

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

Effective Date:	07- <b>J</b> un-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-0123-00023

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

Retest Date: 4/11/25

Manufacturing/Packaging Date: 6/21/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Analysis	SPECIFICATION	TEST RESULT
Appearance and Color	White to Slightly Yellow Crystalline Powder	Slightly yellow crystalline powder.
Assay (Dried Basis)	98.0% - 102.0%	99.47%
Bioburden	$\leq 100 \text{ CFU/g}$	05 CFU/g
Chloride	22.2% - 23.5%	22.52%
Endotoxin	<0.02 EU/mg	Complies
Heavy Metals (Pb)	<10 ppm	0.473 ppm
Identification (IR Spectrum)	Passes Test	Complies
Loss on Drying @ 105°C	≤ 0.5%	0.10%
pH (0.1% soln.)	Report	2.21
Residue on Ignition	≤ 0.1%	0.03%
Specific Rotation (Free Basis) @ 20°C	-225.0° to -215.0°	-218.30°
Solubility	Passes Test	Complies

COUNTRY OF ORIGIN: India

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

INTENDED USE: 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.

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

Prepared by: Aud McCall Date: 7/31/23 Job Title: QA Support Fech

Reviewed by: Job Title: QA Moder Disp. Supervisor