

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-0086 v.4.3	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

TRIS HYDROCHLORIDE

BIO EXCIPIENT GRADE / THCL-3203

LOT: THCL-S03-0825-0126

 $\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3 \cdot \text{HCl}$ * F.W. 157.60 g/mol. * CAS# 1185-53-1

Manufacturing Date: 08/22/25 Expiration Date: 08/31/28

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.
Appearance and Color	White / Crystals	< 0.06 a.u.
Assay, Dried	$\geq 99.5\%$	White / Crystals
Bioburden	TAMC	$\geq 99.5\%$
	TYMC	≤ 1000 CFU/g
Endotoxin	≤ 2.5 EU/g	< 10 CFU/g
Identification (IR)	Passes Test	< 10 CFU/g
Insoluble Matter	$\leq 0.001\%$	< 1.9 EU/g
Karl Fischer	$\leq 0.5\%$	Passes Test
Melting Range	150 – 153 °C	< 0.001%
pH (0.5M)	4.0 – 5.0	0.3%
pK _a	8.0 – 8.4	151-152°C
Residue on Ignition	$\leq 0.1\%$	4.2
Solubility (1M)	Passes Test	8.2

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: Shirley McCall Date: 12/17/25 Job Title: QA Tech III

Reviewed by: Jason Bingham Date: 12/17/25 Job Title: QA Supervisor