BIOSPECTRA

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

Effective Date:	24-Jul-2020	24-Jul-2023	: Date of Next Review
Prepared By:	Amy Hosein	19-002973 v.7.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE / TR3255-G500

LOT: TR3255-012-0820

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

Manufacturing Date: 7/14/20 Retest Date: 7/31/22

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 8/6/20 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, crystalline powder to needle-like crystals	White, crystalline powder to needle-like crystals
Assay (Dried Basis)	99.0-101.0%	99.7%
Identification A	Passes Test	Passes Test
Identification B	Passes Test	Passes Test
Identification C	Passes Test	Passes Test
Loss on Drying	1.0% max.	0.1%
Melting Range	168-172°C	170 - 172 °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%	99.7%
Chloride (Cl)	≤ 100 ppm	<100 ppm
Identification A	Passes Test	Passes Test
Identification B (Melting Range)	168-172°C	170 - 172 °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.	0.1%
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%	99.7%
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.	0.1%
Melting Point	168-172°C	170 - 172 °C
pH	10.3 – 10.7	10.5
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.	0.001 a.u.
Absorbance (40%)	290nm	0.2 a.u. max.	<0.2 a.u.
APHA Color, 20% Solution		20 APHA max.	<20 APHA
Assay (Ultrapure, Dried Basis)		99.9% min	100.3%
Endotoxins		≤ 2.5 EU/g	<1.0 EU/g
Enzymes	DNase	None	None
	Protease	None	None
	RNase	None	None
Heavy Metals (As Pb)		1 ppm max.	≤ 1 ppm
Insoluble Matter		0.005% max.	<0.002%
Karl Fischer Water		1.0% max.	0.1%
Loss on Drying		0.3% max.	0.1%
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.	<0.03%
Trace Metals	Arsenic (As)	< 1.6 ppm	< 1.6 ppm
	Calcium (Ca)	< 1 ppm	< 1ppm
	Copper (Cu)	< 1 ppm	<1ppm
	Iron (Fe)	< 1 ppm	< 1ppm
	Lead (Pb)	< 1 ppm	< 1ppm

	ANALYSIS	SPECIFICATION	TEST RESULT
Trace Metals	Magnesium (Mg)	< 5 ppm	< 5ppm
	Manganese (Mn)	< 1 ppm	< 1ppm
	Zinc (Zn)	< 1 ppm	< 1ppm

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: 8/25/20 Job Title: QA Supervisor

Reviewed by: _____ Date: 08/25/20 Job Title: QA Manager