BIOSPECTRA

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

Effective Date:	12-Dec-2019	12-Dec-2022	: Date of Next Review
Prepared By:	Hannah Bernier	18-002600 v.3.1	: Supersedes
QA/QC Approval:	Carissa McCollian	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TREHALOSE, DIHYDRATE

BIO EXCIPIENT GRADE / TE3250 – G100

LOT: TE3250-008-0220

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

Manufacture Date: 2/9/2019 Retest Date: 2/28/2021

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 2/18/2020

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Trehalose, Dihydrate is currently undergoing a stability shelf life study in accordance with BioSpectra's Stability Program. The proposed retest period is 24 months based on information obtained from development, industry review and raw material supply chain. This retest period may be used for material represented by this CoA unless otherwise notified by BioSpectra.

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)	≤ 0.0125%	≤ 0.0125 %
	(EP)	≤ 0.0125%	≤ 0.0125 %
	(JP)	< 0.018%	< 0.018 %
Color and Clarity of Solution	A720	≤ 0.050	0.002 a.u.
	A420 – A720	≤ 0.100	0.016 a.u.
Dextrin, Soluble Starch, Sulfite		Passes Test	Passes Test
Endotoxins		≤ 2.4 EU/g	<1.2 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

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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	*Escherichia coli*	Absent	Absent
	Salmonella species	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 to be used only as the following: ICH Q7 Compliant cGMP Manufactured Excipient for use in further Manufacturing. 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: C. L IOA Supervisor Date: 2/19/20

Reviewed by: H. Burns IOA Manager Date: 2/19/20

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