

TRIS/TROMETHAMINE

USP, EP, JPC, 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-3257

BIO EXCIPIENT GRADE

ANALYSIS		SPECIFICATIONS
Absorbance (1M)	260nm	< = 0.05 a.u.
	280nm	< = 0.05 a.u.
	300nm	< = 0.004 a.u.
Absorbance (10%)	260nm	< = 0.03 a.u.
	280nm	< = 0.02 a.u.
	430nm	< = 0.004 a.u.
Absorbance (40%)	290nm	< = 0.01 a.u.
APHA Color (20% Solution)		< = 20 APHA
Appearance of Solution (EP)		Passes Test
Assay, Dried Basis (USP/EP/JPC)		99.0 – 100.5%
Assay, Dried Basis (Ultrapure)		> = 99.5%
Chloride (EP)		< = 20 ppm
Clarity and Color of Solution (JPC)		Passes Test
Endotoxin		< = 2.5 EU/g
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identification, IR (USP-A /EP-C)		Conforms to Reference Standard
Identification A (EP), pH 5% (USP/EP)		10.0 – 11.5
Identification A (JPC)		Passes Test
Identification B (USP)		Passes Test
Identification B (EP), Melting Range (USP/JPC)		168 – 172 °C
Identification B (JPC)		Passes Test
Identification C (USP)		Passes Test
Identification D (EP)		Conforms to Reference Standard
Insoluble Matter		< = 0.005%
Loss on Drying (USP/EP/JPC)		< = 0.3%
Microbial Content	TAMC	< 50 CFU/g
	TYMC	< 50 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

ANALYSIS		SPECIFICATIONS
Non-Volatile Residue (JPC)		< = 0.10%
Odor (JPC)		Passes Test
pH (1 in 100) (JPC)		10.3 – 10.7
Related Substances (EP)		< = 0.1%
Residual Solvents 2-Propanol		< = 0.5%
Residue on Ignition/Sulfated Ash (USP/EP/JPC)		< = 0.05%
Solubility (40%)		< = 0.20%
Sulfate		< = 5 ppm
Trace Metals	Aluminum (Al)	< = 5 ppm
	Arsenic (As) (JPC)	< = 0.2 ppm
	Barium (Ba)	< = 1 ppm
	Bismuth (Bi)	< = 1 ppm
	Cadmium (Cd)	< = 1 ppm
	Calcium (Ca)	< = 1 ppm
	Chromium (Cr)	< = 1 ppm
	Cobalt (Co)	< = 1 ppm
	Copper (Cu)	< = 1 ppm
	Iron (Fe) (EP)	< = 1 ppm
	Lead (Pb) (JPC)	< = 1 ppm
	Lithium (Li)	< = 1 ppm
	Potassium (K)	< = 50 ppm
	Magnesium (Mg)	< = 5 ppm
	Manganese (Mn)	< = 1 ppm
	Molybdenum (Mo)	< = 1 ppm
	Nickel (Ni)	< = 2.5 ppm
	Sodium (Na)	< = 50 ppm
	Strontium (Sr)	< = 5 ppm
	Zinc (Zn)	< = 1 ppm
Volatile Residue (JPC)		< = 0.5%
Water, KF		< = 0.5%

*Bioburden and Endotoxin Tested

Refer to page 2 for additional product details.

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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-3257 is performed at BioSpectra's Stroudsburg, PA facility.
- Appears as a white crystalline powder
- 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

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

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