

## cGMP Microbiology Services



Intertek BioClin has extensive experience in testing a full range of products. These include Oral products (liquid, tablet and capsule), Topical (creams and ointments), Injectables, Transdermal, Ophthalmic products and purified water. Intertek BioClin has broad experience using client's methods and internationally recognised methods such as USP, Ph. Eur, BP and more. Alternatively, procedures can be developed at the client's request.

### Serving the Pharmaceutical Industry:

- **Microbial Limit Testing / Validation**  
Of raw materials and finished products for parameters such as Total Bacteria Counts, Combined Yeast and Mould Counts (Also know as bioburden analysis). Testing for specified organisms: Such as E-coli, Salmonella, Staphylococcus aureus, Pseudomonas aeruginosa etc. All according to the relevant recognized standards such as United States Pharma, Eur. Pharma , British Pharma etc.
- **Preservative Efficacy Testing/Validation**  
For the following product types: Oral, Parenterals and Injectable's, Topical and Antacid products. All according to the relevant recognized standards as above.
- **Incubation of Environmental monitoring Samples**  
Air monitoring. Surface monitoring etc

### BioClin Research Laboratories Ltd

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Intertek Bioclin provides cGMP Microbiology services, cGMP Pharmaceutical analysis, GLP Bioanalysis and data analysis services for a wide range of pharmaceutical, biotechnology, healthcare product and chemical manufacturing clients.

- **Validation of Water Systems**  
Systems at all stages i.e. in-process, potable, purified waters etc. For parameters such as Total Bacterial Count, Coliforms, E-coli, Pseudomonas aeruginosa/ species etc.
- **Endotoxin testing**  
Of water, raw materials and a variety of dosage forms using the gel clot method.
- **Growth Promotion / Fertility testing of culture media**  
All according to the relevant recognized standards as above.
- **Efficacy testing of detergents and disinfectants**  
Testing of detergents and disinfectants for parameters such as contact time, concentration, surfaces etc
- **Routine water testing**

### Serving the Medical Device Industry

- Bioburden Validation and Analysis
- Sterility testing on biological indicator strips/ampules
- Population and purity verification of biological indicators strips/ampules
- Bacterial endotoxins on waters and devices using the gel clot method
- Validation of water purification systems: For parameters such as Total Bacterial Count, Coliforms, E-coli, Pseudomonas aeruginosa etc
- Incubation of environmental samples including air monitoring and surface monitoring etc
- Efficacy testing of detergents and disinfectants
- Routine water testing

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