

February 13th, 2025 Revision 2

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 Excipient Grade manufactured by BioSpectra.

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

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun Senior Compliance Specialist

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