BIOSPECTRA
Premium Pharmaceutical Ingredients

August 13th, 2021
Revision 3

GENOTOXIC IMPURITY STATEMENT

MES, Monohydrate 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.

MES, Monohydrate, Bio Excipient Grade, and Bio Pharma Grade manufactured by BioSpectra conforms to the limits established in USP <232>, USP <233>, and ICH Q3D guidance for Elemental Impurities. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, MES, Monohydrate, Bio Excipient Grade, and 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.

BioSpectra does not specifically analyze MES, Monohydrate, Bio Excipient Grade, and Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number	Historic Product Number
MESM-3220	ME3220
MESM-3221	ME3221
MESM-3222	ME3222
MESM-3223	ME3223
MESM-3250	N/A
MESM-4220	ME4220

For further information, please contact info@biospectra.us

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