BIOSPECTRA

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

Effective Date:	28-Mar-2018	28-Mar-2021	: Date of Next Review
Prepared By:	Jamie Storm	16-001164 v.2.0	: Supersedes
QA/QC Approval:	Crystal Hamelburg	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur.		

TRIS

CERTIFICATE OF ANALYSIS

BIO EXCIPIENT GRADE / TR3220-G100

LOT: TR3220-009-0718

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

Manufacture Date: 03/15/2018 Retest Date: 03/31/2020

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 07/31/2018

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.	0.0283 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0 - 101.0%	99.85%
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	<0.0010%
Karl Fischer Water		2.0% max.	0.08%
Loss on Drying		1.0% max.	0.1168%
Melting Range		168-172°C	170.5 – 171.6 °C
pH (5%)		10.0 – 11.5	10.846 @ 21.77 °C
Residue On Ignition		0.1% max.	<0.0200%
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.

RESIDUAL SOLVENTS 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: S. Hinton Date: 8/1/18

Reviewed by: H. Beeman Date: 8/1/18