

BIOSPECTRA

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

Effective Date:	01-Mar-2021	01-Mar-2024	: Date of Next Review
Prepared By:	Jared L Lobb	16-001173 v.4.1	: Supersedes
QA/QC Approval:	Jaron Hughes	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS
MES MONOHYDRATE
BIO EXCIPIENT GRADE / NEW CODE MESM-3220-12
(HISTORICAL CODE ME3220-K012)
LOT: MESM-0121-00235

$C_6H_{13}NO_5 \cdot H_2O$ * F.W. 213.3 g mol. * CAS# 145224-94-8

Manufacturing Date: 9/9/21 Retest Date: 9/30/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 9/11/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance	260 nm	0.1000 a.u. max.	0.0020 a.u.
(1M)	280 nm	0.1000 a.u. max.	0.0016 a.u.
Appearance and Color	White / Crystals		White / Crystals
Assay	99.0% min.		99.6%
Chloride	0.005% max.		<0.005%
Color (1M, Alkaline)	Colorless		Colorless
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	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% Soln.)	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% max.		0.02%
Solubility (5%)	Passes Test		Passes Test
Sulfate	0.005% max.		<0.005%
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

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-001016

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: Jason Bingham Date: 10/26/21 Job Title: QA Specialist

Reviewed by: C. Curran Date: 10/26/21 Job Title: QA Manager