

BIOSPECTRA

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

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|----------------------|---------------------------------------|-----------------|-----------------------|
| Effective Date: | 13-Jun-2023 | 13-Jun-2026 | : Date of Next Review |
| Prepared By: | Amy Yenko | Not Applicable | : Supersedes |
| QA/QC Approval: | Carissa McCollian | Wayne Talamonti | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl | | |

CERTIFICATE OF ANALYSIS

MES MONOHYDRATE

BIO EXCIPIENT GRADE / MESM-3251-92

LOT: MESM-0123-00237

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

Manufacturing Date: 6/14/23 Retest Date: 6/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 9/21/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | SPECIFICATION | TEST RESULT | |
|------------------------|------------------|------------------|------------------|
| Absorbance (0.1M) | 260 nm | ≤ 0.04 a.u. | <0.04 a.u. |
| Appearance and Color | White / Crystals | White / Crystals | White / Crystals |
| Assay | ≥ 99.5% | 100.4% | 100.4% |
| Chloride | ≤ 0.005% | <0.005% | <0.005% |
| Color (1M, Alkaline) | Colorless | Colorless | Colorless |
| Endotoxin | < 50 EU/g | <24 EU/g | <24 EU/g |
| Enzymes | DNase | None Detected | None Detected |
| | RNase | None Detected | None Detected |
| | Protease | None Detected | None Detected |
| Heavy Metals (as Pb) | ≤ 2 ppm | <0.15 ppm | <0.15 ppm |
| Identification (IR) | Passes Test | Passes Test | Passes Test |
| Loss on Drying @ 130°C | 7 – 9% | 9% | 9% |
| pH (1% Solution) | 3.0 – 5.0 | 3.8 | 3.8 |
| pK _a | 5.9 – 6.3 | 6.1 | 6.1 |
| Residue on Ignition | ≤ 0.05% | <0.01% | <0.01% |
| Solubility (5%) | Passes Test | Passes Test | Passes Test |
| Sulfate | ≤ 0.005% | <0.005% | <0.005% |
| TAMC | ≤ 100 CFU/g | <10 CFU/g | <10 CFU/g |
| TYMC | ≤ 100 CFU/g | <10 CFU/g | <10 CFU/g |
| Trace Elements | Arsenic (As) | ≤ 1.5 ppm | <0.45 ppm |
| | Antimony (Sb) | ≤ 9 ppm | <2.7 ppm |
| | Barium (Ba) | ≤ 70 ppm | <21 ppm |

| ANALYSIS | SPECIFICATION | TEST RESULT |
|-------------------------|---------------|-------------|
| Cadmium (Cd) | ≤0.2 ppm | <0.06 ppm |
| Cobalt (Co) | ≤ 0.5 ppm | <0.15 ppm |
| Copper (Cu) | ≤ 30 ppm | <1.5 ppm |
| Chromium (Cr) | ≤ 110 ppm | <1.5 ppm |
| Iron (Fe) | ≤ 2 ppm | <1.5 ppm |
| Lead (Pb) | ≤ 0.5 ppm | <0.15 ppm |
| Trace Elements | | |
| Lithium (Li) | ≤ 25 ppm | <7.5 ppm |
| Mercury (Hg) | ≤ 0.3 ppm | <0.09 ppm |
| Molybdenum (Mo) | ≤ 150 ppm | <4.5 ppm |
| Nickel (Ni) | ≤ 2 ppm | <0.60 ppm |
| Tin (Sn) | ≤ 60 ppm | <18 ppm |
| Vanadium (V) | ≤ 1 ppm | <0.30 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: Shil McLall Date: 9/27/23 Job Title: QA Tech 1

Reviewed by: Janet Rugh Date: 9/27/23 Job Title: QA Mater. Disp. Supervisor