

### **GMP BIOTECH PRODUCT**

## L-CYSTINE DIHYDROCHLORIDE, SYNTHETIC

**BIOBURDEN AND ENDOTOXIN TESTED, GMP** 

CAS #: 30925-07-6 Formula: C<sub>6</sub>H<sub>12</sub>N<sub>2</sub>O<sub>4</sub>S<sub>2</sub> 2HCl F.W.: 313.22 g/mol

LCYS-6250

## **BIO QUALIFIED GRADE**

Analysis	Specifications
Appearance and Color	White to Slightly Yellow Crystalline Powder
Assay, Dried Basis	98.0 - 102.0%
Microbial Content 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 a 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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