

TRIS/TROMETHAMINE

MEETS USP, EP, JPC, ChP, BET*, 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%

*Bioburden and Endotoxin Tested

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.](#)

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.