BIOSPECTRA
Premium Pharmaceutical Ingredients

December 27th, 2024
Revision 1

GENOTOXIC IMPURITIES STATEMENT

D-Galactose Plant Derived GMP

BioSpectra performs process validation in accordance with the approved Manufacturing Process Validation Master Plan, which includes Degradation and Impurity Profiling to identify and quantify potential impurities.

BioSpectra does not intentionally add any of the elements listed in ICH Q3D, USP <232>, and USP <233> to the product or the manufacturing process. BioSpectra's D-Galactose Plant Derived material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D, with results reported in the associated Elemental Impurity Profile.

Based on the manufacturing process and the controlled handling, storage, and analysis of this product, D-Galactose, Bio Pharma Grade complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4 for Residual Solvents. Isopropyl Alcohol is used by BioSpectra in the manufacture of the D-Galactose Finished Good, and the product adheres to the specification of ≤ 5000ppm. D-Galactose Plant Derived is analyzed annually for residual solvents, and each batch is analyzed as detailed in the Certificate of Analysis for the specific product code purchased.

BioSpectra does not specifically analyze D-Galactose, Bio Pharma Grade for genotoxic impurities, as they are not intentionally added or used in the BioSpectra manufacturing process.

Current Product Number
GALP-4250

For further information, please contact info@biospectra.us

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