

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://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-N02-1224-0022

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

Manufacturing Date: 11/13/24 Retest Date: 11/30/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 11/14/24 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%	31.1%
Assay (HPLC Weight %)	98.0 – 102.0%	99.4%
Bioburden	≤ 100 CFU/g	< 100 CFU/g
Endotoxin	≤ 50 EU/g	< 33 EU/g
HPLC Minor Component 1 (Area %)	Cystamine ≤2.0%	1.4%
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)	≤ 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	< 0.018 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
Trace Metal Analysis (ICP)	Sodium (Na)	≤ 50 ppm	38 ppm
	Nickel (Ni)	≤ 1 ppm	0.36 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%	98.6%
Purity (Cysteamine (HPLC))	≥ 92.0%	98.6%	
	≤ 8.0% related substances	1.4%	
Residual Solvents	Ethanol	≤ 5000 ppm	< 2380 ppm
	Isopropyl Alcohol (IPA)	≤ 5000 ppm	< 2630 ppm
	Tert-Butylmethyl Ether	≤ 5000 ppm	< 2520 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: Anil McCall Date: 12/18/24 Job Title: QA Tech III

Reviewed by: Joan Ringer Date: 12/18/24 Job Title: QA Supervisor