

# BIOSPECTRA

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

Effective Date:	28-May-2020	28-May-2023	: Date of Next Review
Prepared By:	Amy Hosein	16-001162 v.4.0	: Supersedes
QA/QC Approval:	Wendy Santay	Amy Yenko	: Management Approval
Reason for Revision:	See Revision History in ensur.		

## CERTIFICATE OF ANALYSIS

### TRIS

### BIO PHARMA GRADE / TR4220-K010

### LOT: TR4220-041-0920

 $\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3$  ^ F.W. 121.14 ^ CAS#: 77-86-1

Manufacturing Date: 7/4/20 Retest Date: 7/31/22

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 9/23/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or exceeds USP Specifications

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance (40%)	290 nm	0.2 a.u. maximum	<0.2 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0-101.0%	99.9%
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals		5 ppm maximum	< 5 ppm
Identification B		Passes Test	Passes Test
Identification C		Passes Test	Passes Test
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		0.005% maximum	<0.001%
Karl Fischer Water		2% maximum	1%
Loss on Drying		1% maximum	<1%
Melting Range		168-172 °C	170 - 171 °C
pH (5%)		10.0-11.5	10.8 @ 24.9°C
Residue on Ignition		0.1% maximum	<0.1%
Trace Metals	Arsenic (As)	5 ppm maximum	< 5 ppm
	Calcium (Ca)	5 ppm maximum	< 5 ppm
	Copper (Cu)	5 ppm maximum	< 5 ppm
	Iron (Fe)	5 ppm maximum	< 5 ppm
	Lead (Pb)	5 ppm maximum	< 5 ppm
	Magnesium (Mg)	5 ppm maximum	< 5 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000496

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a GMP process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

RESIDUAL SOLVENT STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

Prepared by: C. [Signature] Date: 9/24/20 Job Title: QA Supervisor

Reviewed by: Willie [Signature] Date: 09/25/20 Job Title: QI Manager