

# BIOBUFFER SOLUTIONS

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

Effective Date:	11-Jul-2024	11-Jul-2027	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0131 v.6.2	: Supersedes
QA/QC Approval:	Jaron Hughes	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### L-CYSTINE diHCl

### BIO PHARMA GRADE / LCYS-4250-25

### LOT: LCYS-L02-1024-0023

 $C_6H_{12}N_2O_4S_2 \cdot 2HCl$  F.W. 313.22 g/mol. CAS# 30925-07-6

Retest Date: 05/31/26

Manufacturing/Packaging Date: 10/02/24 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%	99.9%
Bioburden	≤ 100 CFU/g	< 10 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%	< 0.5%
pH (0.1% soln.)	Report	2.32 @ 23.5°C
Residue on Ignition	≤ 0.1%	< 0.1%
Specific Rotation (Free Basis) @ 20°C	-225.0° to -215.0°	-221.8°
Solubility	Passes Test	Passes Test

COUNTRY OF ORIGIN: India

**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: Anil McCall Date: 10/4/24 Job Title: QA Tech I

Reviewed by: *Janet Anglin* Date: 10/4/24 Job Title: QA Supervisor