

GENOTOXIC IMPURITY STATEMENT

Sodium Hydroxide Solution Bio Pharma

NH4101 NH4102 NH4103 NH4122 NH4123 NH4124 NH4150 NH4151 NH4152 NH4153 NH4154 NH4155

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. Sodium Hydroxide Solution, Bio Pharma Grade manufactured by BioSpectra has been analyzed for trace metals Arsenic (As), Copper (Cu), Iron (Fe), Lead (Pb), and Potassium (K), as well as additional impurity and degradation analyses, with material meeting pre-established specifications at raw material, in-process, and finished good stages. Sodium Hydroxide Solution is not routinely analyzed for elemental impurities.

BioSpectra has evaluated the Raw Material Supply through the Supplier Approval Program and can state based on this evaluation that the raw material may contain impurities / trace elements known to the State of California to cause cancer or reproductive toxicity, including Arsenic, Cadmium, Chromium, Lead, and Nickel. Please reference the Sodium Hydroxide Proposition 65 Statement for further details.

Based on the manufacturing process and the controlled handling, storage, and analysis of this product, Sodium Hydroxide Solution, Bio Pharma Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4. BioSpectra does not specifically analyze Sodium Hydroxide, Bio Pharma Grade product codes NH4101, NH4102, NH4103, NH4122, NH4123, NH4124, NH4150, NH4151, NH4152, NH4153, NH4154, NH4155 for residual solvents, or other genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

For further information, please contact info@biospectra.us

Cassie Baun
Cassie Baun
Compliance Specialist