

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-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-S05-0825-0064

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

Manufacturing Date: 08/13/25 Retest Date: 08/31/27

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
Assay (Dried Basis)		99.5 – 101.0%	100.0%
Chloride and Sulfate, <i>Sulfate</i>		≤ 0.005%	<0.005%
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	≤ 0.2000 a.u.	0.1008 a.u.
	260nm	≤ 0.0300 a.u.	0.0089 a.u.
	275nm	≤ 0.0300 a.u.	0.0037 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	185 - 187°C
pH (6M)		4.5 - 6.0	5.1
Residue on Ignition		≤ 0.05%	<0.05%
Solubility (6M)		Passes Test	Passes Test
Trace Metals	Arsenic (As)	≤ 5 ppm	<0.45 ppm
	Copper (Cu)	≤ 5 ppm	<0.15 ppm
	Iron (Fe)	≤ 5 ppm	<0.90 ppm
	Lead (Pb)	≤ 5 ppm	<0.15 ppm
Water by Karl Fischer		≤ 0.3% w/w	0.1% w/w
Water Insoluble		≤ 0.05%	<0.05%

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