

BIS-TRIS BLE, GMP, EXCIPIENT

CAS #: 6976-37-0

 Formula: $C_8H_{19}NO_5$

F.W.: 209.24 g/mol

BTRI-3250
Bio EXCIPIENT GRADE

ANALYSIS		SPECIFICATIONS
Absorbance (0.1M)	280 nm 340 nm	< = 0.04 a.u. < = 0.02 a.u.
Appearance and Color		White Crystals
Assay, Dried Basis		99.0% – 101.0%
Microbial Content	TAMC TYMC	< = 100 CFU/g < = 100 CFU/g
Chloride		< = 50 ppm
Endotoxin		< = 50 EU/g
Enzymes	DNase Protease RNase	None Detected None Detected None Detected
Identification, IR		Conforms to Reference Standard
Loss on Drying		< = 1.0%
Melting Point		100 – 105 °C
pH (1%)		8.8 – 9.8
pK _a		6.3 – 6.7
Residue on Ignition		< = 0.1%
Solubility (0.1M)		Clear and Complete
Trace Metals	Iron (Fe) Lead (Pb)	< = 3 ppm < = 3 ppm
Water, KF		< = 1.0%

General Product Overview

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 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.

Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

Key Product Features

- The manufacturing of Bis-Tris, BTRI-3250 is performed at BioSpectra's Bangor, PA facility.
- Appears as white crystals
- Manufactured in accordance with ICH Q7
- 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.
- It is not subject to genetic modification
- Synonyms: 2,2-Bis(hydroxymethyl)-2,2',2"- nitrilotriethanol; Bis(2-hydroxyethyl) aminotris(hydroxymethyl)methane; 2-(bis(2-hydroxyethyl)amino)-2(hydroxymethyl)-1,3-propanediol
- Visit the product page on our website for additional information, supporting regulatory documents, and CoAs.

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf-Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

10kg, 25kg and 50kg pails

Standard Lead Time

1-3 months

Minimum Order Quantity

50kg

Country of Origin: USA

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