BIOSPECTRA
Premium Pharmaceutical Ingredients

October 10th, 2022
Revision 1

GENOTOXIC IMPURITY STATEMENT

Uridine 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. Uridine, 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, Uridine, 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. Uridine manufactured by BioSpectra was analyzed for additional trace metal impurities during process validation and met the pre-established specifications. BioSpectra does not specifically analyze Uridine, Bio Excipient Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

For further information, please contact info@biospectra.us

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