

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

Effective Date:	16-Apr-2021	16-Apr-2024	: Date of Next Review
Prepared By:	Shana Geffken	18-002383 v.3.0	: Supersedes
QA/QC Approval:	Jess DeMaio	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

## CERTIFICATE OF ANALYSIS

### TRIS

BIO EXCIPIENT GRADE / NEW CODE TRIS-3251-01

(HISTORICAL CODE TR3251-K001)

LOT: TRIS-0123-00131

$\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3$  \* F.W. 121.14 g/mol. \* CAS# 77-86-1

Manufacturing Date: 4/14/23 Expiration Date: 4/30/26

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 5/2/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (40%)	290nm	0.2 a.u. max.	<0.2 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0 - 101.0%	100.2%
Bioburden	TAMC	≤ 1000 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
Chloride		0.01% max.	<0.01%
Endotoxin Concentration		≤ 30 EU/g	<1 EU/g
	DNase	None Detected	None Detected
Enzymes	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals (Pb)		5 ppm max.	< 5 ppm
Identification B		Passes Test	Passes Test
Identification C		Passes Test	Passes Test
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		0.005% max	<0.001%
Karl Fischer Water		2% max.	<2%
Loss on Drying		0.6% max.	0.1%
Melting Range		168 – 172°C	170 - 172 °C
Microorganisms	Bile tolerant Gram Neg. Bacteria	Absence in 1g	Absence in 1g
	<i>Escherichia coli</i>	Absence in 1g	Absence in 1g
	<i>Pseudomonas aeruginosa</i>	Absence in 1g	Absence in 1g
	<i>Staphylococcus aureus</i>	Absence in 1g	Absence in 1g

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