

## GENOTOXIC IMPURITY STATEMENT

### MOPS 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 has analyzed MOPS for Arsenic (As), Iron (Fe), Sodium (Na), and Lead (Pb) with results meeting the 5-ppm maximum specification.

BioSpectra has evaluated the Raw Material Supply through the Supplier Approval Program and can state based on this evaluation that MOPS can expose you to the chemical 1,3-Propane Sultone (CAS# 1120-71-4), which is known to the State of California to cause cancer. BioSpectra's approved Raw Material Supplier uses 1,3-Propane Sultone as an early stage raw material in the manufacture of the MOPS raw material supplied to BioSpectra.

Based on the manufacturing process and the controlled handling, storage, and analysis of this product, MOPS, 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 MOPS, 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
MOPS-3201	MP3201
MOPS-3220	MP3220
MOPS-4220	MP4220

For further information, please contact [info@biospectra.us](mailto:info@biospectra.us)

  
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