

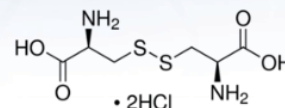
### CYSTINE(L) Dihydrochloride, LBLE\*, GMP Grade

\*Low Bioburden, Low Endotoxin

#### INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES AND PRODUCTS

L-Cystine is a dimer of two Cysteine residues and is a non-essential amino acid. It is synthesized from non-animal derived raw materials under appropriate controls for use in Pharm and Bio-Pharm production under a fully validated GMP manufacturing system. It is also suitable for cell culture media component for the commercial biomanufacturer of therapeutic recombinant proteins and monoclonal antibodies.

**Minimum Order Quantity: 25kg**



**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

**EC Number:** 250-391-9

**MDL Number:** MFC00070399

### BIO PHARMA GRADE | Product Code: LCYS-4250 | Previously: CY4250

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. • CAS# 30925-07-6

These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

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 Spectrum)	Passes Test
Loss on Drying @ 105°C	0.5% max.
pH (0.1% soln.)	Report
Residue on Ignition	≤ 0.1%
Specific Rotation (Free Basis) @ 20°C	-225.0° to -215.0°
Solubility	Passes Test



## General Product Description:

L-Cystine DiHydrochloride is produced at our cGMP platform in India and then shipped to our Bangor, PA facility where it is tested and repackaged under cGMP conditions.

- L-Cystine dihydrochloride is a White to Pale Yellow Crystalline Powder.
- Molecular Formula:  $C_6H_{12}N_2O_4S_2 \cdot 2HCl$
- Molecular Weight: 313.22 g/mol.
- CAS Number: 30925-07-6

## GMP Compliance:

Bio Pharma Grade L-Cystine DiHydrochloride LCYS-4250 is suitable for use as a process chemical. It is GMP manufactured by the approved supplier in accordance with the approved supplier's ISO 9001:2015 certified management system. It is manufactured in accordance with International Organization for Standardization (ISO) registered Quality Managed Systems. This grade of L-Cystine DiHydrochloride is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

## Retest Date:

The recommended retest period for L-Cystine dihydrochloride is two years from the date of manufacture.

## Storage and Shipping Conditions:

Keep away from heat. Keep away from sources of ignition. Keep container tightly closed, store in a dry and well ventilated place.

## GHS Classification:

Pictogram:



Signal word: Warning

Hazardous Statements:

H315 - Causes skin irritation

H320 - Causes eye irritation

## Physical and Chemical Properties:

Form: Solid

Color: White to Pale Yellow

Melting Point: 228-232 °C

Relative Density: 1.5178 g/cm<sup>3</sup> at 20 °C

Soluble in Water

## Package Sizes:

10 kg and 25 kg pails

## Country of Origin:

India