



## 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, and Bio Pharma Grade has been profiled for elemental impurities, with results reported in the associated Elemental Impurity Profile.

Urea, Bio Excipient Grade, and Bio Pharma 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, and Bio Pharma Grade.

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 Code |
|----------------------|
| UREA-3220            |
| UREA-3223            |
| UREA-3224            |
| UREA-3250            |
| UREA-4221            |

For further information, please contact [Customer.Service@BioSpectra.us](mailto:Customer.Service@BioSpectra.us)

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