

## GENOTOXIC IMPURITIES STATEMENT

### 2-MEA 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.

2-MEA, Bio Excipient Grade has been profiled for elemental impurities via ICP utilizing USP <232> and USP <233> in accordance with the ICH Q3D Guidance for Elemental Impurities. BioSpectra does not intentionally add any elemental impurities to the product or the manufacturing process.

Based on the manufacturing process and the controlled handling, storage, and analysis of this product, 2-MEA, Bio Excipient Grade complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline, and USP <467> Residual Solvents. Isopropyl Alcohol is used by BioSpectra in the manufacture of 2-MEA, Bio Excipient Grade, and the product adheres to the specification of  $\leq 5000\text{ppm}$ .

BioSpectra does not specifically analyze 2-MEA, Bio Excipient Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
CSMH-3250

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

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