

## GENOTOXIC IMPURITY STATEMENT

### Water for Injection (WFI) GMP

Water for Injection, Bio Excipient Grade manufactured by BioSpectra starts from potable water and is processed through BioSpectra's Pretreatment System, RO/CEDI Loop, WFI Storage and Distribution System.

BioSpectra does not use elemental impurities in the manufacturing process of Water for Injection, Bio Excipient Grade. BioSpectra's Water for Injection has been profiled for elemental impurities utilizing USP <232> and USP <233> in accordance with ICH Q3D, with results reported in the associated Elemental Impurity Profile.

Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Water for Injection, Bio Excipient Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

BioSpectra's Water for Injection System utilizes Ozone for water sanitization, and is equipped with Ozone Destruct Units. The Ozone concentration is assessed on a daily basis, and must meet the established specification of  $\leq 0.01$  ppm in the Water for Injection Loop Supply.

Current Product Number
WAFI-3150

For further information, please contact [info@biospectra.us](mailto:info@biospectra.us)

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