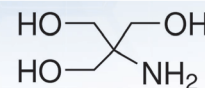


TRIS, USP, LBLE*, GMP, API Grade

*Low Bioburden, Low Endotoxin

INTENDED FOR USE AS AN ACTIVE PHARMACEUTICAL INGREDIENT

Bio Active LBLE Grade of Tromethamine is intended to be used in parenteral drug formulations as an Active Pharmaceutical Ingredient. This product is not to be considered sterile and requires further terminal sterilization.



CAS #: 77-86-1

Formula: C₄H₁₁NO₃

Solubility in Water

@ 25°C (g/L): 550

F.W.: 121.14 g/mol

pH @ 20°C (5% aq. Soln.): 10.0 - 11.5

Useful pH: 7.0 - 9.0

pKa @ 20°C: 8.3

BIO ACTIVE GRADE | Product Code: TRIS-2255 | Previously: TR2255

C₄H₁₁NO₃ • F.W. 121.14 g/mol. • CAS# 77-86-1



ANALYSIS		SPECIFICATIONS
Absorbance (40%)	290 nm	≤ 0.2 a.u.
Appearance and Color		White / Crystals
Assay		99.0–101.0%
Bacterial Endotoxins		≤ 3.0 EU/g
Enzymes	DNase	None Detected
	RNase	None Detected
	Protease	None Detected
Heavy Metals (as Pb)		≤ 0.012 ppm
USP Identifications	A (IR)	Passes Test
	B	Passes Test
	C	Passes Test
Insoluble Matter		≤ 0.005%
Karl Fischer Water		≤ 2.0%
Loss on Drying		≤ 1.0%
Melting Range		168-172 °C
Microbial Content	<i>Escherichia coli</i>	Negative
	<i>Pseudomonas aeruginosa</i>	Negative
	<i>Salmonella</i>	Negative
	<i>Staphylococcus aureus</i>	Negative
	TAMC	≤ 100 CFU/g
	TYMC	≤ 10 CFU/g
Organic Impurities	2-Nitropropane-1,3-diol	NMT 1 ppm
	Tris(hydroxymethyl)nitromethane (EP Related Impurity)	NMT 1 ppm
	2-Nitroethanol	NMT 1 ppm
	Formaldehyde	NMT 15 ppm
	Any Unspecified Impurities	NMT 300 ppm
	Total Impurities	NMT 300 ppm



TROMETHAMINE (Tris) API Grade

ANALYSIS		SPECIFICATIONS
pH (1 in 20)		10.0 – 11.5
Residue on Ignition		≤ 0.1 %
Residual Solvents	Methanol	≤ 300 ppm
	Nitromethane	≤ 15 ppm
Trace Metals	Aluminum (Al)	≤ 0.400 ppm
	Calcium (Ca)	≤ 1 ppm
	Iron (Fe)	≤ 1 ppm
	Magnesium (Mg)	≤ 1 ppm
Elemental Impurities	Cadmium (Cd)	≤ 0.005 ppm
	Lead (Pb)	≤ 0.012 ppm
	Arsenic (As)	≤ 0.036 ppm
	Mercury (Hg)	≤ 0.007 ppm
	Cobalt (Co)	≤ 0.012 ppm
	Vanadium (V)	≤ 0.024 ppm
	Nickel (Ni)	≤ 0.079 ppm
	Thallium (Tl)	≤ 0.019 ppm
	Gold (Au)	≤ 0.238 ppm
	Palladium (Pd)	≤ 0.024 ppm
	Iridium (Ir)	≤ 0.024 ppm
	Osmium (Os)	≤ 0.024 ppm
	Rhodium (Rh)	≤ 0.024 ppm
	Ruthenium (Ru)	≤ 0.024 ppm
	Selenium (Se)	≤ 0.191 ppm
	Silver (Ag)	≤ 0.024 ppm
	Platinum (Pt)	≤ 0.024 ppm
	Lithium (Li)	≤ 0.595 ppm
	Antimony (Sb)	≤ 0.214 ppm
	Barium (Ba)	≤ 1.667 ppm
Molybdenum (Mo)	≤ 3.572 ppm	
Copper (Cu)	≤ 0.714 ppm	
Tin (Sn)	≤ 1.429 ppm	
Chromium (Cr)	≤ 2.619 ppm	

General Product Description:

- The manufacturing of LBLE API Grade Tromethamine TRIS-2255 is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of LBLE API Grade Tromethamine TRIS-2255 is cleaned in accordance with BioSpectra's Cleaning Validation Plan.
- Tromethamine is a White Crystalline product.
- Molecular Formula: $C_4H_{11}NO_3$
- Molecular Weight: 121.14 g/mol.
- CAS Number: 77-86-1.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Tromethamine TRIS-2255 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products, and/or byproducts.
- Tromethamine manufactured at BioSpectra and any raw materials used in the manufacture of Tromethamine at BioSpectra are not subject to genetic modification.

Synonyms: Tris, Tromethamine, Tris (hydroxymethyl) aminomethane.

GMP Compliance:

LBLE API Grade Tromethamine TRIS-2255 is suitable for use as a non-Sterile Active Pharmaceutical Ingredient manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide.

Retest Date:

The recommended retest period for Tromethamine is two years from the date of manufacture.

Storage and Shipping Conditions:

- Store in a clean and dry area.
- Store in the original container.

Package Sizes:

10kg, 25kg and 50kg pails.