BIOSPECTRA

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

Effective Date:	05-Apr-2024		05-Apr-2027	: Date of Next Review
Prepared By:	Hannah Kuchmas		BSI-COA-0091 v.4.1	: Supersedes
QA/QC Approval:	Taylor Yurick		Jessica DeMaio	: Management Approval
Reason for Revision:	See Revision History in MasterControl.			

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE / TRIS-3251-95

LOT: TRIS-0123-00158

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

Manufacturing Date: 04/14/23 Expiration Date: 04/30/26

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 04/26/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	260nm	≤ 0.06 a.u.	0.01 a.u.
	280nm	≤ 0.06 a.u.	<0.06 a.u.
	430nm	≤ 0.01 a.u.	<0.01 a.u.
Absorbance (10%)	260nm	≤ 0.03 a.u.	0.01 a.u.
	280nm	≤ 0.02 a.u.	<0.02 a.u.
	430nm	≤ 0.004 a.u.	<0.004 a.u.
Absorbance (40%)	290nm	≤ 0.2 a.u.	<0.2 a.u.
APHA Color, 20% Solution		≤ 20 APHA	< 20 APHA
Appearance and Color		White/Crystals	Passes Test
Appearance of Solution (EP)		Passes Test	Passes Test
Assay (Dried Basis) (USP/EP/ChP/JPC)		99.0 – 100.5%	100.2%
Assay (Ultrapure, Dried Basis)		≥ 99.9%	100.0 %
Chloride (ChP/EP)		≤ 100 ppm	<100 ppm
Clarity and Color of Solution (ChP/JPC)		Passes Test	Passes Test
Endotoxins		≤ 2.5 EU/g	<1.0 EU/g
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals (as Pb) (ChP/JPC)		≤ 1 ppm	<0.30 ppm
Identification IR (USP-A/ChP-3/EP-C)		Passes Test	Passes Test
Identification A (JPC)		Passes Test	Passes Test
Identification B (USP/ChP-1)		Passes Test	Passes Test
Identification B (JPC)		Passes Test	Passes Test
Identification C (USP)		Passes Test	Passes Test
Identification D (EP/ChP-2)		Passes Test	Passes Test
Insoluble Matter		≤ 0.005%	0.001%
Karl Fischer Water		≤ 1.0%	0.1%

ANALYSIS		SPECIFICATION	TEST RESULT
Loss on Drying (USP/ChP/EP/JPC)		≤ 0.3%	0.1%
Melting Range (USP/ChP/IDB-EP/JPC)		168 – 172°C	170 - 172 °C
Methanol		≤ 3000 ppm	<300 ppm
Microbial Content	TAMC	≤ 100 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
	Bile tolerant Gram Neg. Bacteria	Absence in 1g	Absence in 1g
	Escherichia coli	Absence in 1g	Absence in 1g
	Pseudomonas aeruginosa	Absence in 1g	Absence in 1g
	Staphylococcus aureus	Absence in 1g	Absence in 1g
	Candida albicans	Absence in 1g	Absence in 1g
	Salmonella sp	Absence in 10g	Absence in 10g
pH (5%) (USP/IDA-EP/ChP)		10.0 – 11.5	10.8
pH (1 in 100) (JPC)		10.3 – 10.7	10.4
Related Substances (ChP/EP)		≤ 0.1%	0.1%
Residue on Ignition/Sulfated Ash (USP/ChP/EP/JPC)		≤ 0.05%	<0.02%
Trace Metals	Arsenic (As)	≤ 1.6 ppm	<0.45ppm
	Calcium (Ca)	≤ 1 ppm	<0.60ppm
	Copper (Cu)	≤ 1 ppm	<0.15 ppm
	Iron (Fe)	≤ 1 ppm	<0.30 ppm
	Lead (Pb)	≤ 1 ppm	<0.30 ppm
	Magnesium (Mg)	≤ 5 ppm	<0.60 ppm
	Manganese (Mn)	≤ 1 ppm	<0.60 ppm
	Nickel (Ni)	≤ 15 ppm	<0.75 ppm
	Zinc (Zn)	≤ 1 ppm	<0.60 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0007

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.

OVI 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.

Prepared by: Zaira Ragin Date: 5/1/24 Job Title: QA Tech I

Reviewed by: Jason Bryan Date: 5/1/24 Job Title: QA Supervisor