

TRIS/TROMETHAMINE

MEETS USP/EP, BET*, GMP

CAS #: 77-86-1

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

F.W.: 121.14 g/mol

TRIS-4252

BIO PHARMA GRADE

ANALYSIS		SPECIFICATIONS
Absorbance (40%)	290 nm	≤ 0.20 a.u.
Appearance and Color		White Crystalline Powder
Appearance of Solution (EP)		Passes Test
Assay, Dried Basis (USP/EP)		99.0 – 100.5%
Chloride (EP)		≤ 100 ppm
Endotoxin		≤ 2.5 EU/g
Identification, IR (USP-A/EP-C)		Conforms to Reference Standard
Identification A (EP), pH (5%) (USP/EP)		10.0 – 11.5
Identification B (USP)		Passes Test
Identification B (EP), Melting Range (USP)		168 - 172°C
Identification C (USP)		Passes Test
Identification D (EP)		Conforms to Reference Standard
Insoluble Matter		$\leq 0.005\%$
Loss on Drying (USP/EP)		$\leq 0.5\%$
Microbial Content	TAMC TYMC	≤ 50 CFU/g ≤ 50 CFU/g
Related Substances (EP)		$\leq 1.0\%$
Residue on Ignition / Sulfated Ash (USP/EP)		$\leq 0.1\%$
Solubility (40%)		Passes Test
Trace Metals	Iron (Fe) (EP) Lead (Pb)	≤ 5 ppm ≤ 5 ppm
Water, KF		$\leq 0.3\%$

General Product Overview

Tris/Tromethamine 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 biological/biotech process applications from R&D through scale cGMP production.

Key Product Features

- The manufacturing of Tris/Tromethamine, Tris-4252 is performed at BioSpectra's Stroudsburg, PA facility.
- Appears as a white crystalline product
- 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: Tris(hydroxymethyl) aminomethane; Trometamol; THAM; Trisaminol

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

*Bioburden and Endotoxin Tested

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

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