



GENOTOXIC IMPURITIES 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 has been profiled for elemental impurities via ICP utilizing USP <232> and USP <233> in accordance with ICH Q3D. 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 of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

Sodium Decanoate manufactured by BioSpectra was analyzed for additional impurities during process validation and has met the pre-established specifications. 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
NDEC-3201

For further information, please contact Customer.Service@BioSpectra.us

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Page 1 of 1