

TRIS Excipient, Ch.P., LBLE*, GMP, Excipient Grade

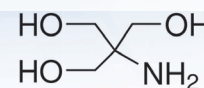
*Low Bioburden, Low Endotoxin

INTENDED FOR USE AS AN EXCIPIENT

Tromethamine (Tris), is commonly used as a buffer and excipient in biological applications downstream in 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.

Lead Time: 3-months

Minimum Order Quantity: 500kg



CAS #: 77-86-1

Formula: C₄H₁₁NO₃

Solubility in Water

@ 25°C (g/L): 550

F.W.: 121.14 g/mol

pH @ 20°C (5% aq. Soln.): 10.0 - 11.5

Useful pH: 7.0 - 9.0

pKa @ 20°C: 8.3

BIO EXCIPIENT GRADE | Product Code: TRIS-3251 | Previously: TR3251

C₄H₁₁NO₃ • F.W. 121.14 g/mol • CAS# 77-86-1



These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

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 (Ultrapure, Dried Basis)		≥ 99.9%
Chloride (ChP/EP)		≤ 100 ppm
Clarity and Color of Solution (ChP/JPC)		Passes Test
Endotoxins		≤ 2.5 EU/g
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Heavy Metals (as Pb) (ChP/JPC)		≤ 1 ppm
Identification IR, (USP-A/ChP-3/EP-C)		Passes Test
Identification A (JPC)		Passes Test
Identification B (USP/ChP-1)		Passes Test
Identification B (JPC)		Passes Test
Identification C (USP)		Passes Test
Identification D (EP/ChP-2)		Passes Test



Made in the USA

ANALYSIS		SPECIFICATIONS
Insoluble Matter		≤ 0.005%
Karl Fischer Water		≤ 1.0%
Loss on Drying (USP/ChP/EP/JPC)		≤ 0.3%
Melting Range (USP/ChP/IDB-EP/JPC)		168 - 172°C
Methanol		≤ 3000 ppm
Microbial Content	TAMC	≤ 100 CFU/g
	TYMC	≤ 100 CFU/g
	Bile tolerant Gram Neg. Bacteria	Absence in 1g
	<i>Escherichia Coli</i>	Absence in 1g
	<i>Pseudomonas aeruginosa</i>	Absence in 1g
	<i>Staphylococcus aureus</i>	Absence in 1g
	<i>Candida albicans</i>	Absence in 1g
	<i>Salmonella sp</i>	Absence in 10g
pH (5%) (USP/IDA-EP/ChP)		10.0 – 11.5
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

GMP Compliance:

Bio Excipient Grade Tromethamine, Chinese Pharmacopeia TRIS-3251 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Tromethamine, Chinese Pharmacopeia is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Expiration:

The recommended expiration period for Tromethamine is three years from the date of manufacture.

Storage and Shipping Conditions:

Store in a cool, dry place. Store in a cool, dry, well-ventilated area away from incompatible substances. Keep away from acids. Keep containers tightly closed.

Package Sizes:

10kg, 25kg and 50kg pails.

Residual Solvents Statement:

Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

General Product Description:

- The manufacturing of Tromethamine TRIS-3251 is performed at BioSpectra's Stroudsburg, PA facility and is conducted in a dedicated processing area using only dedicated equipment.
- Tromethamine is a White Crystalline product
- Molecular Formula: $C_4H_{11}NO_3$
- Molecular Weight: 121.14 g/mol.
- CAS Number: 77-86-1
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Tromethamine TRIS-3251 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts. Tromethamine manufactured at BioSpectra and any raw materials used in the manufacture of Tromethamine at BioSpectra are not subject to genetic modification.
- Synonyms: Tris, Tromethamine, Tris(hydroxymethyl)aminomethane