

GMP BIOTECH PRODUCT

TRIS HYDROCHLORIDE

BIOTECH, HIGH ASSAY, LBLE, GMP

CAS #: 1185-53-1

Formula: C₄H₁₁NO₃ HCl

F.W.: 157.60 g/mol

THCL-4251

BIO PHARMA GRADE

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 Crystalline Powder to Needle-Like Crystals
Assay, Dried Basis		<u>></u> 99.0%
Bioburden		≤ 100 CFU/g
Endotoxin		≤ 2.5 EU/g
Enzymes	DNase Protease RNase	None Detected None Detected None Detected
Identification, Chloride		Passes Test
Identification, IR		Conforms to Reference Standard
Insoluble Matter		<u><</u> 0.005%
Loss on Drying		<u><</u> 0.5%
Melting Range		147 - 152 °C
pH (1% solution)		4.0 - 5.0
pH (0.5M)		3.5 - 5.0
Ca Co Trace Metals Magne	rsenic (As) lcium (Ca) opper (Cu) Iron (Fe) Lead (Pb) sium (Mg) nese (Mn) Zinc (Zn)	<pre>≤ 5 ppm ≤ 1 ppm ≤ 5 ppm ≤ 1 ppm ≤ 1 ppm ≤ 1 ppm</pre>
Water, KF		<u>≤</u> 1.0%

Country of Origin: USA

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

This is an ultra-high purity, GMP, Reagent grade of Tris Hydrochloride, purified under full cGMP conditions. It is suitable for critical applications where high assay, GMP material is required. Tris Hydrochloride is considered a Good's buffer because it has a low UV absorptivity, minimum reactivity, stable pH and is highly soluble in water.

General Product Description

- Appears as a white crystalline product
- Manufactured under an ICH-Q7 Quality Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- No known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts/derivatives.
- Is not subject to genetic modification
- Synonyms: Tris Hydrochloride (HCl), 2-Amino-2-(Hydroxymethyl)-1,3-Propanediol Hydrochloride, Tris (Hydroxymethyl) Aminomethane Hydrochloride
- Visit the product page on our website (<u>www.biospectra.us</u>) for additional information, supporting regulatory documents, and CofAs.

Storage and Shipping Conditions Refer to SDS.

Standard Shelf Life Policy

Each Certificate of Analysis will contain a 2-year retest/recertification date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

100g, 500g, 1kg, 5kg, 10kg, 25kg, 50kg

Standard Lead Time

1-2 weeks