

# Pharmaceutical Microbiology

The Pharmaceutical Microbiology Group at Lancaster Laboratories performs a full array of services in support of sterile products, non-sterile products and facility monitoring and control. Whether you need microbial limits tests on a raw material or sterility testing on your parenteral, our knowledgeable professionals can meet your needs. With our strict adherence to cGMP requirements and our strong commitment to client service, we can operate as a capable extension of your own in-house laboratory. Some of the microbiology services we offer are outlined below.

## Microbial Limits:

- Harmonized USP, EP and JP-based microbial limit tests.
- Total combined yeast and mold.
- Total aerobic microbial count.
- *Escherichia coli*.
- *Salmonella* species.
- *Staphylococcus aureus*.
- *Pseudomonas aeruginosa*.
- Product validation.

## Laboratory Support for Process Validation and Manufacturing:

- Process water testing.
- Environmental monitoring/viable surface and air sample analysis.
- On-site sample collection services.
- Consulting.
- Organism identification using a GC-based microbial identification system and DuPont Qualicon Riboprinter®.
- Growth promotion.
- Biological indicator analysis.
- Endotoxin indicator preparation and analysis.
- Disinfectant efficacy studies.
- Microbial immersion/container integrity testing.

## Particulate Matter Analysis:

- Harmonized USP and EP-based methods.
- HIAC™ particle counting.
- Microscopic methods.

## Endotoxin Testing:

- Harmonized USP and EP-based methods.
- Kinetic turbidimetric.
- Kinetic chromogenic.
- Gel clot.
- Inhibition/enhancement screening.

*continued on reverse*



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## **Sterility Testing Using an Isolator System:**

- USP, EP and JP-based methods.
- Membrane filtration.
- Direct transfer.
- Bacteriostasis/fungistasis.

## **Antimicrobial Preservative Effectiveness:**

- USP and EP-based methods.
- Client protocols.
- Product validation.

Our operations and facilities at Lancaster Laboratories include barrier isolator technology for sterility testing. We also have pharmaceutical microbiology laboratories equipped with 15 biological safety cabinets and a regularly certified HEPA air filtration system.

For more information on our pharmaceutical microbiological testing capabilities or any of our pharmaceutical capabilities, please contact your project manager or Pharmaceutical Business Development at 717-656-2300.



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