## **GMP BIOTECH PRODUCT**

# TRIS HYDROCHLORIDE

HIGH ASSAY, LBLE, GMP

CAS #: 1185-53-1 Formula: NH<sub>2</sub>C(CH<sub>2</sub>OH)<sub>3</sub> HCl F.W.: 157.60 g/mol

### THCL-4251

## **BIO PHARMA GRADE**

Analysis		SPECIFICATIONS
Absorbance (1	260 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		> = 99.0%
Microbial Conte	ent TAMC TYMC	< = 100 CFU/g < = 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		< = 0.005%
Loss on Drying		< = 0.5%
Melting Range		147 - 152°C
pH (1%)		4.0 - 5.0
pH (0.5M)		3.5 - 5.0
Trace Metals	Arsenic (As) Calcium (Ca) Copper (Cu) Iron (Fe) Lead (Pb) Magnesium (Mg) Manganese (Mn) Zinc (Zn)	< = 5 ppm < = 1 ppm < = 1 ppm < = 1 ppm < = 1 ppm < = 5 ppm < = 1 ppm < = 1 ppm
Water, KF		< = 1.0%
Country of Origin: USA		

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# 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 IPEC 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

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