

### **GMP BIOTECH PRODUCT**

# TRIS (TROMETHAMINE)

HIGH ASSAY, USP, GMP

CAS #: 77-86-1 Formula: C<sub>4</sub>H<sub>11</sub>NO<sub>3</sub> F.W.: 121.14 g/mol

### TRIS-4223

## **BIO PHARMA GRADE**

Analys	IS	SPECIFICATIONS
Absorbance (1M)	260 nm 280 nm 430 nm	< = 0.06 a.u. < = 0.06 a.u. < = 0.01 a.u.
Absorbance (10%)	260 nm 280 nm 430 nm	< = 0.03 a.u. < = 0.02 a.u. < = 0.004 a.u.
Absorbance (40%)	290 nm	< = 0.20 a.u.
APHA Color (20% Solution)		< = 20 APHA
Assay, Dried Basis (USP)		99.0 - 101.0%
Assay, Dried Basis (Ultrapure)		> = 99.9%
Chloride		< = 20 ppm
Endotoxin		< = 2.5 EU/g
Enzymes	DNase Protease RNase	None Detected None Detected None Detected
Identification A, IR (USP)		Conforms to Reference Standard
Identification B (USP)		Passes Test
Identification C (USP)		Passes Test
Insoluble Matter		< = 0.005%
Loss on Drying (USP)		< = 0.3%
Melting Range (USP)		168 - 172°C
Microbial Content	TAMC TYMC	< = 100 CFU/g < = 100 CFU/g
pH (5%)		10.0 - 11.5
Related Substances		< = 0.1%
Residue on Ignition		< = 0.05%
Trace Metals	Aluminum (Al) Arsenic (As) Barium (Ba) Bismuth (Bi) Cadmium (Cd) Calcium (Ca) Chromium (Cr) Cobalt (Co) Copper (Cu) Iron (Fe) Lead (Pb) Lithium (Li) Magnesium (Mg) Manganese (Mn) Molybdenum (Mo) Nickel (Ni) Potassium (Na) Zinc (Zn)	< = 5 ppm < = 1.6 ppm < = 5 ppm < = 5 ppm < = 5 ppm < = 1 ppm < = 5 ppm < = 1 ppm < = 1 ppm < = 1 ppm < = 1 ppm < = 5 ppm < = 1 ppm
Water, KF		< = 1.0%

# Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

This is a high purity, GMP, reagent grade product, purified under a full cGMP system. It is used when high purity, high assay, GMP Tromethamine is required. Tris is considered a Good's buffer because it has low UV absorptivity, minimum reactivity, stable pH and is 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, Tromethamine, Tris(hydroxymethyl) aminomethane
- 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

# **Country of Origin: USA**

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