BIOSPECTRA

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

Effective Date:	1-Dec-2020	1-Dec-2023	: Date of Next Review
Prepared By:	Amy Hosein	20-003401 v.1.1	: Supersedes
QA/QC Approval:	Carissa McCollian	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

MES MONOHYDRATE

BIO EXCIPIENT GRADE / ME3222-G100

LOT: ME3222-015-1120

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

Manufacturing Date: 6/8/20 Retest Date: 6/30/22

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 11/30/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm	0.1000 a.u. max.	0.0053 a.u.
	280 nm	0.1000 a.u. max.	0.0040 a.u.
Appearance and Color		White Crystalline Powder	White Crystalline Powder
Assay		99.5% min.	99.7%
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)		Conforms to Reference	Conforms to Reference
Loss on Drying @ 130°C		7 – 10%	9%
pH (5% Soln.)		3.1 – 3.5	3.4
pH (1.0M)		2.7 – 3.7	3.0
pH (0.5M)		2.5 – 4.5	3.2
pK_a		5.9 – 6.3	6.1
Turbidimetry/PVS Limit Test		≤ 1 ppm	≤1 ppm
Residue on Ignition		0.05% max.	<0.01%
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
Water (by Karl Fischer)		7.9 – 8.9%	8.9%

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.

RESIDUAL SOLVENT 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: Jaron Hughes Date: 12/1/20 Job Title: QA Specialist

Reviewed by: [signature] Date: 12/1/20 Job Title: QA Supervisor