

RESIDUAL SOLVENTS STATEMENT

Dextran Sulfate 8000 Sodium Salt GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Dextran Sulfate 8000 Sodium Salt, Bio Pharma Grade manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the Class 2 solvent Methanol is used in the manufacture of the Dextran Sulfate raw material supplied to BioSpectra. BioSpectra's approved Raw Material Supplier has stated that the Methanol is removed to trace amounts during the manufacturing process, and that the Dextran Sulfate raw material complies with the limits of <3000ppm Methanol. BioSpectra has additionally analyzed Dextran Sulfate 8000 Sodium Salt, Bio Pharma Grade for residual solvents during degradation and impurity profiling for manufacturing process validation, with results conforming to the requirements.

Current Product Number
DXSE-4250

For further information, please contact info@biospectra.us



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