BIOSPECTRA

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

Effective Date:	19-Dec-2022	19-Dec-2025	: Date of Next Review
Prepared By:	Amy Hosein	Not Applicable	: Supersedes
QA/QC Approval:	Carissa Albert	Amy Yencho	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS
BIS-TRIS
BIO EXCIPIENT GRADE / BTRI-3250-
LOT: BTRI- -

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

Manufacturing Date: / /

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: / / Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (0.1M)	280 nm	≤ 0.04 a.u.	a.u.
	340 nm	≤ 0.02 a.u.	a.u.
Appearance and Color		White / Crystals	White Crystalline Powder
Assay (Dried basis)		99.0-101.0%	%
Bioburden	TAMC	≤ 100 CFU/g	CFU/g
	TYMC	≤ 100 CFU/g	CFU/g
Chloride		≤ 0.005%	%
Endotoxin		≤ 50 EU/g	EU/g
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals (Pb)		≤ 3 ppm	ppm
Identification (IR)		Conforms to Reference Standard	Conforms to Reference Standard
Iron		≤ 3 ppm	ppm
Loss on Drying (LOD)		≤ 1.0%	%
Melting Point		100 - 105 ºC	- °C
pH (1% aqueous)		8.8 – 9.8	
pKa		6.3 – 6.7	
Residue on Ignition (ROI)		≤ 0.1%	%
Solubility 0.1M in H_2O		Clear and Complete	Clear and Complete
Water (KF)		≤ 1.0%	%

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 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.

SHELF LIFE: A retest date is to be determined based on the data obtained from the stability study.

Prepared by: _____ Date: _____ Job Title: _____

Reviewed by: _____ Date: _____ Job Title: _____