

RESIDUAL SOLVENTS STATEMENT

Tris Hydrochloride GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Tris Hydrochloride, 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 Hydrochloride is analyzed annually for residual solvents, with specifications for Methanol ≤ 3000 ppm, and Nitromethane ≤ 50 ppm.

Current Product Number
THCL-3203
THCL-3220
THCL-3221
THCL-3250
THCL-3252
THCL-3253
THCL-3254
THCL-3257
THCL-3259
THCL-3260
THCL-4250

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



Cassie Baum
Senior Compliance Specialist