

BIOSPECTRA

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

Effective Date:	4-Feb-2025	4-Feb-2028	: Date of Next Review
Prepared By:	Taylor Yurick	BSI-COA-0031 v.5.1	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

MES MONOHYDRATE

BIO EXCIPIENT GRADE / MESM-3220

LOT: MESM-E02-0625-0023

C₆H₁₃NO₄S·H₂O ▲ F.W. 213.3 g/mol. ▲ CAS# 145224-94-8

Manufacturing Date: 06/03/25 Retest Date: 06/30/27

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Absorbance	260 nm	0.1000 a.u. max.
(1M)	280 nm	0.1000 a.u. max.
Appearance and Color	White / Crystals	White / Crystals
Assay	99.0% min.	100.0%
Chloride	0.005% max.	< 0.005%
Color (1M, Alkaline)	Colorless	Colorless
Enzymes	DNase	None Detected
	RNase	None Detected
	Protease	None Detected
Heavy Metals (as Pb)	2 ppm max.	< 2 ppm
Identification (IR)	Passes Test	Passes Test
Loss on Drying @ 130°C	7 – 10%	9%
pH (5% Soln.)	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% max.	< 0.01%
Solubility (5%)	Passes Test	Passes Test
Sulfate	0.005% max.	< 0.005%
Trace Elements	Arsenic (As)	< 0.45 ppm
	Copper (Cu)	< 1.5 ppm
	Iron (Fe)	< 1.5 ppm
	Lead (Pb)	< 0.15 ppm

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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.

OVI 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: Amil McLane Date: 10/2/25 Job Title: QA Tech III

Reviewed by: James Hughes Date: 10/2/25 Job Title: QA Supervisor