

BIO SPECTRA

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-3250-05

(HISTORICAL CODE CH3250-K005)

LOT: CSMH-0123-00006

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

Manufacturing Date: 03/30/22 Retest Date: 03/31/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 06/23/23 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%	30.7%
Assay (HPLC Weight %)	98.0 – 102.0%	100.3%
Bioburden	≤ 100 CFU/g	< 100 CFU/g
Endotoxin	≤ 50 EU/g	< 33 EU/g
HPLC Minor Component 1 (Area %)	Cystamine ≤ 2.0%	< 2.0%
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%	< 1.0%
	Aluminum (Al)	< 0.80 ppm
	Arsenic (As)	< 0.03 ppm
	Barium (Ba)	< 1.4 ppm
	Bismuth (Bi)	< 0.40 ppm
Trace Metal Analysis (ICP)	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	
Mercury (Hg)	≤ 1 ppm	0.03 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	
	Nickel (Ni)	≤ 1 ppm	
	Lead (Pb)	≤ 1 ppm	
	Antimony (Sb)	≤ 1 ppm	
	Selenium (Se)	≤ 1 ppm	
	Strontium (Sr)	≤ 5 ppm	
	Vanadium (V)	≤ 1 ppm	
	Zinc (Zn)	≤ 1 ppm	
	Purity (HPLC Area %)	≥ 98.0%	100.0%
	Purity (Cysteamine (HPLC))	≥ 92.0%	100.0%
≤ 8.0% related substances		< 8.0%	
Residual Solvents	Ethanol	≤ 5000 ppm	
	Isopropyl Alcohol (IPA)	≤ 5000 ppm	
	Tert-Butylmethyl Ether	≤ 5000 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: M. Mhaffez Date: 07/07/23 Job Title: QA Mater. Disp. Tech. III

Reviewed by: Janet Simpson Date: 7/7/23 Job Title: QA Mater. Disp. Supervisor