

BIOSPECTRA

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

TREHALOSE, DIHYDRATE

SPECIFICATION SHEET

BIO EXCIPIENT GRADE / TE3250

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

ANALYSIS		SPECIFICATIONS
Appearance		White to off-white crystalline powder
Assay % w/w		98.0% – 101.0%
Chloride		≤ 0.0125%
Clarity of Solution		Clear
Color and Clarity of Solution		A720 – ≤ 0.050 A420 – A720 ≤ 0.100
Color of Solution		Colorless
Endotoxins		≤ 2.4 EU/g
Heavy Metals (as Pb)		≤ 5 ppm
Identification A		Conforms to standard
Identification B		Passes Test
Identification C		Passes Test
Impurities	Maltotriose (Impurity B)	≤ 0.5%
	Total Impurities with RRT <1.0	≤ 0.5%
	Total Impurities with RRT >1.0	≤ 0.5%
	Glucose (Impurity A)	≤ 0.5%
	Any other Impurities	≤ 0.2%
Microbial Content	<i>Escherichia coli</i>	Absent
	<i>Salmonella species</i>	Absent
	TAMC	≤ 100 CFU/g
	TYMC	≤ 100 CFU/g
Nitrogen Content		≤ 0.005%
pH		4.5 – 6.5
Residual Ethanol		≤ 5000 ppm
Residual Methanol		≤ 3000 ppm
Residue on Ignition		≤ 0.1%

ANALYSIS	SPECIFICATIONS
Soluble Starch	Passes Test
Specific Rotation	+197° to +201°
Sulfate	≤ 0.0200%
Sum of Glucose, Maltotriose and Other Impurities	≤ 1.0%
Water (Karl Fischer)	9.0% to 11.0%

DRAFT