BIOSPECTRA

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

Effective Date:	26-Mar-2018	26-Mar-2021	: Date of Next Review
Prepared By:	Jamie Storm	Not Applicable	: Supersedes
QA/QC Approval:	Crystal Hamelburg	Dora Meissner	: Management Approval
Reason for Revision:	See Revision History in ensur		

TRIS / TROMETHAMINE

CERTIFICATE OF ANALYSIS

BIO ACTIVE GRADE / TR2250 – K010

LOT: TR2250-001-0519

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

Manufacturing Date: 3/21/2018 Retest Date: 3/31/2020

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013 Packaging Date: 8/16/2018

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.	0.0118 a.u.
Appearance and Color		White / Crystals	White / Crystals
Assay		99.0 – 101.0%	99.87%
Bacterial Endotoxins		3.0 EU/gram max.	<1.1 EU/gram
Enzymes	DNase	None Detected	None Detected
	RNase	None Detected	None Detected
	Protease	None Detected	None Detected
Heavy Metals		5 ppm max.	< 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.	<0.0015%
Karl Fischer Water		2% max.	0.33%
LOD		1.0% max.	0.0408%
Melting Range		168 – 172°C	170.4-171.4 °C

ANALYSIS		SPECIFICATION	TEST RESULT
Microbial Content	*Escherichia coli*	Negative	Negative
	Pseudomonas aeruginosa	Negative	Negative
	Salmonella	Negative	Negative
	Staphylococcus aureus	Negative	Negative
	TAMC	1000CFU/g max.	< 1000 CFU/g
	TYMC	100CFU/g max.	<100 CFU/g
pH (1 in 20)		10.0 – 11.5	10.957 @ 21.09 °C
Residue on Ignition		0.1% max.	<0.0300%
Trace Elements	Arsenic (As)	5 ppm max.	< 5 ppm
	Calcium (Ca)	5 ppm max.	< 5 ppm
	Copper (Cu)	5 ppm max.	< 5 ppm
	Iron (Fe)	5 ppm max.	< 5 ppm
	Lead (Pb)	5 ppm max.	< 5 ppm
	Magnesium (Mg)	5 ppm max.	< 5 ppm

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: 16-000496

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

INTENDED USE: Material represented by this Certificate of Analysis is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured non-Sterile Active Pharmaceutical Ingredient for use in further processing for sterile applications or Drug Product Manufacturing. 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 and storage of this product, there is no potential for any of the residual solvents listed in the current USP method <467> Tables 1, 2, 3, or 4 to be present at the specified limits; furthermore, if tested this product would comply with USP/NF requirements.

Prepared by: H. Bennett Date: 5/8/19

Reviewed by: Date: 5/8/19