

BIOSPECTRA

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

| | | | |
|----------------------|---------------------------------------|--------------------|-----------------------|
| Effective Date: | 23-Aug-2022 | 23-Aug-2025 | : Date of Next Review |
| Prepared By: | Amy Hosein | BSI-COA-0218 v.4.3 | : Supersedes |
| QA/QC Approval: | Carissa Albert | Dora Meissner | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl | | |

CERTIFICATE OF ANALYSIS

CYSTEAMINE HCl (2-MEA)

BIO EXCIPIENT GRADE / NEW CODE CSMH-3250-10

(HISTORICAL CODE CH3250-K010)

LOT: CSMH-N02-1224-0023

$C_2H_7N_1S \cdot HCl$ * F.W. 113.61 g/mol. * CAS# 156-57-0

Manufacturing Date: 12/03/24 Retest Date: 12/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 12/04/24 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% | 31.0% |
| Assay (HPLC Weight %) | 98.0 – 102.0% | 99.6% |
| Bioburden | ≤ 100 CFU/g | < 100 CFU/g |
| Endotoxin | ≤ 50 EU/g | < 33 EU/g |
| HPLC Minor Component 1 (Area %) | Cystamine ≤2.0% | 0.2% |
| Heavy Metals | ≤ 20 mg/kg (ppm) | < 20 mg/kg (ppm) |
| Identification (IR) | Conforms to reference standard | Conforms to reference standard |
| Loss on Drying | ≤ 1.0% | 0.1% |
| Aluminum (Al) | ≤ 5 ppm | < 0.80 ppm |
| Arsenic (As) | ≤ 1 ppm | < 0.03 ppm |
| Barium (Ba) | ≤ 5 ppm | < 1.4 ppm |
| Bismuth (Bi) | ≤ 5 ppm | < 0.40 ppm |
| Trace Metal Analysis (ICP) | Calcium (Ca) ≤ 10 ppm | < 1.5 ppm |
| | Cadmium (Cd) ≤ 1 ppm | < 0.004 ppm |
| | Cobalt (Co) ≤ 1 ppm | < 0.01 ppm |
| | Chromium (Cr) ≤ 1 ppm | < 0.10 ppm |
| | Copper (Cu) ≤ 1 ppm | < 0.05 ppm |
| | Iron (Fe) ≤ 1 ppm | < 0.40 ppm |

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

| ANALYSIS | SPECIFICATION | TEST RESULT | |
|----------------------------------|----------------------------|---------------------|------------|
| Mercury (Hg) | ≤ 1 ppm | < 0.018 ppm | |
| Potassium (K) | ≤ 50 ppm | < 4.0 ppm | |
| Lithium (Li) | ≤ 5 ppm | < 0.50 ppm | |
| Magnesium (Mg) | ≤ 5 ppm | < 0.40 ppm | |
| Manganese (Mn) | ≤ 1 ppm | < 0.05 ppm | |
| Molybdenum (Mo) | ≤ 5 ppm | < 0.10 ppm | |
| Trace Metal Analysis (ICP) | Sodium (Na) | ≤ 50 ppm | < 4.0 ppm |
| | Nickel (Ni) | ≤ 1 ppm | < 0.04 ppm |
| | Lead (Pb) | ≤ 1 ppm | < 0.01 ppm |
| | Antimony (Sb) | ≤ 1 ppm | < 0.18 ppm |
| | Selenium (Se) | ≤ 1 ppm | < 0.10 ppm |
| | Strontium (Sr) | ≤ 5 ppm | < 0.40 ppm |
| | Vanadium (V) | ≤ 1 ppm | < 0.02 ppm |
| | Zinc (Zn) | ≤ 1 ppm | < 0.40 ppm |
| | Purity (HPLC Area %) | ≥ 98.0% | 99.8% |
| Purity (Cysteamine (HPLC)) | ≥ 92.0% | 99.8% | |
| | ≤ 8.0% related substances | 0.2% | |
| Residual Solvents | Ethanol | ≤ 5000 ppm | < 2390 ppm |
| | Isopropyl Alcohol (IPA) | ≤ 5000 ppm | < 2660 ppm |
| | Tert-Butylmethyl Ether | ≤ 5000 ppm | < 2510 ppm |
| Solubility | Clear and colorless | Clear and colorless | |

COUNTRY OF ORIGIN: U.S.A.

MANUFACTURING SUITE: Process Suite N02

TEST METHOD REFERENCE: DCN: BSI-ATM-0055

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: David McCall Date: 12/18/24 Job Title: QA Tech III

Reviewed by: Jonny Rhymer Date: 12/18/24 Job Title: QA Supervisor