

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

|                      |                                |                 |                       |
|----------------------|--------------------------------|-----------------|-----------------------|
| Effective Date:      | 5-Mar-2021                     | 5-Mar-2024      | : Date of Next Review |
| Prepared By:         | Shana Geffken                  | 16-001146 v.3.0 | : Supersedes          |
| QA/QC Approval:      | Jess DeMaio                    | Hannah Bernier  | : Management Approval |
| Reason for Revision: | See Revision History in ensur. |                 |                       |

**CERTIFICATE OF ANALYSIS**  
**GUANIDINE HYDROCHLORIDE**  
**BIO EXCIPIENT GRADE / NEW CODE GHCL-3220-10**  
**(HISTORICAL CODE GH3220 – K010)**  
**LOT#: GHCL-0122-00007**

$\text{NH}_2\text{C}(\text{NH})\text{NH}_2\cdot\text{HCl}$  ^ F.W. 95.53 g/mol. ^ CAS# 50-01-1

Manufacturing Date: 11/15/21    Retest Date: 11/30/23

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 1/12/22 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS             | SPECIFICATIONS   | RESULT           |               |
|----------------------|------------------|------------------|---------------|
| Absorbance (6M)      | 230 nm           | 0.2000 a.u. max. | 0.1477 a.u.   |
|                      | 260 nm           | 0.0300 a.u. max. | 0.0117 a.u.   |
|                      | 275 nm           | 0.0300 a.u. max. | 0.0049 a.u.   |
| Appearance and Color | White / Crystals | White / Crystals |               |
| Assay                | 99.5% min.       | 99.8%            |               |
| 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% max.       | <0.15%           |               |
| Loss on Drying       | 0.5% max.        | 0.1%             |               |
| Melting Range        | 184-188°C        | 185 - 186°C      |               |
| Nitrate              | 0.01% max.       | <0.01%           |               |
| pH (6M)              | 4.5-6.0          | 5.1 @ 23.8°C     |               |
| Residue on Ignition  | 0.05% max.       | <0.05%           |               |
| Solubility (6M)      | Passes Test      | Passes Test      |               |
| Sulfate              | 0.01% max.       | <0.01%           |               |
| Trace Metals         | Arsenic (As)     | 5 ppm max.       | < 5 ppm       |
|                      | Copper (Cu)      | 5 ppm max.       | < 5 ppm       |
|                      | Iron (Fe)        | 5 ppm max.       | < 5 ppm       |
|                      | Lead (Pb)        | 5 ppm max.       | < 5 ppm       |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000493

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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: Jason Hughes Date: 1/19/22 Job Title: QA Specialist

Reviewed by: Car Date: 1/19/22 Job Title: QA Manager