BIOSPECTRA

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

Effective Date:	05-Jul-2022	05-Jul-2025	: Date of Next Review
Prepared By:	Krista Rehrig	BSI-COA-0197 v.4.0	: Supersedes
QA/QC Approval:	Amy Yencho/Dora Meissner	Mark Uhlig	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

TREHALOSE, DIHYDRATE

BIO EXCIPIENT GRADE / NEW CODE TRED-3252-93

(HISTORICAL CODE TE3252-G500)

LOT: TRED-0122-00036

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

Manufacturing Date: 6/22/22 Retest Date: 6/30/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 10/29/22 Packaging Site: 100 Majestic Way, Bangor PA, 18013

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

NF COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
Assay[1]		98.0 - 101.0%[3]	100.4%
Chloride and Sulfate, *Chloride*		≤ 0.0125%	≤ 0.0125 %
Color and Clarity of Solution	A720	≤ 0.050	<0.003
	A420 – A720	≤ 0.100	0.016
Endotoxins[2]		≤ 0.3 EU/g[3]	≤ 0.2 EU/g
Identification A[2]		Conforms to Standard	Conforms to standard
Identification B[2]		Passes Test	Passes Test
Identification C[2]		Passes Test	Passes Test
Microbial Content[2]	*Escherichia coli*	Absent/g	Absent/g
	Salmonella species	Absent/10g	Absent/10g
	TAMC	≤ 50 CFU/g	10 CFU/g
	TYMC	≤ 20 CFU/g	<10 CFU/g
Nitrogen Determination[2]		≤ 0.005%	≤ 0.001%
Optical Rotation, Specific Rotation @ 20°C[2]		+197° to +201°	+199°
pH @ 25°C[2]		4.5 - 6.5	5.6
Related Substances[1]	Total Impurities with RRT <1.0	≤ 0.5%	<0.5%
	Total Impurities with RRT >1.0	≤ 0.5%	<0.5%
Residue on Ignition[2]		≤ 0.1%	<0.1%

ANALYSIS	SPECIFICATION	TEST RESULT
Soluble Starch[2]	Passes Test	Passes Test
Chloride and Sulfate, *Sulfate*	≤ 0.0200%	<0.0200%
Water Determination[2]	9.0% to 11.0%	10.2%

EP COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
Assay[1]		98.0 – 101.0%[3]	100.4%
Appearance of Solution		Clear, colorless	Clear, colorless
Chlorides		≤ 0.0125%	<0.0125%
Endotoxins[2]		≤ 0.3 EU/g[3]	<0.2 EU/g
Identification A[2]		Conforms to Standard	Conforms to standard
Identification B[2]		Passes Test	Passes Test
Identification C[2]		Passes Test	Passes Test
Related Substances[1]	Impurity A	≤ 0.5%	<0.5%
	Impurity B	≤ 0.2%	<0.2%
	Unspecified Impurities	≤ 0.2%	<0.2%
	Total Impurities	≤ 1.0%	<0.2%
Microbial Content[2]	*Escherichia coli*	Absent/g	Absent/g
	Salmonella species	Absent/10g	Absent/10g
	TAMC	≤ 50 CFU/g	10 CFU/g
	TYMC	≤ 20 CFU/g	<10 CFU/g
pH @ 25°C[2]		4.5 – 6.5	5.6
Soluble Starch[2]		Passes Test	Passes Test
Specific, Optical Rotation @ 20°C[2]		+197° to +201°	+199°
Sulfated Ash		≤ 0.1%	<0.1%
Sulfate		≤ 0.0200%	<0.0200%
Water[2]		9.0% to 11.0%	10.2%

JP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Assay[1]	98.0 – 101.0%	100.4%
Chloride	≤ 0.018%	<0.018%
Dextrin, Soluble Starch, Sulfite[2]	Passes Test	Passes Test

ANALYSIS		SPECIFICATION	TEST RESULT
Heavy Metals (as Pb)		≤ 5 ppm	<5 ppm
Identification 1[2]		Passes Test	Passes Test
Identification 2[2]		Passes Test	Passes Test
Identification 3[2]		Conforms to Standard	Conforms to standard
Nitrogen[2]		≤ 0.005%	0.001%
Optical Rotation @ 20°C[2]		+197° to +201°	+199°
pH @ 25°C[2]		4.5 - 6.5	5.6
Residue on Ignition[2]		≤ 0.1%	<0.1%
Related Substances[1]	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%
Water[2]		9.0% to 11.0%	10.2%

NON-COMPENDIAL ANALYSES

ANALYSIS		SPECIFICATION	TEST RESULT
Appearance and Color		White to Off White Crystalline Powder	White to Off White Crystalline Powder
Microbial Content	*Staphylococcus aureus*	Absent/g	Absent/g
	Pseudomonas aeruginosa	Absent/g	Absent/g
Residual Ethanol[1]		≤ 200 ppm	<200ppm
Residual Isopropyl Alcohol[1]		≤ 250 ppm	<250ppm
Residual Methanol[1]		≤ 50 ppm	<50ppm
Trace Metals	Cadmium (Cd)	≤50 ppb	<2 ppb
	Arsenic (As)	≤50 ppb	<15 ppb
	Mercury (Hg)	≤50 ppb	<3 ppb
	Nickel (Ni)	≤100 ppb	<20 ppb
	Molybdenum (Mo)	≤100 ppb	<50 ppb
	Copper (Cu)	≤100 ppb	<50 ppb
	Chromium (Cr)	≤100 ppb	<50 ppb
	Iron (Fe)	≤100 ppb	<50 ppb
	Aluminum (Al)	≤100 ppb	<50 ppb
	Zinc (Zn)	≤100 ppb	<50 ppb

[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: BSI-ATM-0027

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: [signature] Date: 10/31/22 Job Title: QA Specialist

Reviewed by: Caissie Allert Date: 10/31/22 Job Title: Assoc. Director of Quality