

# BIOSPECTRA

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

|                      |                                       |                    |                       |
|----------------------|---------------------------------------|--------------------|-----------------------|
| Effective Date:      | 12-Feb-2025                           | 12-Feb-2028        | : Date of Next Review |
| Prepared By:         | Taylor Yurick                         | BSI-COA-0218 v.4.4 | : Supersedes          |
| QA/QC Approval:      | Jaron Hughes                          | Carissa Albert     | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl |                    |                       |

## CERTIFICATE OF ANALYSIS

### CYSTEAMINE HCl (2-MEA)

### BIO EXCIPIENT GRADE / CSMH-3250

### LOT: CSMH-N02-1025-0024

 $\text{C}_2\text{H}_7\text{N}_1\text{S}_1 \cdot \text{HCl}$  \* F.W. 113.61 g/mol. \* CAS# 156-57-0

Manufacturing Date: 10/20/25 Retest Date: 10/31/27  
 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013  
 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%                                             | 31.6%                                                    |
| Assay (HPLC Weight %)           | 98.0 – 102.0%                                            | 99.8%                                                    |
| Bioburden                       | $\leq 100$ CFU/g                                         | $< 100$ CFU/g                                            |
| Endotoxin                       | $\leq 50$ EU/g                                           | $< 33$ EU/g                                              |
| HPLC Minor Component 1 (Area %) | Cystamine $\leq 2.0\%$                                   | $< 0.2\%$                                                |
| Heavy Metals                    | $\leq 20$ mg/kg (ppm)                                    | $< 20$ mg/kg (ppm)                                       |
| Identification (IR)             | Conforms to reference standard                           | Conforms to reference standard                           |
| Loss on Drying                  | $\leq 1.0\%$                                             | 0.1%                                                     |
| Trace Metal Analysis (ICP)      | Aluminum (Al)                                            | $< 0.80$ ppm                                             |
|                                 | Arsenic (As)                                             | $< 0.03$ ppm                                             |
|                                 | Barium (Ba)                                              | $< 1.4$ ppm                                              |
|                                 | Bismuth (Bi)                                             | $< 0.40$ ppm                                             |
|                                 | Calcium (Ca)                                             | $< 1.5$ ppm                                              |
|                                 | Cadmium (Cd)                                             | $< 0.004$ ppm                                            |
|                                 | Cobalt (Co)                                              | $< 0.01$ ppm                                             |
|                                 | Chromium (Cr)                                            | $< 0.10$ ppm                                             |
|                                 | Copper (Cu)                                              | $< 0.05$ ppm                                             |
|                                 | Iron (Fe)                                                | $< 0.40$ ppm                                             |

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| ANALYSIS                   |                         | SPECIFICATION                   | TEST RESULT         |
|----------------------------|-------------------------|---------------------------------|---------------------|
| Trace Metal Analysis (ICP) | Mercury (Hg)            | $\leq 1$ ppm                    | < 0.018ppm          |
|                            | Potassium (K)           | $\leq 50$ ppm                   | < 4.0ppm            |
|                            | Lithium (Li)            | $\leq 5$ ppm                    | < 0.50ppm           |
|                            | Magnesium (Mg)          | $\leq 5$ ppm                    | < 0.40ppm           |
|                            | Manganese (Mn)          | $\leq 1$ ppm                    | < 0.05ppm           |
|                            | Molybdenum (Mo)         | $\leq 5$ ppm                    | < 0.10ppm           |
|                            | Sodium (Na)             | $\leq 50$ ppm                   | < 4.0ppm            |
|                            | Nickel (Ni)             | $\leq 1$ ppm                    | 0.19ppm             |
|                            | Lead (Pb)               | $\leq 1$ ppm                    | < 0.01ppm           |
|                            | Antimony (Sb)           | $\leq 1$ ppm                    | < 0.18ppm           |
|                            | Selenium (Se)           | $\leq 1$ ppm                    | < 0.10ppm           |
|                            | Strontium (Sr)          | $\leq 5$ ppm                    | < 0.40ppm           |
|                            | Vanadium (V)            | $\leq 1$ ppm                    | < 0.02ppm           |
|                            | Zinc (Zn)               | $\leq 1$ ppm                    | < 0.40ppm           |
| Purity (HPLC Area %)       |                         | $\geq 98.0\%$                   | 99.8%               |
| Purity (Cysteamine (HPLC)) |                         | $\geq 92.0\%$                   | 99.8%               |
|                            |                         | $\leq 8.0\%$ related substances | < 0.2%              |
| Residual Solvents          | Ethanol                 | $\leq 5000$ ppm                 | < 2410ppm           |
|                            | Isopropyl Alcohol (IPA) | $\leq 5000$ ppm                 | < 2630ppm           |
|                            | Tert-Butylmethyl Ether  | $\leq 5000$ ppm                 | < 2530ppm           |
| 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: Amel McCall Date: 11/7/25 Job Title: QA Tech III

Reviewed by: Joan Egan Date: 11/7/25 Job Title: QA Supervisor