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## Vital Statistics

**Year Founded:** 1970

**Key Personnel:** Daniel L. Prince, Ph.D., president;  
Herbert N. Prince, Ph.D., scientific director

## Who We Are

THIS 38-YEAR OLD COMPANY HAS an international reputation for quality services and testing in Chemistry, Microbiology, Mycology, Packaging, Stability and Virology. The company, headed by Daniel L. Prince, Ph.D., operates two laboratories in Fairfield, NJ. Gibraltar Laboratories performs rapid and accurate testing services under CGMP at reasonable prices in a timely manner. Further, the company is unique in that

- all departments are headed by Ph.D. or master's level scientists with prior experience in industry or academia,
- it has a research policy that has resulted in over 60 papers or publications in the archive or trade literature
- it maintains contacts with regulatory or compendial personnel in FDA, EPA, USP and PDA.

Furthermore, the company is involved with trade organizations such as CSPA, PDA, ASM, AAMI, CTFA, AATB, ASTM and NJPQCA. Gibraltar is FDA registered, ISO 17025 certified and is accredited by the American Association of Laboratory Accreditation.

## Major Markets

GIBRALTAR LABORATORIES PROVIDES microbiology and analytical chemistry services in stability and quality control to the pharmaceutical, medical device, biotech, nutraceutical, cosmetic, specialty chemical and tissue bank industries.

## Services Offered

### Analytical Chemistry

- Compendial Release Testing of Raw Materials and Drug Products
- Forced Degradation and Stability Studies
- Development and Validation of Test Methods for Testing of Active Drug Substances and Dosage Forms



- Dissolution Test Method Validation
- Plan and Development of Analytical Cleaning Validation Studies
- Method Transfer
- Process Validation
- Residual Solvents/Volatile Organic Impurities USP <467>

### Microbiology

- State-of-the-Art Facility
- Bioburden and Sterilization Validation
- USP/EP Microbial Limits and Preservative Challenge
- Environmental Monitoring and Package Testing
- Antimicrobial Agents
- Endotoxins and *in-vitro* Toxicology
- Steam Autoclave Studies
- Cleaning Validations
- Microbial Identifications
- Purified Water Validation
- Antibiotic Studies
- EPA Chemical Germicides
- Specialized Research Studies

### Virology

- BSL-3 Laboratory
- Biopharmaceuticals (Adventitious Agents)
- Viral Content
- Formulation Efficacy Studies

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