

BIO SPECTRA

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

Effective Date:	16-Apr-2021	16-Apr-2024	: Date of Next Review
Prepared By:	Shana Geffken	17-002230 v.3.0	: Supersedes
QA/QC Approval:	Jess DeMaio	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS HYDROCHLORIDE

BIO EXCIPIENT GRADE / NEW CODE THCL-3203-05

(HISTORICAL CODE TH3203-K005)

LOT: THCL-0122-00010

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

Manufacturing Date: 9/27/21 Retest Date: 9/30/23

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 1/6/22 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	280 nm	0.06 a.u. max.	0.01 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay, Dried		99.5% min.	99.6%
Bioburden	TAMC	≤ 1000 CFU/g	<10 CFU/g
	TYMC	≤ 100 CFU/g	<10 CFU/g
Endotoxin		≤ 2.5 EU/g	<1.9 EU/g
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.	0.5%
Melting Range		150 – 153 °C	150-152°C
pH (0.5M)		4.0 – 5.0	4.3 @ 23.2°C
pK _a		8.0 – 8.4	8.1
Residue on Ignition		0.1% max.	<0.1%
Solubility (1M)		Passes Test	Passes Test
Trace Elements	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: 16-000042

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: John Hargan Date: 1/10/22 Job Title: QA Specialist

Reviewed by: Cur Date: 1/10/22 Job Title: QA Manager