

BIOSPECTRA

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-0260 v.1.3	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

GUANIDINE HYDROCHLORIDE

NF, LBLE, GMP

BIO EXCIPIENT GRADE / GHCL-3253

LOT#: GHCL-0224-00005

NH₂C(NH)NH₂·HCl ★ F.W. 95.53 ★ CAS#: 50-01-1

Manufacturing Date: 03/01/23 Retest Date: 03/31/25

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

ANALYSIS		SPECIFICATIONS	RESULT
Acidity		≤ 0.01%	< 0.01%
Appearance and Color		White / Crystals	White / Crystals
Appearance of Solution (6mol/l; water)		Clear and Colorless	Clear and Colorless
Assay (Dried Basis)		99.5 – 101.0%	99.8%
Bacterial Endotoxins		≤ 2.5 IU/g	< 2.0 IU/g
Chloride (Cl) (argentometric)		36.5 – 37.5%	37.0%
Chloride and Sulfate, Sulfate		≤ 0.005%	< 0.005%
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals (as Pb)		≤ 10 ppm	< 0.30 ppm
Identification A, (IR)		Passes Test	Passes Test
	280nm, 6 mol/l, 1cm, water	≤ 0.10 a.u.	< 0.10 a.u.
Identification	275nm, 6 mol/l, 1cm, water	≤ 0.03 a.u.	< 0.03 a.u.
B,	260nm, 6 mol/l, 1cm, water	≤ 0.03 a.u.	0.01 a.u.
(Absorbance)	235nm, 6 mol/l, 1cm, water	≤ 0.20 a.u.	0.13 a.u.
	230nm, 6 mol/l, 1cm, water	≤ 0.20 a.u.	0.15 a.u.
Identification C, (Chloride)		Meets the Requirements of test A	Meets the Requirements of test A

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ANALYSIS	SPECIFICATIONS	RESULT
Limit of Nitrate	$\leq 0.005\%$	0.004%
Loss on Drying	$\leq 0.5\%$	0.1%
Melamine (HPLC)	$\leq 0.01\%$	$< 0.01\%$
Melting Range	184-188°C	186 - 187°C
pH (6M)	4.5 – 6.0	5.2
pH (0.5mol/l, water)	5.0 – 6.5	5.4
Residue on Ignition	$\leq 0.05\%$	0.02%
Solubility (6M)	Passes Test	Passes Test
Sulfated ash (600°C)	$\leq 0.05\%$	0.02%
TAMC	≤ 100 CFU/g	< 10 CFU/g
TYMC	≤ 10 CFU/g	< 10 CFU/g
Bile-Tolerant gram-negative bacteria (absent in 1g)	Passes Test	Passes Test
Candida albicans (absent in 1g)	Passes Test	Passes Test
Escherichia coli (absent in 1g)	Passes Test	Passes Test
Pseudomonas aeruginosa (absent in 1g)	Passes Test	Passes Test
Salmonella (absent in 10g)	Passes Test	Passes Test
Staphylococcus aureus (absent in 1g)	Passes Test	Passes Test
Trace Metals	Arsenic (As)	≤ 5 ppm
	Copper (Cu)	≤ 5 ppm
	Iron (Fe)	≤ 5 ppm
	Lead (Pb)	≤ 5 ppm
Water (according to Karl Fischer)	$\leq 0.5\%$	0.3%
Water Insoluble	$\leq 0.05\%$	0.03%

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: BSI-ATM-0013

RESIDUAL SOLVENTS STATEMENT: Residual solvents (ICH (Q3C)) excluded by manufacturing process.

ELEMENTAL IMPURITY STATEMENT: Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

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: Cheryl McCall Date: 7/21/25 Job Title: QA Tech III

Reviewed by: Carrie Albert Date: 7/21/25 Job Title: Senior Quality Manager

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