

BIOSPECTRA

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

Effective Date:	14-Nov-2019	14-Nov-2022	: Date of Next Review
Prepared By:	Kyle Snyder	18-002600 v.2.0	: 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 / TE3250 – K001

LOT: TE3250-002-1119

C₁₂H₂₂O₁₁ · 2H₂O * F.W. 378.33 g/mol. * CAS# 6138-23-4

Manufacture Date: 2/9/2019

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 11/20/2019

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 %
	(NF) ≤ 0.0125%	≤ 0.0125 %
Chloride	(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	≤ 2.4 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
	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 %
Impurities	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 %
	<i>Escherichia coli</i>	Absent	Absent
Microbial Content	<i>Salmonella species</i>	Absent	Absent
	TAMC	≤ 100 CFU/g	≤ 100 CFU/g
	TYMC	≤ 100 CFU/g	≤ 100 CFU/g
	Nitrogen Content	≤ 0.005%	≤ 0.005 %
	pH @ 25°C	4.5 – 6.5	5.7 @ 23.3°C
	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. C. W. Date: 11/21/19

Reviewed by: S. Johnson Date: 11/22/19