

RESIDUAL SOLVENTS STATEMENT

MOPS GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the MOPS, 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 solvents in the manufacturing process of MOPS, 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 MOPS raw material supplied to BioSpectra. BioSpectra's approved Raw Material Suppliers have stated that the MOPS raw material complies with the allowed limits of 3000ppm Methanol, or 5000ppm Ethanol. BioSpectra has additionally analyzed MOPS finished good for residual solvents during process validation, and has confirmed that the product complies to the limits of <3000ppm Methanol, and <5000ppm Ethanol.

Current Product Number
MOPS-4221

For further information, please contact info@biospectra.us

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