

### TRIS HCL, High Assay, LBLE\*, GMP, Excipient, Reagent Grade

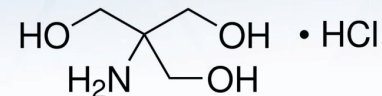
\*Low Bioburden, Low Endotoxin

#### 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 Tris Hydrochloride is required. Tris Hydrochloride is considered a "Good's" buffer because it has low UV absorptivity, minimum reactivity, stable pH and is soluble in water.

**Lead Time: 3 Months**

**Minimum Order Quantity: 500kg**



**CAS #:** 1185-53-1

**Molecular Formula:** C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub> · HCl

**Solubility in Water (g/L):** 1,010

**F.W.:** 157.60 g/mol

**pH @ 20°C:** 4.5 - 6.0

**Useful pH:** 7.0 - 9.0

**pKa @ 20°C:** 8.2

### BIO EXCIPIENT GRADE | Product Code: THCL-3257 | Previously: TH3257

C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub> · HCl · HCl · F.W. 157.60 g/mol · CAS# 1185-53-1



ANALYSIS		SPECIFICATIONS
Absorbance (1M)	260 nm	≤ 0.06 a.u.
	280 nm	≤ 0.06 a.u.
	400 nm	≤ 0.01 a.u.
Appearance		White, Crystalline Powder to Needle-Like Crystals
Assay, Dried		≥ 99.0%
Bioburden		≤ 100 CFU/g
Endotoxin		≤ 2.5 EU/g
Enzymes	DNase	None
	RNase	None
	Protease	None
Identification	(IR)	Passes Test
	(Chloride)	Passes Test
Insolubles		< 0.005%
Loss on Drying @ 105°C		≤ 0.5%
Melting Range		147 – 152°C
pH	(1% Aqueous Solution)	4.0 – 5.0
	(0.5M) @ 25°C	3.5 – 5.0
Trace Metals	Arsenic (As)	≤ 5 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
	Water	

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



 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	✓

<p>✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.</p> <p><b>Bio Excipient Grade:</b> Intended for use as ICH-Q7 Compliant Excipient</p> <p><b>LBLE:</b> 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.</p>
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## Storage and Shipping Conditions:

Ship and store in ambient temperature. Store in a clean and dry area. Store in the original container.

## Package Sizes:

10kg, 25kg and 50kg drums.

## General Product Description:

- The manufacturing of Tris Hydrochloride THCL-3257 is performed at BioSpectra's Stroudsburg, PA facility and is conducted in a dedicated processing area using only dedicated equipment.
- Tris Hydrochloride is a White Crystalline product
- Molecular Formula:  $C_4H_{11}NO_3 \cdot HCl$
- Molecular Weight: 157.60 g/mol.
- CAS Number: 1185-53-1
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Tris Hydrochloride THCL-3257 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- Tris Hydrochloride manufactured at BioSpectra and any raw materials used in the manufacture of Tris Hydrochloride at BioSpectra are not subject to genetic modification.
- Synonyms: Tris Hydrochloride, 2-Amino-2-(Hydroxymethyl)-1,3-Propanediol Hydrochloride; Tris (Hydroxymethyl) Aminomethane Hydrochloride

## GMP Compliance:

Bio Excipient Grade Tris Hydrochloride THCL-3257 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Tris Hydrochloride is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

## Expiration:

The recommended expiration period for Tromethamine Hydrochloride is three years from the date of manufacture.

## Product Statements:

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

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