

# BIOSPECTRA

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

Effective Date:	15-May-2023	15-May-2026	: Date of Next Review
Prepared By:	Jaron Hughes	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl		

## CERTIFICATE OF ANALYSIS

### TRIS / TROMETHAMINE

### BIO ACTIVE GRADE / TRIS-2255-10

### LOT: TRIS-0123-00145

 $\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3$  \* F.W. 121.14 g/mol. \* CAS# 77-86-1

Manufacturing Date: 6/13/22 Retest Date: 6/30/24

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 5/9/23 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (40%)	290nm	$\leq 0.2$ a.u.	<0.2 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0 – 101.0%	99.9%
Bacterial Endotoxins		$\leq 3.0$ EU/g	<1.5 EU/g
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Elemental Impurities	Cadmium (Cd)	$\leq 0.005$ ppm	<0.002 ppm
	Lead (Pb)	$\leq 0.012$ ppm	<0.005 ppm
	Arsenic (As)	$\leq 0.036$ ppm	<0.015 ppm
	Mercury (Hg)	$\leq 0.007$ ppm	<0.003 ppm
	Cobalt (Co)	$\leq 0.012$ ppm	<0.005 ppm
	Vanadium (V)	$\leq 0.024$ ppm	<0.01 ppm
	Nickel (Ni)	$\leq 0.079$ ppm	0.05 ppm
	Thallium (Tl)	$\leq 0.019$ ppm	<0.008 ppm
	Gold (Au)	$\leq 0.238$ ppm	<0.10 ppm
	Palladium (Pd)	$\leq 0.024$ ppm	<0.01 ppm
	Iridium (Ir)	$\leq 0.024$ ppm	<0.01 ppm
Osmium (Os)	$\leq 0.024$ ppm	<0.01 ppm	

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ANALYSIS		SPECIFICATION	TEST RESULT
Elemental Impurities	Rhodium (Rh)	≤ 0.024 ppm	<0.01 ppm
	Ruthenium (Ru)	≤ 0.024 ppm	<0.01 ppm
	Selenium (Se)	≤ 0.191 ppm	<0.05 ppm
	Silver (Ag)	≤ 0.024 ppm	<0.01 ppm
	Platinum (Pt)	≤ 0.024 ppm	<0.01 ppm
	Lithium (Li)	≤ 0.595 ppm	<0.25 ppm
	Antimony (Sb)	≤ 0.214 ppm	<0.09 ppm
	Barium (Ba)	≤ 1.667 ppm	<0.70 ppm
	Molybdenum (Mo)	≤ 3.572 ppm	<0.05 ppm
	Copper (Cu)	≤ 0.714 ppm	<0.025 ppm
	Tin (Sn)	≤ 1.429 ppm	<0.60 ppm
Heavy Metals (as Pb)	Chromium (Cr)	≤ 2.619 ppm	<0.05 ppm
		≤ 0.012 ppm	<0.005 ppm
USP Identifications	A (IR)	Passes Test	Passes Test
	B	Passes Test	Passes Test
	C	Passes Test	Passes Test
Insoluble Matter		≤ 0.005%	<0.001%
Karl Fischer Water		≤ 2.0%	0.3%
Loss on Drying		≤ 1.0%	0.1%
Melting Range		168 – 172°C	171-172 °C
Microbial Content	<i>Escherichia coli</i>	Negative	Negative
	<i>Pseudomonas aeruginosa</i>	Negative	Negative
	<i>Salmonella</i>	Negative	Negative
	<i>Staphylococcus aureus</i>	Negative	Negative
	TAMC	100 CFU/g max.	< 100 CFU/g
	TYMC	10 CFU/g max.	<10 CFU/g
	2-Nitropropane-1,3-diol	NMT 1 ppm	<1 ppm
Organic Impurities	Tris(hydroxymethyl) nitromethane (EP Related Impurity)	NMT 1 ppm	<1 ppm
	2-Nitroethanol	NMT 1 ppm	<1 ppm
	Formaldehyde	NMT 15ppm	1 ppm
	Any Unspecified Impurities	NMT 300 ppm	<300 ppm
	Total Impurities	NMT 300 ppm	<300 ppm

ANALYSIS		SPECIFICATION	TEST RESULT
pH (1 in 20)		10.0 – 11.5	10.9
Residue on Ignition		≤ 0.1%	<0.1%
Residual Solvents	Methanol	≤ 300 ppm	<300 ppm
	Nitromethane	≤ 15 ppm	<15 ppm
	Aluminum (Al)	≤ 0.400 ppm	<0.40 ppm
Trace Metals	Calcium (Ca)	≤ 1 ppm	<0.60 ppm
	Iron (Fe)	≤ 1 ppm	<0.20 ppm
	Magnesium (Mg)	≤ 1 ppm	<0.60 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0007

CAUTION: For use in development only not for commercial distribution.

CAUTION: Rx only.

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a non-Sterile Active Pharmaceutical Ingredient 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 a Sterile or Injectable Active Pharmaceutical Ingredient, Drug Product or Household Item.

RESIDUAL SOLVENTS STATEMENT: Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4

Prepared by: Cheryl McCall Date: 5/16/23 Job Title: QA Support Tech

Reviewed by: John Bligh Date: 5/16/23 Job Title: QA Mater. Disp. Supervisor

