BIOSPECTRA
Premium Pharmaceutical Ingredients

May 7th, 2021
Revision 2

GENOTOXIC IMPURITY STATEMENT

Uracil 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. BioSpectra does not intentionally add any of the elements listed in ICH Q3D, USP <232>, and USP <233> to the product or the manufacturing process. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Uracil, Bio Pharma 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 Uracil, Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number	Historic Product Number
URAC-4201	UC4201
URAC-4202	UC4202
URAC-4250	UC4250
URAC-4301	UC4301

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun
Compliance Specialist

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