

Microbiological Test

- Sterile and Non-sterile APIs and drug products
- Pharmaceutical and Biological products and Medical devices
- Certificate of analysis for batch release





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MICROBIOLOGY SERVICES

Kymos is a reliable partner to outsource the microbiological testing for your APIs and/or drug products.

We offer a high quality service, fast and competitive. A wide range of microbial testing for quality control of biopharmaceuticals under GMP is avalaible. Our facilities count with a clean room, a laminar flow hood, a safety cabinet and an isolator for microbial testing (isolator Isoflex-S® coupled to Steritest® pump and H2O2 sterilizer).

Kymos is authorized for quality control of non-sterile and sterile pharmaceutical products for human use, veterinary use, investigational purposes as well as quality control of medical devices. Additional services for phytopharmaceuticals, dietary supplements and cosmetics are also available.

QUALITY CONTROL

- Microbial limit test: TAMC, TYMC and pathogenic microorganisms
- Microorganism identification
- Total viable spore count
- Sterility test (isolator technology)
- Bacterial endotoxins (LAL test)
- Particulate matter: visible and subvisible particles
- Antibiotic assay
- Water for pharmaceutical use: microbial monitoring and other tests (TOC, conductivity)

OTHER TESTS

- Growth promotion test of culture media
- Antibiotic assay validation
- Method validation and suitability: microbial test, sterility test, etc.
- Antimicrobial effectiveness testing
- Minimum inhibitory concentration (MIC)
- Environmental monitoring
- Cleaning validation
- Biocides effectiveness
- Analysis of bioindicators
- Particulate matter

