

RESIDUAL SOLVENTS STATEMENT

Dextran Powder MW 10,000 GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Dextran Powder MW 10,000, Bio Excipient Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline, and USP <467> Residual Solvents.

BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the Class 3 solvent Isopropyl Alcohol is used in the manufacture of the raw material supplied to BioSpectra, which complies with the <5000 ppm specification. BioSpectra does not specifically analyze Dextran Powder MW 10,000, Bio Excipient Grade for Residual Solvents, as solvents are not utilized in the BioSpectra manufacturing process.

Current Product Number
D010-3201

For further information, please contact info@biospectra.us

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