

BIOBUFFER SOLUTIONS

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

Effective Date:	9-Apr-2025	9-Apr-2028	: Date of Next Review
Prepared By:	Carissa Albert	Not Applicable	: Supersedes
QA/QC Approval:	Jaron Hughes	Krista Rehrig	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

L-CYSTINE diHCl

BIOTECH, LBLE, GMP

BIO QUALIFIED GRADE / LCYS-6350

LOT: LCYS-L03-0425-0013

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

Manufacturing Date: 6/18/24

Packaging Site: 100 Majestic Way, Bangor PA, 18013

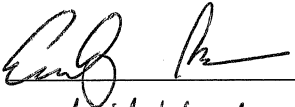

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	White to Slightly Yellow Crystalline Powder	Slightly Yellow Powder
Assay, Dried Basis	98.0 - 102.0 %	99.5 %
Bioburden	≤ 100 CFU/g	< 10 CFU/g
Chloride	22.2 - 23.5 %	22.5 %
Endotoxin	< 0.02 EU/mg	< 0.02 EU/mg
Heavy Metals (Pb)	< 10 ppm	< 0.15 ppm
Identification, IR	Conforms to Reference Standard	Conforms to Reference Standard
Loss on Drying @ 105°C	$\leq 0.5\%$	$< 0.5\%$
pH (0.1% solution)	Report	2.32
Residue on Ignition	$\leq 0.1\%$	$< 0.1\%$
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 BioSpectra's 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:  Date: 4/14/25 Job Title: QA Tech I
Reviewed by:  Date: 4/14/25 Job Title: QA Tech III