BIOSPECTRA

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

Effective Date:	18-Feb-2019	18-Feb-2022	: Date of Next Review
Prepared By:	Kyle Snyder	16-000103 v. 4.1	: Supersedes
QA/QC Approval:	Jenna Miller	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur		

GUANIDINE HYDROCHLORIDE

CERTIFICATE OF ANALYSIS

BIO PHARMA GRADE / GH4220-K025

LOT#: GH4220-093-0419

$NH_2C(NH)NH_2 \cdot HCl$ • F.W. 95.53 g/mol. • CAS# 50-01-1

Manufacturing Date: 8/10/2018 Retest Date: 8/31/2020

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 4/12/2019

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATIONS	RESULT
Absorbance	275 nm	0.0300 a.u. maximum	0.0051 a.u.
	260 nm	0.0300 a.u. maximum	0.0101 a.u.
	230 nm	0.2000 a.u. maximum	0.1284 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.5% minimum	99.73%
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		0.15% maximum	<0.0004%
Loss on Drying		0.5% maximum	0.0335%
Melting Range		184-188°C	185.1 – 186.8 °C
Nitrate		0.01% maximum	<0.01%
pH (6M)		4.5-6.0	4.774 @ 16.81 °C
Residue on Ignition		0.05% maximum	<0.0100%
Solubility (6M)		Passes Test	Passes Test
Sulfate		0.01% maximum	<0.01%
Trace Metals	Arsenic (As)	5 ppm maximum	< 5 ppm
	Copper (Cu)	5 ppm maximum	< 5 ppm
	Iron (Fe)	5 ppm maximum	< 5 ppm
	Lead (Pb)	5 ppm maximum	< 5 ppm

COUNTRY OF ORIGIN: U.S.A.

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TEST METHOD REFERENCE: 16-000493

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: IPEC Compliant GMP Manufactured Chemical for use in further manufacturing or as a Reagent for Laboratory and Research. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household item.

RESIDUAL SOLVENTS STATEMENT: Based on the manufacturing process and the controlled handling and storage of this product, there is no potential for any of the residual solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 to be present at the specified limits; furthermore, if tested this product would comply with USP/NF requirements.

Prepared by: _____ Date: 4/18/19

Reviewed by: _____ Date: 4/18/19

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