

## GENOTOXIC IMPURITY STATEMENT

### Sodium Decanoate 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. Sodium Decanoate, Bio Excipient 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, Sodium Decanoate, Bio Excipient 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 Sodium Decanoate, Bio Excipient Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number	Historic Product Number
NDEC-3201	ND3201
NDEC-3220	ND3220
NDEC-3320	ND3320

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

*Cassie Baun*  
**Cassie Baun**  
Compliance Specialist