

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. Urea, Bio Excipient Grade has been profiled for elemental impurities, with results reported in the associated Elemental Impurity Profile.

Urea, Bio Excipient Grade complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents. There are no solvents added or used in the manufacturing process of Urea, Bio Excipient Grade.

BioSpectra does not specifically analyze Urea, Bio Excipient Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
UREA-3220
UREA-3221
UREA-3222
UREA-3223
UREA-3224
UREA-3250

For further information, please contact Customer.Service@BioSpectra.us

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