

TRIS

USP, LBLE, GMP, API

CAS #: 77-86-1

Formula: $\text{NH}_2\text{C}(\text{CH}_2\text{OH})_3$

F.W.: 121.14 g/mol

TRIS-2255

BIO ACTIVE GRADE

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
	Protease	None Detected
	RNase	None Detected
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	
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

ANALYSIS		SPECIFICATIONS
Microbial Content	<i>Escherichia coli</i>	Negative
	<i>Pseudomonas aeruginosa</i>	Negative
	<i>Salmonella</i>	Negative
	<i>Staphylococcus aureus</i>	Negative
	TAMC TYMC	< = 100 CFU/g < = 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
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

General Product Overview

Bio Active 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.

Refer to page 2 for additional product details.

This is not considered a controlled document. We are not responsible for any errors or omissions, and the user is responsible for any decisions based on the information herein.

GMP Compliance

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. This grade of Tromethamine is not suitable to be used as a Sterile or Injectable Active Pharmaceutical Ingredient, Drug Product or Household Item.

Key Product Features

- The manufacturing of Tris/Tromethamine, TRIS-2255 is performed at BioSpectra's Bangor, PA facility.
- Appears as white crystals
- Manufactured in accordance with ICH Q7
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: Trometamol, THAM, Tris (Hydroxymethyl) Aminomethane; Trisaminol; Trismethylolaminomethane; 2-Amino-2 (Hydroxymethyl) propane-1,3-diol; Tromethamine

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

10kg, 25kg and 50kg pails

[Click here to view SDS, CoAs and other supporting regulatory documents on our website.](#)

This is not considered a controlled document. We are not responsible for any errors or omissions, and the user is responsible for any decisions based on the information herein.