

December 26<sup>th</sup>, 2024 Revision 1

## NITROSAMINE STATEMENT

D-Galactose Plant Derived GMP

BioSpectra can state that a Nitrosamine Risk Evaluation prepared in accordance with European Medicines Agency (EMA) requirements and US FDA Control of Nitrosamine Impurities in Human Drugs Guidance for Industry is available upon request for D-Galactose Plant Derived, Bio Pharma Grade manufactured by BioSpectra.

> Current Product Number GALP-4250

For further information, please contact info@biospectra.us

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