GMP BIOTECH PRODUCT

TRIS (TROMETHAMINE)

HIGH ASSAY, USP, GMP

CAS #: 77-86-1

Formula: NH₂C(CH₂OH)₃

F.W.: 121.14 g/mol

TRIS-4223

BIO PHARMA GRADE

Analysis	9	SPECIFICATIONS
Absorbance (1M)	260 nm	< = 0.06 a.u.
	280 nm	< = 0.06 a.u.
	430 nm	< = 0.01 a.u.
Absorbance (10%)	260 nm	< = 0.03 a.u.
	280 nm	< = 0.02 a.u.
Al (400/)	430 nm	< = 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 (Ultrapur	re)	> = 99.9%
Chloride		< = 20 ppm
Endotoxin		< = 2.5 EU/g
Enzymes	DNase	None Detected
	Protease RNase	None Detected None Detected
	MAGC	Conforms to
Identification A, IR (USP)		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%) (USP)		10.0 - 11.5
Related Substances		<= 0.1%
Residue on Ignition (USP)		<= 0.05%
and the second of the second o	Aluminum (Al)	< = 5 ppm
Trace Metals	Arsenic (As)	< = 1.6 ppm
	Barium (Ba)	< = 5 ppm
	Bismuth (Bi) Cadmium (Cd)	< = 5 ppm < = 5 ppm
	Calcium (Ca)	< = 1 ppm
	Chromium (Cr)	< = 5 ppm
	Cobalt (Co)	< = 5 ppm
	Copper (Cu)	< = 1 ppm
	Iron (Fe)	< = 1 ppm
	Lead (Pb)	< = 1 ppm
	Lithium (Li) Magnesium (Mg)	< = 5 ppm < = 5 ppm
	Manganese (Mn)	< = 1 ppm
	Molybdenum (Mo)	< = 5 ppm
	Nickel (Ni)	< = 5 ppm
	Potassium (K)	< = 50 ppm
	Sodium (Na)	< = 50 ppm
M-4-: 1/5	Zinc (Zn)	< = 1 ppm
Water, KF		< = 1.0%

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

This is a high purity, reagent grade product, purified under a cGMP system. It is used when high purity, high assay, GMP grade 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 in accordance with IPEC
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains 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 or derivatives.
- Is not subject to genetic modification
- Synonyms: Tris(hydroxymethyl) aminomethane, Trometamol, THAM, Trisaminol
- Visit the product page on our website (<u>www.biospectra.us</u>) for additional information, supporting regulatory documents, and CoAs.

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf Life Policy

Each Certificate of Analysis will contain a 2-year retest 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

2-4 weeks

Country of Origin: USA

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