BIOSPECTRA
Premium Pharmaceutical Ingredients

October 10th, 2022
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 Excipient Grade manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

BioSpectra does not intentionally add or use any solvents in the manufacturing process of Uridine, Bio Excipient 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 Ethanol is used in the manufacture of the Uridine raw material supplied to BioSpectra. BioSpectra's approved Raw Material Supplier has indicated that the Uridine raw material complies with the allowed limit of 5000 ppm Ethanol. BioSpectra analyzes Uridine finished good for residual solvents during process validation, and has confirmed that the product complies to the limits of 5000 ppm Ethanol and 2-Propanol.

For further information, please contact info@biospectra.us

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