

BIOSPECTRA

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-3250-10

(HISTORICAL CODE CH3250-K010)

LOT: CSMH-0122-00046

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

Manufacturing Date: 03/12/22 Retest Date: 03/31/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 07/28/22 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%	98.7%
Bioburden	≤ 100 CFU/g	< 100 CFU/g
Endotoxin	≤ 50 EU/g	< 33 EU/g
HPLC Minor Component 1 (Area %)	Cystamine ≤2.0%	0.5%
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%
	Aluminum (Al)	< 0.80ppm
	Arsenic (As)	< 0.03ppm
	Barium (Ba)	< 1.4ppm
	Bismuth (Bi)	< 0.40ppm
Trace Metal	Calcium (Ca)	< 1.5ppm
Analysis (ICP)	Cadmium (Cd)	< 0.004ppm
	Cobalt (Co)	< 0.01ppm
	Chromium (Cr)	0.15ppm
	Copper (Cu)	< 0.05ppm
	Iron (Fe)	<0.40ppm

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ANALYSIS	SPECIFICATION	TEST RESULT		
	Mercury (Hg)	≤ 1 ppm	0.04ppm	
	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	
Trace Metal Analysis (ICP)	Sodium (Na)	≤ 50 ppm	< 4.0ppm	
	Nickel (Ni)	≤ 1 ppm	0.09ppm	
	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	
	Zinc (Zn)	≤ 1 ppm	< 0.40ppm	
	Purity (HPLC Area %)		≥ 98.0%	99.5%
			≥ 92.0%	99.5%
Purity (Cysteamine (HPLC))	≤ 8.0% related substances		0.5%	
	Ethanol	≤ 5000 ppm	< 5000ppm	
Residual Solvents	Isopropyl Alcohol (IPA)	≤ 5000 ppm	< 5000ppm	
	Tert-Butylmethyl Ether	≤ 5000 ppm	< 5000ppm	
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 McCall Date: 1/29/24 Job Title: QA Tech I

Reviewed by: James Hughes Date: 1/29/24 Job Title: QA Mater. Disp. Supervisor