

BIO SPECTRA

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

| | | | |
|----------------------|--------------------------------|-----------------|-----------------------|
| Effective Date: | 22-May-2020 | 22-May-2023 | : Date of Next Review |
| Prepared By: | Kyle Snyder | 16-001173 v.3.0 | : Supersedes |
| QA/QC Approval: | Carissa McCollan | Hannah Bernier | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

CERTIFICATE OF ANALYSIS

MES MONOHYDRATE

BIO EXCIPIENT GRADE / ME3220-K012

LOT: ME3220-022-0520

C₆H₁₃NO₄S·H₂O ▲ F.W. 213.25 g/mol. ▲ CAS# 145224-94-8

Manufacturing Date: 5/7/2020 Retest Date: 5/31/2022

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 5/8/2020 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. | 0.0055 a.u. 0.0042 a.u. |
| Appearance and Color | White / Crystals | White / Crystals | |
| Assay | 99.0% min. | 99.8% | |
| 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 (as Pb) | 2 ppm max. | < 2 ppm | |
| Identification (IR) | Passes Test | Passes Test | |
| Loss on Drying @ 130°C | 7 – 10% | 9% | |
| pH (5% Soln.) | 3.1 – 3.5 | 3.4 | |
| pH (0.5M) | 2.5 – 4.5 | 3.2 | |
| 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) | 2 ppm max. | < 2 ppm |
| | Copper (Cu) | 2 ppm max. | < 2 ppm |
| | Iron (Fe) | 2 ppm max. | < 2 ppm |
| | Lead (Pb) | 2 ppm max. | < 2 ppm |

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 an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, 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: C. ~ Date: 5/29/20 Job Title: QA Supervisor

Reviewed by: Wendy Pate Date: 05/29/20 Job Title: QA Manager