

May 7th, 2024 Revision 2

MELAMINE STATEMENT

Bis-Tris GMP

Bis-Tris, Bio Excipient Grade is a synthetic chemical and has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that melamine is not a risk based on this evaluation. BioSpectra has not specifically analyzed Bis-Tris, Bio Excipient Grade or its raw materials for melamine. Bis-Tris, Bio Excipient Grade is not considered at-risk per the US FDA Guidance for Industry, Pharmaceutical Components at Risk for Melamine Contamination.

Current Product Number

BTRI-3250

For further information, please contact info@biospectra.us

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