

# Research & Quality Control



**GIBRALTAR**  
LABORATORIES

A  Nelson Labs. Company



**Safeguarding Global Health™**  
with every test we complete.

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

ML-0018 rev 1

Gibraltar Laboratories, a Nelson Labs company, is a contract testing organization with two New Jersey locations. Since 1970, we have delivered exceptional research, quality control and testing in bacteriology, virology, chemistry, and *in vitro* toxicology.

## Microbiology Services

Gibraltar Laboratories is your trusted partner in innovation. We have had a leading role in launching well-known and respected healthcare and household brands. Gibraltar Laboratories can do the same for your company. We perform creative research and development to allow brands to leapfrog over their competition. Gibraltar Laboratories has helped small and large sized companies successfully enter and earn market share by providing our knowledge and resources in the disciplines of microbiology, virology and analytical chemistry to support successful regulatory submissions.



### Full Compendial Support

- Rapid Sterility Testing, <71>
- Microbial Limits, <61/62>
- LAL/Endotoxin, <85>
- Antibiotics, <81>
- Mycoplasma, <63>
- Antimicrobial Effectiveness Testing <51>
- Bioburden
- Microbial ID's
- Cytotoxicity
- BI-Resistance, <55>
- Reprocessing of Surgical Equipment/ST79
- ...and Many More



### Cleaning Validations, Molecular Biology, Virology & Research

- Cleaning and Disinfectant Validations (EPA: AOAC & ASTM)
- Western Blot Analysis
- Adventitious Agents
- Microbial Ingress
- Viral Studies
- PCR Detection
- ELISA
- 9-CFR Testing
- Viral Inactivation
- Viral Reduction
- Custom Research

## Analytical & Wet Chemistry Services

### QC Chemistry & Method Development/ Method Validation

Trust Gibraltar to develop and validate your non-compendial raw materials and finished formulations. Gibraltar is experienced at qualifying raw material vendors for critical biotech products and drug manufacturing. All raw data is reviewed by the Chemistry analyst and study director prior to an independent review by the Chemistry quality assurance department. The Chemistry department also works with the Microbiology department to provide expert cleaning validation support.

### Compendial Release Testing for Raw Materials & Drug Products (USP, EP, JP & BP)

Gas Chromatography (GC) // HPLC // FTIR // UV/VIS // AA // TOC // Stability Studies  
Residual Solvents // Elemental Analyzer // Method Transfer // Dissolution Studies // EO Residuals



## Why Choose Gibraltar Laboratories?

In 2018, Gibraltar Laboratories was acquired by Nelson Labs' parent company Sotera Health. Combined, we are the industry-leading provider of global lab testing and expert advisory services – performing microbiological and analytical chemistry tests across the medical device, pharmaceutical, and tissue industries. As a Nelson Labs company, we perform over 700 rigorous microbiological and analytical laboratory tests in 13 state-of-the-art global locations.

Contact our team of experts today.



### **Gibraltar Laboratories**

#### Audits

122 Fairfield Road  
Fairfield, NJ 07004-2405  
TEL: +1.973.227.6882  
FAX: +1.973.882.9520



### **Gibraltar Laboratories**

#### Sample Delivery

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