

## GENOTOXIC IMPURITY STATEMENT

### L-Histidine Monochloride Monohydrate

BioSpectra has evaluated the material supply through the Supplier Qualification Program, and can state that none of the elements listed in ICH Q3D, USP <232>, and USP <233> are added to the L-Histidine Monochloride Monohydrate, Bio Pharma Grade for BioBuffer Solutions Product line material or manufacturing process. There are no metal catalysts, metal reagents, or metal residues used in the manufacturing process or present in the raw materials. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, L-Histidine Monochloride Monohydrate, Bio Pharma Grade for BioBuffer Solutions product line complies with the requirements and specifications listed in the USP method <467> Tables 1, 2, 3, or 4 for residual solvents.

Current Product Number
LHMM-4250

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

*Cassie Baun*

**Cassie Baun**

Senior Compliance Specialist