

# BIOSPECTRA

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

Effective Date:	23-Jan-2025	23-Jan-2028	: Date of Next Review
Prepared By:	Amy Yenko	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

## CERTIFICATE OF ANALYSIS

### TRIS HYDROCHLORIDE

### BIOTECH, HIGH ASSAY, LBLE, GMP, PREMIUM REAGENT

### BIO PHARMA GRADE / THCL-4251

### LOT: THCL-0224-00033

$\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3 \cdot \text{HCl}$  \* 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, Crystalline Powder to Needle-Like Crystals	White Crystals	
Assay, Dried Basis	≥ 99.0 %	99.6 %	
Bioburden	≤ 100 CFU/g	< 100 CFU/g	
Endotoxin	≤ 2.5 EU/g	< 1.9 EU/g	
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Identification, Chloride	Passes Test	Passes Test	
Identification, IR	Conforms to Reference Standard	Conforms to Reference Standard	
Insoluble Matter	≤ 0.005 %	< 0.005 %	
Loss on Drying	≤ 0.5 %	0.1 %	
Melting Range	147 – 152 °C	151 - 152 °C	
pH (1% solution)	4.0 – 5.0	4.7	
pH (0.5M)	3.5 – 5.0	4.4	

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ANALYSIS	SPECIFICATION	TEST RESULT	
Trace Metals	Arsenic (As)	$\leq 5$ ppm	< 0.45 ppm
	Calcium (Ca)	$\leq 1$ ppm	< 0.60 ppm
	Copper (Cu)	$\leq 1$ ppm	< 0.15 ppm
	Iron (Fe)	$\leq 1$ ppm	< 0.30 ppm
	Lead (Pb)	$\leq 1$ ppm	< 0.30 ppm
	Magnesium (Mg)	$\leq 5$ ppm	< 0.60 ppm
	Manganese (Mn)	$\leq 1$ ppm	< 0.60 ppm
	Zinc (Zn)	$\leq 1$ ppm	< 0.60 ppm
Water, KF	$\leq 1.0$ %	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 a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Prepared by: Shail McCall Date: 1/31/25 Job Title: QA Tech III

Reviewed by: Car Albert Date: 1/31/25 Job Title: Senior Quality Manager