

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://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-3252-92

#### (HISTORICAL CODE TE3252-G100)

#### LOT: TRED-0124-00011

$C_{12}H_{22}O_{11} \cdot 2H_2O$  \* F.W. 378.33 g/mol. \* CAS# 6138-23-4  
 Manufacturing Date: 08/13/23    Retest Date: 08/31/25  
 Manufacturing Site: 100 Majestic Way, Bangor PA, 18013  
 Packaging Date: 05/10/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013  
 Meets or Exceeds USP/NF, EP, and JP Specifications

#### NF COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Assay <sup>1</sup>	98.0 - 101.0% <sup>3</sup>	99.3%
Chloride and Sulfate, <i>Chloride</i>	≤ 0.0125%	< 0.0125 %
Color and Clarity of Solution	A720 ≤ 0.050 A420 – A720 ≤ 0.100	0.001 0.011
Endotoxins <sup>2</sup>	≤ 0.3 EU/g <sup>3</sup>	< 0.2 EU/g
Identification A <sup>2</sup>	Conforms to Standard	Conforms to standard
Identification B <sup>2</sup>	Passes Test	Passes Test
Identification C <sup>2</sup>	Passes Test	Passes Test
Microbial Content <sup>2</sup>	<i>Escherichia coli</i>	Absent/g
	<i>Salmonella species</i>	Absent/10g
	TAMC	≤ 50 CFU/g
	TYMC	≤ 20 CFU/g
Nitrogen Determination <sup>2</sup>	≤ 0.005%	< 0.005%
Optical Rotation, Specific Rotation @ 20°C <sup>2</sup>	+197° to +201°	+199°
pH @ 25°C <sup>2</sup>	4.5 - 6.5	5.9
Related Substances <sup>1</sup>	Total Impurities with RRT <1.0	≤ 0.5% 0.11%
	Total Impurities with RRT >1.0	≤ 0.5% <0.01%
Residue on Ignition <sup>2</sup>	≤ 0.1%	<0.1%

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ANALYSIS	SPECIFICATION	TEST RESULT
Soluble Starch <sup>2</sup>	Passes Test	Passes Test
Chloride and Sulfate, <i>Sulfate</i>	≤ 0.0200%	<0.0200%
Water Determination <sup>2</sup>	9.0% to 11.0%	9.5%

## EP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT	
Assay <sup>1</sup>	98.0 – 101.0% <sup>3</sup>	99.3%	
Appearance of Solution	Clear, colorless	Clear, colorless	
Chlorides	≤ 0.0125%	<0.0125%	
Endotoxins <sup>2</sup>	≤ 0.3 EU/g <sup>3</sup>	<0.2 EU/g	
Identification A <sup>2</sup>	Conforms to Standard	Conforms to standard	
Identification B <sup>2</sup>	Passes Test	Passes Test	
Identification C <sup>2</sup>	Passes Test	Passes Test	
Related Substances <sup>1</sup>	Impurity A	≤ 0.5%	<0.10%
	Impurity B	≤ 0.2%	<0.10%
	Unspecified Impurities	≤ 0.2%	0.11%
	Total Impurities	≤ 1.0%	0.11%
Microbial Content <sup>2</sup>	<i>Escherichia coli</i>	Absent/g	Absent/g
	<i>Salmonella species</i>	Absent/10g	Absent/10g
	TAMC	≤ 50 CFU/g	<10 CFU/g
	TYMC	≤ 20 CFU/g	<10 CFU/g
pH @ 25°C <sup>2</sup>	4.5 – 6.5	5.9	
Soluble Starch <sup>2</sup>	Passes Test	Passes Test	
Specific, Optical Rotation @ 20°C <sup>2</sup>	+197° to +201°	+199°	
Sulfated Ash	≤ 0.1%	<0.1%	
Sulfate	≤ 0.0200%	<0.0200%	
Water <sup>2</sup>	9.0% to 11.0%	9.5%	

## JP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Assay <sup>1</sup>	98.0 – 101.0%	99.3%
Chloride	≤ 0.018%	<0.018%
Dextrin, Soluble Starch, Sulfite <sup>2</sup>	Passes Test	Passes Test