

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, Dried Basis (USP)		99.0 – 101.0%
Chloride		≤ 100 ppm
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identification A, IR (USP)		Conforms to Reference Standard
Identification B (USP)		Passes Test
Identification C (USP)		Passes Test
Insoluble Matter		$\leq 0.005\%$
Loss on Drying (USP)		$\leq 1.0\%$
Melting Range (USP)		168 – 172°C
pH (5%) (USP)		10.0 – 11.5
Residue on Ignition (USP)		$\leq 0.1\%$
Trace Metals	Arsenic (As)	≤ 5 ppm
	Calcium (Ca)	≤ 5 ppm
	Copper (Cu)	≤ 5 ppm
	Iron (Fe)	≤ 5 ppm
	Lead (Pb)	≤ 5 ppm
	Magnesium (Mg)	≤ 5 ppm
Water, KF		$\leq 2.0\%$

General Product Overview

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.

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. 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.](#)

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