BIOSPECTRA
Premium Pharmaceutical Ingredients

April 2nd, 2025
Revision 4

GENOTOXIC IMPURITIES 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.

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 HEPES material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D, with results reported in the associated HEPES Elemental Impurity Profile.

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 of the ICH Q3C Residual Solvents Guideline and USP <467> 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
HEPE-3220
HEPE-3221
HEPE-3222
HEPE-3250
HEPE-3251
HEPE-3320
HEPE-3351
HEPE-4220

For further information, please contact info@biospectra.us

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