

# BIO SPECTRA

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

|                      |  |                    |                       |
|----------------------|--|--------------------|-----------------------|
| Effective Date:      | 31-Jan-2025                            | 31-Jan-2028        | : Date of Next Review |
| Prepared By:         | Taylor Yurick                          | BSI-COA-0097 v.8.3 | : Supersedes          |
| QA/QC Approval:      | Jaron Hughes                           | Carissa Albert     | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. |                    |                       |

## CERTIFICATE OF ANALYSIS

### TREHALOSE, DIHYDRATE

### BIO EXCIPIENT GRADE / TRED-3250

LOT: TRED-0123-00024

$C_{12}H_{22}O_{11} \cdot 2H_2O$  ▲ F.W. 378.33 g/mol. ▲ CAS# 6138-23-4

Manufacturing Date: 08/23/23      Expiration Date: 08/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds NF, ChP, EP and JP Specifications

| ANALYSIS                                     | SPECIFICATION                               | TEST RESULT                       |
|--|---|-----------------------------------|
| Appearance and Color                         | White to Almost White<br>Crystalline Powder | White Crystalline<br>Powder       |
| Assay (NF/ChP/EP/JP)                         | 98.0 – 101.0%                               | 99.0%                             |
| Appearance of Solution (EP)                  | Clear, Colorless                            | Clear, Colorless                  |
| Chloride                                     | Chloride (NF)                               | ≤ 0.0125%                         |
|  | Chloride (ChP)                              | ≤ 0.0125%                         |
|  | Chloride (EP)                               | ≤ 0.0125%                         |
|  | Chloride (JP)                               | ≤ 0.018%                          |
| Color and Clarity<br>of Solution (NF)        | A720  | ≤ 0.050                           |
|  | A420 – A720                                 | ≤ 0.100                           |
| Clarity and Color<br>of Solution (ChP)       | A720  | ≤ 0.033                           |
|  | A420 – A720                                 | ≤ 0.067                           |
| Dextrin, soluble starch, and sulfite (JP)    | Passes Test                                 | Passes Test                       |
| Endotoxins (NF/ChP/EP)                       | ≤ 2.4 EU/g                                  | < 0.2 EU/g                        |
| Heavy Metals (ChP/JP)                        | ≤ 5ppm                                      | < 5 ppm                           |
| Identification, IR<br>(NF-A/EP-A/JP-3/ChP-4) | Conforms to Reference<br>Standard           | Conforms to Reference<br>Standard |
| Identification B<br>(NF-B/EP-B/JP-1/ChP-1)   | Passes Test                                 | Passes Test                       |
| Identification C<br>(NF-C/EP-C/JP-2/ChP-2)   | Passes Test                                 | Passes Test                       |
| Identification 3 (JP)                        | Conforms to Reference<br>Standard           | Conforms to Reference<br>Standard |

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping, and the prevention of unauthorized appropriation, use, disclosure and copying.

| Identification 3 (ChP)                                    |                                   | Conforms to Reference Standard | Conforms to Reference Standard |
|---|-----------------------------------|--------------------------------|--------------------------------|
| ANALYSIS  |                                   | SPECIFICATION                  | TEST RESULT                    |
| Microbial Content (NF/ChP/EP)                             | <i>Escherichia coli</i>           | Absent/g                       | Absent/g                       |
|   | <i>Salmonella species</i>         | Absent/10g                     | Absent/10g                     |
|   | TAMC                              | $\leq 100$ CFU/g               | $< 10$ CFU/g                   |
|   | TYMC                              | $\leq 100$ CFU/g               | $< 10$ CFU/g                   |
| Nitrogen Determination (NF/JP)                            |                                   | $\leq 0.005\%$                 | $< 0.005\%$                    |
| Optical Rotation, Specific Rotation @ 20°C (NF/ChP/EP/JP) |                                   | +197° to +201°                 | +200°                          |
| pH @ 25°C (NF/EP/JP), Acidity (ChP)                       |                                   | 4.5 – 6.5                      | 5.9                            |
| Related Substances (NF/EP/JP)                             | Impurity A                        | $\leq 0.5\%$                   | $< 0.10\%$                     |
|   | Impurity B                        | $\leq 0.5\%$                   | $< 0.10\%$                     |
|   | Unspecified Impurities            | $\leq 0.2\%$                   | 0.13%                          |
|   | Total Impurities                  | $\leq 1.0\%$                   | 0.13%                          |
|   | Total Impurities with RRT $< 1.0$ | $\leq 0.5\%$                   | 0.13%                          |
|   | Total Impurities with RRT $> 1.0$ | $\leq 0.5\%$                   | $< 0.01\%$                     |
|   | Related Substances (ChP)          | $\leq 0.5\%$                   | 0.13%                          |
| Residue on Ignition (NF/ChP/JP)                           |                                   | $\leq 0.1\%$                   | $< 0.1\%$                      |
| Residual Ethanol  |                                   | $\leq 200$ ppm                 | $< 95$ ppm                     |
| Residual Isopropyl Alcohol                                |                                   | $\leq 250$ ppm                 | $< 135$ ppm                    |
| Residual Methanol   |                                   | $\leq 50$ ppm                  | $< 25$ ppm                     |
| Soluble Starch (NF/ChP/EP)                                |                                   | Passes Test                    | Passes Test                    |
| Sulfated Ash (EP)   |                                   | $\leq 0.1\%$                   | $< 0.1\%$                      |
| Sulfate   | Sulfate (NF)                      | $\leq 0.0200\%$                | $< 0.0200\%$                   |
|   | Sulfate (ChP)                     | $\leq 0.020\%$                 | $< 0.020\%$                    |
|   | Sulfate (EP)                      | $\leq 0.0200\%$                | $< 0.0200\%$                   |
|   | Sulfate (JP)                      | $\leq 0.024\%$                 | $< 0.024\%$                    |
| Water Determination (NF/ChP/EP/JP)                        |                                   | 9.0% to 11.0%                  | 9.8%                           |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0027

SPECIFICATION STATEMENT: When Applicable, the most stringent monograph specification will be referenced as the specification.

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. Ethanol and Methanol are not used in the manufacturing process.

Prepared by: Anil McCall Date: 7/18/25 Job Title: QA Tech III

Reviewed by: Car Albert Date: 7/21/25 Job Title: Senior Quality Manager