BI●SPECTRA

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

Effective Date:	8-Mar-2021	8-Mar-2024	: Date of Next Review
Prepared By:	Shana Geffken	19-003073 v.2.0	: Supersedes
QA/QC Approval:	Jess DeMaio	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS
GUANIDINE HYDROCHLORIDE 6 MOLAR SOLUTION
BIO EXCIPIENT GRADE / NEW CODE GHCL-3101-78
(HISTORICAL CODE GH3101-L1135)
LOT: GHCL-0123-00101

$NH_2C(NH)NH_2 \cdot HCl$ ▲ F.W. 95.53 g/mol. ▲ CAS# 50-01-1
Manufacturing Date: 10/29/23 Retest Date: 10/31/25
Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
Packaging Date: 10/30/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance	260nm	0.1 a.u. max.	<0.1 a.u.
Appearance and Color		Clear, Colorless Liquid	Clear, Colorless Liquid
Cyanide		Passes Test	Passes Test
Heavy Metals		≤ 10 ppm	<10 ppm
Identification (IR)		Passes Test	Passes Test
Iron		≤ 3 ppm	<0.30 ppm
Molarity		5.8 – 6.2M	5.9M
pH		4.5 - 6.5	6.3 @ 23.2 °C

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000039

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.

OVI STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

Prepared by: _Zaire Ragin_ Date: 11/9/23 Job Title: QA Tech 1

Reviewed by: _____ Date: 11/9/23 Job Title: QA Mater. Disp. Supervisor