

GENOTOXIC IMPURITIES 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.

BioSpectra has evaluated Dextran Sulfate 8000 Sodium Salt, Bio Pharma Grade for applicable USP <467> Residual Solvents.

Current Product Number
DXSE-4250

For further information, please contact Customer.Service@BioSpectra.us



Cassie Baum
Senior Compliance Specialist