

BIOSPECTRA

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

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|----------------------|--|----------------|-----------------------|
| Effective Date: | 19-Dec-2022 | 19-Dec-2025 | : Date of Next Review |
| Prepared By: | Amy Hosein | Not Applicable | : Supersedes |
| QA/QC Approval: | Carissa Albert | Amy Yenko | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. | | |

CERTIFICATE OF ANALYSIS

BIS-TRIS

BIO EXCIPIENT GRADE / BTRI-3250-10

LOT: BTRI-0123-00014

$C_8H_{19}NO_5$ * F.W. 209.24 g/mol. * CAS# 6976-37-0

Manufacturing Date: 3/14/23

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 5/4/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|-------------------------------------|----------|--------------------------------|--------------------------------|
| Absorbance (0.1M) | 280 nm | ≤ 0.04 a.u. | 0.01 a.u. |
| | 340 nm | ≤ 0.02 a.u. | <0.02 a.u. |
| Appearance and Color | | White / Crystals | White Crystalline Powder |
| Assay (Dried basis) | | 99.0-101.0% | 100.0% |
| Bioburden | TAMC | ≤ 100 CFU/g | <100 CFU/g |
| | TYMC | ≤ 100 CFU/g | <100 CFU/g |
| Chloride | | ≤ 0.005% | <0.005% |
| Endotoxin | | ≤ 50 EU/g | <10 EU/g |
| Enzymes | DNase | None Detected | None Detected |
| | Protease | None Detected | None Detected |
| | RNase | None Detected | None Detected |
| Heavy Metals (Pb) | | ≤ 3 ppm | <0.15 ppm |
| Identification (IR) | | Conforms to Reference Standard | Conforms to Reference Standard |
| Iron | | ≤ 3 ppm | <3.0 ppm |
| Loss on Drying (LOD) | | ≤ 1.0% | <1.0% |
| Melting Point | | 100 - 105 °C | 104 °C |
| pH (1% aqueous) | | 8.8 – 9.8 | 9.3 |
| pKa | | 6.3 – 6.7 | 6.6 |
| Residue on Ignition (ROI) | | ≤ 0.1% | <0.1% |
| Solubility 0.1M in H ₂ O | | Clear and Complete | Clear and Complete |
| Water (KF) | | ≤ 1.0% | 0.1% |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0095

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.

SHELF LIFE: A retest date is to be determined based on the data obtained from the stability study.

Prepared by: David McCall Date: 5/18/23 Job Title: QA Support Tech

Reviewed by: John Bingham Date: 5/18/23 Job Title: QA Mater. Disp. Supervisor