



# Your Local Testing Partner Across the Country.



Infinity Laboratories is your end-to-end contract testing partner for pharmaceutical drug products. We leverage over 30 years of laboratory experience to provide method development, validation, and execution to support the entire drug development lifecycle. Founded on the core principles of excellence, integrity, and quality, Infinity comprises life science leaders with the expertise necessary to guide your project.

### Material Characterization

Material characterization is the process of defining the chemical properties of one or more components of a substance. Infinity provides our clients with characterization techniques under the relevant ISO 10993 guidance to identify product materials, detect the presence of impurities and degradants, and create a chemical profile of an unknown formulation. Techniques include:

- Isolation
- Purification
- Structural Elucidation
- Purity Characterization

### Container Testing

Container testing is necessary to ensure that your drug product's container is suitable for direct contact with the drug product. Infinity's analytical experts ensure the safety of your drug product with a breadth of experience in a diverse range of container compositions and configurations. Container testing performed at Infinity includes:

- Closure Integrity Testing
- Elastomeric Closures
- Permeation Testing
- Plastic Materials of Construction and Plastic Packaging Systems for Pharmaceutical Use
- Plastic Packaging Systems & Materials of Construction



## 30+ Years

Testing Experience

## 7 Facilities

State-of-the-art laboratories providing contract services

## 130+ Staff

with the scientific and regulatory knowledge to guide your project to success

## 60k Assays

Processed Annually



# Comprehensive Extractables & Leachables Solutions.

Infinity Laboratories is a one-stop solution for extractables and leachables (E&L) studies to identify potentially harmful contaminants within your pharmaceutical drug product. We go beyond off-the-shelf assays by providing robust method development, validation, and testing. Powered by decades of testing experience, our team partners with yours to understand the intricacies of your drug product. Infinity performs E&L analytical techniques, including chromatographic characterization, spectroscopy characterization, and extraction techniques under the appropriate FDA, ICG, BPOG, and USP standards.

## What are Extractables & Leachables?

### Extractables

Compounds can be pulled out of a container or product when exposed to extreme solvents and/or conditions such as elevated temperatures.

### Leachables

Compounds originating in container closures that seep into a finished product. Leachables can affect products under standard conditions but can be traced to monomers, polymer additives, or release agents in the manufacturing process.

### E&L Studies Performed By Infinity

- Elemental Impurities
- Impurity Identification
- Material Compatibility
- Plastic Components & Systems
- Plastic Packaging Systems & Materials for Construction
- Plastic Materials of Constrictions and Plastic Packaging Systems for Pharmaceutical Use
- Single-Use Bioprocessing Systems



Precision Results

Rapid Turnaround Time

Comprehensive Reporting

Discover Limitless Testing

#### Contact

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