

TROMETHAMINE (TRIS), USP, EP, LBLE (Standard), GMP Excipient Grade

Low Bioburden, Low Endotoxin, Multicompendial, GMP Manufactured

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-3254 | Previously: TR3254

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



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


USP COMPENDIA

ANALYSIS		SPECIFICATIONS
Appearance and Color		White/Crystals
Assay		99.0 – 101.0%
Endotoxin		≤ 2.5 EU/g
Identification A		Passes Test
Identification B		Passes Test
Identification C		Passes Test
Loss on Drying		≤ 1.0%
Melting Range		168 - 172°C
pH (1 in 20)		10.0 – 11.5
Residue on Ignition		≤ 0.1%
Microbial Content	TAMC	≤ 500 CFU/g
	TYMC	≤ 200 CFU/g

EP COMPENDIA

ANALYSIS		SPECIFICATIONS
Appearance of Solution		Passes Test
Assay		99.0-100.5%
Chloride (Cl)		≤ 100 ppm
Identification A		Passes Test
Identification B		168 - 174°C
Identification C		Passes Test
Iron (Fe)		< 10ppm
Loss on Drying at 105°C		≤0.5%
pH		10.0 – 11.5
Related Substances		≤ 1.0%
Sulfated Ash		≤ 0.1%



 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.

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-3254 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-3254 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 TRIS-3254 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Tromethamine 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.