

BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

Effective Date:	26-May-2021	26-May-2024	: Date of Next Review
Prepared By:	Amy Hosein	20-003627 v. 3.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yenko	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

L-CYSTEAMINE HCL (2-MEA)

BIO EXCIPIENT GRADE / NEW CODE CSMH-3250-10

(HISTORICAL CODE CH3250-K006.55)

LOT: CSMH-0121-00012

C₂H₇N₁S · HCl ▲ F.W. 113.61 g/mol. ▲ CAS# 156-57-0

Manufacturing Date: 4/27/21 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 4/28/21 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%	100.1%
Bioburden	≤ 100 CFU/g	<100CFU/g
Endotoxin	≤ 50 EU/g	≤40EU/g
HPLC Minor Component 1 (Area %)	Cystamine ≤2.0%	≤1.2%
Heavy Metals	≤ 20 mg/kg (ppm)	≤20mg/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 Analysis (ICP)	Calcium (Ca)	<1.5ppm
	Cadmium (Cd)	<0.004ppm
	Cobalt (Co)	<0.01ppm
	Chromium (Cr)	0.12ppm
	Copper (Cu)	0.11ppm
	Iron (Fe)	0.71ppm

ANALYSIS	SPECIFICATION	TEST RESULT	
	Mercury (Hg)	≤ 1 ppm	0.49ppm
	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	5.1ppm
	Nickel (Ni)	≤ 1 ppm	0.049ppm
	Lead (Pb)	≤ 1 ppm	0.029ppm
	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%	98.8%
	≥ 92.0%	98.8%	
Purity (Cysteamine (HPLC))	≤ 8.0% related substances	≤ 1.2%	
	Ethanol	≤ 5000 ppm	≤ 2500ppm
Residual Solvents	Isopropyl Alcohol (IPA)	≤ 5000 ppm	≤ 2500ppm
	Tert-Butylmethyl Ether	≤ 5000 ppm	≤ 2500ppm
Solubility	Clear and colorless	Clear and colorless	

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 20-003580

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.

SHELF LIFE: A Retest Date is to be determined based on the data obtained from the stability study.

Prepared by: C. W. Date: 5/27/21 Job Title: QA Manager

Reviewed by: James Hughes Date: 5/27/21 Job Title: QA Specialist