



June 2nd, 2023
Revision 1

RESIDUAL SOLVENTS STATEMENT

Dextran Sulfate GMP

BioSpectra does not intentionally add or use any solvents in the manufacture of Dextran Sulfate, Bio Pharma Grade. BioSpectra has evaluated the source of the raw materials used in its production through the Supplier Qualification Program, and can state that the Class III Solvent Isopropyl Alcohol, and the Class II solvent Methanol are used in the manufacture of the raw material. BioSpectra's approved Raw Material Supplier has stated that these solvents comply with the limits as required by ICH Q3C for residual solvents of <5000ppm Isopropyl Alcohol, and <3000ppm Methanol. BioSpectra will additionally analyze Dextran Sulfate for Isopropyl Alcohol and Methanol during degradation and impurity profiling for manufacturing process validation.

For further information, please contact info@biospectra.us

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