

### TRIS Excipient, USP, EP, JP, 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:** 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-3255 | Previously: TR3255**

C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub> • F.W. 121.14 g/mol • CAS# 77-86-1



#### USP Compendia

ANALYSIS	SPECIFICATIONS
Assay (dried basis)	99.0-101.0%
Identification A	Passes Test
Identification B	Passes Test
Identification C	Passes Test
Loss on Drying	1.0% max.
Melting Range	168-172°C
pH (1 in 20)	10.0-11.5
Residue on Ignition	0.1% max.

#### EP Compendia

ANALYSIS	SPECIFICATIONS
Appearance of Solution	Passes Test
Assay (dried basis)	99.0-100.5%
Chloride (Cl)	≤ 100 ppm
Identification A	Passes Test
Identification B (Melting Range)	168-172°C
Identification C	Passes Test
Identification D	Passes Test
Iron (Fe)	10 ppm max.
Loss on Drying @ 105°C	0.5% max.
pH (5%)	10.0-11.5
Related Substances	≤ 1.0%
Sulfated Ash	0.1% max.

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



## JPC Analysis


ANALYSIS	SPECIFICATIONS
Arsenic (As)	1.6 ppm max.
Assay (Dried Basis)	99.0-101.0%
Clarity and Color of Solution	Passes Test
Heavy Metals	8 ppm max.
Identification A	Passes Test
Identification B	Passes Test
Loss on Drying	0.5% max.
Melting Point	168-172°C
pH	10.3-10.7
Residue on Ignition	0.1% max.

## Other

ANALYSIS	SPECIFICATIONS
Absorbance (1M)	260nm 0.06 a.u. max.
	280nm 0.06 a.u. max.
	430nm 0.01 a.u. max.
Absorbance (10%)	260nm 0.03 a.u. max.
	280nm 0.02 a.u. max.
	430nm 0.004 a.u. max.
Absorbance (40%)	290nm 0.2 a.u. max.
APHA Color, 20% Solution	20 APHA max.
Appearance and Color	White, Crystalline powder to needle-like crystals
Assay (dried basis)	99.9% min
Endotoxins	≤ 2.5 EU/g
Enzymes	DNase None Detected
	Protease None Detected
	RNase None Detected
Heavy Metals (as Pb)	1 ppm max.
Insoluble Matter	0.005% max.
Karl Fischer Water	1.0% max.
Loss on Drying	0.3% max.
Microbial Content	TAMC ≤ 100 CFU/g
	TYMC ≤ 100 CFU/g
Related Substances	0.1% max.
Residue on Ignition	0.05% max.
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
	Zinc (Zn) < 1 ppm

## General Product Description:

- The manufacturing of Tromethamine TRIS-3255 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-3255 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

 Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH-Q7 Compliant Manufactured
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

**Bio Excipient Grade:** Intended for use as ICH-Q7 Compliant Excipient

**LBLE:** LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).

LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

## GMP Compliance:

Bio Excipient Grade Tromethamine Multicompendial TRIS-3255 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-3255, manufactured by BioSpectra is of Synthetic origin. BioSpectra certifies that Tris, Product Code TRIS-3255, is not derived from Plant or Animal Origin.

**Metal Residue Statement:** BioSpectra certifies that Tris, Product Code TRIS-3255, 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-3255, 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.