

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 Yencho	: 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-K010)
LOT: CSMH-0121-00013

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

Manufacturing Date: 5/6/21 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 5/7/21 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%	31.3%	
Assay (HPLC Weight %)	98.0 – 102.0%	100.7%	
Bioburden	≤ 100 CFU/g	<100CFU/g	
Endotoxin	≤ 50 EU/g	≤40EU/g	
HPLC Minor Component 1 (Area %)	Cystamine ≤2.0%	≤0.6%	
Heavy Metals	≤ 20 mg/kg (ppm)	≤20mg/kg (ppm)	
Identification (IR)	Conforms to reference standard	Conforms to reference standard	
Loss on Drying	≤ 1.0%	≤0.4%	
Trace Metal Analysis (ICP)	Aluminum (Al)	≤ 5 ppm	<0.80ppm
	Arsenic (As)	≤ 1 ppm	<0.03ppm
	Barium (Ba)	≤ 5 ppm	<1.4ppm
	Bismuth (Bi)	≤ 5 ppm	<0.40ppm
	Calcium (Ca)	≤ 10 ppm	<1.5ppm
	Cadmium (Cd)	≤ 1 ppm	<0.004ppm
	Cobalt (Co)	≤ 1 ppm	<0.01 ppm
	Chromium (Cr)	≤ 1 ppm	<0.10ppm
	Copper (Cu)	≤ 1 ppm	<0.05ppm
	Iron (Fe)	≤ 1 ppm	0.75ppm

ANALYSIS	SPECIFICATION	TEST RESULT	
	Mercury (Hg)	≤ 1 ppm	0.33ppm
	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	20ppm
	Nickel (Ni)	≤ 1 ppm	<0.04ppm
	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%	99.3%
	Purity (Cysteamine (HPLC))	≥ 92.0%	99.3%
	≤ 8.0% related substances	≤ 0.7%	
	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. V. Date: 5/27/21 Job Title: QA Manager

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

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