

BIOSPECTRA

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

Effective Date:	13-Jun-2023	13-Jun-2026	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Carissa McCollian	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

CERTIFICATE OF ANALYSIS

MES MONOHYDRATE

BIO EXCIPIENT GRADE / MESM-3251-25

LOT: MESM-0123-00323

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

Manufacturing Date: 6/20/23 Retest Date: 6/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 6/22/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Absorbance (0.1M)	260 nm	≤ 0.04 a.u.
Appearance and Color	White / Crystals	<0.04 a.u.
Assay	≥ 99.5%	White / Crystals
Chloride	≤ 0.005%	100.2%
Color (1M, Alkaline)	Colorless	<0.005%
Endotoxin	< 50 EU/g	Colorless
	DNase	<25 EU/g
Enzymes	RNase	None Detected
	Protease	None Detected
Heavy Metals (as Pb)	≤ 2 ppm	None Detected
Identification (IR)	Passes Test	None Detected
Loss on Drying @ 130°C	7 – 9%	Passes Test
pH (1% Solution)	3.0 – 5.0	9%
pK _a	5.9 – 6.3	3.8
Residue on Ignition	≤ 0.05%	6.1
Solubility (5%)	Passes Test	<0.03%
Sulfate	≤ 0.005%	Passes Test
TAMC	≤ 100 CFU/g	<0.005%
TYMC	≤ 100 CFU/g	<10 CFU/g
	Arsenic (As)	<10 CFU/g
Trace Elements	Antimony (Sb)	<0.45 ppm
	Barium (Ba)	<2.7 ppm
		<21 ppm

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
Lead (Pb)	≤ 0.5 ppm	<0.15 ppm
Trace Elements	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 (by Karl Fischer)	7.8 – 8.9%	8.8%

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: 11/2/23 Job Title: QA Tech 1

Reviewed by: John English Date: 11/2/23 Job Title: QA Mater. Disp. Supervisor