BIOSPECTRA
Premium Pharmaceutical Ingredients

January 28th, 2025
Revision 1

GENOTOXIC IMPURITIES STATEMENT

Sodium Hydroxide Solution GMP

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. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program, and can state based on this evaluation that the raw material may contain trace amounts of Arsenic, Cadmium, Chromium, Lead, and Nickel, which are known to the State of California to cause cancer or reproductive harm. Sodium Hydroxide Solution, Bio Pharma Grade has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D. The results are reported in the associated Elemental Impurity Profile and are available upon request.

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 of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

BioSpectra does not specifically analyze Sodium Hydroxide, 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
NAHY-4126

For further information, please contact info@biospectra.us

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