

## Pharmaceutical Microbiology Services – Mumbai, India

The Microbiology Services at Mumbai, offer a fully equipped contract microbiology laboratory and a wide spectrum of laboratory tests. All microbiological aspects of product development, process development; development/validation of microbiological test methods and quality control testing is undertaken at our lab.

Our experts understand your needs for quality testing ,accurate results. We carry out microbiological testing, contract R & D and microbiological audits.

### Key Services Include:

- Microbiological analysis
- Complete support services for method development, testing of:
  - Formulations
  - Active Pharma Ingredients
  - In-process and stability samples
- Trouble shooting of in plant contamination problems,
- Consulting services to testing needs based on relevant regulations



## Pharmaceutical Testing

- Microbiological Testing for Pharmaceuticals: IP/BP/USP/Harmonized
- Antibiotic assay, Vitamin assay – Diffusion assay, Turbidimetric Assay
- Total plate count – membrane filtration, pour plate, spread plate
- Yeast & mould count – membrane filtration, pour plate, spread plate
- Tests for absence of E. coli, Coliform, Salmonella, Pseudomonas aeruginosa
- Staphylococcus aureus, Bile tolerant Gram Negative organisms
- Clostridium, Streptococci, Enterobacteriaceae
- Microbial limit tests IP / USP
- Test for microbial contamination BP / Harmonized method
- LAL test (Bacterial endotoxin test, limulus amoebocyte lysate)
- RWC for disinfectants
- Microscopic observations
- Preservative efficacy Test- IP/BP/USP
- Sterility Tests- Direct inoculation, membrane filtration



### Microbiological Testing for NCEs formulation development

- Microbial Limit Test- Method development and validation for oral solid dosage forms
- Microbial Limit Test- Method development and validation for oral liquid dosage forms
- Effectiveness of preservatives-Method development and validation for oral liquid, ophthalmic, parenterals, topical dosage forms
- Sterility test - Method development and validation for ophthalmic, parenteral dosage forms
- Container Closure Integrity Testing – for parenteral dosage forms
- D value evaluation- we can determine D value for an environment isolate with the help of our hi-end sterilizer.

We undertake validation of clean rooms, w.r.t. viable particle counting. This in-depth and detailed process includes establishing defined control limits, developing monitoring programs and documenting all results for review, reference, and record. As a partner to global retailers, manufacturers, and distributors, we enable our customers to set, meet and evolve their quality, safety and performance standards



### Microbiology Capabilities

- Incubators set at various required temperatures which are undergo temperature mapping every six months. The data for temperature is captured online at every hour.
- Fully automatic autoclaves which are validated for the heat distribution and penetration using Biological Indicators
- Validated biocontainment work stations
- Authentic test microorganisms obtained from ATCC/NCIM
- Good Documentation Practices
- Experienced and qualified staff

To find out more, please contact:

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