DCN: BSI-COA-0260 v.1.4



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

NH<sub>2</sub>C(NH)NH<sub>2</sub>·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

Appearance and Color  Appearance of Solution (6mol/l; water)  Appearance of Solution (6mol/l; water)  Clear and Colorless  Assay (Dried Basis)  99.5 – 101.0%  99.8%  4 2.0 IU/g  Chloride (Cl) (argentometric)  Chloride (Cl) (argentometric)  Chloride (Cl) (argentometric)  60.005%  Chloride (Cl) (argentometric)  Chloride (Cl) (argentometric)  60.005%  6		8	, 8,		
Appearance and Color Appearance of Solution (6mol/l; water) Appearance of Solution (6mol/l; water)  Appearance of Solution (6mol/l; water)  Clear and Colorless  Clear and Colorless  Clear and Colorless  Clear and Colorless  Sasay (Dried Basis)  99.5 – $101.0\%$ 99.8%  Sacterial Endotoxins $\leq 2.5 \text{ IU/g}$ $\leq 2.0 \text{ IU/g}$ Chloride (Cl) (argentometric) $\leq 0.005\%$ Chloride and Sulfate, Sulfate  DNase  DNase  None Detected  Solution (Appearance of Solution (Coloride)  Passes Test $\leq 0.005\%$ $\leq 10 \text{ ppm}$ $\leq 0.30 \text{ ppm}$ $\leq 0.30 \text{ ppm}$ $\leq 0.30 \text{ ppm}$ dentification $\leq 275 \text{ mm}$ , 6 mol/l, 1 cm, water $\leq 0.03 \text{ a.u.}$ Onlianu.  Absorbance)  235 nm, 6 mol/l, 1 cm, water $\leq 0.20 \text{ a.u.}$ Meets the Requirements of	Analysis		SPECIFICATIONS	RESULT	
Appearance of Solution (6mol/l; water)  Appearance of Solution (6mol/l; water)  Assay (Dried Basis)  Bacterial Endotoxins	Acidity		≤ 0.01%	< 0.01%	
Assay (Dried Basis) $99.5 - 101.0\%$ $99.8\%$ Bacterial Endotoxins $\leq 2.5 \text{ IU/g}$ $< 2.0 \text{ IU/g}$ Chloride (CI) (argentometric) $36.5 - 37.5\%$ $37.0\%$ Chloride and Sulfate, Sulfate $\leq 0.005\%$ $< 0.005\%$ DNase None Detected None Detected Enzymes Protease None Detected None Detected Heavy Metals (as Pb) $\leq 10 \text{ ppm}$ $< 0.30 \text{ ppm}$ dentification A, (IR) Passes Test Passes Test $280 \text{nm}$ , 6 mol/l, 1cm, water $\leq 0.10 \text{ a.u.}$ $< 0.10 \text{ a.u.}$ dentification $\frac{275 \text{nm}}{3}$ , 6 mol/l, 1cm, water $\leq 0.03 \text{ a.u.}$ $= 0.03 \text{ a.u.}$ $= 0.01 \text{ a.u.}$ Absorbance) $\frac{235 \text{nm}}{3}$ , 6 mol/l, 1cm, water $= 0.20 \text{ a.u.}$ $= 0.10 \text$	Appearance and Color		White / Crystals	White / Crystals	
Bacterial Endotoxins $\leq 2.5 \text{ IU/g}$ $< 2.0 \text{ IU/g}$ Chloride (Cl) (argentometric) $36.5 - 37.5\%$ $37.0\%$ Chloride and Sulfate, Sulfate $\leq 0.005\%$ $< 0.005\%$ None Detected None Detected None Detected None Detected RNase None Detected Non	Appearance of Solution (6mol/l; water)		Clear and Colorless	Clear and Colorless	
Chloride (Cl) (argentometric) $36.5 - 37.5\%$ $37.0\%$ Chloride and Sulfate, Sulfate $\leq 0.005\%$ $< 0.005\%$ None Detected None Det	Assay (Dried Basis)		99.5 - 101.0%	99.8%	
Chloride and Sulfate, Sulfate $\leq 0.005\%$ None Detected No	Bacterial Endotoxins		$\leq$ 2.5 IU/g	< 2.0 IU/g	
DNase None Detected None Dete	Chloride (Cl) (argentometric)		36.5 - 37.5%	37.0%	
Enzymes Protease None Detected None Detected Heavy Metals (as Pb) $\leq 10 \text{ ppm}$ $< 0.30 \text{ ppm}$ dentification A, (IR) Passes Test Passes Test Passes Test $\leq 0.10 \text{ a.u.}$ $< 0.10 \text{ a.u.}$ $< 0.10 \text{ a.u.}$ $\leq 0.03 \text{ a.u.}$ $\leq 0.03 \text{ a.u.}$ $\leq 0.03 \text{ a.u.}$ $\leq 0.01 \text{ a.u.}$ $\leq 0.03 \text{ a.u.}$	Chloride and Sulfate, Sulfate		$\leq 0.005\%$	< 0.005%	
RNase None Detected None Detected  Heavy Metals (as Pb) $\leq 10 \text{ ppm}$ $< 0.30 \text{ ppm}$ dentification A, (IR) Passes Test Passes Test $280 \text{nm}$ , 6 mol/l, 1cm, water $\leq 0.10 \text{ a.u.}$ $< 0.10 \text{ a.u.}$ dentification $\geq 275 \text{nm}$ , 6 mol/l, 1cm, water $\leq 0.03 \text{ a.u.}$ $\leq 0.01 $		DNase	None Detected	None Detected	
Heavy Metals (as Pb) $\leq 10 \text{ ppm}$ $< 0.30 \text{ ppm}$ dentification A, (IR) Passes Test Passes Test $\leq 0.10 \text{ a.u.}$ $< 0.10 \text{ a.u.}$ $< 0.10 \text{ a.u.}$ $< 0.03 \text{ a.u.}$ $< 0.01 \text{ a.u.}$ $< 0.03 \text{ a.u.}$ $< 0.03 \text{ a.u.}$ $< 0.01 \text{ a.u.}$ $<$	Enzymes	Protease	None Detected	None Detected	
dentification A, (IR)  Passes Test $280 \text{nm}$ , 6 mol/l, 1cm, water  dentification $275 \text{nm}$ , 6 mol/l, 1cm, water $260 \text{nm}$ , 6 mol/l, 1cm, water $260 \text{nm}$ , 6 mol/l, 1cm, water $260 \text{nm}$ , 6 mol/l, 1cm, water $235 \text{nm}$ , 6 mol/l, 1cm, water $235 \text{nm}$ , 6 mol/l, 1cm, water $230 \text{nm}$ , 6 mol/l, 1cm, water $230 \text{nm}$ , 6 mol/l, 1cm, water $20.20 \text{ a.u.}$ $20.20 \text{ a.u.}$ $20.13 \text{ a.u.}$ $20.13 \text{ a.u.}$ $20.13 \text{ a.u.}$ $20.13 \text{ a.u.}$ Meets the Requirements of Meets the Requiremen		RNase	None Detected	None Detected	
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	Heavy Metals (	(as Pb)	≤ 10 ppm	< 0.30 ppm	
dentification 275nm, 6 mol/l, 1cm, water $\leq 0.03$ a.u. $< 0.03$ a.u. $< 0.03$ a.u. $< 0.03$ a.u. Absorbance) 235nm, 6 mol/l, 1cm, water $\leq 0.20$ a.u. $< 0.13$ a.u. $< 0.13$ a.u. $< 0.15$ a.u. $< 0.15$ a.u. $< 0.15$ a.u. $< 0.15$ a.u.	Identification A, (IR)		Passes Test	Passes Test	
260nm, 6 mol/l, 1cm, water $\leq$ 0.03 a.u. 0.01 a.u. Absorbance) 235nm, 6 mol/l, 1cm, water $\leq$ 0.20 a.u. 0.13 a.u. 230nm, 6 mol/l, 1cm, water $\leq$ 0.20 a.u. 0.15 a.u. dentification C. (Chloride) Meets the Requirements of Meets the Requirements of		280nm, 6 mol/l, 1cm, water	$\leq$ 0.10 a.u.	< 0.10 a.u.	
Absorbance) 260nm, 6 mol/l, 1cm, water $\leq 0.03$ a.u. 0.01 a.u. 235nm, 6 mol/l, 1cm, water $\leq 0.20$ a.u. 0.13 a.u. 230nm, 6 mol/l, 1cm, water $\leq 0.20$ a.u. 0.15 a.u. dentification C. (Chloride) Meets the Requirements of Meets the Requirements of	Identification	275nm, 6 mol/l, 1cm, water	$\leq$ 0.03 a.u.	< 0.03 a.u.	
230nm, 6 mol/l, 1cm, water ≤ 0.20 a.u. 0.15 a.u.  230nm, 6 mol/l, 1cm, water ≤ 0.20 a.u. 0.15 a.u.  dentification C. (Chloride) Meets the Requirements of Meets the Requirements of	B, (Absorbance)	260nm, 6 mol/l, 1cm, water	$\leq$ 0.03 a.u.	0.01 a.u.	
dentification C. (Chloride)  Meets the Requirements of  Meets the Requirements of		235nm, 6 mol/l, 1cm, water	$\leq$ 0.20 a.u.	0.13 a.u.	
denification C. (Unioride)		230nm, 6 mol/l, 1cm, water	$\leq$ 0.20 a.u.	0.15 a.u.	
	Identification C, (Chloride)		-		

Analy	SIS	SPECIFICATIONS	RESULT
Limit of Nitrate		≤ 0.005%	0.004%
Loss on Drying		≤ 0.5%	0.1%
Melamine (HPLC)		≤ 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		≤ 0.05%	0.02%
Solubility (6M)		Passes Test	Passes Test
Sulfated ash (600°C)		$\leq 0.05\%$	0.02%
TAMC		$\leq 100 \text{ CFU/g}$	< 10 CFU/g
TYMC		$\leq 10 \text{ CFU/g}$	< 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 10	g)	Passes Test	Passes Test
Staphylococcus aureus (absent in 1g)		Passes Test	Passes Test
	Arsenic (As)	≤ 5 ppm	< 0.45 ppm
m	Copper (Cu)	≤ 5 ppm	< 0.15 ppm
Trace Metals	Iron (Fe)	≤ 5 ppm	< 0.30 ppm
	Lead (Pb)	≤ 5 ppm	< 0.30 ppm
Water (according to Karl Fischer)		≤ 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.

<u>ELEMENTAL IMPURITY STATEMENT:</u> 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 (\*).

<u>INTENDED USE:</u> 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:	Anil McCall	Date:	7/21/25	_ Job Title:	QA Tech III	
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Reviewed by:	1 m Allen	_Date:	1101105	_ Job Title: 📐	entor Quality 1 Juliager	