

# BIOSPECTRA

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

Effective Date:	23-Jan-2025	23-Jan-2028	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

## CERTIFICATE OF ANALYSIS

### MES HYDRATE

### BIOTECH, LBLE, GMP

### BIO PHARMA GRADE / MESH-4250

### LOT: MESH-0123-00001

 $C_6H_{13}NO_4S \cdot xH_2O$  ^ F.W. 195.24 g/mol. (anhydrous basis) ^ CAS# 1266615-59-1

Manufacturing Date: 06/14/23    Retest Date: 06/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance (0.1M)	260 nm 280 nm	$\leq 0.04$ a.u. $\leq 0.02$ a.u.	< 0.04 a.u. < 0.02 a.u.
Appearance	White Powder	White Crystals	
Assay, Anhydrous Basis	$\geq 99.5$ %	100.4 %	
Cytotoxicity (50% Concentration)	Passes Test	Passes Test	
Enzymes	DNase, Exonuclease	Passes Test	Passes Test
	NICKase, Endonuclease	Passes Test	Passes Test
	RNase	Passes Test	Passes Test
	Protease	Passes Test	Passes Test
Identification, IR	Conforms to Reference Standard	Conforms to Reference Standard	
pH (1% solution)	3.5 – 4.1	3.8	
Solubility (0.1M)	Clear and Colorless	Clear and Colorless	
Microbial Content	TAMC	$\leq 100$ CFU/g	< 10 CFU/g
	TYMC	$\leq 100$ CFU/g	< 10 CFU/g

ANALYSIS	SPECIFICATION	TEST RESULT	
Aluminum (Al)	≤ 5 ppm	< 1.5 ppm	
Antimony (Sb)	≤ 5 ppm	< 1.5 ppm	
Arsenic (As)	≤ 3 ppm	< 0.45 ppm	
Barium (Ba)	≤ 5 ppm	< 1.5 ppm	
Bismuth (Bi)	≤ 5 ppm	< 1.5 ppm	
Cadmium (Cd)	≤ 5 ppm	< 0.06 ppm	
Calcium (Ca)	≤ 20 ppm	< 15 ppm	
Chromium (Cr)	≤ 5 ppm	< 1.5 ppm	
Cobalt (Co)	≤ 5 ppm	< 0.15 ppm	
Trace Metals	Copper (Cu)	≤ 5 ppm	< 1.5 ppm
	Iron (Fe)	≤ 5 ppm	< 1.5 ppm
	Lead (Pb)	≤ 5 ppm	< 0.15 ppm
	Lithium (Li)	≤ 5 ppm	< 1.5 ppm
	Manganese (Mn)	≤ 5 ppm	< 1.5 ppm
	Magnesium (Mg)	≤ 5 ppm	< 1.5 ppm
	Molybdenum (Mo)	≤ 5 ppm	< 1.5 ppm
	Nickel (Ni)	≤ 5 ppm	< 0.60 ppm
	Sodium (Na)	≤ 20 ppm	< 6.0 ppm
	Zinc (Zn)	≤ 5 ppm	< 1.5 ppm
Water, KF	5.0 – 8.9 %	8.8 %	

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0123

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a 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: Anil McCall Date: 1/31/25 Job Title: QA-Tech III

Reviewed by: Car Albert Date: 2/3/25 Job Title: Senior Quality Manager