

RESIDUAL SOLVENTS STATEMENT

HEPES GMP

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

BioSpectra does not intentionally add or use any Class 1, 2, 3, or other solvents in the manufacturing process of HEPES, Bio Excipient Grade, and Bio Pharma Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the Class 2 solvent Methanol, and the Class 3 solvent Ethanol are used in the manufacture of the HEPES raw material supplied to BioSpectra. BioSpectra's approved Raw Material Suppliers have stated that the HEPES raw material complies with the allowed limits of 3000ppm Methanol, or 5000ppm Ethanol. BioSpectra has additionally analyzed HEPES finished good for residual solvents during process validation, and confirmed that the product complies with the limits of 3000ppm max Methanol, and 5000ppm max Ethanol.

Current Product Number
HEPE-3220
HEPE-3221
HEPE-3222
HEPE-3250
HEPE-3251
HEPE-3320
HEPE-3351
HEPE-4220

For further information, please contact info@biospectra.us

Cassie Baun
Cassie Baun
Senior Compliance Specialist