

BIO SPECTRA

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

Effective Date:	22-Jan-2025	22-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 MONOHYDRATE

BIOTECH, GMP

BIO PHARMA GRADE / MESM-4221

LOT: MESM-0124-00003

$C_6H_{13}NO_4S \cdot H_2O$ * F.W. 213.3 g/mol. * CAS# 145224-94-8

Manufacturing Date: 01/11/24 Retest Date: 01/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm	≤ 0.1000 a.u.	0.0015 a.u.
	280 nm	≤ 0.1000 a.u.	0.0016 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		≥ 99.0 %	99.8 %
Chloride		≤ 50 ppm	< 50 ppm
Color (1M, Alkaline)		Colorless	Colorless
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Heavy Metals (as Pb)		≤ 2 ppm	< 0.15 ppm
Identification, IR		Conforms to Reference Standard	Passes Test
Loss on Drying @ 130°C		7 – 10 %	9 %
pH (5% solution)		3.1 – 3.5	3.4
pH (0.5M)		2.5 – 4.5	3.3
pK _a		5.9 – 6.3	6.2
Residue on Ignition		≤ 0.05 %	< 0.01 %
Sulfate		≤ 50 ppm	< 50 ppm

ANALYSIS	SPECIFICATION	TEST RESULT	
Trace Metals	Arsenic (As)	≤ 2 ppm	< 0.45 ppm
	Calcium (Ca)	≤ 50 ppm	< 15 ppm
	Cadmium (Cd)	≤ 5 ppm	< 0.06 ppm
	Cobalt (Co)	≤ 5 ppm	< 0.15 ppm
	Copper (Cu)	≤ 2 ppm	< 1.5 ppm
	Chromium (Cr)	≤ 5 ppm	< 1.5 ppm
	Iron (Fe)	≤ 2 ppm	< 1.5 ppm
	Lead (Pb)	≤ 2 ppm	< 0.15 ppm
	Magnesium (Mg)	≤ 5 ppm	< 1.5 ppm
	Manganese (Mn)	≤ 5 ppm	< 1.5 ppm
	Nickel (Ni)	≤ 5 ppm	< 0.60 ppm
	Potassium (K)	≤ 50 ppm	< 15 ppm
Sodium (Na)	≤ 50 ppm	< 15 ppm	
Zinc (Zn)	≤ 5 ppm	< 1.5 ppm	

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0009

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: Shirley McCall Date: 11/31/25 Job Title: QA Tech III

Reviewed by: Car Albert Date: 11/31/25 Job Title: Senior Quality Manager