

BIOSPECTRA

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

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|----------------------|--------------------------------|------------------|-----------------------|
| Effective Date: | 21-Oct-2021 | 21-Oct-2024 | : Date of Next Review |
| Prepared By: | Amy Hosein | 20-003627 v. 3.1 | : Supersedes |
| QA/QC Approval: | Carissa McCollan | Amy Yencho | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

CERTIFICATE OF ANALYSIS
L-CYSTEAMINE HCL (2-MEA)
BIO EXCIPIENT GRADE / NEW CODE CSMH-3250-10
(HISTORICAL CODE CH3250-K003.35)
LOT: CSMH-0121-00013
 $C_2H_7N_1S \cdot HCl$ * F.W. 113.61 g/mol. * CAS# 156-57-0
 Manufacturing Date: 5/6/21 Retest Date: 11/30/21
 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
 Packaging Date: 5/7/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | SPECIFICATION | TEST RESULT |
|---------------------------------|--|--|
| Appearance and Color | White or colorless crystals or powder, may contain lumps | White or colorless crystals or powder, may contain lumps |
| Appearance of Solution | Colorless, clear solution | Colorless, clear solution |
| Argentometric Titration | 30.6 - 31.8% | 31.3% |
| Assay (HPLC Weight %) | 98.0 – 102.0% | 100.7% |
| Bioburden | ≤ 100 CFU/g | <100CFU/g |
| Endotoxin | ≤ 50 EU/g | ≤40EU/g |
| HPLC Minor Component 1 (Area %) | Cystamine ≤2.0% | ≤0.6% |
| Heavy Metals | ≤ 20 mg/kg (ppm) | ≤20mg/kg (ppm) |
| Identification (IR) | Conforms to reference standard | Conforms to reference standard |
| Loss on Drying | ≤ 1.0% | ≤0.4% |
| | Aluminum (Al) | <0.80ppm |
| | Arsenic (As) | <0.03ppm |
| | Barium (Ba) | <1.4ppm |
| | Bismuth (Bi) | <0.40ppm |
| Trace Metal Analysis (ICP) | Calcium (Ca) | <1.5ppm |
| | Cadmium (Cd) | <0.004ppm |
| | Cobalt (Co) | <0.01ppm |
| | Chromium (Cr) | <0.10ppm |
| | Copper (Cu) | <0.05ppm |
| | Iron (Fe) | 0.75ppm |

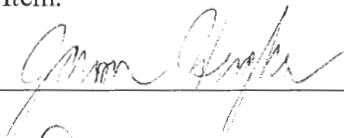
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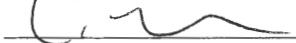
| ANALYSIS | SPECIFICATION | TEST RESULT | |
|----------------------------------|----------------------------|---------------------|-----------|
| Mercury (Hg) | ≤ 1 ppm | 0.33ppm | |
| Potassium (K) | ≤ 50 ppm | <4.0ppm | |
| Lithium (Li) | ≤ 5 ppm | <0.50ppm | |
| Magnesium (Mg) | ≤ 5 ppm | <0.40ppm | |
| Manganese (Mn) | ≤ 1 ppm | <0.05ppm | |
| Molybdenum (Mo) | ≤ 5 ppm | <0.10ppm | |
| Trace Metal Analysis (ICP) | Sodium (Na) | ≤ 50 ppm | 20ppm |
| | Nickel (Ni) | ≤ 1 ppm | <0.04ppm |
| | Lead (Pb) | ≤ 1 ppm | <0.01ppm |
| | Antimony (Sb) | ≤ 1 ppm | <0.18ppm |
| | Selenium (Se) | ≤ 1 ppm | <0.10ppm |
| | Strontium (Sr) | ≤ 5 ppm | <0.40ppm |
| | Vanadium (V) | ≤ 1 ppm | <0.02ppm |
| | Zinc (Zn) | ≤ 1 ppm | <0.40ppm |
| | Purity (HPLC Area %) | ≥ 98.0% | 99.3% |
| Purity (Cysteamine (HPLC)) | ≥ 92.0% | 99.3% | |
| | ≤ 8.0% related substances | ≤ 0.7% | |
| | Ethanol | ≤ 5000 ppm | ≤ 2500ppm |
| Residual Solvents | Isopropyl Alcohol (IPA) | ≤ 5000 ppm | ≤ 2500ppm |
| | Tert-Butylmethyl Ether | ≤ 5000 ppm | ≤ 2500ppm |
| Solubility | Clear and colorless | Clear and colorless | |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 20-003580

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:  Date: 10/21/21 Job Title: QA Specialist

Reviewed by:  Date: 10/21/21 Job Title: QA Manager