

BIO SPECTRA

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

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|----------------------|--|--------------------|-----------------------|
| 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 McCollian | Amy Yencho | : Management Approval |
| Reason for Revision: | See Revision History in MasterControl. | | |

CERTIFICATE OF ANALYSIS

TREHALOSE, DIHYDRATE

BIO EXCIPIENT GRADE / NEW CODE TRED-3250-93

(HISTORICAL CODE TE3250-G500)

LOT: TRED-0124-00018

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

Manufacturing Date: 08/11/23 Retest Date: 08/31/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 08/04/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP/NF, EP and JP Specifications

NF COMPENDIA

| ANALYSIS | SPECIFICATION | TEST RESULT |
|---|--|--|
| ¹ Assay | ³ 98.0% - 101.0% | 100.0% |
| Chloride and Sulfate, <i>Chloride</i> | ≤ 0.0125% | < 0.0125% |
| Color and Clarity of Solution | A720 ≤ 0.050 A420 – A720 ≤ 0.100 | < 0.003 0.013 |
| ² Endotoxins | ³ ≤ 2.4 EU/g | < 0.2 EU/g |
| ² Identification A | Conforms to Standard | Conforms to standard |
| ² Identification B | Passes Test | Passes Test |
| ² Identification C | Passes Test | Passes Test |
| | <i>Escherichia coli</i> | Absent/g |
| ² Microbial Content | <i>Salmonella species</i> Absent/10g TAMC ≤ 100 CFU/g TYMC ≤ 100 CFU/g | Absent/10g < 100 CFU/g < 100 CFU/g |
| ² Nitrogen Determination | ≤ 0.005% | < 0.005 % |
| ² Optical Rotation, Specific Rotation @ 20°C | +197° to +201° | +199° |
| ² pH @ 25°C | 4.5 – 6.5 | 5.6 |
| ¹ Related Substances | Total Impurities with RRT <1.0 ≤ 0.5% Total Impurities with RRT >1.0 ≤ 0.5% | 0.11% < 0.01% |
| ² Residue on Ignition | ≤ 0.1% | < 0.1% |

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| ANALYSIS | SPECIFICATION | TEST RESULT |
|--------------------------------------|---------------|-------------|
| ² Soluble Starch | Passes Test | Passes Test |
| Chloride and Sulfate, <i>Sulfate</i> | ≤ 0.0200% | < 0.0200% |
| ² Water Determination | 9.0% to 11.0% | 9.4% |

EP COMPENDIA

| ANALYSIS | SPECIFICATION | TEST RESULT |
|---|----------------------------|----------------------|
| ¹ Assay | ³ 98.0 - 101.0% | 100.0% |
| Appearance of Solution | Clear, colorless | Clear, colorless |
| Chlorides | ≤ 0.0125% | < 0.0125% |
| ² Endotoxins | ³ ≤ 2.4 EU/g | < 0.2 EU/g |
| ² Identification A | Conforms to Standard | Conforms to standard |
| ² Identification B | Passes Test | Passes Test |
| ² Identification C | Passes Test | Passes Test |
| | Impurity A | ≤ 0.5% |
| | Impurity B | ≤ 0.5% |
| ¹ Related Substances | Unspecified Impurities | ≤ 0.2% |
| | Total Impurities | ≤ 1.0% |
| | <i>Escherichia coli</i> | Absent/g |
| | <i>Salmonella species</i> | Absent/10g |
| ² Microbial Content | TAMC | ≤ 100 CFU/g |
| | TYMC | ≤ 100 CFU/g |
| ² pH @ 25°C | 4.5 - 6.5 | 5.6 |
| ² Soluble Starch | Passes Test | Passes Test |
| ² Specific Optical Rotation @ 20°C | +197° to +201° | +199° |
| Sulfated Ash | ≤ 0.1% | < 0.1% |
| Sulfates | ≤ 0.0200% | < 0.0200% |
| ² Water | 9.0% to 11.0% | 9.4% |

JP COMPENDIA

| ANALYSIS | SPECIFICATION | TEST RESULT |
|---|----------------|-------------|
| ¹ Assay | 98.0% - 101.0% | 100.0% |
| Chloride | ≤ 0.018% | < 0.018% |
| ² Dextrin, Soluble Starch, Sulfite | Passes Test | Passes Test |
| Heavy Metals (as Pb) | ≤ 5 ppm | < 5 ppm |
| ² Identification 1 | Passes Test | Passes Test |

| ANALYSIS | SPECIFICATION | TEST RESULT |
|--------------------------------------|--|----------------------|
| ² Identification 2 | Passes Test | Passes Test |
| ² Identification 3 | Conforms to Standard | Conforms to Standard |
| ² Nitrogen | ≤ 0.005% | < 0.005% |
| ² Optical Rotation @ 20°C | +197° to +201° | +199° |
| ² pH @ 25°C | 4.5 – 6.5 | 5.6 |
| ² Residue on Ignition | ≤ 0.1% | < 0.1% |
| ¹ Related Substances | Total Impurities with RRT <1.0 ≤ 0.5% | 0.11% |
| | Total Impurities with RRT >1.0 ≤ 0.5% | < 0.1% |
| Sulfate | ≤ 0.024% | < 0.024% |
| ² Water | 9.0% to 11.0% | 9.4% |

NON-COMPENDIAL ANALYSES

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

¹Alternate Validated Method²Analyses are Harmonized³Specifications 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: David McCall Date: 8/16/24 Job Title: QA Tech I

Reviewed by: Janet Hoffman Date: 8/16/24 Job Title: QA Supervisor

