BIOSPECTRA
Premium Pharmaceutical Ingredients

April 29th, 2024
Revision 1

GENOTOXIC IMPURITY STATEMENT

MES, Hydrate 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 intentionally add any of the elements listed in ICH Q3D, USP <232>, and USP <233> to the product or the manufacturing process. BioSpectra's MES, Monohydrate 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, MES, Hydrate, Bio Excipient Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents. MES, Monohydrate 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 MES, Hydrate, Bio Excipient Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
MESH-3201
MESH-3250

For further information, please contact info@biospectra.us

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