

### TRIS CH.P., LBLE, GMP, EXCIPIENT

CAS #: 77-86-1

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

F.W.: 121.14 g/mol

#### TRIS-3251

#### BIO EXCIPIENT GRADE

ANALYSIS		SPECIFICATIONS
Absorbance (1M)	260nm	< = 0.06 a.u.
	280nm	< = 0.06 a.u.
	430nm	< = 0.01 a.u.
Absorbance (10%)	260nm	< = 0.03 a.u.
	280nm	< = 0.02 a.u.
	430nm	< = 0.004 a.u.
Absorbance (40%)	290nm	< = 0.2 a.u.
APHA Color (20% Solution)		< = 20 APHA
Appearance and Color		White Crystals
Appearance of Solution (EP)		Passes Test
Assay, Dried Basis (USP/EP/ChP/JPC)		99.0 – 100.5%
Assay, Dried Basis (Ultrapure)		> = 99.9%
Chloride (ChP/EP)		< = 100 ppm
Clarity and Color of Solution (ChP/JPC)		Passes Test
Endotoxin		< = 2.5 EU/g
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identification, IR (USP-A/ChP-3/EP-C)		Conforms to Reference Standard
Identification A (EP), pH 5% (USP/ChP/EP)		10.0 – 11.5
Identification A (JPC)		Passes Test
Identification B (USP/ChP-1)		Passes Test
Identification B (EP), Melting Range (USP/ChP/JPC)		168 – 172 °C
Identification B (JPC)		Passes Test
Identification C (USP)		Passes Test
Identification D (EP/ChP-2)		Passes Test

ANALYSIS		SPECIFICATIONS
Insoluble Matter		< = 0.005%
Loss on Drying (USP/ChP/EP/JPC)		< = 0.3%
Residual Solvents	Methanol	< = 3000 ppm
Microbial Content	TAMC	< = 100 CFU/g
	TYMC	< = 100 CFU/g
	Bile tolerant Gram Neg. Bacteria	Absent/g
	Escherichia coli	Absent/g
	Pseudomonas aeruginosa	Absent/g
	Staphylococcus aureus	Absent/g
	Candida albicans	Absent/g
	Salmonella sp.	Absent/10g
pH (1 in 100) (JPC)		10.3 – 10.7
Related Substances (ChP/EP)		< = 0.1%
Residue on Ignition/Sulfated Ash (USP/ChP/EP/JPC)		< = 0.05%
Trace Metals	Arsenic (As)	< = 1.6 ppm
	Calcium (Ca)	< = 1 ppm
	Copper (Cu)	< = 1 ppm
	Iron (Fe)	< = 1 ppm
	Lead (Pb)	< = 1 ppm
	Magnesium (Mg)	< = 5 ppm
	Manganese (Mn)	< = 1 ppm
	Nickel (Ni)	< = 15 ppm
	Zinc (Zn)	< = 1 ppm
Water, KF		< = 1.0%

**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.*

### General Product Overview

Tromethamine (Tris) is commonly used as a buffer and excipient in downstream biological applications during the manufacture of drug products. Tris is considered a Good's buffer because it has low UV absorptivity, minimal reactivity, stable pH and is soluble in water.

### Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

### Key Product Features

- The manufacturing of Tris, TRIS-3251 is performed at BioSpectra's Stroudsburg, 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.](#)