

GMP BIOTECH PRODUCT

L-CYSTINE DIHYDROCHLORIDE, SYNTHETIC

BIOBURDEN AND ENDOTOXIN TESTED, GMP

CAS #: 30925-07-6 Formula: C₆H₁₂N₂O₄S₂ 2HCl F.W.: 3

F.W.: 313.22 g/mol

LCYS-6350

BIO QUALIFIED GRADE

Analysis		Specifications
Appearance and Color		White to Slightly Yellow Crystalline Powder
Assay, Dried Basis		98.0 - 102.0%
Bioburden	TAMC TYMC	< = 100 CFU/g < = 100 CFU/g
Chloride		22.2 - 23.5%
Endotoxin		< 0.02 EU/mg
Heavy Metals (Pb)		< 10 ppm
Identification, IR		Conforms to Reference Standard
Loss on Drying		< = 0.5%
pH (0.1%)		Report
Residue on Ignition		<= 0.1%
Specific Rotation, Free Basis, 20°C		-225.0° to -215.0°
Solubility		Passes Test

Country of Origin: India

Blended, Tested, Packaged in Bangor, PA, USA under full GMP conditions.

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

L-Cystine Dihydrochloride is a dimer, synthesized under full GMP conditions and is suitable for cell culture media used in the commercial biomanufacturer of therapeutic recombinant proteins, and monoclonal antibodies.

General Product Description

- Appears as an off-white to slightly yellow crystalline powder
- Manufactured under a Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- 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/derivatives.
- Is not subject to genetic modification
- Visit the product page on our website (<u>www.biospectra.us</u>) for additional information, supporting regulatory documents, and CofAs.

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf Life Policy

Each Certificate of Analysis (CofA) will contain a 2-year retest/recertification date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg

Standard Lead Time

1-2 weeks

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