

TRIS HYDROCHLORIDE

BIOTECH, HIGH ASSAY, LBLE, GMP

CAS #: 1185-53-1

Formula: $C_4H_{11}NO_3HCl$

F.W.: 157.60 g/mol

THCL-4251

BIO PHARMA GRADE

ANALYSIS		SPECIFICATIONS
Absorbance (1M)	260 nm	≤ 0.06 a.u.
	280 nm	≤ 0.06 a.u.
	400 nm	≤ 0.01 a.u.
Appearance and Color		White Crystalline Powder to Needle-Like Crystals
Assay, Dried Basis		$\geq 99.0\%$
Bioburden		≤ 100 CFU/g
Endotoxin		≤ 2.5 EU/g
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Identification, Chloride		Passes Test
Identification, IR		Conforms to Reference Standard
Insoluble Matter		$\leq 0.005\%$
Loss on Drying		$\leq 0.5\%$
Melting Range		147 – 152 °C
pH (1% solution)		4.0 – 5.0
pH (0.5M)		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, KF		$\leq 1.0\%$

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 (www.biospectra.us) 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