## BI BUFFER SOLUTIONS

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

| Effective Date:      | 11-Ju1-2024                           | 11-Ju1-2027        | : Date of Next Review |
|----------------------|---------------------------------------|--------------------|-----------------------|
| Prepared By:         | Carissa Albert                        | BSI-COA-0131 v.6.2 | : Supersedes          |
| QA/QC Approval:      | Jaron Hughes                          | Wayne Talamonti    | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl |                    |                       |

## CERTIFICATE OF ANALYSIS

## L-CYSTINE diHCl

## BIO PHARMA GRADE / LCYS-4250-92

LOT: LCYS-L02-1124-0025

 $C_6H_{12}N_2O_4S_2 \cdot 2HC1 - F.W. 313.22 \text{ g/mol.} - CAS# 30925-07-6$ 

Retest Date: 05/31/26

Manufacturing/Packaging Date: 11/06/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| Analysis                              | SPECIFICATION                                  | TEST RESULT                                    |
|---------------------------------------|--|--|
| Appearance and Color                  | White to Slightly Yellow<br>Crystalline Powder | White to Slightly Yellow<br>Crystalline Powder |
| Assay (Dried Basis)                   | 98.0% - 102.0%                                 | 99.8%  |
| Bioburden                             | $\leq 100 \text{ CFU/g}$                       | < 10 CFU/g                                     |
| Chloride                              | 22.2% - 23.5%                                  | 22.6%  |
| Endotoxin                             | <0.02 EU/mg                                    | < 0.02 EU/mg                                   |
| Heavy Metals (Pb)                     | <10 ppm  | < 0.15 ppm                                     |
| Identification (IR Spectrum)          | Passes Test                                    | Passes Test                                    |
| Loss on Drying @ 105°C                | ≤ 0.5%   | < 0.5%   |
| pH (0.1% soln.)                       | Report   | 2.38 @ 23.5°C                                  |
| Residue on Ignition                   | ≤ 0.1%   | < 0.1%   |
| Specific Rotation (Free Basis) @ 20°C | -225.0° to -215.0°                             | -222.0°  |
| Solubility                            | Passes Test                                    | Passes Test                                    |

COUNTRY OF ORIGIN: India

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a process chemical. It is GMP manufactured by the approved supplier in accordance with the approved supplier's ISO 9001:2015 certified management system. 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.

<u>RETEST DATE:</u> The retest date is obtained from the approved supplier's certificate of analysis.

| Prepared by: Am Mulm  | Date: 11/11/24 | Job Title: QATech 111    |
|-----------------------|----------------|--------------------------|
| Reviewed by: Jam High | Date: /////24  | Job Title: OA Supervisor |

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