

CERTIFICATE OF ANALYSIS
CYSTEAMINE HCl (2-MEA)
BIO EXCIPIENT GRADE / NEW CODE CSMH-3250-10
(HISTORICAL CODE CH3250-K010)
LOT: CSMH-0124-00006
C₂H₇N₁S · HCl ▲ F.W. 113.61 g/mol. ▲ CAS# 156-57-0
Manufacturing Date: 5/31/24 Retest Date: 5/31/26
Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
Packaging Date: 6/1/24 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%	99.5%
Bioburden ¹	≤ 100 CFU/g	Pending
Endotoxin	≤ 50 EU/g	<33EU/g
HPLC Minor Component 1 (Area %)	Cystamine ≤2.0%	<0.2%
Heavy Metals	≤ 20 mg/kg (ppm)	<20mg/kg (ppm)
Identification (IR)	Conforms to reference standard	Conforms to reference standard
Loss on Drying	≤ 1.0%	<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	0.040ppm	
Potassium (K)	≤ 50 ppm	<4.0ppm	
Lithium (Li)	≤ 5 ppm	<0.5ppm	
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	0.10ppm
	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	<0.2%	
Residual Solvents	Ethanol	≤ 5000 ppm	<2400ppm
	Isopropyl Alcohol (IPA)	≤ 5000 ppm	<2630ppm
	Tert-Butylmethyl Ether	≤ 5000 ppm	<2510ppm
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

¹BIOBURDEN TESTING: Pending testing results.

Prepared by: Yaylor Yumel Date: 10/5/24 Job Title: QA Tech III

Reviewed by: Janet Bingham Date: 6/5/24 Job Title: QA Supervisor

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