SAFC®
Pharma & Biopharma Raw Material Solutions

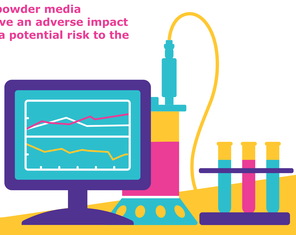
MERCK

MINIMIZING THE PRESENCE OF BIOBURDEN

Strategies to Protect Dry Powder Media

If not properly controlled during the dry powder media manufacturing process, bioburden can have an adverse impact on product quality and stability, creating a potential risk to the biomanufacturing process.

Our comprehensive approach of procedures and policies across our global network results in effective control of bioburden in dry powder media. Risk mitigation strategies to minimize the possibility of introducing microbial contamination into the process spans from raw materials through production and packaging.



RAW MATERIALS

- As part of our global raw material and vendor management program, all raw materials are evaluated for bioburden risk per qualification, requalification, and standard lot release
- Industry accepted sampling plan based on the number of raw material containers received in a single shipment

PEOPLE

- Gloved and fully gowned in manufacturing attire
- Gowning and gloves changed as needed
- Additional layer of personal protective equipment may be added when handling materials

ENVIRONMENT

- Raw material weighing, mixing and milling as well as dispensing and packaging of the media are performed in controlled and monitored rooms
- Air is pressure cascaded to prevent air movement into rooms with open product or raw materials
- Rooms are cleaned top down between each batch per approved procedures
- Routine environmental monitoring is performed to confirm rooms are under control

Our manufacturing process and environmental conditions are consistent across all our global dry powder media manufacturing sites.

PROCESS

- Raw material containers wiped down prior to moving into dedicated weighing room
- Dust plenum in close proximity to weigh scale to minimize dust dispersal
- One raw material is handled at a time and must be removed from weigh zone prior to weighing next raw material
- Machinery used for blending, milling and dispensing is cleaned using validated cleaning methods between products

SAMPLING AND QC TESTING

- Representative samples of dry powder media are taken for quality control testing and retention
- Testing follows compendial methods and uses either membrane filtration or pour plate. Results are reported to include both total aerobic (TAMC) and total yeast and mold counts (TYMC)
- Product specific verifications ensure no interference of bioburden detection
- Operating procedures are in place to control out of specification investigations

The presence of bioburden is not homogeneous. After final blending samples are taken from multiple locations and combined to create a composite sample. This composite sample results are reported on the CoA.

FINISHED PRODUCT PACKAGING

- Packaging materials are inspected for cleanliness and cleaned as necessary prior to use
- Finished good containers, either polypropylene or HDPE bottles, are designed to prevent moisture ingress
- Tamper evident seals are applied to maintain the integrity of the product as it travels to the customer and throughout storage

The life science business of Merck operates as MilliporeSigma in the U.S. and Canada.