

BIOSPECTRA

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

Effective Date:	25-Jun-2020	25-Jun-2023	: Date of Next Review
Prepared By:	Amy Hosein	Not Applicable	: Supersedes
QA/QC Approval:	Carissa McCollian	Wendy Santay	: Management Approval
Reason for Revision:	See Revision History in ensur.		

CERTIFICATE OF ANALYSIS

TRIS / TROMETHAMINE

BIO ACTIVE GRADE / TR2250 – K001

LOT: TR2250-005-0620

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

Manufacturing Date: 2/11/20 Retest Date: 2/28/22

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 6/20/20 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
	DNase	None Detected	None Detected
Enzymes	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
	<i>Escherichia coli</i>	Negative	Negative
	<i>Pseudomonas aeruginosa</i>	Negative	Negative
Microbial	<i>Salmonella</i>	Negative	Negative
Content	<i>Staphylococcus aureus</i>	Negative	Negative
	TAMC	100 CFU/g max.	< 100 CFU/g
	TYMC	10 CFU/g max.	<10 CFU/g

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	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 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.

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: C. [Signature] Date: 6/29/20 Job Title: QA Supervisor

Reviewed by: [Signature] Date: 6/29/20 Job Title: QC Manager