

BIOSPECTRA

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

Effective Date:	9-Apr-2020	9-Apr-2023	: Date of Next Review
Prepared By:	Kyle Snyder	19-002949 v.7.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Hannah Bernier	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS HYDROCHLORIDE

BIO EXCIPIENT GRADE / TH3250-K012

LOT: TH3250-021-0520

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

Manufacturing Date: 5/8/2020 Retest Date: 5/31/2022

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 5/21/2020 Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
	260 nm	≤ 0.06 a.u.	<0.06a.u.
Absorbance (1M)	280 nm	≤ 0.06 a.u.	<0.06a.u.
	400 nm	≤ 0.01 a.u.	<0.01a.u.
Appearance	Passes Test	Passes Test	
Assay, Dried	≥ 99.0%	99.8%	
Bioburden	≤ 100 CFU/g	Conforms	
Endotoxin	≤ 2.5 EU/g	≤2.0 EU/g	
Identification	(IR) Passes Test	Passes Test	
	(Chloride) Passes Test	Passes Test	
Loss on Drying @ 105°C	≤ 0.5%	0.1%	
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%	0.3%	

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 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: Cc Date: 5/29/20 Job Title: QA Supervisor

Reviewed by: Wendy Patez Date: 05/29/20 Job Title: QA Manager