

BIOSPECTRA

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

TRIS SPECIFICATION SHEET BIO EXCIPIENT GRADE / TR3251 NH₂C(CH₂OH)₃ * F.W. 121.14 g/mol. * CAS# 77-86-1

ANALYSIS		SPECIFICATIONS
Absorbance (40%)	290 nm	0.2 a.u. max.
Appearance and Color		White / Crystals
Assay		99.0-101.0%
Bioburden	TAMC	≤ 1000 CFU/g
	TYMC	≤ 100 CFU/g
Chloride		0.01% max.
Endotoxin Concentration		≤ 30 EU/g
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Heavy Metals (Pb)		5 ppm max.
Identification B		Passes Test
Identification C		Passes Test
Identification (IR)		Passes Test
Insoluble Matter		0.005% max.
Karl Fischer Water		2% max.
Loss on Drying		0.6% max.
Melting Range		168 – 172 °C

ANALYSIS		SPECIFICATIONS
Microorganisms	Bile tolerant Gram Neg. Bacteria	Absence in 1g
	<i>Escherichia coli</i>	Absence in 1g
	<i>Pseudomonas aeruginosa</i>	Absence in 1g
	<i>Staphylococcus aureus</i>	Absence in 1g
	<i>Candida albicans</i>	Absence in 1g
	<i>Salmonella sp</i>	Absence in 10g
pH (5%)		10.0 – 11.5
Related Substances (TLC)		1% max.
Residue on Ignition		0.1% max
Trace Metals	Arsenic (As)	5 ppm max.
	Calcium (Ca)	5 ppm max.
	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.
	Magnesium (Mg)	5 ppm max.
	Nickel (Ni)	15 ppm max.