

BIOSPECTRA

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

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|----------------------|-------------------------------|-----------------|-----------------------|
| 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: ME4220-194-0320

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

Manufacturing Date: 7/14/2019

Retest Date: 7/31/2021

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 3/16/2020

Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | SPECIFICATION | TEST RESULT |
|------------------------|------------------|------------------|
| Absorbance (1M) | 260 nm | 0.1000 a.u. max. |
| | 280 nm | 0.1000 a.u. max. |
| Appearance and Color | White / Crystals | White / Crystals |
| Assay | 99.0% min. | 99.5% |
| 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 | 3.2 @ 23.1 °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. |

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: Hyun Snyder / QA Specialist Date: 3/18/20

Reviewed by: C. W. / QA Supervisor Date: 3/18/20