

July 28th, 2021 Revision 2

ELEMENTAL IMPURITY STATEMENT

Sodium Hydroxide Solution

BioSpectra does not routinely analyze Sodium Hydroxide Solution, Bio Excipient Grade, and Bio Pharma Grade for elemental 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) with material meeting pre-established specifications.

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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