BIOSPECTRA

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

Effective Date:	06-Feb-2025	06-Feb-2028	: Date of Next Review
Prepared By:	Taylor Yurick	BSI-COA-0135 v.11.1	: Supersedes
QA/QC Approval:	Jaron Hughes	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

TRIS HYDROCHLORIDE

BIO EXCIPIENT GRADE / THCL-3250

LOT: THCL-S03-0926-0068

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

Manufacturing Date: 10/02/26 Expiration Date: 10/31/29

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm	≤ 0.06 a.u.	< 0.06 a.u.
	280 nm	≤ 0.06 a.u.	< 0.06 a.u.
	400 nm	≤ 0.01 a.u.	< 0.01 a.u.
Appearance		Passes Test	Passes Test
Assay, Dried		≥ 99.0%	99.6%
Bioburden		≤ 100 CFU/g	< 100 CFU/g
Endotoxin		≤ 2.5 EU/g	< 1.9 EU/g
Identification	(IR)	Passes Test	Passes Test
	(Chloride)	Passes Test	Passes Test
Loss on Drying @ 105°C		≤ 0.5%	0.1%
Melting Range		147 – 152 °C	150-151°C
pH	(1% Aqueous Solution)	4.0 – 5.0	4.7
	(0.5M) @ 25°C	3.5 – 5.0	4.3
Trace Elements	Arsenic (As)	≤ 10 ppm	< 0.45 ppm
	Calcium (Ca)	≤ 10 ppm	< 0.60 ppm
	Copper (Cu)	≤ 10 ppm	< 0.15 ppm
	Iron (Fe)	≤ 10 ppm	< 0.30 ppm
	Lead (Pb)	≤ 10 ppm	< 0.30 ppm
	Magnesium (Mg)	≤ 10 ppm	< 0.60 ppm
Water		≤ 2.0%	0.2%

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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.

ANIMAL ORIGIN: Tris Hydrochloride manufactured at BioSpectra is not derived from and does not come in contact with animal parts, products and/or byproducts.

Prepared by: [signature] Date: 11/2/26 Job Title: QA Tech III

Reviewed by: [signature] Date: 11/2/26 Job Title: QA Supervisor

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