

April 26th, 2024 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 Excipient Grade manufactured by BioSpectra.

Current Product Number	
MESH-3201	
MESH-3250	

For further information, please contact info@biospectra.us

Cassia Raun

Senior Compliance Specialist