

# 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-E04-1124-0026

 $C_8H_{19}NO_5$  \* F.W. 209.24 g/mol. \* CAS# 6976-37-0

Manufacturing Date: 11/23/24 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
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals (Pb)		≤ 3 ppm	< 0.15 ppm
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%

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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
	Lead (Pb)	≤ 10 ppm
	Phosphorus (P)	≤ 500 ppm
Water, KF	≤ 1.0%	< 30 ppm
		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: *Emily* Date: 2/3/25 Job Title: QA Technician 1

Reviewed by: *Car Allert* Date: 2/5/25 Job Title: Senior Quality Manager