BIOSPECTRA

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

Effective Date:	8-Feb-2021	8-Feb-2024	: Date of Next Review
Prepared By:	Amy Hosein	Not Applicable	: Supersedes
QA/QC Approval:	Jaron Hughes	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS HYDROCHLORIDE

BIO EXCIPIENT GRADE / TH3259-K010

LOT: TH3259-001-0221

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

Manufacturing Date: 1/2/21 Retest Date: 1/31/23

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 1/25/21 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm	≤ 0.06 a.u.	0.01 a.u.
	280 nm	≤ 0.06 a.u.	0.01 a.u.
	400 nm	≤ 0.01 a.u.	<0.01 a.u.
Appearance and Color		White / Crystals	Passes Test
Assay, Dried		99.5% min.	99.7%
Bioburden		≤ 100 CFU/g	<10 CFU/g
Endotoxin		≤ 2.5 EU/g	<2.0 EU/g
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
	(Chloride)	Passes Test	Passes Test
Insoluble Matter		0.001% max.	<0.001%
Loss on Drying @ 105°C		≤ 0.5%	0.1%
Melting Range		150 – 152 °C	150-152°C
pH (1% Aqueous Solution)		4.0 – 5.0	4.7
pH (0.5M) @ 25°C		3.5 – 5.0	4.2
pK_a		8.0 – 8.4	8.2
Residue on Ignition		0.1% max.	<0.1%
Solubility 35%		Passes Test	Passes Test
Sulfated Ash (EP)		≤ 300 ppm	<300 ppm

ANALYSIS		SPECIFICATION	TEST RESULT
Trace Metals	Arsenic (As)	1 ppm max.	<1 ppm
	Cadmium (Cd)	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
Water (Karl Fischer)		0.5% max.	0.2 %

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000042

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. 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, 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: Jason Hughes Date: 4/7/21 Job Title: QA Specialist

Reviewed by: [signature] Date: 4/7/21 Job Title: QA Manager