

TRIS

USP, 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-3220

BIO EXCIPIENT GRADE

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

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 Tromethamine (Tris), TRIS-3220 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.](#)

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