BIOSPECTRA

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

Effective Date:	27-Jun-2016	27-Jun-2019	: Date of Next Review
Prepared By:	Kirstin Ackerman	16-001164 v1.0	: Supersedes
QA/QC Approval:	Chad Pezoldt	Sarah DeMaio	: Management Approval
Reason for Revision:	See Revision History		

TRIS

CERTIFICATE OF ANALYSIS

BIO EXCIPIENT GRADE / TR3220-K001

LOT: TR3220-006-0118

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

Manufacture Date: 02/20/2017 Retest Date: 02/28/2019

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 01/16/2018

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. 0650 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0 - 101.0%	99.91%
Enzymes	RNase	None Detected	None Detected
	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
Heavy Metals		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	0.0025%
Karl Fischer Water		2.0% max.	0.61%
LOD		1.0% max.	0.3453%
Melting Range		168-172°C	170.7 – 171.7 °C
pH		10.0 – 11.5	10.88 @ 22.3 °C
Residue On Ignition		0.1% max.	<0.0300%
Trace Metals	Arsenic (As)	5 ppm max.	< 5 ppm
	Calcium (Ca)	5 ppm max.	< 5 ppm
	Copper (Cu)	5 ppm max.	< 5 ppm
	Iron (Fe)	5 ppm max.	< 5 ppm
	Lead (Pb)	5 ppm max.	< 5 ppm
	Magnesium (Mg)	5 ppm max.	< 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: ICH Q7 Compliant cGMP Manufactured Excipient for use in further manufacturing. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, 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 or 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: H. Bennett Date: 1/10/18

Reviewed by: Signature Date: 1/17/18