

GENOTOXIC IMPURITY STATEMENT

Sodium Chloride 5M 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. Sodium Chloride 5M Solution, Bio Excipient Grade will be analyzed for elemental impurities in accordance with the limits established in USP <232>, USP <233>, and ICH Q3D guidance. Trace metals will additionally be analyzed during process validation. Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Sodium Chloride 5M Solution, Bio Excipient Grade complies with the requirements and specifications listed in the USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents. BioSpectra does not specifically analyze Sodium Chloride 5M Solution, Bio Excipient Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number	Historic Product Number
NACL-3150	NC3150

For further information, please contact info@biospectra.us

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