

BIOSPECTRA

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

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|----------------------|--------------------------------|----------------|-----------------------|
| Effective Date: | 27-Aug-2020 | 27-Aug-2023 | : Date of Next Review |
| Prepared By: | Amy Hosein | 20-003378v.1.0 | : Supersedes |
| QA/QC Approval: | Carissa McCollan | Hannah Bernier | : Management Approval |
| Reason for Revision: | See Revision History in ensur. | | |

CERTIFICATE OF ANALYSIS

TREHALOSE, DIHYDRATE

BIO EXCIPIENT GRADE / TE3252 – K001

LOT: TE3252-007-0820

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

Manufacturing Date: 2/9/19 Retest Date: 5/31/21

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 8/25/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds EP/BP, JP and NF Specifications

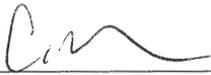
| ANALYSIS | SPECIFICATION | TEST RESULT |
|----------------------------------|---------------------------------------|---------------------------------------|
| Appearance and Color | White to Off-White Crystalline Powder | White to Off-White Crystalline Powder |
| Appearance of Solution (EP) | Clear, Colorless | Clear, Colorless |
| Assay % w/w | 98.0% - 101.0% | 99.5% |
| Chloride | (NF) $\leq 0.0125\%$ | $\leq 0.0125\%$ |
| | (EP) $\leq 0.0125\%$ | $\leq 0.0125\%$ |
| | (JP) $< 0.018\%$ | $< 0.018\%$ |
| Color and Clarity of Solution | A720 ≤ 0.050 | 0.002 |
| | A420 – A720 ≤ 0.100 | 0.016 |
| Dextrin, Soluble Starch, Sulfite | Passes Test | Passes Test |
| Endotoxins | ≤ 0.3 EU/g | < 0.2 EU/g |
| Heavy Metals (as Pb) | ≤ 5 ppm | ≤ 5 ppm |
| Identification A | Conforms to Standard | Conforms to standard |
| Identification B | Passes Test | Passes Test |
| Identification C | Passes Test | Passes Test |
| Identification 1 | (JP) Passes Test | Passes Test |
| Identification 2 | (JP) Passes Test | Passes Test |
| Identification 3 | (JP) Passes Test | Passes Test |

| ANALYSIS | | SPECIFICATION | TEST RESULT |
|----------------------------|---|----------------|-------------|
| Impurities | Maltotriose (Impurity B) | ≤ 0.5% | ≤ 0.5 % |
| | Total Impurities with RRT < 1.0 | ≤ 0.5% | ≤ 0.5 % |
| | Total Impurities with RRT > 1.0 | ≤ 0.5% | ≤ 0.5 % |
| | Glucose (Impurity A) | ≤ 0.5% | ≤ 0.5 % |
| | Any Other Impurities | ≤ 0.2% | ≤ 0.2 % |
| | Sum of Glucose, Maltotriose, and Other Impurities | ≤ 1.0% | ≤ 1.0 % |
| Microbial Content | <i>Escherichia coli</i> | Absent | Absent |
| | <i>Salmonella species</i> | Absent | Absent |
| | TAMC | ≤ 100 CFU/g | ≤ 10 CFU/g |
| | TYMC | ≤ 100 CFU/g | ≤ 10 CFU/g |
| Nitrogen Content | | ≤ 0.005% | ≤ 0.005 % |
| pH @ 25°C | | 4.5 – 6.5 | 5.7 |
| Residual Ethanol | | ≤ 5000 ppm | ≤ 5000 ppm |
| Residual Isopropyl Alcohol | | ≤ 5000 ppm | ≤ 5000 ppm |
| Residual Methanol | | ≤ 3000 ppm | ≤ 3000 ppm |
| Residue on Ignition | | ≤ 0.1% | ≤ 0.1% |
| Soluble Starch | | Passes Test | Passes Test |
| Specific Rotation @ 20°C | | +197° to +201° | +198° |
| Sulfate | (NF) | ≤ 0.0200% | ≤ 0.0200 % |
| | (EP) | ≤ 0.0200% | ≤ 0.0200 % |
| | (JP) | ≤ 0.024% | ≤ 0.024 % |
| Water (Karl Fischer) | | 9.0% to 11.0% | 9.3% |

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 18-002375

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:  Date: 8/27/20 Job Title: QA Supervisor

Reviewed by:  Date: 08/27/20 Job Title: QA Manager