

## 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.

MOPS, 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, MOPS, Bio Pharma Grade complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the chemical 1,3-Propane Sultone (CAS# 1120-71-4) is used in the initial synthesis step of the MOPS raw material supplied to BioSpectra. 1,3-Propane Sultone is known to the State of California to cause cancer.

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

Current Product Number
MOPS-4221

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

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