BIOSPECTRA

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

Effective Date:	22-May-2025	22-May-2028	: Date of Next Review
Prepared By:	Amy Yencho	BSI-COA-0124 v.4.1	: Supersedes
QA/QC Approval:	Hannah Kuchmas	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE TRIS-3252

LOT: TRIS-S01-1025-0213

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

Manufacturing Date: 10/18/25 Expiration Date: 10/31/28

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging 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%	100.0%
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	171-172°C
pH (1 in 20)		10.0 – 11.5	10.8 @ 23.4°C
Residue on Ignition		≤0.1%	< 0.1%
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%	100.0%
Chloride (Cl)	≤100 ppm	< 100ppm
Identification A	Passes Test	Passes Test
Identification B	168-174°C	171-172°C
Identification C	Passes Test	Passes Test

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EP COMPENDIA		
ANALYSIS	SPECIFICATION	TEST RESULT
Iron (Fe)	≤ 10ppm	< 0.30ppm
Loss on Drying at 105°C	≤ 0.5%	0.1%
pH	10.0 – 11.5	10.8 @ 23.4°C
Related Substances	≤1.0%	< 0.03%
Sulfated Ash	≤0.1%	< 0.1%

ADDITIONAL ANALYSES			
ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (0.2M)	260nm	≤0.06 a.u.	< 0.06 a.u.
	280nm	≤0.06 a.u.	< 0.06 a.u.

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0007

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.

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 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: Anil McCall Date: 11/7/25 Job Title: QA Tech III

Reviewed by: Joan Hughes Date: 11/7/25 Job Title: QA Supervisor

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