BIOSPECTRA

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

Effective Date:	2-Jan-2024	2-Jan-2027	: Date of Next Review
Prepared By:	Amy Yencho	BSI-COA-0026 v.5.1	: Supersedes
QA/QC Approval:	Carissa Albert	Wayne Talamonti	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

TRIS

BIO EXCIPIENT GRADE / NEW CODE TRIS-3220-92

(HISTORICAL CODE TR3220-G100)

LOT: TRIS-0124-00061

$NH_2C(CH_2OH)_3$ ⅄ 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: 04/30/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (40%)	290nm	0.2 a.u. max.	<0.2 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0 - 101.0%	100.2%
Chloride		≤ 100 ppm	< 100 ppm
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals		5 ppm max.	< 0.30 ppm
Identification B		Passes Test	Passes Test
Identification C		Passes Test	Passes Test
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		0.005% max	0.001%
Karl Fischer Water		2.0% max.	0.1%
Loss on Drying		1.0% max.	0.1%
Melting Range		168-172°C	170 - 172°C
pH (5%)		10.0 – 11.5	10.8
Residue on Ignition		0.1% max.	<0.1%
Trace Metals	Arsenic (As)	5 ppm max.	<0.45 ppm
	Calcium (Ca)	5 ppm max.	<0.60 ppm
	Copper (Cu)	5 ppm max.	<0.15 ppm
	Iron (Fe)	5 ppm max.	<0.30 ppm
	Lead (Pb)	5 ppm max.	<0.30 ppm
	Magnesium (Mg)	5 ppm max.	<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.

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.

Prepared by: Zaira Ragin Date: 5/3/24 Job Title: QA Tech I

Reviewed by: [signature] Date: 5/3/24 Job Title: QA Supervisor