

BIOSPECTRA

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

Effective Date:	30-Jan-2025	30-Jan-2028	: Date of Next Review
Prepared By:	Catherine Sutton	BSI-COA-0325 v.1.0	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

TRIS

BIOTECH, HIGH ASSAY, MEETS USP, GMP

PREMIUM REAGENT

BIO PHARMA GRADE / TRIS-4223

LOT: TRIS-S01-0125-0006

$\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3$ ^ F.W. 121.14 ^ CAS#: 77-86-1

Manufacturing Date: 1/15/25 Retest Date: 1/31/27

Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm	≤ 0.06 a.u.	< 0.06 a.u.
	280 nm	≤ 0.06 a.u.	< 0.06 a.u.
	430 nm	≤ 0.01 a.u.	< 0.01 a.u.
Absorbance (10%)	260 nm	≤ 0.03 a.u.	< 0.03 a.u.
	280 nm	≤ 0.02 a.u.	< 0.02 a.u.
Absorbance (40%)	430 nm	≤ 0.004 a.u.	< 0.004 a.u.
	290 nm	≤ 0.20 a.u.	0.01 a.u.
APHA Color (20% Solution)		≤ 20	< 20
Assay, Dried Basis (Ultrapure)		≥ 99.9 %	99.9 %
Chloride		≤ 20 ppm	< 20 ppm
Endotoxin		≤ 2.5 EU/g	< 1.0 EU/g
Enzymes	DNase	None Detected	None Detected
	Protease	None Detected	None Detected
	RNase	None Detected	None Detected
Heavy Metals (as Pb)		≤ 1 ppm	< 0.30 ppm
Insoluble Matter		≤ 0.005 %	< 0.001 %
Loss on Drying		≤ 0.3 %	0.2 %
Melting Range		168-172 °C	171 - 172 °C
Microbial Content	TAMC	≤ 100 CFU/g	< 10 CFU/g
	TYMC	≤ 100 CFU/g	< 10 CFU/g
pH (5% solution)		10.0 - 11.5	10.8

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ANALYSIS	SPECIFICATION	TEST RESULT
Related Substances	$\leq 0.1 \%$	$< 0.03 \%$
Residue on Ignition	$\leq 0.05 \%$	$< 0.01 \%$
Aluminum (Al)	$\leq 5 \text{ ppm}$	$< 1.5 \text{ ppm}$
Arsenic (As)	$\leq 1.6 \text{ ppm}$	$< 0.45 \text{ ppm}$
Barium (Ba)	$\leq 5 \text{ ppm}$	$< 1.5 \text{ ppm}$
Bismuth (Bi)	$\leq 5 \text{ ppm}$	$< 3.0 \text{ ppm}$
Cadmium (Cd)	$\leq 5 \text{ ppm}$	$< 0.30 \text{ ppm}$
Calcium (Ca)	$\leq 1 \text{ ppm}$	$< 0.60 \text{ ppm}$
Chromium (Cr)	$\leq 5 \text{ ppm}$	$< 1.5 \text{ ppm}$
Cobalt (Co)	$\leq 5 \text{ ppm}$	$< 1.5 \text{ ppm}$
Copper (Cu)	$\leq 1 \text{ ppm}$	$< 0.15 \text{ ppm}$
Trace Metals		
Iron (Fe)	$\leq 1 \text{ ppm}$	$< 0.30 \text{ ppm}$
Lead (Pb)	$\leq 1 \text{ ppm}$	$< 0.30 \text{ ppm}$
Lithium (Li)	$\leq 5 \text{ ppm}$	$< 1.5 \text{ ppm}$
Magnesium (Mg)	$\leq 5 \text{ ppm}$	$< 0.60 \text{ ppm}$
Manganese (Mn)	$\leq 1 \text{ ppm}$	$< 0.60 \text{ ppm}$
Molybdenum (Mo)	$\leq 5 \text{ ppm}$	$< 3.0 \text{ ppm}$
Nickel (Ni)	$\leq 5 \text{ ppm}$	$< 0.75 \text{ ppm}$
Potassium (K)	$\leq 50 \text{ ppm}$	$< 15 \text{ ppm}$
Sodium (Na)	$\leq 50 \text{ ppm}$	$< 15 \text{ ppm}$
Zinc (Zn)	$\leq 1 \text{ ppm}$	$< 0.6 \text{ ppm}$
Water, KF	$\leq 1.0 \%$	$< 1.0 \%$

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0007

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: 2/11/25 Job Title: QA Tech 1

Reviewed by:  Date: 2/11/25 Job Title: QA Supervisor