

# **CYSTEAMINE HYDROCHLORIDE (2-MEA) LBLE, GMP, EXCIPIENT**

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

### Formula: $\text{C}_2\text{H}_7\text{NS} \cdot \text{HCl}$

F.W.: 113.61 g/mol

## CSMH-3250

## Bio EXCIPIENT GRADE

ANALYSIS		SPECIFICATIONS
Appearance and Color		White or Colorless Crystals or Powder, May Contain Lumps
Appearance of Solution		Colorless, Clear Solution
Chloride Content		30.6 – 31.8%
Assay, HPLC		98.0 – 102.0%
Microbial Content	TAMC	< 50 CFU/g
	TYMC	< 50 CFU/g
Endotoxin		< = 50 EU/g
Cystamine		< = 2.0%
Identification, IR		Conforms to Reference Standard
Loss on Drying		< = 1.0%
Trace Metals	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
	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, HPLC	Cysteamine	> = 92.0%
	Related Substances	< = 8.0%
Residual Solvents	Ethanol	< = 5000 ppm
	Isopropyl Alcohol	< = 5000 ppm
	Tert-Butylmethyl Ether	< = 5000 ppm
Solubility		Clear and Colorless

## General Product Overview

Cysteamine HCl, also known as 2-MEA, 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 is considered to be an excipient grade product.

## Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

## Key Product Features

- The manufacturing of Cysteamine HCl, CSMH-3250 is performed at BioSpectra's Bangor, PA facility.
- Appears as white or colorless crystals or powder
- Manufactured in accordance with ICH Q7
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives
- Is not subject to genetic modification
- Synonyms: 2 Aminoethanethiol Hydrochloride

## Storage and Shipping Conditions

Refer to SDS.

## Standard Shelf-Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

## Package Sizes

5kg, 10kg, and 25kg pails

Click here to view SDS, CoAs and other supporting regulatory documents on our website.

*This is not considered a controlled document. We are not responsible for any errors or omissions, and the user is responsible for any decisions based on the information herein.*