

# Microbiological Testing for Pharma & BioPharma Products

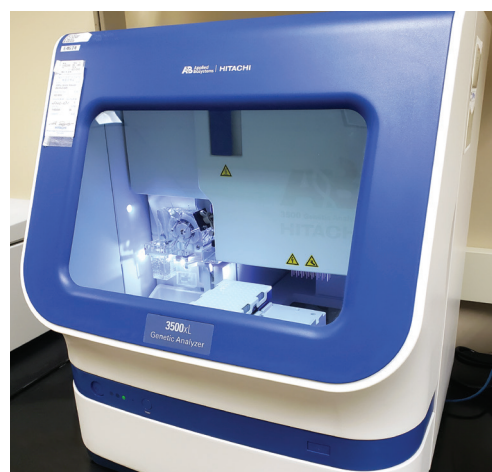


Nelson Labs is a global provider of microbiological testing, analytical chemistry, and advisory services, supporting pharma and biopharma companies. We have over 35 years of experience solving challenges that are not typically addressed in routine testing. We have the capabilities and expertise to support the CMC testing needs and lifecycle management of your drug products. We are US FDA registered, cGMP compliant, and ISO17025 accredited and have laboratories located throughout North America and Europe.

## The following are some of the services Nelson Labs offers to support your pharma & biopharma products:

- **API and Excipients**
  - Microbial Limit USP <61>, USP <62>
  - Bioburden
- **Sterility Assurance USP <71>**
  - Cleanroom
  - Isolator
- **Bacterial Endotoxin USP <85>**
- **Container Closure Integrity Testing (CCIT)**
  - Mass Extraction (ASTM F3287)
  - Dye Ingress
  - Microbial Ingress (Aerosol and Immersion)
- **Preservative Efficacy Test USP and EP**
- **Antibiotic Potency Test USP <81>**
- **Viral Clearance Studies**
- **Water Testing**
- **Environmental Monitoring**
- **Disinfectant Efficacy Testing**
- **Microbial Identification**
  - Gram Stain, Genetic Identification,  
and Bacterial 16S rDNA Full Gene Sequencing
- **Sterilization Validations**
  - Steam
  - Radiation
  - Filtration Validation
  - Others

**Note:** Nelson Labs offers method feasibility, verification, and suitability for all compendial procedures.



## Contact us today!

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US FDA registered and third-party accredited to ISO 17025 standards