BIOSPECTRA
Premium Pharmaceutical Ingredients

February 8th, 2021
Revision 1

GENOTOXIC IMPURITY STATEMENT

Urea Bio Active Bio Excipient Bio Pharma

UR2220 UR2250 UR3220 UR3221 UR3250 UR4205 UR4220

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. BioSpectra has analyzed Urea, Bio Active Grade, Bio Excipient Grade, and Bio Pharma Grade for Arsenic (As), Copper, (Cu), Iron (Fe), and Lead (Pb), as well as additional impurity analyses, with material meeting the pre-established specifications. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Urea, Bio Active Grade, Bio Excipient Grade, and 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 analyze Urea for residual solvents, as they are not intentionally added or used during the Urea manufacturing process. BioSpectra does not specifically analyze Urea, Bio Active Grade, Bio Excipient Grade, and Bio Pharma Grade product codes UR2220, UR2250, UR3220, UR3221, UR3250, UR4205, UR4220 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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