



RESIDUAL SOLVENTS STATEMENT

D-Galactose Plant Derived GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the D-Galactose Plant Derived, Bio Pharma Grade manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4.

BioSpectra uses the Class 3 solvent Isopropyl Alcohol in the manufacturing process of D-Galactose Plant Derived, Bio Pharma Grade, and adheres to the specification of ≤ 5000 ppm. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program, and can state that the Class 2 solvent Methanol is used in the manufacture of the D-Galactose raw material supplied to BioSpectra, with the material conforming to the specification of <3000ppm. BioSpectra analyzes D-Galactose Plant Derived annually for residual solvents, with results meeting the specifications of NMT 100 ppm Methanol, and NMT 5000 ppm Isopropyl Alcohol. D-Galactose Plant Derived is additionally analyzed for residual solvents as detailed in the Certificate of Analysis for the specific product code purchased.

Current Product Number
GALP-4250

For further information, please contact info@biospectra.us

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