

# BIOSPECTRA

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

|                      |                                        |                   |                       |
|----------------------|----------------------------------------|-------------------|-----------------------|
| Effective Date:      | 18-AUG-2023                            | 18-AUG-2026       | : Date of Next Review |
| Prepared By:         | Carissa Albert                         | BSI-COA-0247 v1.0 | : Supersedes          |
| QA/QC Approval:      | Carissa Albert                         | Amy Yench         | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. |                   |                       |

## CERTIFICATE OF ANALYSIS

### GUANIDINE HYDROCHLORIDE

### BIO EXCIPIENT GRADE / NEW CODE GHCL-3224-25

### (HISTORICAL CODE GH3224-K025)

### LOT: GHCL-0124-00059

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

Manufacturing Date: 05/03/24 Retest Date: 05/31/26

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 08/08/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS                               | SPECIFICATION                       | TEST RESULT                      |
|----------------------------------------|-------------------------------------|----------------------------------|
| Acidity                                | $\leq 0.01\%$                       | $<0.01\%$                        |
| Appearance and Color                   | White / Crystals                    | White / Crystals                 |
| Assay (Dried Basis)                    | 99.5 - 101.0%                       | 100.0%                           |
| Cyanide                                | $\leq 0.1$ ppm                      | $<0.1$ ppm                       |
| Chloride and Sulfate, <i>Sulfate</i>   | $\leq 0.005 \%$                     | $<0.005\%$                       |
| Enzymes                                | DNase                               | None Detected                    |
|                                        | Protease                            | None Detected                    |
|                                        | RNase                               | None Detected                    |
| Identification A, (IR)                 | Passes Test                         | Passes Test                      |
| Identification B,<br><i>Absorbance</i> | 230nm                               | $\leq 0.2000$ a.u.               |
|                                        | 260nm                               | $\leq 0.0300$ a.u.               |
|                                        | 275nm                               | $\leq 0.0300$ a.u.               |
| Identification C, (Chloride)           | Meets the Requirements of<br>Test A | Meets the Requirements of Test A |
| Limit of Nitrate                       | $\leq 0.005 \%$                     | $<0.005\%$                       |
| Loss on Drying                         | $\leq 0.5\%$                        | $<0.5\%$                         |
| Melting Range                          | 184 – 188°C                         | 186 - 187°C                      |
| pH (5% solution)                       | 4.5 – 6.0                           | 5.4                              |
| Residue on Ignition                    | $\leq 0.05\%$                       | 0.02%                            |
| Solubility (6M)                        | Passes Test                         | Passes Test                      |

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| ANALYSIS        | SPECIFICATION | TEST RESULT    |
|-----------------|---------------|----------------|
| Trace Metals    | Arsenic (As)  | $\leq 0.5$ ppm |
|                 | Antimony (Sb) | $\leq 0.5$ ppm |
|                 | Copper (Cu)   | $\leq 5$ ppm   |
|                 | Iron (Fe)     | $\leq 2$ ppm   |
|                 | Lead (Pb)     | $\leq 0.5$ ppm |
| Water Insoluble |               | $\leq 0.05\%$  |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0013

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.

Prepared by: Shirley McCall Date: 8/12/24 Job Title: QA Tech I

Reviewed by: John R. Rhyne Date: 8/12/24 Job Title: QA Supervisor