

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: ME4220-193-0320

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

Manufacturing Date: 7/27/2019

Retest Date: 7/31/2021

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 3/13/2020

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm 280 nm	0.1000 a.u. max. 0.1000 a.u. max.
		0.0035 a.u. 0.0026 a.u.
Appearance and Color	White / Crystals	White / Crystals
Assay	99.0% min.	99.7%
Chloride	0.005% max.	<0.005%
Color (1M, Alkaline)	Colorless	Colorless
Enzymes	DNase	None Detected
	RNase	None Detected
	Protease	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	3.4 @ 23.1 °C
pH (0.5M)	2.5 – 4.5	3.3 @ 23.7 °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%
Trace Elements	Arsenic (As)	5 ppm max.
	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.
		< 5 ppm < 5 ppm < 5 ppm < 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: C. [Signature] / QA Supervisor Date: 3/17/20

Reviewed by: [Signature] / QA Specialist Date: 3/17/20