

WHITEHOUSE, NJ

# PHARMACEUTICAL TESTING

Pharmaceutical Expertise for GMP & CMC Testing



# Our Pharmaceutical Expertise

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With more than 20 years of experience in a variety of industries, our Whitehouse, New Jersey facility offers expertise in the development of drug products, pharmaceutical devices, formulations, and delivery systems to clients around the globe.

With comprehensive solutions for pharmaceutical stability, discovery support, trace analysis, bioanalytical testing, regulatory compliance, and more, we are fully equipped to meet all of your needs for pharmaceutical testing. As a contract consulting analytical laboratory, we can help you address any challenges you may face in bringing your pharmaceutical products to market, ranging from the simplest solutions to the most complex analysis.

Partnering with our Whitehouse facility brings the assurance, confidence, and peace of mind that comes with collaborating with a current good manufacturing practice (cGMP) compliant facility, ensuring that testing will be carried out to the most up-to-date and highest quality standards, preserving the integrity of your products.

## Analytical Research & Development Discovery Support Services

Bringing any pharmaceutical product to market requires an extensive amount of research and development to ensure the methods employed will serve the purpose of a particular product. Our discovery support services provide assurance that proper methods are developed and proper analyses and validations are conducted.

### cGMP Method Development, Validation and Remediation

Method development works to establish the techniques that will be employed at each stage of the process in order to meet your objectives. Validation ensures that the methods are appropriate for a given product.

Once methods have been developed and validated, the process then moves into the remediation phase, where these methods are continually evaluated and managed throughout the method's lifecycle to ensure it will continue to serve its purpose.

We provide you with reliable, accurate, and efficient analytical methods necessary to establish the data needed to develop your products. Our technology includes chromatography, mass spectrometry, elemental analysis, and spectroscopy. Through our cGMP method development, validation, and remediation services, we ensure that the methods established meet regulatory requirements through our adherence to International Conference on Harmonisation (ICH) guidelines.

We possess extensive expertise across a wide variety of formulations and molecules, including:

- Small molecules
- Biologics
- Nanoparticles
- Solids
- Patches
- Gels
- Ointments
- Liquids
- Inhaled products

### Cleaning Validations

Ensuring the purity of drug products is crucial for reaching the market with speed and efficiency. Cleaning validations play a major role in ensuring drug products are free of contamination and suitable for manufacturing.

Our cleaning validation techniques provide solutions for all manners of residues, from the simple to the complex. Through these methods, we are able to identify potential contaminants in formulations such as API residues and degradation species, as well as residues from detergents or solvents. This provides assurance that your products are free of any contaminants that would pose a danger to users and hinder the product's ability to enter the market.

Cleaning validation capabilities:

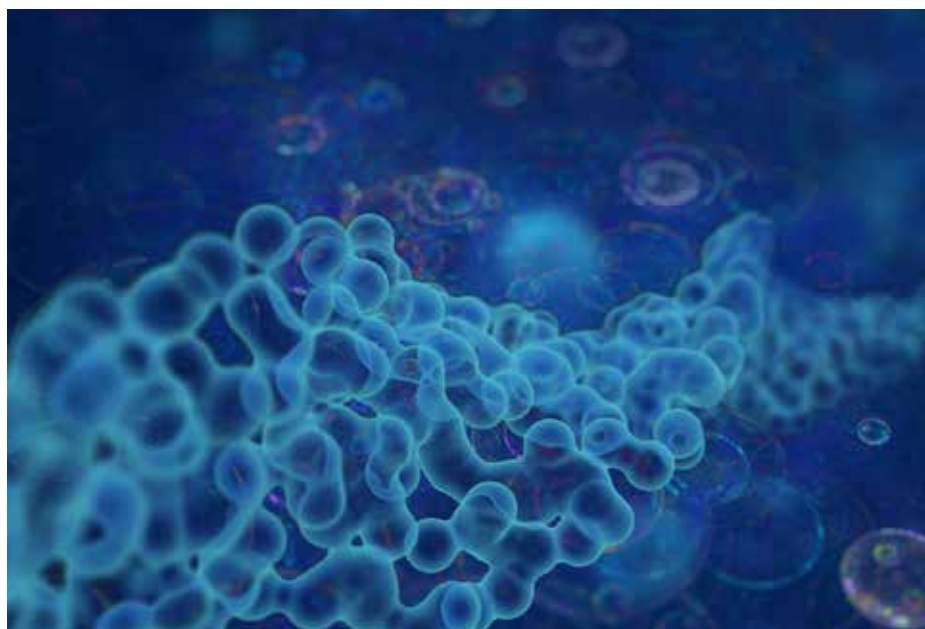
- High pressure liquid chromatography-mass spectrometry (HPLC-MS)
- Ion chromatography (IC)
- Inductively coupled plasma spectroscopy with mass spectrometry (ICP-MS)
- Optical emission spectroscopy (ICP-OES) detection

## Pharmaceutical Analysis

Conducting a pharmaceutical analysis helps provide a greater understanding of your substances, products, and processes. As a result, it can improve outcomes through all phases of the process from product development and submission to the FDA, manufacturing to post-marketing. Our pharmaceutical analysis services offer the capability to address concerns about drug safety, assuring that your products comply with regulatory requirements.

Pharmaceutical Analysis Services:

- Research and development analytical support
- CMC analytical support
- Formulation development
- Clinical manufacturing
- Post-approval analytical support
- Manufacturing analytical support



# Extractables and Leachables

The study of extractables and leachables (E&L) is a complex and involved process, which requires an in-depth analysis of drug products and devices.

E&L studies are necessary to ensure packaging and/or container closure systems do not have the potential to release harmful compounds that could negatively impact drug products and pose a danger to consumers.

Through controlled extractable studies (CES), we can quickly and accurately identify any such impurities that could potentially contaminate your products. All of our E&L studies are carried out in accordance with cGMP, PQRI recommendations, USP requirements, and FDA guidelines. We also provide complete identification of leachables and leachability and/or migration studies on polymeric medical devices or packaging.

Our extensive array of extractables and leachables studies includes:

- Identification of extractables using GC/MS, GC/MS/MS, and LC MS/MS, according to USP <1663>
- Complex polymer formulation component identification

- Fast and accurate identification of extractables including transformation and degradation products
- Validation of leachables methods for use in stability and storage programs
- Custom studies for all types of container closure systems and primary packaging materials
- Modifying specific controlled extractables methods for routine E&L testing
- Screening or quantitative studies for additives and stabilizer ingredients and their degradation products
- Developing and validating methods for controlled extractables from pharmaceutical containers, closure and devices



# Trace Analysis

Any impurities in drug formulations and products, no matter how small, must be identified to ensure they are at levels that will not cause harm to consumers.

Trace analysis identifies impurities present at trace levels (e.g., parts per million (ppm) levels) within a drug formulation, providing valuable data to make informed decisions about your products.

## Elemental Analysis and Trace Metals

Given the toxicity of trace metals and the overall complexity of pharmaceutical products, it is critical to conduct elemental analysis and trace metals testing. Employing these measures brings an added element of quality control to the development process.

Our techniques span a wide range of analytical technologies, including:

- Inductively coupled plasma – mass spectrometry (ICP-MS)

- Inductively coupled plasma – optical emission spectroscopy
- Ion chromatography (IC)
- Flame atomic absorption spectroscopy (FLAA)
- X-ray fluorescence (XRF)

## USP <232> and USP <233> Elemental Impurities Services

If elemental impurities exist in pharmaceutical products, they must be quickly identified and corrected given their toxicity and the risk they would pose to a user. Elements such as lead, arsenic, cadmium, and mercury pose a known risk due to their toxicity, requiring an elemental analysis to quantify at what levels they are present.

Through our strategic approach to demonstrating a product's compliance with both USP <232> (Elemental Impurities Limits) and <233> (Elemental Impurities Procedures), we offer routine analysis, semi-quantitative screening, and method development and validation.

Our comprehensive elemental impurities services include:

- Quality control testing
- Reference materials certification
- Stability testing

- GMP batch release testing

## Organic Volatile Impurity Analysis

Although solvents may be necessary for the manufacture of APIs and drug substances the harm they could potentially cause requires that permissible daily exposure (PDE) be established to control the solvents present in products.

We have extensive experience in residual solvent testing, specifically to USP <467>, providing assurance that any solvents found in your formulations are present at acceptable levels.

## Organic Volatile Impurity Analytical Capabilities

- Headspace gas chromatography
- Gas chromatography-mass spectrometry (GC-MS)
- Gravimetric techniques
- Method development to ICH

**Contact our industry experts today for your pharmaceutical testing needs  
+1 (800) 967 5352**





# Stability & Pharmaceutical Testing

Stability testing provides the capability to evaluate the stability of your active pharmaceutical ingredients (APIs) and drug products under a number of different conditions including light, humidity, and temperature.

Given the challenges such testing can present, it is important to collaborate with a partner that has expertise in developing stability methods and analyzing leachable substances.

## Storage and Stability Testing (Including Photostability):

Storage and stability testing provide valuable information to pharmaceutical developers by assessing the stability of their products, particularly with regard to the risk for extractable and leachable components.

Our worldwide network of ICH stability storage facilities provides the capability to assess the potential for extractable and leachable compounds in your products. Stability studies provide valuable data on recommended storage conditions, reset intervals, and shelf lives.

Our vast storage and stability capabilities include:

- cGMP registration stability programs
- Design, storage, and management
- Tailored reporting (timepoint and final reports)
- Development and validation of stability indicating methods
- Real time stability testing
- Accelerated stability testing
- Formulation stability testing
- Extractables & leachables
- Forced degradation testing with degradation product identification & quantification
- Stability testing for APIs, clinical trial materials, and formulated products GC/M

## Comparator Studies

Knowing how your products measure up against the competition provides a competitive advantage when entering the market. Our comparator studies allow you to see how your products compare in bioequivalence, efficacy, and safety.

Our comprehensive comparator studies include:

- Method development and method validation
- Stability storage and testing
- Compendial and proprietary products
- Dissolution testing for Apparatus I, II, and IV
- Reference standard programs

## cGMP QC Testing Services and Laboratory Analysis

To develop an effective and successful product, you must first ensure the raw materials used to produce it are of the highest quality. Given that these materials can vary between suppliers and batches, it is crucial to institute quality control measures to ensure the same level of quality across all of the raw materials in your products.

To ensure you are utilizing the best materials throughout the development and manufacturing process, we provide testing of:

- Raw materials
- Excipients
- In-process samples
- Finished product batches

## Reference Standard Materials (RSM) Program

In order to achieve accurate results for analytical methods, it's necessary to assess the purity and quality of reference standards. Our RSM qualification programs offer custom solutions in the areas of process impurity identification, assay, metabolite quantification, and degradation product quantification, among others.

We provide custom study requirements that are tailored to your specific needs. Employing a three-tiered approach to qualification and requalification, we work with you to help avoid interruptions in your programs and address issues if a sample has shown to degrade.

Our RSM programs include:

- Initial characterization
- Generation of a certificate of analysis
- Expiry dating through stability testing with ICH stability storage
- Repository and distribution
- Periodic requalification
- Complete characterization of reference standard materials (including sample limited materials)

**Safely speed your time to market with our comprehensive pharmaceutical testing.**



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