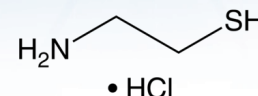


# Cysteamine HCl (2-MEA), LBLE, GMP Excipient Grade

Low Bioburden, Low Endotoxin, GMP Manufactured

### INTENDED FOR USE AS AN EXCIPIENT

Cysteamine HCl, a.k.a. 2MEA, has been manufactured for use as a critical process chemical for downstream biological drug manufacturing. Cysteamine HCl has been manufactured and purified under strict ICH-Q7 guidelines for excipient materials and can be considered an excipient grade product.



**CAS #:** 156-57-0

**Molecular Formula:** C<sub>2</sub>H<sub>7</sub>N<sub>1</sub>S • HCl

**Solubility in Water (g/L):** 113.6

**F.W.:** 113.61 g/mol

**pH @ 25°C:** 3.5 - 5.0

**BIO EXCIPIENT GRADE | Product Code: CSMH-3250 | Previously: CH3250**

C<sub>2</sub>H<sub>7</sub>N<sub>1</sub>S • HCl F.W. 113.61 g/mol. CAS# 156-57-0



These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

ANALYSIS		SPECIFICATIONS
Appearance and Color		White or colorless crystals or powder, may contain lumps
Appearance of Solution		Colorless, clear solution
Argentometric Titration		30.6 – 31.8%
Assay (HPLC Weight %)		98.0 – 102.0%
Bioburden		≤ 100 CFU/g
Endotoxin		≤ 50 EU/g
HPLC Minor Component 1 (Area %)		Cystamine ≤ 2.0%
Heavy Metals		≤ 20 mg/kg (ppm)
Identification (IR)		Conforms to reference standard
Loss on Drying		≤ 1.0%.
Trace Metal Analysis (ICP)	Aluminum (Al)	≤ 5 ppm
	Arsenic (As)	≤ 1 ppm
	Barium (Ba)	≤ 5 ppm
	Bismuth (Bi)	≤ 5 ppm
	Calcium (Ca)	≤ 10 ppm
	Cadmium (Cd)	≤ 1 ppm
	Cobalt (Co)	≤ 1 ppm
	Chromium (Cr)	≤ 1 ppm
	Copper (Cu)	≤ 1 ppm
	Iron (Fe)	≤ 1 ppm
	Mercury (Hg)	≤ 1 ppm



# BIO EXCIPIENT GRADE | Product Code: CSMH-3250 | Previously: CH3250

C<sub>2</sub>H<sub>7</sub>N<sub>1</sub>S • HCl • F.W. 113.61 g/mol. • CAS# 156-57-0

## General Product Description:

ANALYSIS		SPECIFICATIONS
Trace Metal Analysis (ICP)	Potassium (K)	≤ 50 ppm
	Lithium (Li)	≤ 5 ppm
	Magnesium (Mg)	≤ 5 ppm
	Manganese (Mn)	≤ 1 ppm
	Molybdenum (Mo)	≤ 5 ppm
	Sodium (Na)	≤ 50 ppm
	Nickel (Ni)	≤ 1 ppm
	Lead (Pb)	≤ 1 ppm
	Antimony (Sb)	≤ 1 ppm
	Selenium (Se)	≤ 1 ppm
	Strontium (Sr)	≤ 5 ppm
	Vanadium (V)	≤ 1 ppm
	Zinc (Zn)	≤ 1 ppm
Purity (HPLC Area %)	≥ 98.0%	
Purity (Cysteamine (HPLC))	≥ 92.0% ≤ 8.0% related substances	
Residual Solvents	Ethanol	≤ 5000 ppm
	Isopropyl Alcohol (IPA)	≤ 5000 ppm
	Tert-Butylmethyl Ether	≤ 5000 ppm
Solubility	Clear and Colorless	

- The manufacturing of Cysteamine HCl (2-MEA), CSMH-3250 is performed at BioSpectra's Bangor, PA facility utilizing multi-use equipment. Equipment used in the manufacturing of Cysteamine HCl (2-MEA), CSMH-3250 is cleaned in accordance with BioSpectra's Process Cleaning Validation Master Plan.
- Cysteamine HCl (2-MEA) is a White Crystalline product
- Molecular Formula: C<sub>2</sub>H<sub>7</sub>N<sub>1</sub>S • HCl
- Molecular Weight: 113.61 g/mol.
- CAS Number: 156-57-0
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Cysteamine HCl (2-MEA), CSMH-3250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Cysteamine HCl (2-MEA) manufactured at BioSpectra and any raw materials used in the manufacture of Cysteamine HCl (2-MEA) at BioSpectra are not subject to genetic modification.
- Synonyms: 2 Aminoethanethiol Hydrochloride

**ELEMENTAL IMPURITIES:** This product complies with ICHQ3D, USP <232> and USP <233> requirements for Elemental Impurities.

**RESIDUAL SOLVENTS:** Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

**Lead Time: 9-months**

**Minimum Order Quantity: Stock- 25kg / No Stock: 100kg**

## GMP Compliance:

Bio Excipient Grade Cysteamine HCl (2-MEA), CSMH-3250 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Cysteamine HCl (2-MEA) is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

## Retest Date:

The recommended retest period for Cysteamine HCl (2-MEA) is one year from the date of manufacture.

## Storage and Shipping Conditions:

Store in a tightly closed container, under nitrogen or argon blanket, at 2-8°C (36-46°F). Store in a dry, well-ventilated area away from incompatible substances.

## Package Sizes:

10kg, 25kg and 50kg pails.