BIOSPECTRA
Premium Pharmaceutical Ingredients

June 13th, 2025
Revision 1

GENOTOXIC IMPURITIES STATEMENT

Dextran Powder MW 10,000 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 add any of the elements listed in ICH Q3D, USP <232>, and USP <233> to the manufacturing process of Dextran Powder MW 10,000, Bio Excipient Grade.

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

BioSpectra does not specifically analyze Dextran Powder MW 10,000, Bio Excipient Grade for genotoxic impurities, as they are not used in the BioSpectra manufacturing process.

Current Product Number
D010-3201

For further information, please contact info@biospectra.us

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