

# BIOSPECTRA

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

Effective Date:	23-Mar-2020	23-Mar-2023	: Date of Next Review
Prepared By:	Kyle Snyder	19-002949 v.6.0	: Supersedes
QA/QC Approval:	Hannah Bernier	Amy Yenko	: Management Approval
Reason for Revision:	See Revision History in ensur.		

## CERTIFICATE OF ANALYSIS

### TRIS HYDROCHLORIDE

### BIO EXCIPIENT GRADE / TH3250-SAMPLE CoA

### LOT: TH3250-019-0320

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

Manufacturing Date: 11/27/2019 Retest Date: 11/30/2021

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: Sample CoA

Packaging Date: Sample CoA

ANALYSIS	SPECIFICATION	TEST RESULT	
	260 nm	≤ 0.06 a.u.	0.01a.u.
Absorbance (1M)	280 nm	≤ 0.06 a.u.	0.01a.u.
	400 nm	≤ 0.01 a.u.	<0.01a.u.
Appearance	Passes Test	Passes Test	
Assay, Dried	≥ 99.0%	99.9%	
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%	0.2%	
Melting Range	147 – 152 °C	151-152°C	
pH	(1% Aqueous Solution) 4.0 – 5.0	4.7	
	(0.5M) @ 25°C 3.5 – 5.0	4.2	
Trace Elements	Arsenic (As) ≤ 10 ppm	≤ 10 ppm	
	Calcium (Ca) ≤ 10 ppm	≤ 10 ppm	
	Copper (Cu) ≤ 10 ppm	≤ 10 ppm	
	Iron (Fe) ≤ 10 ppm	≤ 10 ppm	
	Lead (Pb) ≤ 10 ppm	≤ 10 ppm	
	Magnesium (Mg) ≤ 10 ppm	≤ 10 ppm	
Water	≤ 2.0%	0.2%	

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000042

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INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured Excipient for use in further Manufacturing. 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: C. [Signature] Date: 3/24/20 Job Title: QA Supervisor

Reviewed by: H. [Signature] Date: 3/24/20 Job Title: QA Manager