

BIOSPECTRA

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

Effective Date:	27-Jan-2020	27-Jan-2023	: Date of Next Review
Prepared By:	Hannah Bernier	19-002903 v.3.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yenko	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

L-CYSTINE diHCl

BIO PHARMA GRADE / CY4250-K010

LOT: CY4250-009-0120

$C_6H_{12}N_2O_4S_2 \cdot 2HCl$ * F.W. 313.22 g/mol. * CAS# 30925-07-6
 Manufacture Date: 1/15/2018 Retest Date: 1/31/2021
 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013
 Packaging Date: 1/23/2020
 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%	99.8%
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	<10ppm
Identification (IR Spectrum)	Passes Test	Passes Test
Loss on Drying @ 105°C	1.0% max.	0.1%
pH (0.1% soln.)	Report	2.250
Residue on Ignition	0.1% max.	<0.1%
Specific Rotation (Free Basis) @ 20°C	-225.0° to -215.0°	-221.8°
Solubility	Passes Test	Passes Test

COUNTRY OF ORIGIN: U.S.A.TEST METHOD REFERENCE: DCN: 17-002319

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: IPEC Compliant GMP Manufactured Chemical for use in further Manufacturing or as a Reagent for Laboratory and Research. 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:  Date: 2/5/20 Job Title: QA SupervisorReviewed by:  Date: 2/6/20 Job Title: QA Manager