BIOSPECTRA
Premium Pharmaceutical Ingredients

Excipient

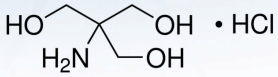
ICH-Q7 GMP Manufactured Product

TRIS HCl, LBLE, LEI, High Assay, GMP Excipient Grade

Low Bioburden, Low Endotoxin, GMP Manufactured

INTENDED FOR USE AS AN EXCIPIENT

Tris Hydrochloride is a stabilizing buffer in biological applications such as electrochromatography, UV analysis and HPLC. It is used to adjust and stabilize the pH ranges for gels used in electrophoresis applications. Tris Hydrochloride is extensively used as a biological buffer or a component of buffer solutions.



CAS #: 1185-53-1
Molecular Formula: $C_4H_{11}NO_3 \cdot HCl$
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-3260

$C_4H_{11}NO_3 \cdot HCl$ • HCl • F.W. 157.60 g/mol. • CAS# 1185-53-1

Made in the USA

ANALYSIS		SPECIFICATIONS
Absorbance (1M)	260 nm 280 nm 400 nm	≤ 0.06 a.u. ≤ 0.06 a.u. ≤ 0.01 a.u.
Appearance and Color		White / Crystals
Assay, Dried		99.5% min.
Bioburden		≤ 100 CFU/g
Endotoxin		≤ 2.5 EU/g
Enzymes	DNase RNase Protease	None Detected None Detected None Detected
Heavy Metals		2 ppm max.
Identification	(IR) (Chloride)	Passes Test Passes Test
Loss on Drying @ 105°C		≤ 0.5%
Melting Range		150 – 152 °C
pH	(1% Aqueous Solution) (0.5M) @ 25°C	4.0 – 5.0 3.5 – 5.0
Residue on Ignition		0.1% max.
Solubility 35%		Passes Test
Trace Metals	Arsenic (As) Calcium (Ca) Copper (Cu) Iron (Fe) Lead (Pb) Magnesium (Mg)	1 ppm max. 1 ppm max. 1 ppm max. 1 ppm max. 1 ppm max. 1 ppm max.
Water (Karl Fischer)		0.5% max.

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

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400

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.

Product Statements:

RESIDUAL SOLVENTS: 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 Tris Hydrochloride THCL-3260 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-3260 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-3260 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.

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.