

BIOSPECTRA

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

Effective Date:	20-Jun-2023	20-Jun-2026	: Date of Next Review
Prepared By:	Virginia Pena	BSI-COA-0277 v.1.0	: 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-3250-05

LOT: BTRI-E04-1024-0014

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

Manufacturing Date: 09/26/23 Retest Date: 03/31/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 10/19/24 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	White Crystalline Powder
Assay (Dried basis)		99.0-101.0%	100.2%
Bioburden	TAMC	≤ 100 CFU/g	< 100 CFU/g
	TYMC	≤ 100 CFU/g	< 100 CFU/g
Chloride		≤ 0.005%	< 0.005%
Endotoxin		≤ 50 EU/g	< 10 EU/g
	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
Enzymes	RNase	None Detected	None Detected
Heavy Metals (Pb)		≤ 3 ppm	< 0.15 ppm
Identification (IR)		Conforms to Reference Standard	Conforms to Reference Standard
Iron		≤ 3 ppm	< 3.0 ppm
Loss on Drying (LOD)		≤ 1.0%	0.1%
Melting Point		100 - 105 °C	103 °C
pH (1% aqueous)		8.8 – 9.8	9.6
pKa		6.3 – 6.7	6.6
Residue on Ignition (ROI)		≤ 0.1%	< 0.1%
Solubility 0.1M in H ₂ O		Clear and Complete	Clear and Complete
Water (KF)		≤ 1.0%	0.2%

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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.

SHELF LIFE: The retest date is assigned based on the industry standard for Bis Tris. BioSpectra's Stability Testing Program is ongoing to further support the retest date.

Prepared by: *Paul McCall* Date: 10/22/24 Job Title: QA Tech III

Reviewed by: *Jason Bingham* Date: 10/23/24 Job Title: QA Supervisor