

January 14<sup>th</sup>, 2025 Revision 1

## NITROSAMINE STATEMENT

MES, Hydrate 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 MES, Hydrate, Bio Pharma Grade manufactured by BioSpectra.

> Current Product Number MESH-4250

For further information, please contact info@biospectra.us

Cassie Baum

**Cassie Baun** Senior Compliance Specialist

The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure, copying or alteration. Decision based on the use of this information is the sole responsibility and liability of the recipient. If you would like a controlled version of this document, please contact info@biospectra.us