DCN: BSI-COA-0131 v.6.6

BI BUFFER SOLUTIONS

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

- 7	Effective Date:	10-Feb-2025	10-Feb-2028	: Date of Next Review
_	Prepared By:	Carissa Albert	BSI-COA-0131 v.6.5	: Supersedes
	QA/QC Approval:	Jaron Hughes	Jessica DeMaio	: Management Approval
_	Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

L-CYSTINE diHCl

BIO PHARMA GRADE / LCYS-4250

LOT: LCYS-L02-0325-0009

 $C_6H_{12}N_2O_4S_2 \cdot 2HC1 + F.W. 313.22 g/mol. + CAS# 30925-07-6$

Manufacturing Date: 6/29/24

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Analysis	SPECIFICATION	TEST RESULT		
Appearance and Color	White to Slightly Yellow Crystalline Powder	White Crystalline Powder		
Assay (Dried Basis)	98.0% - 102.0%	100.1%		
Bioburden	$\leq 100 \text{ CFU/g}$	< 100 CFU/g		
Chloride	22.2% - 23.5%	22.7%		
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	2.26 @ 23.1°C		
Residue on Ignition	≤ 0.1%	< 0.1%		
Specific Rotation (Free Basis) @ 20°C	-225.0° to -215.0°	-221.9°		
Solubility	Passes Test	Passes Test		

COUNTRY OF ORIGIN: India

TEST METHOD REFERENCE: DCN: BSI-ATM-0024

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.

Prepared by: Cul h	Date:	3/20/25	Job Title:	QA Tech 1	
Reviewed by: Malall	Date:	3/20/25	Job Title:	QA TechIII	