BIOSPECTRA

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

Effective Date:	20-Oct-2020	20-Oct-2023	: Date of Next Review
Prepared By:	Amy Yencho	19-002851 v.2.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

CERTIFICATE OF ANALYSIS

TRIS, USP/EP

BIO EXCIPIENT GRADE / TR3254-K025

LOT: TR3254-003-0720

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

Manufacture Date: 7/17/20 Retest Date: 7/31/22

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg PA, 18360

Packaging Date: 7/27/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP and EP Specifications

USP COMPENDIA

ANALYSIS		SPECIFICATION	TEST RESULT
Appearance and Color		White/Crystals	White/Crystals
Assay		99.0 – 101.0%	99.7%
Endotoxin		≤ 2.5 EU/g	<1.0EU/g
Identification A		Passes Test	Passes Test
Identification B		Passes Test	Passes Test
Identification C		Passes Test	Passes Test
Loss on Drying		≤ 1.0%	0.1%
Melting Range		168-172°C	170-172°C
pH (1 in 20)		10.0 – 11.5	10.8
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%	99.7%
Chloride (Cl)	≤ 100 ppm	<100ppm
Identification A	Passes Test	Passes Test
Identification B	168-174°C	170-172°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%	0.1%
pH	10.0 – 11.5	10.8
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 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.

Prepared by: _____ Date: 10/20/20 Job Title: QA Supervisor

Reviewed by: _____ Date: 10/20/20 Job Title: Exec. Director of QC