

# BIOSPECTRA

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

|                      |                                       |                    |                       |
|----------------------|---------------------------------------|--------------------|-----------------------|
| Effective Date:      | 14-Feb-2022                           | 14-Feb-2025        | : Date of Next Review |
| Prepared By:         | Wendy Santay                          | BSI-COA-0126 v.4.0 | : Supersedes          |
| QA/QC Approval:      | Jaron Hughes                          | Carissa McCollan   | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl |                    |                       |

## CERTIFICATE OF ANALYSIS

### TRIS, USP/EP

### BIO EXCIPIENT GRADE / NEW CODE TRIS-3254-01

### (HISTORICAL CODE TR3254-K001)

### LOT: TRIS-0123-00170

 $\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3$  \* F.W. 121.14 g/mol. \* CAS# 77-86-1

Manufacture Date: 07/14/23      Expiration Date: 07/31/26

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 08/10/23      Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP and EP Specifications

#### USP COMPENDIA

| ANALYSIS             | SPECIFICATION  | TEST RESULT    |
|----------------------|----------------|----------------|
| Appearance and Color | White/Crystals | White/Crystals |
| Assay                | 99.0 – 101.0%  | 99.2%          |
| Endotoxin            | ≤ 2.5 EU/g     | < 1.0 EU/g     |
| Identification A     | Passes Test    | Passes Test    |
| Identification B     | Passes Test    | Passes Test    |
| Identification C     | Passes Test    | Passes Test    |
| Loss on Drying       | ≤ 1.0%         | 0.2%           |
| Melting Range        | 168 – 172 °C   | 171 – 172 °C   |
| pH (1 in 20)         | 10.0 – 11.5    | 10.8           |
| Residue on Ignition  | ≤ 0.1%         | < 0.1%         |
| Microbial Content    | TAMC           | ≤ 500 CFU/g    |
|                      | TYMC           | ≤ 200 CFU/g    |
|                      |                | < 10 CFU/g     |
|                      |                | < 10 CFU/g     |

#### EP COMPENDIA

| ANALYSIS               | SPECIFICATION | TEST RESULT  |
|------------------------|---------------|--------------|
| Appearance of Solution | Passes Test   | Passes Test  |
| Assay                  | 99.0 – 100.5% | 99.2%        |
| Chloride (Cl)          | ≤ 100 ppm     | < 100 ppm    |
| Identification A       | Passes Test   | Passes Test  |
| Identification B       | 168 – 174 °C  | 171 - 172 °C |
| Identification C       | Passes Test   | Passes Test  |
| Iron (Fe)              | < 10 ppm      | < 0.30 ppm   |

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## EP COMPENDIA

| ANALYSIS                | SPECIFICATION | TEST RESULT |
|-------------------------|---------------|-------------|
| Loss on Drying at 105°C | ≤ 0.5%        | 0.2%        |
| pH                      | 10.0 – 11.5   | 10.8        |
| Related Substances      | ≤ 1.0%        | < 1.0%      |
| Sulfated Ash            | ≤ 0.1%        | < 0.1%      |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000496

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.

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.

Prepared by: M. Mhafu Date: 08/17/23 Job Title: QA Mater. Disp. Tech. III

Reviewed by: John Bligh Date: 8/17/23 Job Title: QA Mater. Disp. Supervisor