

April 2nd, 2025 Revision 3

NITROSAMINE STATEMENT

HEPES 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 HEPES, Bio Excipient Grade, and Bio Pharma Grade.

Current Product Number
HEPE-3220
HEPE-3221
HEPE-3222
HEPE-3250
HEPE-3251
HEPE-3320
HEPE-3351
HEPE-4220

For further information, please contact info@biospectra.us

Cassie Baun

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