

BIOSPECTRA

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

TREHALOSE, DIHYDRATE SPECIFICATION SHEET BIO EXCIPIENT GRADE / TE3250

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

Meets or Exceeds EP/BP, JP and NF Specifications

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

ANALYSIS		SPECIFICATIONS
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%
Sum of Glucose, Maltotriose and Other Impurities		≤ 1.0%
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 @ 25°C		4.5 – 6.5
Residual Ethanol		≤ 5000 ppm
Residual Isopropyl Alcohol		≤ 5000 ppm
Residual Methanol		≤ 3000 ppm
Residue on Ignition		≤ 0.1%
Soluble Starch		Passes Test
Specific Optical Rotation @ 20°C		+197° to +201°
Sulfate	(NF)	≤ 0.0200%
	(EP)	≤ 0.0200%
	(JP)	≤ 0.024%
Water (Karl Fischer)		9.0% to 11.0%