



# Wickham Laboratories

## Microbiology Services - Pharmaceutical

Wickham Laboratories Ltd is an independent contract analytical Laboratory established for over 40 years. The microbiological testing service has been successfully examining Pharmaceutical products for over 30 years. Located in rural Hampshire, our experienced microbiology team offers a high degree of knowledge and expertise.

Using in- house, clients own methods or standard procedures, the department provides a rapid, cost effective service for all your quality control requirements.

Our mission is to provide our clients with an independent, confidential and professional service. Our customers look to Wickham Laboratories as being experts in our field, confident that testing is being performed with precision and speed. We take pride in having a reputation for high quality standards.



# the right choice

## Outsourcing – Why?

Wickham Laboratories have a large microbiology facility separated into designated laboratory areas, with a staff in excess of 30 people we are able to cope with large and small projects in a timely manner.

Our approach is to listen and understand your outsourcing requirements. We will translate this into an effective plan in order to deliver a solution to your testing needs.

Wickham Laboratories undertakes microbiological testing for the pharmaceutical industry, conducting analysis of a wide variety of pharmaceutical products for batch release into European and International markets.

Data produced by our microbiology department has been used to support license applications in Europe and NDA submissions in the USA.

The microbiology department offers a range of services for the routine quality control, method development and validation of products as well as microbiological testing for the sterilisation and other processes.



## Legislation

The pharmaceutical industry is driven by regulatory pressures and we invest in our quality systems to ensure compliance with GMP, GLP and FDA requirements.

With over 30 years of experience, our microbiology departments at Wickham Laboratories are familiar with the regulatory expectations of microbiological testing, using industry standard harmonised methods compliant with PH Eur, USP and JP.



## **Sterility Testing (Ph.Eur, BP, USP)**

Dedicated clean-room facility (ISO Class 7)

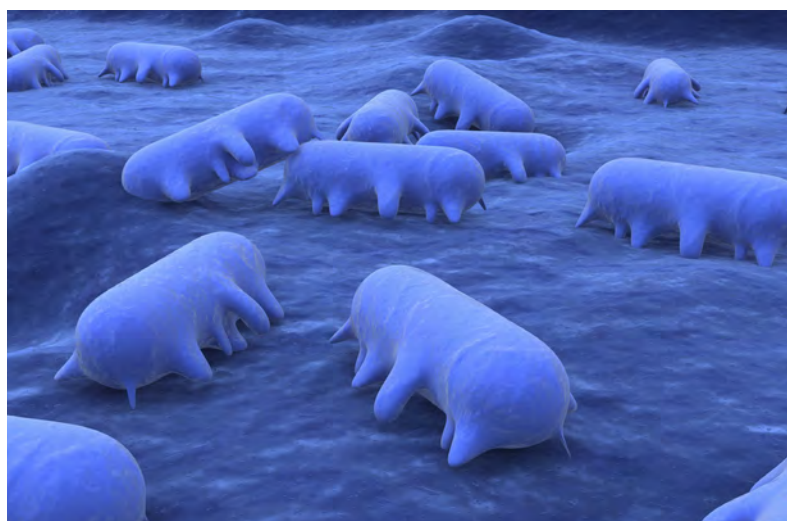
Two Flexible film positive pressure isolators (ISO Class 5)

Membrane filtration methods using the Millipore Steritest® system

Direct inoculation & sterile fluid pathway testing.

## **Efficacy of Antimicrobial Preservative in Pharmaceutical Products (Ph.Eur, BP, USP)**

Validation & analysis is available to assess the efficacy of the preservative system across a wide range of product types including, Parenteral, Ophthalmic, Topical or Oral.



## **Pharmaceutical Quality Control**

### **Routine Quality Control Tests for Microbiological Examination**

At Wickham Laboratories Ltd, the microbiology department has extensive expertise in the microbiological testing of different dosage forms, raw materials, intermediates and final products. Using in-house, clients own methods or standard procedures, the department provides a rapid, cost effective service for all your testing requirements.

**“Data produced by our microbiology department has been used to support license applications in Europe and NDA submissions in the USA”**

### **Microbial Examination of Non Sterile Products (Ph.Eur, BP, USP)**

Total aerobic microbial counts

- Total bacterial count
- Yeasts & Mould count

Tests for specified micro organisms

- Escherichia coli
- Salmonella spp
- Pseudomonas aeruginosa
- Staphylococcus aureus
- Bile tolerant Gram-negative Bacteria

### **Bacterial Endotoxin Testing (Ph.Eur, BP, USP)**

Gel clot method as an end point assay or semi quantitative titration. Kinetic chromogenic and turbidimetric method are available for routine quality control and validation.





## Results & Reporting

Validation and project work may be performed to a protocol and the findings detailed in a final report to GMP. Routine analysis is typically reported on a certificate of analysis. Urgent results may be reported electronically as E-mail, scanned PDF documents or Faxes to speed up the reporting process where required.

## Consultancy Support & Advice

In addition to laboratory services mentioned, Wickham Laboratories Ltd offers support and consultancy for;

- Clean rooms
- Water systems
- Microbiological issues

**GCP** **GMP** **GLP** **FDA**  
Compliant Laboratory Compliant Laboratory Compliant Laboratory Audited Laboratory

**Wickham Laboratories Ltd endeavour to exceed customer's expectations. We provide a professional service tailored to your requirements.**

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