

BIOSPECTRA

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

Effective Date:	14-Nov-2024	14-Nov-2027	: Date of Next Review
Prepared By:	Amy Yenko	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, LBLE

BIO ACTIVE GRADE / TRIS-2257-00

LOT: TRIS-0122-00136

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

Manufacturing Date: 06/13/22 Expiration Date: 06/30/25

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Date: 06/14/22 Packaging Site: 100 Majestic Way, Bangor PA, 18013

Meets or Exceeds EP Specifications

ANALYSIS	SPECIFICATION	TEST RESULT
Appearance and Color	White / Crystals	White / Crystals
Appearance of Solution	Clear and Colorless	Clear and Colorless
Assay, Dried Substance	99.0-100.5%	99.9%
Bacterial Endotoxins	$\leq 0.03\text{EU/mg}$	$< 0.03\text{EU/mg}$
Chloride	$\leq 100\text{ppm}$	$< 100\text{ppm}$
Identification A, pH	10.0-11.5	10.9
Identification B, Melting Point	168-174°C	171-172°C
Identification C, IR	Conforms to Reference Standard	Conforms to Reference Standard
Identification D	Conforms to Reference Standard	Conforms to Reference Standard
Iron	$\leq 10\text{ppm}$	$< 0.20\text{ppm}$
Loss on Drying	$\leq 0.5\%$	0.1%
pH 5%	10.0-11.5	10.9
Related Substances	$\leq 1.0\%$	$< 0.03\%$
Sulfated Ash	$\leq 0.1\%$	$< 0.1\%$

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0007

CAUTION: For manufacturing, processing, or repacking.

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.

Prepared by: Car Albert Date: 12/17/24 Job Title: Senior Quality Manager

Reviewed by: John Bingham Date: 12/17/24 Job Title: QA Supervisor