$	$<0.005\%$
Endotoxin		$\leq 50$ EU/g	$<2$ EU/g
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Identification A, (IR)		Passes Test	Passes Test
Identification B, (Absorbance)	230nm	$\leq 0.1500$ a.u.	0.0877 a.u.
	260nm	$\leq 0.0300$ a.u.	0.0093 a.u.
	275nm	$\leq 0.0300$ a.u.	0.0042 a.u.
Identification C, Chloride		Meets the Requirements of test A	Meets the Requirements of test A
Limit of Nitrate		$\leq 0.005\%$	$<0.005\%$
Loss on Drying		$\leq 0.5\%$	0.1%
Melting Range		184-188°C	186 - 187 °C
Microbial Content	TAMC	$\leq 100$ CFU/g	$<10$ CFU/g
	TYMC	$\leq 100$ CFU/g	$<10$ CFU/g
pH (6M)		4.5-6.0	5.2
Residue on Ignition		$\leq 0.05\%$	$<0.05\%$

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ANALYSIS		SPECIFICATIONS	RESULT
Solubility (6M)		Passes Test	Passes Test
Trace Metals	Arsenic (As)	$\leq 5$ ppm	<0.45 ppm
	Copper (Cu)	$\leq 5$ ppm	<0.15 ppm
	Iron (Fe)	$\leq 5$ ppm	<0.90 ppm
	Lead (Pb)	$\leq 5$ ppm	<0.15 ppm
Water Insoluble		$\leq 0.05\%$	<0.05%

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.

Prepared by: Car Allert Date: 7/23/25 Job Title: Senior Quality Manager

Reviewed by: H. Kuchmas Date: 7/23/25 Job Title: Senior Quality Manager