Your Analytical Partner

Established in 1987, Integrated Analytical Laboratories, LLC (IAL) is a full-service independent contract testing and research laboratory servicing the Pharmaceutical, Cosmetic, Chemical, and Environmental industries. IAL routinely performs a wide array of testing to include raw materials and finished product testing, stability, method development, method optimization and validation, cleaning validation, and so much more. Our services are conducted under strict adherence to cGMP guidelines and are coordinated with client needs. All testing is conducted in accordance with current compendia, IAL developed and validated methods, or client supplied and transferred methods.

IAL strives to meet our clients needs and exceed their expectations.

At Integrated Analytical Laboratories, LLC, we tailor our services to meet the individual requirements of our client. From project start to final reporting, IAL is designed to provide an efficient, time-sensitive and cost-effective response to our clients' request. It is this dedication to excellence that defines our company.

Total Quality…
From Start to Finish

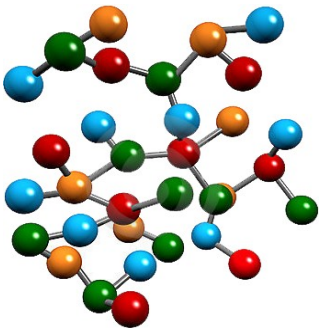
Analytical Services

- Method Development and Optimization
- Method Validation
- Stability Storage and Testing
- Reserve Sample Storage
- Customer Complaint Testing
- Finished Product Testing
- Raw Material Testing
- USP, EP, JP, ACS, FCC
- Natural Products Testing
- Vitamins/Minerals
- Trace Impurity Analysis
- Cleaning Validation
- Personal Care Product Testing

Integrated Analytical Laboratories, LLC
273 Franklin Road, Randolph, NJ 07869 www.ialonline.com
Phone: 973-361-4252

The Partner You Can Trust

Pharmaceutical Raw Material Testing



Delays due to late analytical results can cost thousands of dollars. Integrated Analytical Laboratories, LLC (IAL) understands this and strives to provide analytical results in a timely fashion. Our scientists work diligently to not only provide data quickly but also to give you accurate results. Expedited turnaround time is also available for those times when you must obtain data very quickly.

Typically, IAL utilizes current compendia monographs such as those listed in the United States Pharmacopeia to test raw materials. Client methods and specifications are also utilized when directed. All methods that are received by clients are transferred to our facility according to cGMP practices. Services include but are not limited to:

- Material Analysis by HPLC/UPLC or GC
- Spectrophotometric Analysis
- Metals by ICPMS
- Residual Solvent Testing
- Titrations
- Moisture Karl Fisher
- Wet Chemistry
- Compendial Testing USP, EP, JP, FCC and ACS

If a raw material has an Out-of-Specification (OOS) result, IAL moves quickly to resolve the problem. Our Standard Operating Procedure mandates that we speedily check all the data to rule out analytical error. Once we verify the results, we quickly communicate the OOS to the client so that they can set forth their protocols for an OOS. IAL will take a consultative approach with our clients and we will work according to Quality Agreements and Standard Operating Procedures.

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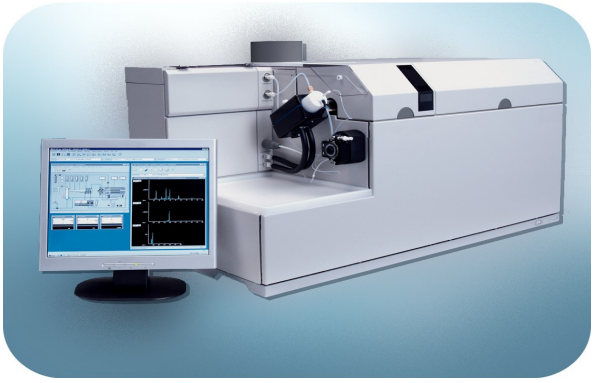
Laboratory Facility

Integrated Analytical Laboratories, LLC (IAL) is located in the IAL Industrial Park at 273 Franklin Road, Randolph, New Jersey. Our Facility occupies more than 25,000 square feet of laboratory and support space. Our services are conducted under strict adherence to cGMP guidelines, and our facility is fully secured.



Instrumentation

- High Performance and Ultra-High Performance Liquid Chromatography
  (PDA, UV/VIS, RI)
- Gas chromatography (FID, Headspace)
- Fourier Transfer Infrared Spectrophotometers
- UV/Visible Spectrophotometers
- Environmental Chambers for Stability Storage
  - Accelerated Conditions (40°C/75% RH)
  - Intermediate Conditions (30°C/65% RH)
  - Long-Term Conditions (25°C/60% RH)
- Dissolution Apparatus
- Disintegration Apparatus

Elemental Impurity Analysis

- ICP/MS

Classical and Wet Chemistry

- Thin Layer Chromatography (TLC)
- Karl Fischer Apparatus
- Melting Point Apparatus
- Moisture Ovens
- Viscosity
- Refractometer
- Conductivity Meter
- Polarimeter
- pH Meter

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Method Development And Validation

Integrated Analytical Laboratories, LLC (IAL) offers a comprehensive program for analytical method development, optimization and validation through a staff of knowledgeable and experienced scientists. The methods we develop and validate cover a large range of analytical technology and can support all phases of pharmaceutical and product development from discovery through to manufacturing.

IAL also transfers methods to our facility from other companies. Our highly trained staff will work with you to find analytical strategies that are both robust and cost effective.

Method Development, Optimization and Validation

One very important consideration when choosing an analytical laboratory for Method Development and Validation is a proven track record of success. IAL has this proven record. We have successfully developed and validated many methods including methods with multiple API's such as methods for nutritional supplements or multi-component drugs.

IAL will develop the protocols, conduct the analytical testing, and produce a fully validated method(s) that will withstand full scrutiny from the Food and Drug Administration (FDA).

Our company's emphasis is to build relationships with our clients that are long lasting and mutually beneficial. It is important to us to be viewed as a trusted partner, a partner that can be relied upon.

Innovative & Efficient Solutions for Your Business

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Stability Testing and Storage

Designing the Protocol

Stability testing is a critical aspect of drug testing. Whether you have predetermined stability protocols or require IAL to develop the protocols, IAL will be an important member of your team. IAL will also develop and validate stability indicating methods for your organization. We will work with your drug product as well as your drug substance to ensure a successful program.

Reporting

Customized reports are available for all our clients. Analytical trending is also conducted on all stability to ensure that the all aspects of stability are carefully monitored. Cumulative reports are issued at each time point. Any out-of-specification results are immediately reported and we will work together to develop the investigation and define the problem.

Environmental Chambers for Stability Storage

- Accelerated Conditions (40°C/75% RH)
- Intermediate Conditions (30°C/65% RH)
- Long-Term Conditions (25°C/60% RH)
- Photostability

Our in-house storage is comprised of environmental chambers that operate independently and have individual temperature and humidity controls. All chambers are continuously monitored and utilize back up generators to prevent loss of power.

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Cleaning Validation

Cleaning Validation

Integrated Analytical Laboratories, LLC (IAL) is a cGMP compliant facility available for developing and validating analytical methods and performing tests required in equipment cleaning validation. Cleaning validation is a multi-step process that begins with focusing on the objective of the validation process. Typically, the objective is to prevent the adulteration or contamination of drug products that are manufactured on non-dedicated equipment.

IAL has expertise with conducting experiments to determine drug substances, drug products and cleaning agents residues on manufacturing equipment. Our scientists have developed and validated methods to quantitatively detect residues of various substances and contaminants from equipment surfaces using swabbing and rinsing techniques. Templates for test methods and protocols are available so that customized protocols can be quickly developed for cleaning validation.

Analytical Methods

- High Performance and Ultra-High Performance Liquid Chromatography
- UV/Visible Spectrophotometer
- Gas Chromatography
- ICP/MS

Method Development

- Develop methods for extraction and detection of residues from cleaning samples.
- Develop techniques for rinsing or swabbing various surfaces with most desirable recoveries.
- Quickly evaluate the available analytical techniques suitable for specific needs.
- Cleaning methods will demonstrate that chemical and elemental residues that are detected are acceptable to predetermined criteria.

Method Validation

- Validate cleaning and extraction procedures and recovery from various surfaces.
- Validate analytical methods for accurate and precise quantitation.
- Establish system suitability and specifications.
- Quickly evaluate the available analytical techniques suitable for specific needs.

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Reserve Sample Storage and Customer Complaint Testing

Reserve Sample Storage

Integrated Analytical Laboratories, LLC (IAL) is a cGMP compliant facility. We offer ICH compliant controlled chambers for Reserve Sample Storage and Customer Complaint Testing. FDA Title 21 Section 2110.170 indicates that reserve samples of active ingredients as well as drug products that are representative of entire lots shall be retained. Each reserve sample needs to have sufficient sample quantity to conduct each test needed to meet it's specification at least twice. Each reserve sample needs to be maintained one year after the expiration date of the last lot of the drug product containing the active.

As you are aware, this can amount to a great volume of reserve samples. 21 CFR Section 2110.170 also states that reserve samples need to be stored under conditions that are consistent with the product or ingredient labeling and statistical procedures need to be in place to determine the number of reserve samples that must undergo a visual inspection annually for evidence of deterioration.

Customer Complaint Testing

- Disintegration
- Package Integrity and Labeling
- Weight, Dimension and Shape
- Color Change and Uniformity
- Tablet Capping and Lamination
- Sticking and Filming
- Cracking and Chipping
- Printing, Impression issues
- Mottling

Environmental Chambers

IAL maintains controlled chambers that are ICH compliant. We are readily able to handle your reserve samples and your customer complaint testing.

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