BIOSPECTRA

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

Effective Date:	17-Feb-2017	17-Feb-2020	: Date of Next Review
Prepared By:	Jamie Storm	16-000062 v3.0	: Supersedes
QA/QC Approval:	Nicole Fisher	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

TRIS HCl

CERTIFICATE OF ANALYSIS

BIO EXCIPIENT GRADE / TH3220-K010

LOT: TH3220-059-0918

$NH_2C(CH_2OH)_3 . HCl$ ⅄ F.W. 157.60 g/mol. ⅄ CAS# 1185-53-1

Manufacturing Date: 05/25/2018 Retest Date: 05/31/2020

Packaging Date: 09/11/2018

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance	280 nm	0.06 a.u. max.	0.0062a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.5% min.	99.68%
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Heavy Metals		2 ppm max.	< 2 ppm
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		0.001% max.	<0.0005%
Karl Fischer		0.5% max.	0.35%
Melting Range		150 – 153 °C	150.5-151.6°C
pH (0.5M)		4.0 – 5.0	4.171 @ 23.03°C
pK_a		8.0 – 8.4	8.2
Residue on Ignition		0.1% max.	<0.0200%
Solubility		Passes Test	Passes Test
Trace Elements	Arsenic (As)	1 ppm max.	< 1 ppm
	Calcium (Ca)	1 ppm max.	< 1 ppm
	Copper (Cu)	1 ppm max.	< 1 ppm
	Iron (Fe)	1 ppm max.	< 1 ppm
	Lead (Pb)	1 ppm max.	< 1 ppm
	Magnesium (Mg)	1 ppm max.	< 1 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000042

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: 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: S. Winton Date: 9/13/18

Reviewed by: A. Beaman Date: 9/13/18