

CERTIFICATE OF ANALYSIS
TRIS HYDROCHLORIDE
BIO EXCIPIENT GRADE / THCL-3254
LOT: THCL-S03-0525-0069

$\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3\cdot\text{HCl}$ ▲ F.W. 157.60 g/mol. ▲ CAS# 1185-53-1

Manufacturing Date: 5/4/25

Expiration Date: 5/31/28

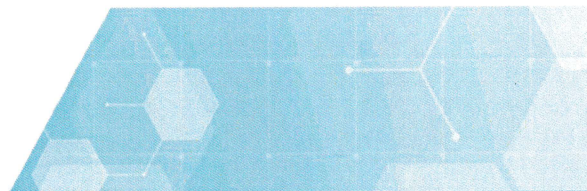
Manufacturing Site: 1474 Rockdale Lane, Stroudsburg, PA 18360

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS	SPECIFICATION	TEST RESULT
Absorbance (1M)	260 nm	≤ 0.06 a.u.
	280 nm	≤ 0.06 a.u.
	400 nm	≤ 0.01 a.u.
Appearance	White to off-white crystalline powder or granules	White to off-white crystalline powder or granules
Assay, Dried	≥ 99.0%	99.6%
Bioburden ¹	≤ 100 CFU/g	Pending
Endotoxin ¹	≤ 2.5 EU/g	Pending
Identification (IR)	Passes Test	Passes Test
Identification (Chloride)	Passes Test	Passes Test
Loss on Drying @ 105°C	≤ 0.5%	0.2%
Melting Range	150 – 153 °C	151-152°C
pH (0.5M) @ 25°C	3.5 – 5.0	4.3
pH (1% Aqueous Solution)	4.0 – 5.0	4.7
Trace Metals	Arsenic (As)	≤ 10 ppm
	Calcium (Ca)	≤ 10 ppm
	Copper (Cu)	≤ 10 ppm
	Iron (Fe)	≤ 10 ppm
	Lead (Pb)	≤ 10 ppm
	Magnesium (Mg)	≤ 10 ppm
Water	≤ 0.5%	0.3%

¹Bioburden and Endotoxin Testing pending results.

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COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0002

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as an excipient. It is 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 an Active Pharmaceutical Ingredient, Drug Product or Household Item.

RESIDUAL SOLVENTS: 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.

ANIMAL ORIGIN: Tris Hydrochloride manufactured at BioSpectra is not derived from and does not come in contact with animal parts, products and/or byproducts.

Prepared by: Shirley McCall Date: 6/5/25 Job Title: QA Tech III

Reviewed by: John Engler Date: 6/5/25 Job Title: QA Supervisor

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