BIOSPECTRA
Premium Pharmaceutical Ingredients
100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

To Whom It May Concern,

BioSpectra manufactures MES, Monohydrate, Bio Excipient Grade, Historic Product Number: ME3250/Current Product Number: MESM-3250, Low Bioburden and Low Endotoxin (LBLE), at the Bangor, PA facility. Although, the processing area is a non-sterile manufacturing area and is not Cleanroom classified, BioSpectra ensures MES, Monohydrate material meets the acceptance criteria for LBLE through prevention of microbial contamination, verification of process steps and assurance through Bioburden and Endotoxin specifications and analysis.

The prevention of microbial contamination is conducted by cleaning in accordance with the Cleaning Worksheet Procedure DCN: 20-003542. The monitoring of microbial contamination is performed through the monthly environmental monitoring (EM) of the process room and equipment used in the manufacturing of MES, Monohydrate in accordance with the Environmental Monitoring Procedure DCN: 17-002062. The acceptable limits for surfaces regarding microbiological activity is as follows: Non- Product contacting surface TAMC specification is 2000 CFU/plate maximum, TYMC specification is 200 CFU/plate maximum and Product Contact surface TAMC specification is ≤100 CFU/swab and the TYMC specification is ≤10 CFU/swab. Through BioSpectra's Cleaning and EM Programs, the process room and equipment are cleaned and monitored to ensure the acceptable levels are met. Additionally, BioSpectra's Product Care procedure DCN: 16-000118 defines and provides guidelines for all BioSpectra employees, visitors, and contract providers regarding gowning and protecting themselves and BioSpectra products from contamination. The Product Care procedure requires the following when a production operator is manufacturing MES, Monohydrate: Company provided uniforms, nitrile or neoprene gloves, safety glasses, safety shoes, disposable lab jackets, disposable sleeves, beard nets and hairnets. Masks are also provided to employees in accordance with the Pandemic Response Plan DCN: 20-003314. Furthermore, employees with apparent illness are prohibited from working where direct contact with the product cannot be avoided.

The verification of process and steps includes a pre-process room inspection criterion, the two-step purification stage, use of approved USP Purified Water, and HEPA filtered dried air during the drying stage. These steps ensure the prevention of microbial growth, while also purifying the product to meet required specifications.

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The assurance through specification and analysis includes the requirement to analyze each batch for microbial content and endotoxin before release for the LBLE code. The analysis of each batch is completed to ensure that BioSpectra can continue to produce material meeting the required LBLE specifications. This will ensure that MESM-3250, MES, Monohydrate LBLE is suitable for use in parenteral drug applications as an excipient that requires further manufacturing of a finished drug product including terminal sterilization and/or aseptic filling by filtration.

BioSpectra has validated the MES, Monohydrate manufacturing process to ensure that all preestablished specifications are met. This validation study has ensured that the manufacturing steps have the controls in place to consistently produce MES, Monohydrate meeting the validation requirements.

If there are any questions regarding this letter, please feel free to contact me directly or your Commercial Team Representative
https://biospectra.us/about-us/commercial-marketing-team

Sincerely,

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