BIOSPECTRA

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

Effective Date:	9-Apr-2019	9-Apr-2022	: Date of Next Review
Prepared By:	Jessica DeMaio	19-002817 v.2.0	: Supersedes
QA/QC Approval:	Jenna Miller	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

TRIS

CERTIFICATE OF ANALYSIS

BIO EXCIPIENT GRADE / TR3252-K050

LOT: TR3252-001-0519

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

Manufacture Date: 4/4/2019 Retest Date: 4/30/2021

Packaging Date: 5/4/2019

Packaging Site: 100 Majestic Way, Bangor PA, 18013

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%	100.00%
Endotoxin		≤ 2.5 EU/g	<1.3EU/g
Identification A		Passes Test	Passes Test
Identification B		Passes Test	Passes Test
Identification C		Passes Test	Passes Test
Loss on Drying		≤1.0%	0.0818%
Melting Range		168-172°C	170.1-171.3°C
pH (1 in 20)		10.0 – 11.5	10.91 @ 23.0°C
Residue on Ignition		≤0.1%	<0.0300%
Microbial Content	TAMC	≤500 CFU/g	<10CFU/g
	TYMC	≤200 CFU/g	<10CFU/g
	Total Bioburden	≤500 CFU/g	<500CFU/g

EP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance of Solution	Passes Test	Passes Test
Assay	99.0 – 100.5%	100.00%
Chloride (Cl)	≤100 ppm	<100ppm
Identification A	Passes Test	Passes Test
Identification B	168-174°C	170.1-171.3°C
Identification C	Passes Test	Passes Test

EP COMPENDIA		
ANALYSIS	SPECIFICATION	TEST RESULT
Iron (Fe)	≤ 10ppm	<10ppm
Loss on Drying at 105°C	≤ 0.5%	0.0818%
pH	10.0 – 11.5	10.91 @ 23.0°C
Related Substances	≤1.0%	<1.0%
Sulfated Ash	≤0.1%	<0.0300%

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.

FREE FLOWING MATERIAL STATEMENT: This material was manufactured utilizing multiple proprietary purification, drying and packaging processes to increase the free-flowing nature of the product in the final package. The final packaging configuration is also designed to help maintain those characteristics.

TRUSCAN STATEMENT: Identification A (EP) is the alternate method for Identification by TruScan to confirm the identity of this product.

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: H. Bennett Date: 5/15/19

Reviewed by: [signature] Date: 5/15/19