

**TRIS****USP, LBLE, GMP, API****CAS #: 77-86-1****Formula: NH<sub>2</sub>C(CH<sub>2</sub>OH)<sub>3</sub>****F.W.: 121.14 g/mol****TRIS-2255****BIO ACTIVE GRADE**

<b>ANALYSIS</b>		<b>SPECIFICATIONS</b>
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 Protease RNase	None Detected None Detected None Detected
Identification A, IR (USP)		Conforms to Reference Standard
Identification B (USP)		Passes Test
Identification C (USP)		Passes Test
Insoluble Matter		< = 0.005%
Loss on Drying (USP)		< = 1.0%
Melting Range (USP)		168 – 172°C
pH (5%) (USP)		10.0 – 11.5
Residue on Ignition (USP)		< = 0.1%
Trace Metals	Arsenic (As) Calcium (Ca) Copper (Cu) Iron (Fe) Lead (Pb) Magnesium (Mg)	< = 5 ppm < = 5 ppm
Water, KF		< = 2.0%

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

**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

*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.*