

# BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

Effective Date:	8-Aug-2022	8-Aug-2025	: Date of Next Review
Prepared By:	Amy Hosein	BSI-COA-0135 v.11.0	: Supersedes
QA/QC Approval:	Brett Brink	Carissa McCollan	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### TRIS HYDROCHLORIDE

### BIO EXCIPIENT GRADE / NEW CODE THCL-3250-58

### (HISTORICAL CODE TH3250-K050)

### LOT: THCL-0223-00205

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

Manufacturing Date: 7/11/23      Retest Date: 7/31/25

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 7/15/23 Packaging Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

ANALYSIS	SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm	$\leq 0.06$ a.u.
	280 nm	$\leq 0.06$ a.u.
	400 nm	$\leq 0.01$ a.u.
Appearance	Passes Test	Passes Test
Assay, Dried	$\geq 99.0\%$	99.4%
Bioburden	$\leq 100$ CFU/g	$<100$ CFU/g
Endotoxin	$\leq 2.5$ EU/g	$<1.9$ EU/g
Identification	(IR)	Passes Test
	(Chloride)	Passes Test
Loss on Drying @ 105°C	$\leq 0.5\%$	0.1%
Melting Range	147 – 152 °C	151-152°C
pH	(1% Aqueous Solution)	4.0 – 5.0
	(0.5M) @ 25°C	3.5 – 5.0
Trace Elements	Arsenic (As)	$\leq 10$ ppm
	Calcium (Ca)	$\leq 10$ ppm
	Copper (Cu)	$\leq 10$ ppm
	Iron (Fe)	$\leq 10$ ppm
	Lead (Pb)	$\leq 10$ ppm
	Magnesium (Mg)	$\leq 10$ ppm
Water	$\leq 2.0\%$	0.4%

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: Taylor Yunker Date: 8/21/23 Job Title: QA Tech II

Reviewed by: [Signature] Date: 8/21/23 Job Title: QA Manager