BIOSPECTRA
Premium Pharmaceutical Ingredients

March 16th, 2021
Revision 2

GENOTOXIC IMPURITY STATEMENT

HEPES 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. HEPES, 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, HEPES, 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 HEPES, 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
HEPE-3220	HE3220
HEPE-3221	HE3221
HEPE-3250	HE3250
HEPE-3251	HE3251
HEPE-4220	HE4220

For further information, please contact info@biospectra.us

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