

# BIO SPECTRA

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

Effective Date:	22-Jan-2025	22-Jan-2028	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### TREHALOSE, DIHYDRATE

### BIOTECH, MEETS NF, EP, JP, LBLE, GMP

### BIO PHARMA GRADE / TRED-4250

### LOT: TRED-N02-0924-0026

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

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

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Appearance and Color		White to Almost White Crystalline Powder	White Crystalline Powder
Assay, Anhydrous Basis (NF/EP/JP)		98.0 – 101.0 %	99.4 %
Appearance of Solution (EP)		Clear, Colorless	Clear, Colorless
Chloride	Chloride (NF)	$\leq 0.0125$ %	$< 0.0125$ %
	Chloride (EP)	$\leq 0.0125$ %	$< 0.0125$ %
	Chloride (JP)	$\leq 0.018$ %	$< 0.018$ %
Color and Clarity of Solution (NF)	A720	$\leq 0.050$	$< 0.003$
	A420 – A720	$\leq 0.100$	0.014
Dextrin, soluble starch, and sulfite (JP)		Passes Test	Passes Test
Endotoxin (NF/EP)		$\leq 2.4$ EU/g	$< 0.2$ EU/g
Heavy Metals (JP)		$\leq 5$ ppm	$< 5$ ppm
Identification, IR (NF-A/EP-A/JP-3)		Conforms to Reference Standard	Conforms to Reference Standard
Identification B (NF-B/EP-B/JP-1)		Passes Test	Passes Test
Identification C (NF-C/EP-C/JP-2)		Passes Test	Passes Test
Microbial Content (NF/EP)	<i>Escherichia coli</i>	Absent/g	Absent/g
	<i>Salmonella species</i>	Absent/10g	Absent/10g
	TAMC	$\leq 100$ CFU/g	$< 10$ CFU/g

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ANALYSIS		SPECIFICATION	TEST RESULT
	TYMC	$\leq 100$ CFU/g	< 10 CFU/g
Nitrogen Determination (NF/JP)		$\leq 0.005$ %	< 0.005 %
Optical Rotation, Specific Rotation @ 20°C (NF/EP/JP)		+197° to +201°	+199 °
pH @ 25°C (NF/EP/JP)		4.5 – 6.5	5.6
	Impurity A	$\leq 0.5$ %	< 0.10 %
	Impurity B	$\leq 0.5$ %	< 0.10 %
Related Substances (NF/EP/JP)	Unspecified Impurities	$\leq 0.2$ %	0.12 %
	Total Impurities	$\leq 1.0$ %	0.12 %
	Total Impurities with RRT <1.0	$\leq 0.5$ %	0.12 %
	Total Impurities with RRT >1.0	$\leq 0.5$ %	< 0.01 %
Residue on Ignition (NF/JP)		$\leq 0.1$ %	< 0.1 %
Residual Ethanol		$\leq 200$ ppm	< 95 ppm
Residual Isopropyl Alcohol		$\leq 250$ ppm	< 130 ppm
Residual Methanol		$\leq 50$ ppm	< 25 ppm
Soluble Starch (NF/EP)		Passes Test	Passes Test
Sulfated Ash (EP)		$\leq 0.1$ %	< 0.1 %
	Sulfate (NF)	$\leq 0.0200$ %	< 0.0200 %
Sulfate	Sulfate (EP)	$\leq 0.0200$ %	< 0.0200 %
	Sulfate (JP)	$\leq 0.024$ %	< 0.024 %
Water, KF (NF/EP/JP)		9.0 - 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 a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Prepared by: Shil McCall Date: 1/31/25 Job Title: QA Tech III

Reviewed by: Car Albert Date: 1/31/25 Job Title: Senior Quality Manager