

# BIOSPECTRA

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

Effective Date:	05-Feb-2025	05-Feb-2028	: Date of Next Review
Prepared By:	Taylor Yurick	BSI-COA-0225 v.3.1	: Supersedes
QA/QC Approval:	Jessica DeMaio	Hannah Kuchmas	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### TRIS HYDROCHLORIDE

### BIO EXCIPIENT GRADE / THCL-3259

### LOT: THCL-S03-0225-0013

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

Manufacturing Date: 03/29/24 Expiration Date: 03/31/27

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance (1M)	260 nm	≤ 0.06 a.u.	0.01 a.u.
	280 nm	≤ 0.06 a.u.	0.01 a.u.
	400 nm	≤ 0.01 a.u.	< 0.01 a.u.
Appearance and Color	White / Crystals	Passes Test	
Assay, Dried	99.5 – 101.0%	99.6%	
Bioburden	≤ 100 CFU/g	< 100 CFU/g	
Endotoxin	≤ 2.5 EU/g	< 1.9 EU/g	
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Heavy Metals	2 ppm max.	< 2 ppm	
Identification	(IR)	Passes Test	Passes Test
	(Chloride)	Passes Test	Passes Test
Insoluble Matter	0.001% max.	< 0.001%	
Loss on Drying @ 105°C	≤ 0.5%	0.1%	
Melting Range	150 – 152 °C	151-152°C	
pH (1% Aqueous Solution)	4.0 – 5.0	4.7	
pH (0.5M) @ 25°C	3.5 – 5.0	4.4	
pK <sub>a</sub>	8.0 – 8.4	8.3	
Residue on Ignition	0.1% max.	< 0.1%	

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ANALYSIS	SPECIFICATION	TEST RESULT
Solubility 35%	Passes Test	Passes Test
Sulfated Ash (EP)	≤ 300 ppm	< 100 ppm
Arsenic (As)	1 ppm max.	< 0.45 ppm
Cadmium (Cd)	1 ppm max.	< 0.30 ppm
Calcium (Ca)	1 ppm max.	< 0.60 ppm
Trace Metals		
Copper (Cu)	1 ppm max.	< 0.15 ppm
Iron (Fe)	1 ppm max.	< 0.30 ppm
Lead (Pb)	1 ppm max.	< 0.30 ppm
Magnesium (Mg)	1 ppm max.	< 0.60 ppm
Water (Karl Fischer)	0.5% max.	0.3 %

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.

Prepared by: David McCall Date: 2/13/25 Job Title: QA Tech III

Reviewed by: John Boylan Date: 2/13/25 Job Title: QA Supervisor