DCN: BSI-COA-0131 v.6.2



100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

Effective Date:	07-Jun-2023	07-Jun-2026	: Date of Next Review
Prepared By:	Virginia Pena	BSI-COA-0131 v.6.1	: Supersedes
QA/QC Approval:	Carissa Albert	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS L-Cystine diHCl Bio Pharma Grade / LCYS-4250-25 LOT: LCYS-0123-00043

C6H12N2O4S2 2HCI & F.W. 313.22 g/mol. A CAS# 30925-07-6

Retest Date: 04/28/25

Manufacturing/Packaging Date: 10/02/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Appearance and Color	White to Slightly Yellow Crystalline Powder	White to Slightly Yellow Crystalline Powder	
Assay (Dried Basis)	98.0% - 102.0%	100.0%	
Bioburden	\leq 100 CFU/g	<100 CFU/g	
Chloride	22.2% - 23.5%	22.6%	
Endotoxin	<0.02 EU/mg	<0.02 EU/mg	
Heavy Metals (Pb)	<10 ppm	<0.15 ppm	
Identification (IR Spectrum)	Passes Test	Passes Test	
Loss on Drying @ 105°C	≤ 0.5%	0.3%	
pH (0.1% soln.)	Report	2.29 @ 25.0°C	
Residue on Ignition	≤ 0.1%	<0.1%	
Specific Rotation (Free Basis) @ 20°C	-225.0° to -215.0°	-221.4°	
Solubility	Passes Test	Passes Test	

COUNTRY OF ORIGIN: India

TEST RESULTS: Test Results are obtained from the approved supplier's certificate of analysis.

<u>INTENDED USE:</u> Material represented by this Certificate of Analysis 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. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

<u>RETEST DATE</u>: The retest date is obtained from the approved supplier's certificate of analysis.

Date: 10/30/23 Job Title: QA Tech 1 Date: 19/34/23 Job Title: QA Mater. Disp. Supervisor Prepared by: <u>Jairle Kongin</u> Reviewed by: <u>Mon Angla</u>