

## RESIDUAL SOLVENTS STATEMENT

### 2-MEA GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the 2-MEA, Bio Excipient Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

BioSpectra has evaluated the raw material supply through the Supplier Qualification Program, and can state that the Class 3 solvent Ethanol is used in the manufacture of the raw material supplied to BioSpectra. BioSpectra's approved Raw Material Supplier has stated that the raw material complies with the allowed limit of 5000 ppm max Ethanol.

Isopropyl Alcohol is used by BioSpectra in the manufacture of 2-MEA, Bio Excipient Grade, and the product adheres to the specification of  $\leq 5000$  ppm.

Current Product Number
CSMH-3250

For further information, please contact [customer.service@biospectra.us](mailto:customer.service@biospectra.us)



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