

RESIDUAL SOLVENTS STATEMENT

Tris GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Tris, Bio Excipient Grade, and Bio Pharma Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents. Tris is analyzed annually for residual solvents, with specifications for Methanol \leq 3000ppm, and Nitromethane \leq 50 ppm.

Current Product Number
TRIS-3201
TRIS-3220
TRIS-3221
TRIS-3251
TRIS-3252
TRIS-3254
TRIS-3255
TRIS-3256
TRIS-3257
TRIS-4221
TRIS-4224

For further information, please contact Customer.Service@BioSpectra.us

Cassie Baum

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