BIOSPECTRA

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

Effective Date:	24-April-2019	24-April-2022	: Date of Next Review
Prepared By:	Jessica DeMaio	Not Applicable	: Supersedes
QA/QC Approval:	Jenna Miller	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur		

TRIS

CERTIFICATE OF ANALYSIS

BIO EXCIPIENT GRADE / TR3254-G500

LOT: TR3254-002-0620

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

Manufacture Date: 5/3/20 Retest Date: 5/31/22

Packaging Date: 6/11/20

Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

USP COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
Appearance and Color		White/Crystals	White/Crystals
Assay		99.0 – 101.0%	100.2%
Endotoxin		≤ 2.5 EU/g	<1.2EU/g
Identification A		Passes Test	Passes Test
Identification B		Passes Test	Passes Test
Identification C		Passes Test	Passes Test
Loss on Drying		≤ 1.0%	0.3%
Melting Range		168-172°C	169-171°C
pH (1 in 20)		10.0 – 11.5	10.7 @ 23.7°C
Residue on Ignition		≤ 0.1%	<0.1%
MicrobialContent	TAMC	≤ 500 CFU/g	<10CFU/g
	TYMC	≤ 200 CFU/g	<10CFU/g

EP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance of Solution	Passes Test	Passes Test
Assay	99.0 – 100.5%	100.2%
Chloride (Cl)	≤ 100 ppm	<100ppm
Identification A	Passes Test	Passes Test
Identification B	168-174°C	169-171°C
Identification C	Passes Test	Passes Test
Iron (Fe)	< 10ppm	<10ppm

EP COMPENDIA		
ANALYSIS	SPECIFICATION	TEST RESULT
Loss on Drying at 105°C	≤ 0.5%	0.3%
pH	10.0 – 11.5	10.7 @ 23.7°C
Related Substances	≤ 1.0%	<1.0%
Sulfated Ash	≤ 0.1%	<0.1%

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000496

RESIDUAL SOLVENTS STATEMENT: 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.

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured non-Sterile Excipient for use in further Manufacturing. The material represented by this Certificate of Analysis is not suitable to be used as a Sterile or Injectable Excipient, Active Pharmaceutical Ingredient, Drug Product or Household Item.

Prepared by: _____ / QA Supervisor Date: 6/11/20

Reviewed by: _____ / QA Manager Date: 06/11/20