

BIOSPECTRA

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

Effective Date:	24-Apr-2020	24-Apr-2023	: Date of Next Review
Prepared By:	Kyle Snyder	19-002903 v.4.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

L-CYSTINE diHCl

BIO PHARMA GRADE / CY4250-K050

LOT: CY4250-018-0520

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

Manufacturing Date: 1/22/2018 Retest Date: 1/31/2021

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 1/26/2018 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%	100.1%
Bioburden	≤ 100 CFU/g	<10 CFU/g
Chloride	22.2% - 23.5%	22.7%
Endotoxin	<0.02 EU/mg	<0.02 EU/mg
Heavy Metals (Pb)	<10 ppm	<10 ppm
Identification (IR Spectrum)	Passes Test	Passes Test
Loss on Drying @ 105°C	1.0% max.	<1.0%
pH (0.1% soln.)	Report	2.243
Residue on Ignition	0.1% max.	<0.1%
Specific Rotation (Free Basis) @ 20°C	-225.0° to -215.0°	-222.8°
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 for use as a GMP process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. 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: 5/26/20 Job Title: QA Supervisor

Reviewed by:  Date: 05/20/20 Job Title: QA Manager