

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-N02-1025-0027

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

Manufacturing Date: 10/24/25 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%	30.8%
Assay (HPLC Weight %)	98.0 – 102.0%	98.4%
Bioburden	≤ 100 CFU/g	< 100 CFU/g
Endotoxin	≤ 50 EU/g	< 33 EU/g
HPLC Minor Component 1 (Area %)	Cystamine $\leq 2.0\%$	1.0%
Heavy Metals	≤ 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)	≤ 1 ppm	< 0.018ppm
	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
	Sodium (Na)	≤ 50 ppm	< 4.0ppm
	Nickel (Ni)	≤ 1 ppm	0.18ppm
	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
Purity (HPLC Area %)		$\geq 98.0\%$	99.0%
Purity (Cysteamine (HPLC))		$\geq 92.0\%$	99.0%
		$\leq 8.0\%$ related substances	1.0%
Residual Solvents	Ethanol	≤ 5000 ppm	< 2410ppm
	Isopropyl Alcohol (IPA)	≤ 5000 ppm	< 2630ppm
	Tert-Butylmethyl Ether	≤ 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: Anil Mcclau Date: 11/7/25 Job Title: QA Technician

Reviewed by: Jon Risher Date: 11/7/25 Job Title: QA Supervisor