BIOSPECTRA

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

Effective Date:	14-Apr-2025	14-Apr-2028	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0001 v.6.1	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

TRIS HCl

BIO EXCIPIENT GRADE / THCL-3220

LOT: THCL-S03-0726-0049

$NH_2C(CH_2OH)_3 \cdot HCl$ ✦ F.W. 157.60 g/mol. ✦ CAS# 1185-53-1

Manufacturing Date: 07/09/26 Expiration Date: 07/31/29

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	280 nm	0.06 a.u. max.	< 0.06 a.u.
Appearance and Color		White / Crystals	Passes Test
Assay		99.5% min.	99.6%
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Heavy Metals		2 ppm max.	< 2 ppm
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		0.001% max.	< 0.001%
Karl Fischer		0.5% max.	0.4%
Melting Range		150 – 153 °C	150-152°C
pH (0.5M)		4.0 – 5.0	4.2 @ 23.4°C
pK_a		8.0 – 8.4	8.2
Residue on Ignition		0.1% max.	< 0.1%
Solubility 35%		Passes Test	Passes Test
Trace Metals	Arsenic (As)	1 ppm max.	< 1 ppm
	Calcium (Ca)	1 ppm max.	< 1 ppm
	Copper (Cu)	1 ppm max.	< 1 ppm
	Iron (Fe)	1 ppm max.	< 1 ppm
	Lead (Pb)	1 ppm max.	< 1 ppm
	Magnesium (Mg)	1 ppm max.	< 1 ppm

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0002

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: 11/24/26 Job Title: QA Tech III

Reviewed by: _____ Date: 11/24/26 Job Title: Senior Quality Manager

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