BIOSPECTRA

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

| | | | |
|---|---|---|---|
| Effective Date: | 23-Feb-2022 | 23-Feb-2025 | : Date of Next Review |
| Prepared By: | Wendy Santay | BSI-COA-0238 v.1.0 | : Supersedes |
| QA/QC Approval: | Carissa McCollian | Amy Yencho | : Management Approval |
| Reason for Revision: | See Revision History in Matsercontrol | | |

# CERTIFICATE OF ANALYSIS

## MES MONOHYDRATE

## BIO EXCIPIENT GRADE / MESM-3250-25

## LOT: MESM-0122-00031

$C_6H_{13}NO_4S \cdot H_2O$ ⅄ F.W. 213.3 g/mol. ⅄ CAS# 145224-94-8

Manufacturing Date: 1/22/22 Retest Date: 1/31/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 1/23/22 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Absorbance (1M) | 260 nm | 0.1000 a.u. max. | 0.0027 a.u. |
| | 280 nm | 0.1000 a.u. max. | 0.0020 a.u. |
| Appearance and Color | | White / Crystals | White / Crystals |
| Assay | | ≥99.5% | 99.9% |
| Chloride | | 0.005% max. | <0.005% |
| Color (1M, Alkaline) | | Colorless | Colorless |
| Endotoxin | | < 50 EU/g | <5 EU/g |
| 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 – 9% | 9% |
| pH (5% Solution) | | 3.1 – 3.5 | 3.3 |
| pH (0.5M) | | 2.5 – 4.0 | 3.2 |
| $pK_a$ | | 5.9 – 6.3 | 6.1 |
| Residue on Ignition | | 0.05% max. | <0.01% |
| Solubility (5%) | | Passes Test | Passes Test |
| Sulfate | | 0.005% max. | <0.005% |
| TAMC | | ≤ 100 CFU/g | <10 CFU/g |
| TYMC | | ≤ 100 CFU/g | <10 CFU/g |
| Trace Elements | Arsenic (As) | 2 ppm max. | < 2 ppm |
| | Copper (Cu) | 2 ppm max. | < 2 ppm |
| | Iron (Fe) | 2 ppm max. | < 2 ppm |

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|---|---|---|---|
| Trace Elements | Lead (Pb) | 2 ppm max. | < 2 ppm |
| Water (by Karl Fischer) | | 7.8 – 8.9% | 8.8% |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0009

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.

RESIDUAL SOLVENTS 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: _____ Date: 3/1/22 Job Title: QA Specialist

Reviewed by: _____ Date: 3/1/22 Job Title: QA Manager