

BIOSPECTRA

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

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|----------------------|--------------------------------|-----------------|-----------------------|
| Effective Date: | 24-Apr-2020 | 24-Apr-2023 | : Date of Next Review |
| Prepared By: | Kyle Snyder | 19-002903 v.4.0 | : Supersedes |
| QA/QC Approval: | Carissa McCollian | Wendy Santay | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

CERTIFICATE OF ANALYSIS

L-CYSTINE diHCl

BIO PHARMA GRADE / CY4250-L035.85

LOT: CY4250-026-0221

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

Manufacturing Date: 1/18/21 Retest Date: 1/31/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 1/24/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | SPECIFICATION | TEST RESULT |
|---------------------------------------|--|--|
| Appearance and Color | White to Slightly Yellow Crystalline Powder | White to Slightly Yellow Crystalline Powder |
| Assay (Dried Basis) | 98.0% - 102.0% | 99.9% |
| Bioburden | ≤ 100 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 | <10 ppm |
| Identification (IR Spectrum) | Passes Test | Passes Test |
| Loss on Drying @ 105°C | 1.0% max. | <1.0% |
| pH (0.1% soln.) | Report | 2.2 |
| Residue on Ignition | 0.1% max. | <0.1% |
| Specific Rotation (Free Basis) @ 20°C | -225.0° to -215.0° | -222.3° |
| Solubility | Passes Test | Passes Test |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 17-002319

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a GMP process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. 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.

Prepared by: Jason Hughes Date: 2/12/21 Job Title: QA Specialist
 Reviewed by: [Signature] Date: 2/21/21 Job Title: QA Supervisor