BIOSPECTRA
Premium Pharmaceutical Ingredients

Excipient

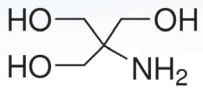
ICH-Q7 GMP Manufactured Product

TRIS, USP, 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.

Lead Time: 3-months
Minimum Order Quantity: 500kg



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-3220 | Previously: TR3220

$C_4H_{11}NO_3$ • 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.

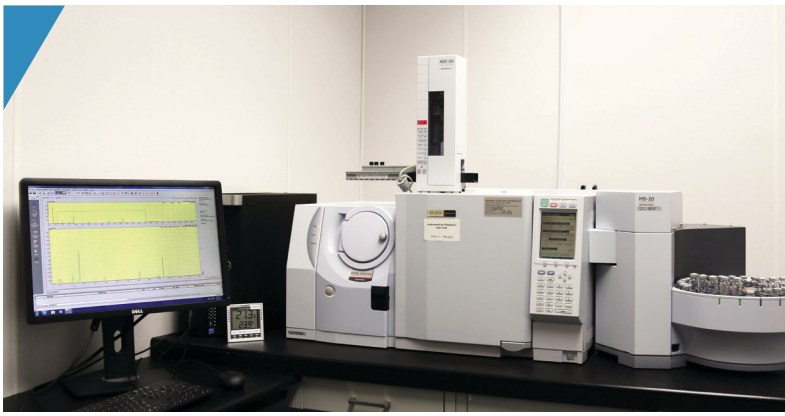
ANALYSIS		SPECIFICATIONS
Absorbance (40%)	290nm	≤ 0.2 a.u.
Appearance and Color		White / Crystals
Assay		99.0 - 101.0%
Chloride		≤ 100 ppm
Enzymes	RNase	None Detected
	DNase	None Detected
	Protease	None Detected
Heavy Metals		≤ 5 ppm
Identification B		Passes Test
Identification C		Passes Test
Identification (IR)		Passes Test
Insoluble Matter		≤ 0.005%
Karl Fischer Water		≤ 2.0%
Loss on Drying		≤ 1.0%
Melting Range		168-172°C
pH (5%)		10.0 - 11.5
Residue On Ignition		≤ 0.1%
Trace Metals	Arsenic (As)	≤ 5 ppm
	Calcium (Ca)	≤ 5 ppm
	Copper (Cu)	≤ 5 ppm
	Iron (Fe)	≤ 5 ppm
	Lead (Pb)	≤ 5 ppm
	Magnesium (Mg)	≤ 5 ppm

BIOSPECTRA 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.



General Product Description:

- The manufacturing of Tromethamine TRIS-3220 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-3220 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, Tri (Hydroxymethyl) Amino Methane.

GMP Compliance:

Bio Excipient Grade Tromethamine TRIS-3220 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:

Ship and Store in ambient temperature.

Package Sizes:

10kg, 25kg and 50kg pails.