

BIOSPECTRA

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

Effective Date:	08-Jul-2022	08-Jul-2025	: Date of Next Review
Prepared By:	Krista Rehrig	Not Applicable	: Supersedes
QA/QC Approval:	Amy Yenko	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF CONFORMANCE

TREHALOSE, DIHYDRATE

BIO EXCIPIENT GRADE / NEW CODE TRED-3252-10

LOT: TRED-0122-00027

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

Manufacturing Date: 06/17/22 Retest Date: 06/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 06/22/22 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	Pending ⁴
Chloride and Sulfate, <i>Chloride</i>	$\leq 0.0125\%$	$\leq 0.0125\%$
Color and Clarity of Solution	A720 ≤ 0.050 A420 – A720 ≤ 0.100	< 0.003 0.013
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	<i>Escherichia coli</i>	Absent/g
	<i>Salmonella species</i>	Absent/10g
	TAMC	≤ 50 CFU/g
	TYMC	≤ 20 CFU/g
Nitrogen Determination ²	$\leq 0.005\%$	0.001 %
Optical Rotation, Specific Rotation @ 20°C ²	+197° to +201°	+199°
pH @ 25°C ²	4.5 - 6.5	5.7 @ 24.2°C
Related Substances ¹	Total Impurities with RRT <1.0	$\leq 0.5\%$
	Total Impurities with RRT >1.0	$\leq 0.5\%$
Residue on Ignition ²	$\leq 0.1\%$	< 0.1%

ANALYSIS	SPECIFICATION	TEST RESULT
Soluble Starch ²	Passes Test	Passes Test
Chloride and Sulfate, <i>Sulfate</i>	≤ 0.0200%	< 0.0200%
Water Determination ²	9.0% to 11.0%	10.1%

EP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Assay ¹	98.0 – 101.0% ³	Pending 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%
	Impurity B	≤ 0.2%
	Unspecified Impurities	≤ 0.2%
	Total Impurities	≤ 1.0%
	<i>Escherichia coli</i>	Absent/g
Microbial Content ²	<i>Salmonella species</i>	Absent/10g
	TAMC	≤ 50 CFU/g
	TYMC	≤ 20 CFU/g
pH @ 25°C ²	4.5 – 6.5	5.7 @ 24.2°C
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%	10.1%

JP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Assay ¹	98.0 – 101.0%	Pending 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	5.7 @ 24.2°C
Residue on Ignition ²	≤ 0.1%	< 0.1%
Related Substances ¹	Total Impurities with RRT <1.0	≤ 0.5%
	Total Impurities with RRT >1.0	≤ 0.5%
Sulfate	≤ 0.024%	< 0.024%
Water ²	9.0% to 11.0%	10.1%

NON-COMPENDIAL ANALYSES

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	White to Off White Crystalline Powder	White to Off White Crystalline Powder
Microbial Content	<i>Staphylococcus aureus</i>	Absent/g
	<i>Pseudomonas aeruginosa</i>	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
	Arsenic (As)	≤50 ppb
	Mercury (Hg)	≤50 ppb
	Nickel (Ni)	≤100 ppb
	Molybdenum (Mo)	≤100 ppb
	Copper (Cu)	≤100 ppb
	Chromium (Cr)	≤100 ppb
	Iron (Fe)	≤100 ppb
	Aluminum (Al)	≤100 ppb
Zinc (Zn)	≤100 ppb	

¹Alternate Validated Method²Analyses are Harmonized³Specifications is more stringent than Compendia Monograph⁴Results are pending completion

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0027

Prepared by: M. Shafiq Date: 07/08/22 Job Title: QA Tech. I

Reviewed by: B. B. Date: 7/8/22 Job Title: QA specialist