

# BIO SPECTRA

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

|                      |  |                    |                       |
|----------------------|--|--------------------|-----------------------|
| Effective Date:      | 1-Aug-2022                             | 1-Aug-2025         | : Date of Next Review |
| Prepared By:         | Wendy Santay                           | BSI-COA-0097 v.8.0 | : Supersedes          |
| QA/QC Approval:      | Carissa McCollan                       | Amy Yencho         | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. |                    |                       |

## CERTIFICATE OF ANALYSIS

### TREHALOSE, DIHYDRATE

### BIO EXCIPIENT GRADE / NEW CODE TRED-3250-92

#### (HISTORICAL CODE TE3250-G100)

#### LOT: TRED-0124-00010

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

Manufacturing Date: 08/16/23      Retest Date: 08/31/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 05/02/24      Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP/NF, EP and JP Specifications

#### NF COMPENDIA

| ANALYSIS  | SPECIFICATION                               | TEST RESULT          |
|---|---|----------------------|
| <sup>1</sup> Assay                                      | <sup>3</sup> 98.0% - 101.0%                 | 99.3%                |
| Chloride and Sulfate, <i>Chloride</i>                   | $\leq 0.0125\%$                             | $\leq 0.0125\%$      |
| Color and Clarity of Solution                           | A720 $\leq 0.050$                           | 0.004                |
|   | A420 – A720 $\leq 0.100$                    | 0.014                |
| <sup>2</sup> Endotoxins                                 | <sup>3</sup> $\leq 2.4$ EU/g                | $\leq 0.2$ EU/g      |
| <sup>2</sup> Identification A                           | Conforms to Standard                        | Conforms to standard |
| <sup>2</sup> Identification B                           | Passes Test                                 | Passes Test          |
| <sup>2</sup> Identification C                           | Passes Test                                 | Passes Test          |
|   | <i>Escherichia coli</i> Absent/g            | Absent/g             |
| <sup>2</sup> Microbial Content                          | <i>Salmonella species</i> Absent/10g        | Absent/10g           |
|   | TAMC $\leq 100$ CFU/g                       | $\leq 10$ CFU/g      |
|   | TYMC $\leq 100$ CFU/g                       | $\leq 10$ CFU/g      |
| <sup>2</sup> Nitrogen Determination                     | $\leq 0.005\%$                              | $\leq 0.005\%$       |
| <sup>2</sup> Optical Rotation, Specific Rotation @ 20°C | +197° to +201°                              | +199°                |
| <sup>2</sup> pH @ 25°C                                  | 4.5 – 6.5                                   | 6.0                  |
| <sup>1</sup> Related Substances                         | Total Impurities with RRT <1.0 $\leq 0.5\%$ | 0.17%                |
|   | Total Impurities with RRT >1.0 $\leq 0.5\%$ | $\leq 0.01\%$        |
| <sup>2</sup> Residue on Ignition                        | $\leq 0.1\%$                                | $\leq 0.1\%$         |

| ANALYSIS                             | SPECIFICATION | TEST RESULT |
|--------------------------------------|---------------|-------------|
| <sup>2</sup> Soluble Starch          | Passes Test   | Passes Test |
| Chloride and Sulfate, <i>Sulfate</i> | ≤ 0.0200%     | ≤ 0.0200%   |
| <sup>2</sup> Water Determination     | 9.0% to 11.0% | 9.5%        |

## EP COMPENDIA

| ANALYSIS                                      | SPECIFICATION              | TEST RESULT          |
|---|----------------------------|----------------------|
| <sup>1</sup> Assay                            | <sup>3</sup> 98.0 - 101.0% | 99.3%                |
| Appearance of Solution                        | Clear, colorless           | Clear, colorless     |
| Chlorides                                     | ≤ 0.0125%                  | ≤ 0.0125%            |
| <sup>2</sup> Endotoxins                       | <sup>3</sup> ≤ 2.4 EU/g    | < 0.2 EU/g           |
| <sup>2</sup> Identification A                 | Conforms to Standard       | Conforms to standard |
| <sup>2</sup> Identification B                 | Passes Test                | Passes Test          |
| <sup>2</sup> Identification C                 | Passes Test                | Passes Test          |
|   | Impurity A                 | ≤ 0.10%              |
| <sup>1</sup> Related Substances               | Impurity B                 | ≤ 0.10%              |
|   | Unspecified Impurities     | 0.17%                |
|   | Total Impurities           | 0.17%                |
|   | <i>Escherichia coli</i>    | Absent/g             |
| <sup>2</sup> Microbial Content                | <i>Salmonella species</i>  | Absent/10g           |
|   | TAMC                       | < 10 CFU/g           |
|   | TYMC                       | < 10 CFU/g           |
| <sup>2</sup> pH @ 25°C                        | 4.5 - 6.5                  | 6.0                  |
| <sup>2</sup> Soluble Starch                   | Passes Test                | Passes Test          |
| <sup>2</sup> Specific Optical Rotation @ 20°C | +197° to +201°             | +199°                |
| Sulfated Ash                                  | ≤ 0.1%                     | ≤ 0.1%               |
| Sulfates                                      | ≤ 0.0200%                  | ≤ 0.0200%            |
| <sup>2</sup> Water                            | 9.0% to 11.0%              | 9.5%                 |

## JP COMPENDIA

| ANALYSIS                                      | SPECIFICATION  | TEST RESULT |
|---|----------------|-------------|
| <sup>1</sup> Assay                            | 98.0% - 101.0% | 99.3%       |
| Chloride                                      | ≤ 0.018%       | ≤ 0.018%    |
| <sup>2</sup> Dextrin, Soluble Starch, Sulfite | Passes Test    | Passes Test |
| Heavy Metals (as Pb)                          | ≤ 5 ppm        | ≤ 5 ppm     |
| <sup>2</sup> Identification 1                 | Passes Test    | Passes Test |

| ANALYSIS                             |                                | SPECIFICATION        | TEST RESULT          |
|--------------------------------------|--------------------------------|----------------------|----------------------|
| <sup>2</sup> Identification 2        |                                | Passes Test          | Passes Test          |
| <sup>2</sup> Identification 3        |                                | Conforms to Standard | Conforms to Standard |
| <sup>2</sup> Nitrogen                |                                | ≤ 0.005%             | < 0.005%             |
| <sup>2</sup> Optical Rotation @ 20°C |                                | +197° to +201°       | +199°                |
| <sup>2</sup> pH @ 25°C               |                                | 4.5 – 6.5            | 6.0                  |
| <sup>2</sup> Residue on Ignition     |                                | ≤ 0.1%               | ≤ 0.1%               |
| <sup>1</sup> Related Substances      | Total Impurities with RRT <1.0 | ≤ 0.5%               | 0.17%                |
|                                      | Total Impurities with RRT >1.0 | ≤ 0.5%               | ≤ 0.01%              |
| Sulfate                              |                                | ≤ 0.024%             | ≤ 0.024%             |
| <sup>2</sup> Water                   |                                | 9.0% to 11.0%        | 9.5%                 |

### NON-COMPENDIAL ANALYSES

| ANALYSIS                                | SPECIFICATION                            | TEST RESULT                              |
|---|--|--|
| Appearance and Color                    | White to Almost White Crystalline Powder | White to Almost White Crystalline Powder |
| <sup>1</sup> Residual Ethanol           | ≤ 200 ppm                                | < 95 ppm                                 |
| <sup>1</sup> Residual Isopropyl Alcohol | ≤ 250 ppm                                | < 135 ppm                                |
| <sup>1</sup> Residual Methanol          | ≤ 50 ppm                                 | < 25 ppm                                 |

<sup>1</sup>Alternate Validated Method

<sup>2</sup>Analyses are Harmonized

<sup>3</sup>Specifications is more stringent than Compendia Monograph

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0027

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: Zaive Ragim Date: 5/3/24 Job Title: QA Tech 1

Reviewed by: John Blythe Date: 5/3/24 Job Title: QA Supervisor

