

RESIDUAL SOLVENTS STATEMENT

MES, Hydrate GMP

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

BioSpectra does not intentionally add or use any solvents in the manufacturing process of MES, Hydrate, Bio Pharma Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program. BioSpectra's approved Raw Material Supplier has indicated residues of the Class 3 solvent Ethanol may be present, and that the raw material meets the <5000ppm requirement. BioSpectra has additionally analyzed MES, Hydrate finished good for residual solvents during process validation, and confirmed that the product complies with the ICH Q3C limit of 5000ppm max Ethanol.

Current Product Number
MESH-4250

For further information, please contact info@biospectra.us

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