BIOSPECTRA

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

Effective Date:	1-Dec-2025	1-Dec-2028	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0218 v.4.5	: Supersedes
QA/QC Approval:	Jaron Hughes	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

CERTIFICATE OF ANALYSIS

CYSTEAMINE HCl (2-MEA)

BIO EXCIPIENT GRADE / CSMH-3250

LOT: CSMH-N02-1026-0008

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

Manufacturing Date: 10/03/26 Retest Date: 10/31/28
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%	30.9%
Assay (HPLC Weight %)		98.0 – 102.0%	98.4%
Bioburden		≤ 100 CFU/g	< 50 CFU/g
Endotoxin		≤ 50 EU/g	< 33 EU/g
HPLC Minor Component 1 (Area %)		Cystamine ≤2.0%	1.3%
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%
Trace Metal Analysis (ICP)	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
	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

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ANALYSIS		SPECIFICATION	TEST RESULT
Trace Metal Analysis (ICP)	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
	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%	98.7%
Purity (Cysteamine (HPLC))		≥ 92.0%	98.7%
		≤ 8.0% related substances	1.3%
Residual Solvents	Ethanol	≤ 5000 ppm	< 2380 ppm
	Isopropyl Alcohol (IPA)	≤ 5000 ppm	< 2620 ppm
	Tert-Butylmethyl Ether	≤ 5000 ppm	< 2510ppm
Solubility		Clear and colorless	Clear and colorless

COUNTRY OF ORIGIN: U.S.A.

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: 10/16/26 Job Title: QA Tech III

Reviewed by: Jason Hughes Date: 10/19/26 Job Title: QA Supervisor

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