BIOSPECTRA
Premium Pharmaceutical Ingredients

February 8th, 2021
Revision 1

GENOTOXIC IMPURITY STATEMENT

Sodium Decanoate Bio Excipient

ND3201 ND3220 ND3320

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 product codes ND3201, ND3220, ND3320 for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun
Compliance Specialist

The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure, copying or alteration. Decision based on the use of this information is the sole responsibility and liability of the recipient. If you would like a controlled version of this document, please contact info@biospectra.us