BIOSPECTRA
Premium Pharmaceutical Ingredients

January 27th, 2025
Revision 1

GENOTOXIC IMPURITIES 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. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Urea, Bio Pharma Grade complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

Urea, Bio Pharma Grade manufactured by BioSpectra has been analyzed for additional impurities during process validation, with results meeting the pre-established specifications. BioSpectra does not specifically analyze Urea, Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
UREA-4221

For further information, please contact info@biospectra.us

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