BIOSPECTRA
Premium Pharmaceutical Ingredients

Excipient

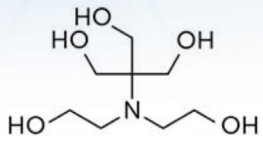
ICH-Q7 GMP Manufactured Product

BIS-TRIS, LBLE, USP, EP, GMP Excipient Grade

Low Bioburden, Low Endotoxin, Multicompendial, GMP Manufactured

INTENDED FOR USE AS AN EXCIPIENT

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.



CAS #: 6976-37-0
Formula: $C_8H_{19}NO_5$
F.W.: 209.24 g/mol
pH @ 25°C: 6.3 - 6.7
Melting Point/Range: 100 - 105 °C

BIO EXCIPIENT GRADE | Product Code: BTRI-3250

$C_8H_{19}NO_5$ • F.W.: 209.24 g/mol • CAS# 6976-37-0

Made in the USA

These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

ANALYSIS		SPECIFICATIONS
Absorbance (0.1M)	280 nm 340 nm	≤ 0.04 a.u. ≤ 0.02 a.u.
Appearance and Color		White Crystalline Powder
Assay (Titration, Dry Basis)		99.0% - 101.0%
Bioburden		≤ 100 CFU/g
Chloride		< 0.005%
Endotoxin		≤ 50 EU/g
Enzymes	DNase Protease RNase	None Detected None Detected None Detected
Heavy Metals (Pb)		≤ 3ppm
Identification (IR) (USP/EP)		Conforms to Reference Standard
Iron		≤ 3ppm
Loss on Drying (LOD)		≤ 1.0%
Melting Point		100 – 105°C
pH (1% aqueous)		8.8 – 9.8
pKa @ 25°C		6.3 – 6.7
Residue on Ignition (ROI)		≤ 0.1%
Solubility 0.1M in H_2O (USP)		Clear + complete
Water (KF)		≤ 1.0%

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400

BIOSPECTRA Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH-Q7 Compliant Manufactured
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Excipient Grade: Intended for use as ICH-Q7 Compliant Excipient

LBLE: LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).
LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

General Product Description:

- The manufacturing of BIS-TRIS, BTRI-3250 is performed at BioSpectra's Bangor, PA facility and is conducted in a dedicated processing area using only dedicated equipment.
- BIS-TRIS is a White Crystalline product
- Molecular Formula: $C_8H_{19}NO_5$
- Molecular Weight: 209.24 g/mol
- CAS Number: 6976-37-0
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- Biospectra certifies that all BIS-TRIS BTRI-3250 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts. BIS-TRIS manufactured at BioSpectra and any raw materials used in the manufacture of BIS-TRIS at BioSpectra are not subject to genetic modification.
- Synonyms: 2,2-Bis(hydroxymethyl)-2,2',2''-nitrilotriethanol; Bis(2-hydroxyethyl) aminotris(hydroxymethyl)methane

GMP Compliance:

Bio Excipient Grade BIS-TRIS, BTRI-3250 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of BIS-TRIS is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

The recommended retest period for BIS-TRIS is two years from the date of manufacture.

Storage and Shipping Conditions:

Store in a cool, dry place. Store in a cool, dry, well-ventilated area away from incompatible substances. Keep away from acids. Keep containers tightly closed.

Package Sizes:

10kg, 25 kg and 50 kg pails.

Residual Solvents Statement:

Based on the manufacturing process and the controlled handling, storage and analysis of this product, this product complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.