BIOSPECTRA
Premium Pharmaceutical Ingredients

October 4th, 2024
Revision 1

GENOTOXIC IMPURITY STATEMENT

Dextran Sulfate 8000 Sodium Salt GMP

BioSpectra performs process validation in accordance with the approved Manufacturing Process Validation Master Plan, which includes Degradation and Impurity Profiling to identify and quantify potential impurities.

BioSpectra does not use any of the elements listed in ICH Q3D, USP <232>, and USP <233> in the manufacturing process. BioSpectra's Dextran Sulfate 8000 Sodium Salt, Bio Pharma Grade material has been profiled for elemental impurities via ICP utilizing USP <232> and USP <233> in accordance with ICH Q3D, with results reported in the associated Elemental Impurity Profile.

Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Dextran Sulfate 8000 Sodium Salt, Bio Pharma Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents. Dextran Sulfate has additionally been analyzed for residual solvents during degradation and impurity profiling, with results conforming to the established ICH Q3C limits.

BioSpectra does not specifically analyze Dextran Sulfate 8000 Sodium Salt, Bio Pharma Grade for genotoxic impurities, as they are not used in the BioSpectra manufacturing process.

Current Product Number
DXSE-4250

For further information, please contact info@biospectra.us

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