

GENOTOXIC IMPURITY STATEMENT

Potassium Bromide API

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. Potassium Bromide, Bio Active Grade manufactured by BioSpectra conforms to the limits established in USP <232>, USP <233>, and ICH Q3D guidance for Elemental Impurities. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Potassium Bromide, Bio Active Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents. BioSpectra does not specifically analyze Potassium Bromide, Bio Active Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number	Historic Product Number
KBRO-2220	PB2220
KBRO-2221	PB2221
KBRO-2301	PB2301
KBRO-2302	N/A

For further information, please contact info@biospectra.us

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