

BIS-TRIS BIOTECH, LBLE, GMP

CAS #: 6976-37-0

Formula: $C_8H_{19}NO_5$

F.W.: 209.24 g/mol

BTRI-4250

BIO PHARMA GRADE

ANALYSIS		SPECIFICATIONS
Absorbance (0.1M)	280 nm	≤ 0.04 a.u.
	340 nm	≤ 0.02 a.u.
Ammonium (NH ₄)		≤ 500 ppm
Appearance and Color		White Crystalline Powder
Assay, Dried Basis		99.0 – 101.0%
Bioburden	TAMC	≤ 100 CFU/g
	TYMC	≤ 100 CFU/g
Chloride		≤ 50 ppm
Endotoxin		≤ 50 EU/g
Enzymes	DNase	None Detected
	Protease	None Detected
	RNase	None Detected
Heavy Metals (Pb)		≤ 3 ppm
Identification, IR		Conforms to Reference Standard
Loss on Drying		$\leq 1.0\%$
Melting Point		100 – 105 °C
pH (1% aqueous)		8.8 - 9.8
pKa		6.3 – 6.7
Residue on Ignition		$\leq 0.1\%$
Solubility 0.1M in H ₂ O		Clear and Complete
Sulfate		≤ 50 ppm
Trace Metals	Aluminum (Al)	≤ 5 ppm
	Calcium (Ca)	≤ 500 ppm
	Iron (Fe)	≤ 3 ppm
	Lead (Pb)	≤ 10 ppm
	Phosphorus (P)	≤ 500 ppm
Water, KF		$\leq 1.0\%$

Country of Origin: USA

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

This is a high purity, GMP, Reagent grade product, purified under full cGMP conditions. BIS-TRIS is a zwitterionic biological “Goods” buffer often used in biological pharmaceutical manufacturing and biochemistry for extraction, separation and purification, as well as an intermediate in synthetic reactions for both proteins and nucleic acid. BIS-TRIS is also used as a process aid in peptide synthesis. It can also be used as a scavenger agent for metal ions such as Cu and Pb.

General Product Description

- Appears as a white crystalline powder
- Manufactured under an ICH-Q7 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: 2,2-Bis(hydroxymethyl)-2,2',2''- nitrile tri ethanol; Bis(2-hydroxyethyl) amino tris (hydroxymethyl)methane
- 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

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