BIOSPECTRA
Premium Pharmaceutical Ingredients

November 30th, 2021
Revision 2

GENOTOXIC IMPURITY STATEMENT

2-MEA 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 analyzed 2-MEA for trace elements / elemental impurities as detailed in the Elemental Impurity Profiles.

Based on the manufacturing process and the controlled handling, storage, and analysis of this product, 2-MEA, Bio Excipient Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents. Isopropyl Alcohol is used by BioSpectra in the manufacture of the 2-MEA Finished Good, and the product adheres to the specification of ≤ 5000ppm.

BioSpectra does not specifically analyze 2-MEA, 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
CSMH-3250	CH3250
CSMH-3251	CH3251

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun
Compliance Specialist