

**Bulk GMP Products** 

**Contract GMP Manufacturing** 

**Custom API Development** 

#### Q

# TRIS HCI

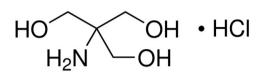
## BIO PHARMA Grade | TH4220 | CAS# 1185-53-1

#### INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES



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.

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



#### **BIO PHARMA Grade / TH4220**

CAS #: 1185-53-1

Molecular Formula:  $C_4H_{11}NO_3HCI$ 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

SDS	Spec Sheet	Compliance	C of As
	ANALYSIS		SPECIFICATIONS
Absorbance (1M)		280 nm	0.06 a.u. max.
Appearance and Color			White / Crystals
Assay, Dried			99.5% min.
		DNase	None Detected
Enzymes		RNase	None Detected
		Protease	None Detected
Heavy Metals			2 ppm max.
Identification (IR)			Passes Test
Insoluble Matter			0.001% max.
LOD at 105°C			0.5% max.
Melting Range			150 – 153°C
pH (0.5M)			4.0 – 5.0
$pK_a$			8.0 – 8.4
Residue on Ignition	on		0.1% max.
Solubility (1M)			Passes Test
		Arsenic (As)	5 ppm max.
		Calcium (Ca)	5 ppm max.
Trace Elements		Copper (Cu)	5 ppm max.
Trace Elements		Iron (Fe)	5 ppm max.
		Lead (Pb)	5 ppm max.
		Magnesium (Mg)	5 ppm max.

#### **General Product Description:**

- BioSpectra manufactures Tris Hydrochloride TH4220 in its Stroudsburg, PA facility.
- Tris Hydrochloride is a White Crystalline product.
- Molecular Formula: NH<sub>2</sub>C(CH<sub>2</sub>OH)<sub>3</sub>
- 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 TH4220 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, Tromethamine, Tri (Hydroxymethyl) Amino Methane Hydrochloride.

#### **GMP Compliance:**

Bio Pharma Grade Tris Hydrochloride TH4220 is manufactured in accordance with cGMP guidelines and is suitable to be used only as the following: IPEC Compliant GMP Manufactured Chemical, for use in further Manufacturing or as a Reagent for Laboratory and Research. This Grade of Tris Hydrochloride is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or household item.

### **Expiration/Retest Date:**

The recommended retest period for Tromethamine Hydrochloride is two years from the date of manufacture.

#### Storage and Shipping Conditions:

Ship and Store in ambient temperature.

#### Package Sizes:

10kg, 25kg and 50kg pails.

