

TRIS/TROMETHAMINE

USP, EP, 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-3254

BIO EXCIPIENT GRADE

ANALYSIS	SPECIFICATIONS
Appearance and Color	White Crystals
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
Iron (Fe) (EP)	< = 10 ppm
Loss on Drying (USP/EP)	< = 0.5%
Microbial Content	TAMC TYMC < = 500 CFU/g < = 200 CFU/g
Related Substances (EP)	< = 1.0%
Residue on Ignition/Sulfated Ash (USP/EP)	< = 0.1%

*Bioburden and Endotoxin Tested

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

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 products.

Key Product Features

- The manufacturing of Tris/Tromethamine, TRIS-3254 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

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

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