



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

Effective Date:	1-Jun-2026	1-Jun-2029	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0281 v.1.0	: Supersedes
QA/QC Approval:	Jaron Hughes	Krista Rehrig	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

CERTIFICATE OF ANALYSIS

MES MONOHYDRATE

BIO EXCIPIENT GRADE / MESM-3251

LOT: MESM-E02-0326-0028

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

Manufacturing Date: 03/17/26 Retest Date: 03/31/28

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	≤ 0.04 a.u.	< 0.04 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		$\geq 99.5\%$	99.9%
Chloride		≤ 50 ppm	< 50 ppm
Color (1M, Alkaline)		Colorless	Colorless
Endotoxin		< 50 EU/g	< 25 EU/g
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Identification, IR		Conforms to Reference Standard	Passes Test
Loss on Drying, 130°C		7 – 9%	9%
Microbial Content	TAMC	≤ 100 CFU/g	< 10 CFU/g
	TYMC	≤ 100 CFU/g	< 10 CFU/g
pH (1%)		3.0 – 5.0	3.8
pK _a		5.9 – 6.3	6.1
Residue on Ignition		$\leq 0.05\%$	$< 0.05\%$
Solubility (5%)		Passes Test	Passes Test
Sulfate		≤ 50 ppm	< 50 ppm
Trace Metals	Arsenic (As)	≤ 1.5 ppm	< 0.45 ppm
	Antimony (Sb)	≤ 9 ppm	< 2.7 ppm
	Barium (Ba)	≤ 70 ppm	< 21 ppm

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ANALYSIS	SPECIFICATION	TEST RESULT
Cadmium (Cd)	≤ 0.2 ppm	< 0.06 ppm
Cobalt (Co)	≤ 0.5 ppm	< 0.15 ppm
Copper (Cu)	≤ 30 ppm	< 1.5 ppm
Chromium (Cr)	≤ 110 ppm	< 1.5 ppm
Iron (Fe)	≤ 2 ppm	< 1.5 ppm
Trace Metals	Lead (Pb)	< 0.15 ppm
	Lithium (Li)	< 7.5 ppm
	Mercury (Hg)	< 0.09 ppm
	Molybdenum (Mo)	< 4.5 ppm
	Nickel (Ni)	< 0.60 ppm
	Tin (Sn)	< 18 ppm
	Vanadium (V)	< 0.30 ppm
Water, KF	7.8 – 8.9%	8.7%

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 an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

RESIDUAL SOLVENTS STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

Prepared by: Shirley McCall Date: 6/9/26 Job Title: QA Tech III

Reviewed by: John Bingham Date: 6/9/26 Job Title: QA Supervisor