

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

Effective Date: 22	-Jan-2025	22-Jan-2028	: Date of Next Review
Prepared By: Am	ny Yencho	Not Applicable	: Supersedes
QA/QC Approval: Kris	ista Rehrig	Carissa Albert	: Management Approval
Reason for Revision: See	e Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS MES MONOHYDRATE

## BIOTECH, GMP

## BIO PHARMA GRADE / MESM-4221

LOT: MESM-E02-0525-0020

C<sub>6</sub>H<sub>13</sub>NO<sub>4</sub>S·H<sub>2</sub>O → F.W. 213.3 g/mol. → CAS# 145224-94-8

Manufacturing Date: 2/23/24 Retest Date: 2/28/26 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	0.0037 a.u.
	280 nm	$\leq$ 0.1000 a.u.	0.0029 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		≥ 99.0 %	99.8 %
Chloride		≤ 50 ppm	< 50 ppm
Color (1M, Alkaline)		Colorless	Colorless
	DNase	None Detected	None Detected
Enzymes	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	Conforms to Reference Standard
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	6.1
Residue on Ignition		≤ 0.05 %	< 0.01 %
Sulfate		≤ 50 ppm	< 50 ppm

Analysis		SPECIFICATION	TEST RESULT
	Arsenic (As)	≤2 ppm	< 0.45 ppm
Trace Metals	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

<u>INTENDED USE:</u> 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: Eng h	Date: 5/20/25 Job Title: QA Tech 1	
Reviewed by:	Date: 5/20/25 Job Title: QA Tech 111	