



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, Bio Excipient Grade 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 Plant Derived, Bio Excipient Grade complies with the requirements of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

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

Current Product Number
GALP-3250
GALP-3251
GALP-3252
GALP-3350
GALP-3351

For further information, please contact info@biospectra.us

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