

# BIOSPECTRA

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

Effective Date:	21-Jan-2025	21-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

### BIS-TRIS

### BIOTECH, LBLE, GMP

### BIO PHARMA GRADE / BTRI-4250

### LOT: BTRI-E04-1124-0028

C<sub>8</sub>H<sub>19</sub>NO<sub>5</sub> \* F.W. 209.24 g/mol. \* CAS# 6976-37-0

Manufacturing Date: 11/29/24 Retest Date: 5/31/26

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT	
Absorbance (0.1M)	280 nm	≤ 0.04 a.u.	0.01 a.u.
	340 nm	≤ 0.02 a.u.	< 0.02 a.u.
Ammonium (NH <sub>4</sub> )	≤ 500 ppm	< 500 ppm	
Appearance and Color	White Crystalline Powder	White Crystalline Powder	
Assay, Dried Basis	99.0 - 101.0%	100.0 %	
Bioburden	TAMC	≤ 100 CFU/g	< 100 CFU/g
	TYMC	≤ 100 CFU/g	< 100 CFU/g
Chloride	≤ 50 ppm	< 50 ppm	
Endotoxin		≤ 50 EU/g	<10 EU/g
	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
Enzymes	RNase	None Detected	None Detected
		≤ 3 ppm	< 0.15 ppm
Heavy Metals (Pb)			
Identification, IR	Conforms to Reference Standard	Conforms to Reference Standard	
Loss on Drying	≤ 1.0%	0.1%	
Melting Point	100 - 105 °C	104 °C	
pH (1% aqueous)	8.8 – 9.8	9.4	
pKa	6.3 – 6.7	6.6	
Residue on Ignition	≤ 0.1%	< 0.1%	

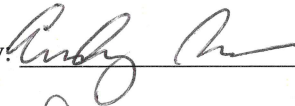
The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

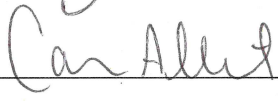
ANALYSIS	SPECIFICATION	TEST RESULT
Solubility 0.1M in H <sub>2</sub> O	Clear and Complete	Clear and Complete
Sulfate	≤ 50 ppm	< 50 ppm
Aluminum (Al)	≤ 5 ppm	< 1.5 ppm
Calcium (Ca)	≤ 500 ppm	< 1.5 ppm
Trace Metals		
Iron (Fe)	≤ 3 ppm	< 3.0 ppm
Lead (Pb)	≤ 10 ppm	< 0.15 ppm
Phosphorus (P)	≤ 500 ppm	< 30 ppm
Water, KF	≤ 1.0%	0.1%

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0095

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:  Date: 2/3/25 Job Title: QA Technician I

Reviewed by:  Date: 2/3/25 Job Title: Senior Quality Manager