## **GMP BIOTECH PRODUCT**

Bulk cGMP Fine Chemical Manufacturer

SPECTR A

# TRIS

## BIOTECH, HIGH ASSAY, MEETS USP, GMP, PREMIUM REAGENT

### BIO PHARMA GRADE / TRIS-4223

C4H11NO3 **^** F.W. 121.14 g/mol **^** CAS# 77-86-1

### Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

Tris (Tromethamine) is a high purity, GMP Reagent Grade, where high purity, high assay, GMP Tromethamine is required. Tris is considered a "Good's" buffer because it has a low UV absorptivity, minimum reactivity, stable pH and is soluble in water.

Analysis		Specifications
Trace Metals	Aluminum (Al)	<u>&lt;</u> 5 ppm
	Arsenic (As)	<u>&lt; 1.6 ppm</u>
	Barium (Ba)	<u>&lt;</u> 5 ppm
	Bismuth (Bi)	$\leq$ 5 ppm
	Cadmium (Cd)	<u>&lt;</u> 5 ppm
	Calcium (Ca	$\leq 1$ ppm
	Chromium (Cr)	<u>&lt;</u> 5 ppm
	Cobalt (Co)	≤ 5 ppm ≤ 1 ppm ≤ 1 ppm ≤ 1 ppm ≤ 5 ppm
	Copper (Cu)	<u>&lt; 1</u> ppm
	Iron (Fe)	<u>&lt;</u> 1 ppm
	Lead (Pb)	<u>&lt; 1</u> ppm
	Lithium (Li)	<u>&lt; 5 ppm</u>
	Magnesium (Mg)	< 5 nnm
	Manganese (Mn)	$\leq 1 \text{ ppm}$ $\leq 5 \text{ ppm}$
	Molybdenum (Mo)	$\leq$ 5 ppm
	Nickel (Ni)	$\leq 5 \text{ ppm}$
	Potassium (K)	$\leq$ 50 ppm
	Sodium (Na)	
	Zinc (Zn)	$\leq 1 \text{ ppm}$
Absorbance (1M)	260 nm	$\leq 0.06$ a.u.
	280 nm	<u>≤</u> 0.06 a.u.
	430 nm	<u>≤</u> 0.01 a.u.
Absorbance (10%)	260 nm	<u>≤</u> 0.03 a.u.
	280 nm	<u>≤</u> 0.02 a.u.
	430 nm	<u>≤</u> 0.004 a.u.
Absorbance (40%)	290 nm	<u>≤</u> 0.20 a.u.
Enzymes	DNase	None
	Protease	None
	RNase	None
APHA Color (20% Solution)		$\leq 20$

### **SPECIFICATIONS**

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Assay, Dried Basis (Ultrapure)	≥ 99.9%
Endotoxin	$\leq$ 2.5 EU/g
Heavy Metals (as Pb)	<u>≤</u> 1 ppm
Insoluble Matter	$\leq$ 0.005%
Water, KF	$\leq 1.0\%$
Loss on Drying	$\leq 0.3\%$
Melting Range	168 – 172°C
Microbial Content TAMC TYMC	≤ 100 CFU/g ≤ 100 CFU/g
pH (5% solution)	10.0 - 11.5
Related Substances	$\leq 0.1\%$
Residue on Ignition	$\leq$ 0.05%
Chloride	≤ 20 ppm

### **General Product Description:**

Molecular Formula: C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub> Molecular Weight: 121.14 g/mol CAS Number: 77-86-1

### **Tromethamine Biotech:**

- Tromethamine is a White Crystalline product. •
- Is manufactured under an ICH-Q7 Quality • Managed cGMP System
- Manufactured in an enzyme free, hormone free and animal free environment
- Has no known major food allergens (as • defined by FDA and WHO)
- The final product nor its raw materials are • not derived from nor come into contact with animals, animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: Tris, Tromethamine, • Tris(hydroxymethyl) aminomethane

### **Shelf Life Policy:**

Three-year expiry from the date of manufacture.

### **Storage and Shipping Conditions:**

Please refer to the SDS for storage and shipping conditions.

### Package Size:

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