BIOSPECTRA

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

Effective Date:	22-Dec-2020	22-Dec-2023	: Date of Next Review
Prepared By:	Amy Hosein	20-003378 v.2.0	: 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 / TE3252 – G500

LOT: TE3252-010-1220

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

Manufacturing Date: 2/12/19 Retest Date: 5/31/21

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 12/31/20 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%	99.9%
Chloride and Sulfate, *Chloride*		≤ 0.0125%	≤ 0.0125 %
Color and Clarity of Solution	A720	≤ 0.050	<0.050
	A420 – A720	≤ 0.100	0.010
[2]Endotoxins		[3]≤ 0.3 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
[2]Microbial Content	*Escherichia coli*	Absent/g	Absent
	Salmonella species	Absent/10g	Absent
	TAMC	≤ 100 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 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	5.7
[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%	9.5%

EP COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
[1]Assay		[3]98.0% – 101.0%	99.9%
Appearance of Solution		Clear, colorless	Clear, colorless
Chlorides		≤ 0.0125%	≤ 0.0125%
[2]Endotoxins		[3]≤ 0.3 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
[1]Related Substances	Impurities A and 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
	Salmonella species	Absent/10g	Absent
	TAMC	≤ 100 CFU/g	≤ 10 CFU/g
	TYMC	≤ 100 CFU/g	≤ 10 CFU/g
[2]pH @ 25°C		4.5 – 6.5	5.7
[2]Soluble Starch		Passes Test	Passes Test
[2]Specific, Optical Rotation @ 20°C		+197° to +201°	+199°
Sulfated Ash		≤ 0.1%	≤0.1%
Sulfate		≤ 0.0200%	≤ 0.0200%
[2]Water		9.0% to 11.0%	9.5%

JP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
[1]Assay	98.0 – 101.0%	99.9%
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
[2]Identification 2	Passes Test	Passes Test
[2]Identification 3	Conforms to Standard	Conforms to standard

ANALYSIS		SPECIFICATION	TEST RESULT
[2]Nitrogen		≤ 0.005%	<0.005%
[2]Optical Rotation @ 20°C		+197° to +201°	+199°
[2]pH @ 25°C		4.5 - 6.5	5.7
[2]Residue on Ignition		≤ 0.1%	≤ 0.1%
[1]Related Substances	Total Impurities with RRT <1.0	≤ 0.5%	≤ 0.5%
	Total Impurities with RRT >1.0	≤ 0.5%	≤ 0.5%
Sulfate		≤ 0.024%	≤ 0.024 %
[2]Water		9.0% to 11.0%	9.5%

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	≤ 5000 ppm	≤ 5000 ppm
[1]Residual Isopropyl Alcohol	≤ 5000 ppm	≤ 5000 ppm
[1]Residual Methanol	≤ 3000 ppm	≤ 3000 ppm

[1]Alternate Validated Method
[2]Analyses are Harmonized
[3]Specifications 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: Jason Hughes Date: 1/4/21 Job Title: QA Specialist

Reviewed by: [signature] Date: 1/4/21 Job Title: QA Supervisor