BIOSPECTRA

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

Effective Date:	24-Apr-2020	24-Apr-2023	: Date of Next Review
Prepared By:	Kyle Snyder	19-002973 v.5.1	: Supersedes
QA/QC Approval:	Carissa McCollian	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE / TR3255-K012

LOT: TR3255-010-0520

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

Manufacturing Date: 5/3/2020 Retest Date: 5/31/2022

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 5/27/2020 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP, EP and JPC Specifications

USP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	White / Crystals	White / Crystals
Assay (Dried Basis)	99.0-101.0%	100.2%
Identification A	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
Identification C	Passes Test	Passes Test
Loss on Drying	1.0% max.	0.3%
Melting Range	168-172°C	169 - 171 °C
pH (1 in 20)	10.0 – 11.5	10.7
Residue on Ignition	0.1% max.	<0.1%

EP COMPENDIA

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance of Solution	Passes Test	Passes Test
Assay (Dried Basis)	99.0-100.5%	100.2%
Chloride (Cl)	≤ 100 ppm	<100 ppm
Identification A	Passes Test	Passes Test
Identification B (Melting Range)	168-172°C	169 - 171 °C
Identification C	Passes Test	Passes Test
Identification D	Passes Test	Passes Test
Iron (Fe)	10 ppm max.	<10 ppm
Loss on Drying @105°C	0.5% max.	0.3%
pH (5%)	10.0-11.5	10.7
Related Substances	≤ 1.0%	<1.0%
Sulfated Ash	0.1% max.	<0.1%

JPC ANALYSIS

ANALYSIS	SPECIFICATION	TEST RESULT
Arsenic (As)	1.6 ppm max.	≤ 1.6ppm
Assay (Dried Basis)	99.0-101.0%	100.2%
Clarity and Color of Solution	Passes Test	Passes Test
Heavy Metals	8 ppm max.	≤ 8ppm
Identification A	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
Loss on Drying	0.5% max.	0.3%
Melting Point	168-172°C	169 - 171 °C
pH	10.3 – 10.7	10.4
Residue on Ignition	0.1% max.	<0.1%

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	260nm	0.06 a.u. max	<0.06 a.u.
	280nm	0.06 a.u. max	<0.06 a.u.
	430nm	0.01 a.u. max	<0.01 a.u.
Absorbance (10%)	260nm	0.03 a.u. max.	0.01 a.u.
	280nm	0.02 a.u. max.	0.01 a.u.
	430nm	0.004 a.u. max.	<0.003 a.u.
Absorbance (40%)	290nm	0.2 a.u. max.	<0.2 a.u.
APHA Color, 20% Solution		20 APHA max.	<20
Assay (Dried Basis)		99.9% min	100.2%
Endotoxins		≤ 2.5 EU/g	<1.2 EU/g
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals (As Pb)		1 ppm max.	≤ 1 ppm
Insoluble Matter		0.005% max.	<0.005%
Karl Fischer Water		2.0% max.	0.1%
Loss on Drying		0.3% max.	0.3%
Microbial Content	TAMC	≤ 100 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
Related Substances		0.1% max.	<0.1%
Residue on Ignition		0.05% max.	<0.05%
Trace Metals	Arsenic (As)	1.6 ppm max.	≤ 1.6 ppm
	Calcium (Ca)	5 ppm max.	≤ 5ppm
	Copper (Cu)	5 ppm max.	≤ 5ppm
	Iron (Fe)	1 ppm max.	≤ 1ppm
	Lead (Pb)	1 ppm max.	≤ 1ppm
	Magnesium (Mg)	5 ppm max.	≤ 5ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000496

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: _____ Date: 5/29/20 Job Title: QA Supervisor

Reviewed by: _____ Date: 05/29/20 Job Title: QA Manager