BIOSPECTRA
Premium Pharmaceutical Ingredients

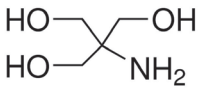
Reagent/Compendial
ICH-Q7 GMP Manufactured Product

TROMETHAMINE (TRIS), 99.9% High Purity, Reagent GMP Grade

Low Bioburden, Low Endotoxin, Multicompendial, GMP Manufactured, Reagent Grade Product

INTENDED FOR USE AS A HIGH PURITY REAGENT GRADE

For Critical Analytical, Diagnostic and Pharmaceutical Applications, and downstream manufacture of drug products where a high purity, high assay, GMP Tromethamine is required. Tris is a considered a "Good's" buffer because it has low UV absorptivity, minimum reactivity, stable pH and is soluble in water.



CAS #: 77-86-1
Formula: $C_4H_{11}NO_3$
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-3257 | Previously: TR3257

$C_4H_{11}NO_3$ • F.W. 121.14 g/mol • CAS# 77-86-1

Made in the USA

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

ANALYSIS		SPECIFICATIONS
Absorbance (1M)	260nm 280nm 430nm	0.06 a.u. max. 0.06 a.u. max. 0.01 a.u. max.
Absorbance (10%)	260nm 280nm 430nm	0.03 a.u. max. 0.02 a.u. max. 0.004 a.u. max.
Absorbance (40%)	290nm	0.2 a.u. max.
APHA Color, 20% Solution		20 APHA max.
Assay (Ultrapure, Dried basis)		99.9% min
Chloride (Cl)		≤ 20 ppm
Endotoxins		≤ 2.5 EU/g
Enzymes	DNase Protease RNase	None None None
Heavy Metals (as Pb)		1 ppm max
Insoluble Matter		0.005% max.
Karl Fischer Water		1.0% max.
Loss on Drying		0.3% max.
Melting Point		168 - 172°C

ANALYSIS		SPECIFICATIONS
Microbial Content	TAMC TYMC	≤ 100 CFU/g ≤ 100 CFU/g
pH (5%)		10.0 – 11.5
Related Substances		0.1% max.
Residue on Ignition		0.05% max
Trace Metals	Arsenic (As) Calcium (Ca) Copper (Cu) Iron (Fe) Lead (Pb) Magnesium (Mg) Manganese (Mn) Zinc (Zn)	≤ 1.6 ppm ≤ 1 ppm ≤ 1 ppm ≤ 1 ppm ≤ 1 ppm ≤ 5 ppm ≤ 1 ppm ≤ 1 ppm

Residual Solvents: 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-3257 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-3257 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

GMP Compliance:

Bio Excipient Grade Tromethamine Multicompendial TRIS-3257 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Tromethamine Multicompendial 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:

10 kg and 25 kg pails and 50 kg drums

Product Statements:

Plant or Animal Origin Statement: BioSpectra certifies that Tris, Product Code TRIS-3257, manufactured by BioSpectra is of Synthetic origin. BioSpectra certifies that Tris, Product Code
TRIS-3257, is not derived from Plant or Animal Origin.

Metal Residue Statement: BioSpectra certifies that Tris, Product Code TRIS-3257, manufactured by BioSpectra is manufactured without the use of metal catalysts and metal reagents. There are no known risks to metal residues in this product.

Melamine Statement: Based on the manufacturing process and the controlled handling, storage, and analysis of Tris, Product Code TRIS-3257, BioSpectra certifies that there is low risk for melamine contamination. Additionally, when tested for melamine, this product reports less than 0.15 ppm.

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.