

CYSTEAMINE HYDROCHLORIDE (2-MEA)

BET*, GMP, EXCIPIENT

CAS #: 156-57-0

Formula: C₂H₇NS • 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	Cystamine	> = 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.

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.](#)

*Bioburden and Endotoxin Tested

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