

GENOTOXIC IMPURITY STATEMENT

Sodium Hydroxide 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. Sodium Hydroxide Solution, Bio Excipient Grade, and 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 Solution Proposition 65 Statement for further details.

Based on the manufacturing process and the controlled handling, storage, and analysis of this product, the Sodium Hydroxide Solution, Bio Excipient Grade, and Bio Pharma Grade manufactured by BioSpectra 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 Sodium Hydroxide, Bio Excipient Grade, and Bio Pharma Grade for residual solvents, or other genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.



Current Product Number	Historic Product Number
NAHY-3150	NH3150
NAHY-3153	NH3153
NAHY-4103	NH4103
NAHY-4122	NH4122
NAHY-4123	NH4123
NAHY-4124	NH4124
NAHY-4150	NH4150
NAHY-4151	NH4151
NAHY-4152	NH4152
NAHY-4153	NH4153
NAHY-4154	NH4154
NAHY-4155	NH4155

For further information, please contact info@biospectra.us

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