

# BIOSPECTRA

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

Effective Date:	19-April-2019	19-April-2022	: Date of Next Review
Prepared By:	Jessica DeMaio	16-000105 v.3.0	: Supersedes
QA/QC Approval:	Jenna Miller	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

## MES MONOHYDRATE

### CERTIFICATE OF ANALYSIS

## BIO PHARMA GRADE / ME4220-K025

### LOT: ME4220-205-0420

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

Manufacturing Date: 3/3/2020

Retest Date: 3/31/2022

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 4/5/2020

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm	0.1000 a.u. max.	0.0088 a.u.
	280 nm	0.1000 a.u. max.	0.0079 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0% min.	99.1%
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		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 @ 23.1 °C
pH (0.5M)		2.5 – 4.5	3.3 @ 23.1 °C
pK <sub>a</sub>		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

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-001016

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: IPEC Compliant GMP Manufactured Chemical, for use in further Manufacturing or as a Reagent for Laboratory and Research. 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 and storage of this product, there is no potential for any of the residual solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 to be present at the specified limits; furthermore, if tested this product would comply with USP/NF requirements.

Prepared by: Kyle Snyder / QA Specialist Date: 4/6/20

Reviewed by: [Signature] / QA Supervisor Date: 4/7/20