

BIO SPECTRA

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

Effective Date:	12-Dec-2019	12-Dec-2022	: Date of Next Review
Prepared By:	Hannah Bernier	18-002600 v.3.1	: Supersedes
QA/QC Approval:	Carissa McCollian	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TREHALOSE, DIHYDRATE

BIO EXCIPIENT GRADE / TE3250 – G100

LOT: TE3250-005-1219

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

Manufacture Date: 2/9/2019 Retest Date: 2/28/2021

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 12/10/2019

Packaging Site: 100 Majestic Way, Bangor PA, 18013

Trehalose, Dihydrate is currently undergoing a stability shelf life study in accordance with BioSpectra's Stability Program. The proposed retest period is 24 months based on information obtained from development, industry review and raw material supply chain. This retest period may be used for material represented by this CoA unless otherwise notified by BioSpectra.

Meets or Exceeds EP/BP, JP and NF Specifications

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	White to Off-White Crystalline Powder	White to Off-White Crystalline Powder
Appearance of Solution (EP)	Clear, Colorless	Clear, Colorless
Assay % w/w	98.0% - 101.0%	99.5 %
	(NF) $\leq 0.0125\%$	$\leq 0.0125\%$
Chloride	(EP) $\leq 0.0125\%$	$\leq 0.0125\%$
	(JP) $< 0.018\%$	$< 0.018\%$
Color and Clarity of Solution	A720 ≤ 0.050	0.002
	A420 – A720 ≤ 0.100	0.016
Dextrin, Soluble Starch, Sulfite	Passes Test	Passes Test
Endotoxins	≤ 2.4 EU/g	< 1.2 EU/g
Heavy Metals (as Pb)	≤ 5 ppm	≤ 5 ppm
Identification A	Conforms to Standard	Conforms to standard
Identification B	Passes Test	Passes Test
Identification C	Passes Test	Passes Test
Identification 1	(JP) Passes Test	Passes Test
Identification 2	(JP) Passes Test	Passes Test
Identification 3	(JP) Passes Test	Passes Test

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