BIOSPECTRA

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

Effective Date:	27-Nov-2024	27-Nov-2027	: Date of Next Review
Prepared By:	Amy Yencho	BSI-COA-0097 v.8.2	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

TREHALOSE, DIHYDRATE

BIO EXCIPIENT GRADE / TRED-3250-00

LOT: TRED-N02-0924-0026

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

Manufacturing Date: 09/16/24 Retest Date: 09/30/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 09/17/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds NF, ChP, EP and JP Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Appearance and Color		White to Almost White Crystalline Powder	White to Almost White Crystalline Powder
Assay (NF/ChP/EP/JP)		98.0 – 101.0%	99.4%
Appearance of Solution (EP)		Clear, Colorless	Clear, Colorless
Chloride	Chloride (NF)	≤ 0.0125%	<0.0125%
	Chloride (ChP)	≤ 0.0125%	<0.0125%
	Chloride (EP)	≤ 0.0125%	<0.0125%
	Chloride (JP)	≤ 0.018%	<0.018%
Color and Clarity of Solution (NF)	A720	≤ 0.050	<0.003
	A420 – A720	≤ 0.100	0.014
Clarity and Color of Solution (ChP)	A720	≤ 0.033	<0.033
	A420 – A720	≤ 0.067	0.016
Dextrin, soluble starch, and sulfite (JP)		Passes Test	Passes Test
Endotoxins (NF/ChP/EP)		≤ 2.4 EU/g	<0.2 EU/g
Heavy Metals (ChP/JP)		≤ 5ppm	<5 ppm
Identification, IR (NF-A/EP-A/JP-3/ChP-4)		Conforms to Reference Standard	Conforms to Reference Standard
Identification B (NF-B/EP-B/JP-1/ChP-1)		Passes Test	Passes Test
Identification C (NF-C/EP-C/JP-2/ChP-2)		Passes Test	Passes Test
Identification 3 (JP)		Conforms to Reference Standard	Conforms to Reference Standard
Identification 3 (ChP)		Conforms to Reference Standard	Conforms to Reference Standard

ANALYSIS		SPECIFICATION	TEST RESULT
Microbial Content (NF/ChP/EP)	*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 (NF/JP)		≤ 0.005%	<0.005 %
Optical Rotation, Specific Rotation @ 20°C (NF/ChP/EP/JP)		+197° to +201°	+199°
pH @ 25°C (NF/EP/JP), Acidity (ChP)		4.5 – 6.5	5.6
Related Substances (NF/EP/JP)	Impurity A	≤ 0.5%	<0.10%
	Impurity B	≤ 0.5%	<0.10%
	Unspecified Impurities	≤ 0.2%	0.12%
	Total Impurities	≤ 1.0%	0.12%
	Total Impurities with RRT <1.0	≤ 0.5%	0.12%
	Total Impurities with RRT >1.0	≤ 0.5%	<0.01%
Related Substances (ChP)		≤ 0.5%	0.12%
Residue on Ignition (NF/ChP/JP)		≤ 0.1%	<0.1%
Residual Ethanol		≤ 200 ppm	<95 ppm
Residual Isopropyl Alcohol		≤ 250 ppm	<130 ppm
Residual Methanol		≤ 50 ppm	<25 ppm
Soluble Starch (NF/ChP/EP)		Passes Test	Passes Test
Sulfated Ash (EP)		≤ 0.1%	<0.1%
Sulfate	Sulfate (NF)	≤ 0.0200%	<0.0200%
	Sulfate (ChP)	≤ 0.020%	<0.020%
	Sulfate (EP)	≤ 0.0200%	<0.0200%
	Sulfate (JP)	≤ 0.024%	<0.024%
Water Determination (NF/ChP/EP/JP)		9.0% to 11.0%	9.5%

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0027

SPECIFICATION STATEMENT: When Applicable, the most stringent monograph specification will be referenced as the specification.

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.

RESIDUAL SOLVENTS STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4. Ethanol and Methanol are not used in the manufacturing process.

Prepared by: _____ Date: 12/10/24 Job Title: Senior Quality Manager

Reviewed by: _____ Date: 12/10/24 Job Title: QA Supervisor