

GENOTOXIC IMPURITY STATEMENT

6N HCl in IPA Solution

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 of 6N HCl in IPA, and therefore does not analyze for these elements.

BioSpectra does not analyze 6N HCl in IPA, Bio Pharma Grade for residual solvents, as the product is an acid solvent blend which contains isopropanol.

BioSpectra does not specifically analyze 6N HCl in IPA, Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number	Historic Product Number
IHCL-4101	IH4101

For further information, please contact info@biospectra.us


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