

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

|                      |                               |                 |                       |
|----------------------|-------------------------------|-----------------|-----------------------|
| Effective Date:      | 10-Jan-2018                   | 10-Jan-2021     | : Date of Next Review |
| Prepared By:         | Jamie Storm                   | 16-000105 v.2.0 | : Supersedes          |
| QA/QC Approval:      | Crystal Hamelburg             | Dora Meissner   | : Management Approval |
| Reason for Revision: | See Revision History in ensur |                 |                       |

## MES MONOHYDRATE

### CERTIFICATE OF ANALYSIS

### BIO PHARMA GRADE / ME4220-K025

### LOT: ME4220-141-0119

C<sub>6</sub>H<sub>13</sub>NO<sub>4</sub>S·H<sub>2</sub>O ^ F.W. 213.25 g/mol. ^ CAS# 145224-94-8

Manufacturing Date: 11/13/2018

Retest Date: 11/30/2020

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 01/09/2019

Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS             | SPECIFICATION    | TEST RESULT                          |         |
|----------------------|------------------|--------------------------------------|---------|
| Absorbance (1M)      | 260 nm<br>280 nm | 0.1000 a.u. max.<br>0.1000 a.u. max. |         |
|                      |                  | 0.0056 a.u.<br>0.0043 a.u.           |         |
| Appearance and Color | White / Crystals | White / Crystals                     |         |
| Assay                | 99.0% min.       | 99.70%                               |         |
| 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                          |         |
| pH (5% Soln.)        | 3.0 – 3.5        | 3.34 @ 23.0 °C                       |         |
| pH (0.5M)            | 2.5 – 4.5        | 3.17 @ 23.6 °C                       |         |
| pK <sub>a</sub>      | 5.9 – 6.3        | 6.1                                  |         |
| Residue on Ignition  | 0.05% max.       | <0.0150%                             |         |
| 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

*The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping, and the prevention of unauthorized appropriation, use, disclosure and copying.*

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: H. Bennett Date: 11/11/19

Reviewed by: Quana Mills Date: 1/14/19