BIOSPECTRA
Premium Pharmaceutical Ingredients

July 28th, 2021
Revision 2

GENOTOXIC IMPURITY STATEMENT

Urea 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. Urea, Bio Excipient Grade, and Bio Pharma 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, Urea, 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 Excipient Grade, and 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
UREA-3220	UR3220
UREA-3221	UR3221
UREA-3222	UR3222
UREA-3223	UR3223
UREA-3224	UR3224
UREA-3250	UR3250
UREA-4205	UR4205
UREA-4220	UR4220

For further information, please contact info@biospectra.us

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