

BIOSPECTRA

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

Effective Date:	8-Apr-2020	8-Apr-2023	: Date of Next Review
Prepared By:	Kyle Snyder	16-000105 v.4.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

MES MONOHYDRATE

BIO PHARMA GRADE / ME4220-K025

LOT: ME4220-209-0620

 $C_6H_{13}NO_4S \cdot H_2O$ * F.W. 213.25 g/mol. * CAS# 145224-94-8

Manufacturing Date: 6/1/2020 Retest Date: 6/30/2022

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 6/12/2020 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm	0.1000 a.u. max.	0.0043 a.u.
	280 nm	0.1000 a.u. max.	0.0033 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
	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
Enzymes	Protease	None Detected	None Detected
Heavy Metals		2 ppm max.	< 2 ppm
Identification (IR)		Passes Test	Passes Test
Loss on Drying @ 130°C		7 – 10%	9%
pH (5% Soln.)		3.0 – 3.5	3.5 @ 23.7°C
pH (0.5M)		2.5 – 4.5	3.3 @ 26.0°C
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%
	Arsenic (As)	5 ppm max.	< 5 ppm
	Copper (Cu)	5 ppm max.	< 5 ppm
	Iron (Fe)	5 ppm max.	< 5 ppm
	Lead (Pb)	5 ppm max.	< 5 ppm

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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 a GMP process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, 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: H. F. Fournier Date: 6/15/20 Job Title: QA Manager

Reviewed by: Amey R. Bha Date: 6/15/20 Job Title: QC Compliance Supervisor