

BIOSPECTRA

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

Effective Date:	12-Jul-2021	12-Jul-2024	: Date of Next Review
Prepared By:	Jared Lobb	Not Applicable	: Supersedes
QA/QC Approval:	Jaron Hughes	Carissa McCollian	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF CONFORMANCE

MES MONOHYDRATE

BIO EXCIPIENT GRADE / MESM-3250-92

LOT: MESM-0121-00120

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

Manufacturing Date: 6/3/21 Retest Date: 6/30/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 7/12/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance (1M)	260 nm	0.1000 a.u. max.	0.0025 a.u.
	280 nm	0.1000 a.u. max.	0.0018 a.u.
Appearance and Color	White / Crystals	White / Crystals	
Assay	99.0% min.	99.8%	
Chloride	0.005% max.	<0.005%	
Color (1M, Alkaline)	Colorless	Colorless	
Endotoxin	< 50 EU/g	Conforms ¹	
	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
Enzymes	Protease	None Detected	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% Solution)	3.1 – 3.5	3.4	
pH (0.5M)	2.5 – 4.5	3.2	
pK _a	5.9 – 6.3	6.1	
Residue on Ignition	0.05% max.	<0.01%	
Solubility (5%)	Passes Test	Passes Test	
Sulfate	0.005% max.	<0.005%	
TAMC	≤ 100 CFU/g	Conforms ¹	
TYMC	≤ 100 CFU/g	Conforms ¹	
Trace Elements	Arsenic (As)	2 ppm max.	< 2 ppm
	Copper (Cu)	2 ppm max.	< 2 ppm
	Iron (Fe)	2 ppm max.	< 2 ppm
	Lead (Pb)	2 ppm max.	< 2 ppm

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-001016

¹Conforms based on the product properties and historical information of previously tested lots manufactured using the MES, Monohydrate Bio Excipient Process.

Prepared by: Jason Birge Date: 7/14/21 Job Title: QA Specialist

Reviewed by: C. [Signature] Date: 7/14/21 Job Title: QA Manager