

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-0122-00017

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

Manufacturing Date: 1/26/22 Retest Date: 3/31/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 1/29/22 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%	99.0%
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%	0.2%
	Aluminum (Al)	≤ 5 ppm
	Arsenic (As)	≤ 1 ppm
	Barium (Ba)	≤ 5 ppm
	Bismuth (Bi)	≤ 5 ppm
Trace Metal Analysis (ICP)	Calcium (Ca)	≤ 10 ppm
	Cadmium (Cd)	≤ 1 ppm
	Cobalt (Co)	≤ 1 ppm
	Chromium (Cr)	≤ 1 ppm
	Copper (Cu)	≤ 1 ppm
	Iron (Fe)	≤ 1 ppm

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ANALYSIS		SPECIFICATION	TEST RESULT
	Mercury (Hg)	≤ 1 ppm	0.03ppm
	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	0.05ppm
	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%	100.0%
	≥ 92.0%	100.0%	
Purity (Cysteamine (HPLC))	≤ 8.0% related substances	< 8.0%	
	Ethanol	≤ 5000 ppm	< 5000ppm
Residual Solvents	Isopropyl Alcohol (IPA)	≤ 5000 ppm	2933ppm
	Tert-Butylmethyl Ether	≤ 5000 ppm	< 5000ppm
Solubility	Clear and colorless	Clear and colorless	

COUNTRY OF ORIGIN: U.S.A.

MANUFACTURING SUITE: Pre-Scale up material produced in Suite N05

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:  Date: 10/6/22 Job Title: QA Specialist

Reviewed by: Cassie Albert Date: 10/6/22 Job Title: Assoc. Director of Quality