

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://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 <b>R</b> evision 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-0123-00050

NH<sub>2</sub>C(NH)NH<sub>2</sub>·HCl ▲ F.W. 95.53 g/mol. ▲ CAS# 50-01-1

Manufacturing Date: 06/22/23 Retest Date: 06/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 06/26/23 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 | Clear, Colorless Liquid |
| Cyanide              | Passes Test             | Passes Test             | Passes Test             |
| Heavy Metals         | ≤ 10 ppm                | <10 ppm                 | <10 ppm                 |
| Identification (IR)  | Passes Test             | Passes Test             | Passes Test             |
| Iron                 | ≤ 3 ppm                 | <3 ppm                  | <3 ppm                  |
| Molarity             | 5.8 – 6.2M              | 6.0M                    | 6.0M                    |
| pH                   | 4.5 - 6.5               | 6.2 @ 24.5 °C           | 6.2 @ 24.5 °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: 8/16/23 Job Title: QA Support TechReviewed by: Jaron Singh Date: 8/16/23 Job Title: QA Mater. Disp. Supervisor