

# BIO SPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

Effective Date:	10-Feb-2022	10-Feb-2025	: Date of Next Review
Prepared By:	Wendy Santay	BSI-COA-0218 v.4.1	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in Mastercontrol		

## CERTIFICATE OF ANALYSIS

### L-CYSTEAMINE HCL (2-MEA)

### BIO EXCIPIENT GRADE / NEW CODE CSMH-3250-05

#### (HISTORICAL CODE CH3250-K005)

#### LOT: CSMH-0122-00043

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

Manufacturing Date: 3/10/22 Retest Date: 5/31/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 4/8/22 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%	30.9%
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%	< 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%	0.1%
	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)	0.11ppm
	Copper (Cu)	0.06ppm
	Iron (Fe)	0.81ppm

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ANALYSIS	SPECIFICATION	TEST RESULT	
	Mercury (Hg)	≤ 1 ppm	0.05ppm
	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%	100.0%	
Purity (Cysteamine (HPLC))	≥ 92.0%	100.0%	
	≤ 8.0% related substances	< 8.0%	
Residual Solvents	Ethanol	≤ 5000 ppm	< 5000ppm
	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.

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: Bob B Date: 4/13/22 Job Title: QA Specialist

Reviewed by: CW Date: 4/13/22 Job Title: QA Manager