

## **GMP BIOTECH PRODUCT**

# L-CYSTINE diHCL BIOTECH, LBLE, GMP BIO QUALIFIED GRADE / LCYS-6250

# Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

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

#### **SPECIFICATIONS**

Analysis	SPECIFICATIONS
Appearance and Color	White to Slightly Yellow Crystalline Powder
Assay, Dried Basis	98.0 - 102.0%
Bioburden	≤ 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 @ 105°C	≤ 0.5%
pH (0.1% solution)	Report
Residue on Ignition	≤ 0.1%
Specific Rotation, Free Basis @ 20°C	-225.0° to -215.0°
Solubility	Passes Test



### **GMP BIOTECH PRODUCT**

#### **General Product Description:**

 $Molecular\ Formula:\ C_6H_{12}N_2O_4S_2\cdot 2HCl$ 

Molecular Weight: 313.22 g/mol CAS Number: 30925-07-6

#### **L-Cystine Dihydrochloride Biotech:**

- Appears as an off-white to pale-yellow crystalline powder
- Is manufactured under an ISO Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- Has no known major food allergens (as defined by FDA and WHO)
- The final product nor its raw materials are not derived from nor come into contact with animals, animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification

#### **Shelf Life Policy:**

Three-year expiry from the date of manufacture.

#### **Storage and Shipping Conditions:**

Please refer to the SDS for storage and shipping conditions.

#### Package Size:

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