BIOSPECTRA

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

Effective Date:	15-Apr-2020	15-Apr-2023	: Date of Next Review
Prepared By:	Amy Hosein	18-002346 v.3.0	: Supersedes
QA/QC Approval:	Wendy Santay	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS / TROMETHAMINE

BIO ACTIVE GRADE / TR2250 – G100

LOT: TR2250-007-0920

$NH_2C(CH_2OH)_3$ ⏅ F.W. 121.14 g/mol. ⏅ CAS# 77-86-1

Manufacturing Date: 02/11/20 Retest Date: 02/28/22

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 09/30/20 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds USP Specifications

ANALYSIS		SPECIFICATION	TEST RESULT
Absorbance (40%)	290 nm	0.2 a.u. max.	<0.2 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0 – 101.0%	99.4%
Bacterial Endotoxins, USP <85>		3.0 EU/g max.	<1.0 EU/g
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Heavy Metals (as Pb)		0.5 ppm max.	< 0.5 ppm
Identification B		Passes Test	Passes Test
Identification C		Passes Test	Passes Test
Identification (IR)		Passes Test	Passes Test
Insoluble Matter		0.005% max.	<0.002%
Karl Fischer Water		2% max.	0.1%
LOD		1.0% max.	0.1%
Melting Range		168 – 172°C	171-172°C
Microbial Content	*Escherichia coli*	Negative	Negative
	Pseudomonas aeruginosa	Negative	Negative
	Salmonella	Negative	Negative
	Staphylococcus aureus	Negative	Negative
	TAMC	100 CFU/g max.	< 100 CFU/g
	TYMC	10 CFU/g max.	<10 CFU/g

ANALYSIS		SPECIFICATION	TEST RESULT
Organic Impurities	2-Nitropropane-1, 3-diol	NMT 1 ppm	< 1 ppm
	Tris(hydroxymethyl)nitromethane	NMT 1 ppm	< 1 ppm
	2-Nitroethanol	NMT 1 ppm	< 1 ppm
	Total Unspecified Impurities	NMT 300 ppm	< 300 ppm
	Formaldehyde	NMT 1 ppm	1 ppm
pH (1 in 20)		10.0 – 11.5	10.7 @ 24.3 °C
Residual Solvents	Methanol	≤ 300 ppm	≤ 300 ppm
	Nitromethane	≤ 15 ppm	≤ 15 ppm
Residue on Ignition		0.1% max.	<0.1%
Trace Elements	Aluminum (Al)	1 ppm max.	< 1 ppm
	Arsenic (As)	1 ppm max.	< 1 ppm
	Calcium (Ca)	1 ppm max.	< 1 ppm
	Copper (Cu)	1 ppm max.	< 1 ppm
	Iron (Fe)	1 ppm max.	< 1 ppm
	Lead (Pb)	0.5 ppm max.	< 0.5 ppm
	Magnesium (Mg)	1 ppm max.	< 1 ppm
	Nickel (Ni)	0.4 ppm max.	< 0.4 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000496

CAUTION: For manufacturing, processing, or repacking in the preparation of a new drug or new animal drug limited by Federal law to investigational use.

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.

ELEMENTAL IMPURITY STATEMENT: Based on the manufacturing process and the controlled handling and storage of this product, the product complies with ICHQ3D, USP method <232> and USP <233> requirements for a Drug Substance.

Prepared by: _____ Date: 10/19/20 Job Title: QA Document Specialist

Reviewed by: _____ Date: 10/19/20 Job Title: QA Supervisor