

BIOSPECTRA

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

Effective Date:	15-Jul-2020	15-Jul-2023	: Date of Next Review
Prepared By:	Amy Hosein	19-002949 v.9.0	: Supersedes
QA/QC Approval:	Carissa McCollian	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS HYDROCHLORIDE

BIO EXCIPIENT GRADE / TH3250-G100

LOT: TH3250-022-0720

NH₂C(CH₂OH)₃.HCl ^ F.W. 157.60 g/mol. ^ CAS# 1185-53-1

Manufacturing Date: 5/8/20 Retest Date: 5/31/22

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Date: 7/18/20 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	≤100 CFU/g	
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
	Arsenic (As)	≤ 10 ppm	≤ 10 ppm
	Calcium (Ca)	≤ 10 ppm	≤ 10 ppm
Trace Elements	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

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: Cecilia Date: 7/20/20 Job Title: QA Supervisor

Reviewed by: Amy Miller Date: 7/20/20 Job Title: QC Compliance Supervisor