

BIO SPECTRA

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

Effective Date:	18-Jun-2026	18-Jun-2029	: Date of Next Review
Prepared By:	Carissa Albert	BSI-COA-0277 v.1.2	: Supersedes
QA/QC Approval:	Jaron Hughes	Krista Rehrig	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

BIS-TRIS

BIO EXCIPIENT GRADE / BTRI-3250

LOT: BTRI-E04-0526-0004

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

Manufacturing Date: 05/31/26 Retest Date: 05/31/28

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.
Appearance and Color		White / Crystals	Passes Test
Assay, Dried basis		99.0-101.0%	99.8%
Microbial Content	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
		Conforms to Reference Standard	Passes Test
Loss on Drying		<= 1.0%	0.1%
Melting Point		100 - 105 °C	104°C
pH (1%)		8.8 – 9.8	9.5
pKa		6.3 – 6.7	6.6
Residue on Ignition		<= 0.1%	< 0.1%
Solubility (0.1M)		Clear and Complete	Passes Test
Trace Metals	Iron (Fe)	<= 3 ppm	< 3.0 ppm
	Lead (Pb)	<= 3 ppm	< 0.15 ppm
Water, KF		<= 1.0%	0.1%

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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.

Prepared by: Anil Mehall Date: 6/18/26 Job Title: QA Tech III

Reviewed by: John Hughes Date: 6/18/26 Job Title: QA Supervisor