BIOSPECTRA

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

Effective Date:	2-Jul-2019	2-Jul-2022	: Date of Next Review
Prepared By:	Kyle Snyder	16-001162 v.2.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur.		

TRIS

CERTIFICATE OF ANALYSIS

BIO PHARMA GRADE / TR4220-K010

LOT: TR4220-037-0120

$NH_2C(CH_2OH)_3$ • F.W. 121.14 • CAS#: 77-86-1

Manufacture Date: 11/22/2019 Retest Date: 11/30/2021

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 1/18/2020

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%	100.1 %
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	<0.005 %
Karl Fischer Water		2% maximum	0.1 %
Loss on Drying		1% maximum	0.2 %
Melting Range		168-172 °C	170 - 172 °C
pH (5%)		10.0-11.5	10.6 @ 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 to be used only as the following: IPEC Compliant GMP Manufactured Chemical for use in further manufacturing or as a reagent for laboratory and research. 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.

OVI STATEMENT: Based on the manufacturing process and the controlled handling and storage of this product, there is no potential for any of the residual solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 to be present at the specified limits; furthermore, if tested this product would comply with USP/NF requirements.

Prepared by: _____ / QA Supervisor Date: 1/24/20

Reviewed by: _____ / QA Manager Date: 1/24/20