BIOSPECTRA
Premium Pharmaceutical Ingredients

January 27th, 2025
Revision 1

RESIDUAL SOLVENTS STATEMENT

Uridine GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Uridine, 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 Uridine, Bio Pharma Grade, with the exception of Isopropyl Alcohol (2-Propanol). BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that Methanol and Dichloromethane, or Ethanol are used in the manufacture of the Uridine raw material supplied to BioSpectra. BioSpectra's approved Raw Material Suppliers have indicated that the Uridine raw material complies with the allowed limits of 3000 ppm Methanol and 600 ppm Dichloromethane, or 5000 ppm Ethanol. BioSpectra has analyzed the raw material for residual solvents during Supplier Qualification with results meeting specification. BioSpectra additionally analyzes Uridine finished good annually for residual solvents, as well as during degradation and impurity profiling as part of manufacturing process validation to confirm that the material complies with the respective limits.

Current Product Number
URID-4250

For further information, please contact info@biospectra.us

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