

# Excipient

ICH-Q7 GMP Manufactured Product

# TRIS Excipient, USP, EP, 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

## BIO EXCIPIENT GRADE | Product Code: TRIS-3254 | Previously: TR3254

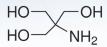
C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub> • F.W. 121.14 g/mol • CAS# 77-86-1

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

	ANALYSIS		SPECIFICATIONS
<b>USP COMPENDIA</b>	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%
	Missobial Contant	TAMC	≤ 500 CFU/g
	Microbial Content	TYMC	≤ 200 CFU/g

	ANALYSIS	SPECIFICATIONS
EP COMPENDIA	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%
	РН	10.0 - 11.5
	Related Substances	≤ 1.0%
	Sulfated Ash	≤ 0.1%

<text>



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 pKg @ 20°C: 8.3

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### Quality Assurance / Regulatory Support / Quality Control

BI©SPECTRA 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	<b>√</b>
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<sub>4</sub>H<sub>11</sub>NO<sub>3</sub>
- 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.

# BISPECTRA

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