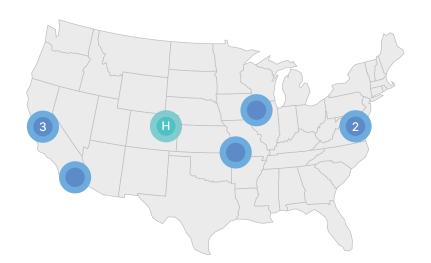


# Enduring Partnerships. Endless Insights.





# **Your Local Testing Partner, Nationwide.**

- 130+ staff
- 8 state-of-the-art laboratories
- FDA registered and operating to cGMP
- DEA licensed
- ISO accredited
- 60,000 assays per year

## Leverage a Single-Source Testing Solution

- Method Development, Validation & Regulatory Support
- Analytical Chemistry Testing
- Stability Testing
- ( Microbiology Testing
- Sterility Assurance Testing
- Gas & Water Testing
- Extractables & Leachables Studies

- ( Extractables & Leachables Studies
- ✓ Container Testing
- Package Testing
- Sterilization, Cleanroom & Instrumentation Services
- (V) EO Sterilization
- Cleanroom Validation & Certification Services
- ( Environmental Monitoring
- ✓ Laboratory & Process Instrumentation Services



Infinity Laboratories has over two decades of experience helping the pharmaceutical industry assure the safety and efficacy of drug products. We offer a full suite of analytical testing services for raw materials, in-process materials, and finished products from our national network of facilities, ensuring regulatory compliance while also accelerating the path to market.

#### **Method Development, Validation & Regulatory Support**

Our team has managed analytical programs for a diverse range of drugs products. This experience allows us to tap into numerous validated internal methods, accelerating your program.

- Chromatography
- Spectroscopy
- Total Organic Carbon (TOC)

#### **Microbiology Testing**

Infinity offers robust microbiological testing for every stage of your drug product's lifecycle to eliminate the risk of microbial contamination.

- · Bioburden testing
- · Biosafety testing
- Media fills
- · Microbial culture media preparation
- · Mycoplasma testing
- · Pyrogen testing
- Cleaning validation
- · Sterility testing

#### **Cleanroom Certification & Testing**

Infinity goes beyond counting pathogen particles by designing and executing comprehensive cleanroom programs.

- cGMP cleanroom certifications
- · Cleanroom validations
- · Environmental monitoring
- ISO 9001 Certified

#### **Analytical Chemistry Testing**

Infinity's team supports the entire product lifecycle from earlyphase development to commercial production, including raw materials, API, and finished products.

- Comprehensive monograph testing (USP, EP & JP)
- · Chemical & physical testing
- · Assays to support the entire lifecycle
- Early phase to commercial production

#### **Extractable & Leachable Studies**

Infinity provides a one-stop solution for extractables and leachables studies to identify potentially harmful contaminants within your drug product.

- · Elemental impurities
- · Impurity identification
- Material compatibility
- Plastic components & systems
- Plastic packaging systems & materials of consruction
- · Single-use bioprocessing systems

#### **Package Testing**

Infinity's A2LA-certified laboratory conducts robust testing to assess your package readiness for distribution.

- · ASTM, ISO, and ISTA standards
- · Distribution-related pressure testing
- · Multiple rounds of assessments for each test



### **Discover Limitless Testing**

#### Contact

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