



CERTIFICATE OF ANALYSIS CYSTEAMINE HCl (2-MEA)

BIO EXCIPIENT GRADE / NEW CODE CSMH-3250-10

(HISTORICAL CODE CH3250-K010)

LOT: CSMH-0124-00011

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

Manufacturing Date: 7/4/24 Retest Date: 7/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 7/5/24 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%	31.0%	
Assay (HPLC Weight %)	98.0 – 102.0%	98.4%	
Bioburden ¹	≤ 100 CFU/g	Pending	
Endotoxin	≤ 50 EU/g	<33EU/g	
HPLC Minor Component 1 (Area %)	Cystamine ≤2.0%	0.42%	
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	<0.01ppm
	Chromium (Cr)	≤ 1 ppm	<0.10ppm
	Copper (Cu)	≤ 1 ppm	<0.05ppm
	Iron (Fe)	≤ 1 ppm	<0.40ppm

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ANALYSIS	SPECIFICATION	TEST RESULT	
	Mercury (Hg)	≤ 1 ppm	<0.018ppm
	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	0.33ppm
	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%	99.6%	
Purity (Cysteamine (HPLC))	≥ 92.0%	99.6%	
	≤ 8.0% related substances	0.42%	
Residual Solvents	Ethanol	≤ 5000 ppm	<2410ppm
	Isopropyl Alcohol (IPA)	≤ 5000 ppm	<2630ppm
	Tert-Butylmethyl Ether	≤ 5000 ppm	<2520ppm
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: *Ariel McCall* Date: 7/15/24 Job Title: QA Tech I

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