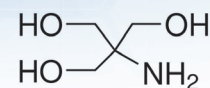


# TROMETHAMINE (TRIS), Ch.P., GMP Excipient Grade

### 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.



**CAS #:** 77-86-1

**Formula:** C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub>

**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**

C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub> • 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 (40%)	290 nm	0.2 a.u. max.
Appearance and Color		White / Crystals
Assay		99.0-101.0%
Bioburden	TAMC	≤ 1000 CFU/g
	TYMC	≤ 100 CFU/g
Chloride		0.01% max.
Endotoxin Concentration		≤ 30 EU/g
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Heavy Metals (Pb)		5 ppm max.
Identification B		Passes Test
Identification C		Passes Test
Identification (IR)		Passes Test
Insoluble Matter		0.005% max.
Karl Fischer Water		2% max.
Loss on Drying		0.6% max.
Melting Range		168 – 172 °C



Made in the USA

ANALYSIS		SPECIFICATIONS
Microorganisms	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%)		10.0 – 11.5
Related Substances (TLC)		1% max.
Residue on Ignition		0.1% max
Trace Metals	Arsenic (As)	5 ppm max.
	Calcium (Ca)	5 ppm max.
	Copper (Cu)	5 ppm max.
	Iron (Fe)	5 ppm max.
	Lead (Pb)	5 ppm max.
	Magnesium (Mg)	5 ppm max.
	Nickel (Ni)	15 ppm max.

### 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.

### Retest Date:

The recommended retest period for Tromethamine is two 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