



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

Effective Date:	13-Jul-2023	13-Jul-2026	: Date of Next Review
Prepared By:	Amy Yenko	BSI-COA-0086 v.4.1	: Supersedes
QA/QC Approval:	Carissa Albert	James Piper	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS
TRIS HYDROCHLORIDE
BIO EXCIPIENT GRADE / NEW CODE THCL-3203-10
(HISTORICAL CODE TH3203-K010)
LOT: THCL-S03-1124-0103

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

Manufacturing Date: 08/22/24 Expiration Date: 08/31/27

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 11/12/24 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	280 nm	≤ 0.06 a.u.	< 0.06 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay, Dried		$\geq 99.5\%$	99.7%
Bioburden	TAMC	≤ 1000 CFU/g	< 10 CFU/g
	TYMC	≤ 100 CFU/g	< 10 CFU/g
Endotoxin		≤ 2.5 EU/g	< 1.9 EU/g
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		$\leq 0.001\%$	$< 0.001\%$
Karl Fischer		$\leq 0.5\%$	0.4%
Melting Range		150 – 153 °C	150-151°C
pH (0.5M)		4.0 – 5.0	4.2
pK _a		8.0 – 8.4	8.1
Residue on Ignition		$\leq 0.1\%$	$< 0.1\%$
Solubility (1M)		Passes Test	Passes Test

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: David McCall Date: 11/20/24 Job Title: QA Tech III

Reviewed by: John Bingham Date: 11/20/24 Job Title: QA Supervisor