



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-N02-0425-0017**

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

Manufacturing Date: 04/08/25 Retest Date: 04/30/27

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%	31.1%
Assay (HPLC Weight %)	98.0 – 102.0%	98.6%
Bioburden	$\leq 100$ CFU/g	$< 100$ CFU/g
Endotoxin	$\leq 50$ EU/g	$< 33$ EU/g
HPLC Minor Component 1 (Area %)	Cystamine $\leq 2.0\%$	0.96%
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	< 0.018 ppm
	Potassium (K)	$\leq 50$ ppm	< 4.0 ppm
	Lithium (Li)	$\leq 5$ ppm	< 0.50 ppm
	Magnesium (Mg)	$\leq 5$ ppm	< 0.40 ppm
	Manganese (Mn)	$\leq 1$ ppm	< 0.05 ppm
	Molybdenum (Mo)	$\leq 5$ ppm	< 0.10 ppm
	Sodium (Na)	$\leq 50$ ppm	18 ppm
	Nickel (Ni)	$\leq 1$ ppm	< 0.04 ppm
	Lead (Pb)	$\leq 1$ ppm	< 0.01 ppm
	Antimony (Sb)	$\leq 1$ ppm	< 0.18 ppm
	Selenium (Se)	$\leq 1$ ppm	< 0.10 ppm
	Strontium (Sr)	$\leq 5$ ppm	< 0.40 ppm
	Vanadium (V)	$\leq 1$ ppm	< 0.02 ppm
	Zinc (Zn)	$\leq 1$ ppm	< 0.40 ppm
Purity (HPLC Area %)		$\geq 98.0\%$	99.0%
Purity (Cysteamine (HPLC))		$\geq 92.0\%$	99.0%
		$\leq 8.0\%$ related substances	0.96%
Residual Solvents	Ethanol	$\leq 5000$ ppm	< 2400 ppm
	Isopropyl Alcohol (IPA)	$\leq 5000$ ppm	< 2650 ppm
	Tert-Butylmethyl Ether	$\leq 5000$ ppm	< 2530 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: 6/23/25 Job Title: QA Technician

Reviewed by: John Hughes Date: 6/23/25 Job Title: QA Supervisor