

January 21st, 2025 Revision 1

NITROSAMINE STATEMENT

Trehalose, Dihydrate 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 Trehalose, Dihydrate, Bio Pharma Grade manufactured by BioSpectra.

> Current Product Number TRED-4250

For further information, please contact info@biospectra.us

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