BIOSPECTRA

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

Effective Date:	14-Jan-2021	14-Jan-2024	: Date of Next Review
Prepared By:	Amy Hosein	18-002663 v.2.3	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur		

CERTIFICATE OF ANALYSIS

TREHALOSE, DIHYDRATE

BIO EXCIPIENT GRADE / TE3251 – K000

LOT: TE3251-003-1220

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

Manufacture Date: 2/14/19 Retest Date: 2/28/21

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: MM/DD/YY

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP/NF, EP, and CP Specifications

NF COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
[1]Assay		[3]98.0% - 102.0%	99.3 %
Chloride and Sulfate, *Chloride*		≤ 0.0125%	≤ 0.0125 %
Color and Clarity of Solution		A720 ≤ 0.050	0.003
		A420 – A720 ≤ 0.100	0.013
[2]Endotoxins		[3]≤ 2.4 EU/g	≤ 1.2 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
[2]Microbial Content	*Escherichia coli*	Absent/g	Absent/g
	Salmonella Species	Absent/10g	Absent/10g
	TAMC	≤ 100 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
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%	≤ 0.5 %
	Total Impurities with RRT >1.0	≤0.5%	≤ 0.5 %
[2]Residue on Ignition		≤ 0.1%	≤ 0.1 %

ANALYSIS	SPECIFICATION	TEST RESULT
[2]Soluble Starch	Passes Test	Passes Test
Chloride and Sulfate, *Sulfate*	≤ 0.0200%	≤ 0.0200 %
[2]Water Determination	9.0% to 11.0%	9.6 %

EP COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
[1]Assay		[3]98.0% – 102.0%	99.3 %
Appearance of Solution		Clear, colorless	Clear, Colorless
Chlorides		≤ 0.0125%	≤ 0.0125 %
[2]Endotoxins		[3]≤ 2.4 EU/g	≤ 1.2 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
[1]Related Substances	Impurity A	≤ 0.5%	≤ 0.5 %
	Impurity B	≤ 0.5%	≤ 0.5 %
	Unspecified Impurities	≤ 0.2%	≤ 0.2 %
	Total Impurities	≤ 1.0%	≤ 1.0 %
[2]Microbial Content	*Escherichia coli*	Absent/g	Absent/g
	Salmonella species	Absent/10g	Absent/10g
	TAMC	≤ 100 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
[2]pH @ 25°C		4.5 – 6.5	5.6
[2]Soluble Starch		Passes Test	Passes Test
[2]Specific Optical Rotation @°20C		+197° to +201°	+199 °
Sulfated Ash		≤ 0.1%	≤ 0.1 %
Sulfates		≤ 0.0200%	≤ 0.0200 %
[2]Water		9.0% to 11.0%	9.6 %

CP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
[2]Acidity	4.5 – 6.5	5.6
[1]Assay	98.0% – 102.0%	99.3 %
Clarity and Color of Solution	A720 ≤ 0.033 A420 – A720 ≤ 0.067	<0.003 0.016
Chloride	≤ 0.0125%	≤ 0.0125 %

ANALYSIS		SPECIFICATION	TEST RESULT
[2]Endotoxins		[3]≤ 2.4 EU/g	≤ 1.2 EU/g
Heavy Metals		≤ 0.0005%	≤ 0.0005 %
[2]Identification 1		Passes Test	Passes Test
[2]Identification 2		Passes Test	Passes Test
[1]Identification 3		Passes Test	Passes Test
[2]Identification 4		Conforms to Standard	Conforms to Standard
[2]Microbial Content	*Escherichia coli*	Absent/g	Absent/g
	Salmonella species	Absent/10g	Absent/10g
	TAMC	[3]≤ 100 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
[1]Related Substances	Total Impurities with RRT <1.0	≤ 0.5%	≤ 0.5 %
	Total Impurities with RRT >1.0	≤ 0.5%	≤ 0.5 %
[2]Residue on Ignition		≤ 0.1%	≤ 0.1 %
[2]Soluble Starch		Passes Test	Passes Test
[2]Specific Optical Rotation @ 20°C		+197° to +201°	+199 °
Sulfate		≤ 0.020%	≤ 0.020 %
[2]Water		9.0% to 11.0%	9.6 %

NON-COMPENDIAL ANALYSIS

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	White to Almost White crystalline powder	White to Almost White crystalline powder
[1]Residual Ethanol	≤ 5000 ppm	≤ 5000 ppm
[1]Residual Methanol	≤ 3000 ppm	≤ 3000 ppm

[1]Alternate Validated Method
[2]Analyses are Harmonized
[3]Specification is more stringent than Compendia Monograph

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: 02/04/21 Job Title: QI Manager

Reviewed by: _____ Date: 2/4/21 Job Title: QA Specialist