Whitehouse, NJ

Pharmaceutical Testing

Pharmaceutical Expertise for GMP & CMC Testing

intertek.com/pharmaceutical/analysis/whitehouse-nj/



Our Pharmaceutical Expertise

The Intertek Whitehouse, New Jersey laboratory supports pharmaceutical and related product development programs for clients around the world. The site brings together analytical chemistry, stability, packaging, container integrity, and device testing expertise to help address challenges from early development through commercialization.

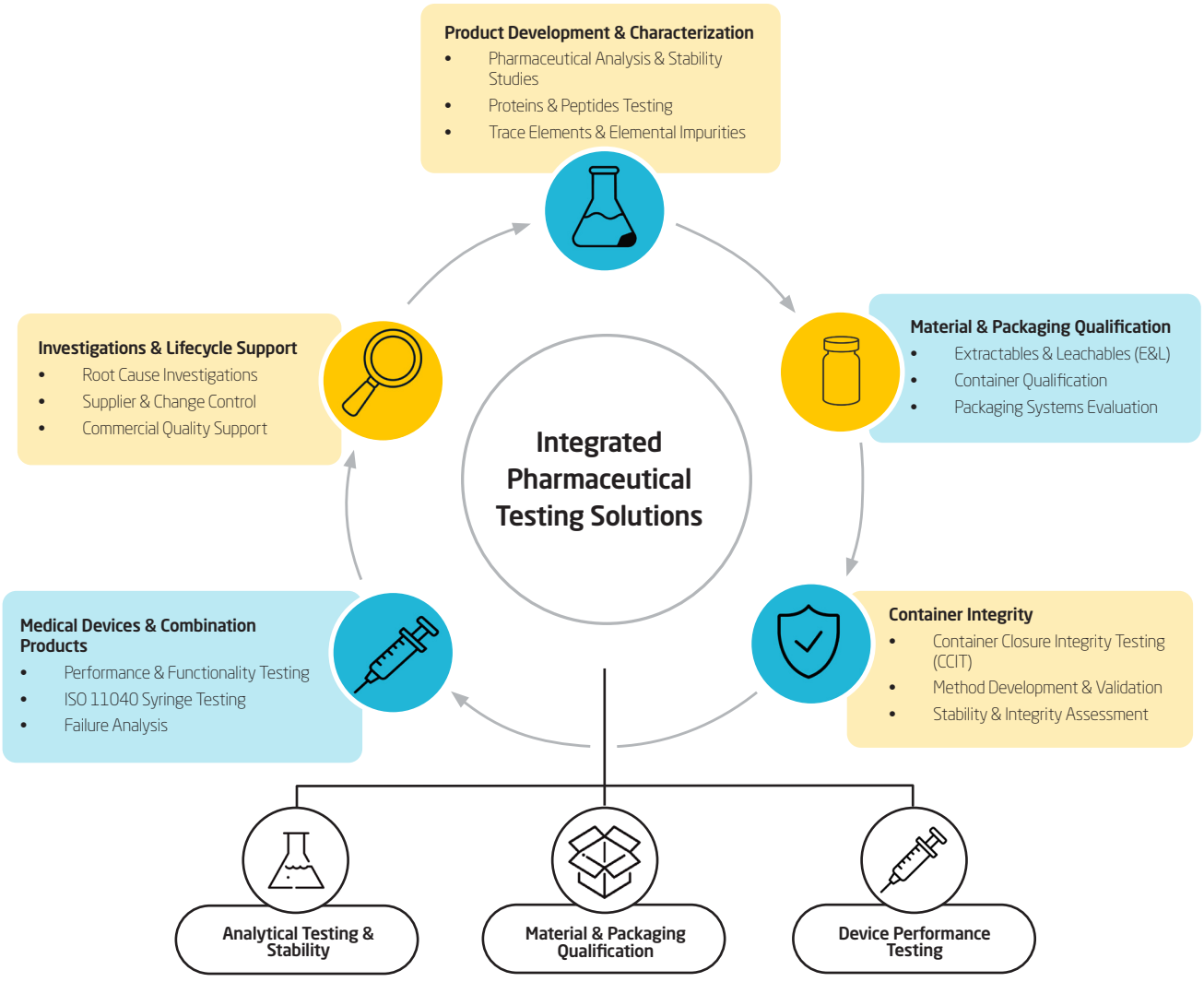
As a contract analytical laboratory, Whitehouse supports pharmaceutical, medical device, raw material, and combination product manufacturers with practical testing strategies, reliable data, and technical guidance. Services range from analytical method development, validation, and GMP testing to extractables and leachables, elemental impurities, container qualification, container closure integrity, and medical device performance testing.

Working with Whitehouse gives clients access to multidisciplinary scientific teams and a quality-focused laboratory environment designed to support regulatory submissions, product release, stability programs, investigations, and ongoing lifecycle management.



Supporting the Pharmaceutical Product Lifecycle

We provide integrated testing solutions that support pharmaceutical products, medical devices, drug delivery systems, and combination products throughout the product lifecycle. Our multidisciplinary approach brings together analytical testing, materials and packaging expertise, container integrity, device performance, and investigative support to help clients advance products from development through commercialization.



Pharmaceutical Analysis & Stability Studies

Delivering reliable analytical data to support informed decisions on product quality, stability, and regulatory requirements.

Pharmaceutical analysis and stability testing play a critical role throughout drug development, from early research and analytical method development to regulatory submissions, commercial manufacturing, and ongoing quality monitoring. Intertek Whitehouse provides analytical testing services to support product characterization, method validation, stability programs, quality control, and pharmaceutical lifecycle management.

Our scientists work with pharmaceutical and biologic manufacturers to develop reliable analytical methods, evaluate product quality, and generate data to support regulatory requirements. Services include cGMP analytical testing, stability studies, comparator assessments, reference standard qualification, and investigation support.

Analytical Method Development & Validation
Intertek provides cGMP analytical method development, optimization, validation, and remediation services to establish reliable testing procedures for pharmaceutical products. Our scientists apply chromatography, mass spectrometry, elemental analysis, and spectroscopy to develop methods appropriate for their intended use.

Services include phase-appropriate validation, method verification, transfer support, and remediation of existing methods in alignment with applicable ICH guidelines.

Stability Testing & Storage Programs
Stability studies assess the effects of temperature, humidity, light, and storage conditions on active pharmaceutical ingredients (APIs) and finished drug products. Our programs support shelf-life determination, recommended storage conditions, and regulatory submissions.

Capabilities include long-term and accelerated stability testing, photostability, forced degradation, stability-indicating method development, formulation stability studies, and cGMP registration stability programs. Intertek also provides stability storage, sample management, monitoring, and reporting.

cGMP Quality Control & Pharmaceutical Analysis
Intertek provides analytical testing to evaluate the identity, quality, and consistency of pharmaceutical materials and products. Services support raw materials, excipients, in-process samples, and finished product batches throughout development and commercial manufacturing.

Our laboratory also supports pharmaceutical research and development, CMC analytical activities, manufacturing investigations, and post-approval testing.

Comparator Studies & Reference Standard Qualification
Comparator studies support analytical comparisons between pharmaceutical products and reference materials through method development, dissolution testing using Apparatus I and II, and stability assessments.

Our Reference Standard Materials programs provide initial characterization, purity and impurity evaluation, certificates of analysis, stability monitoring, expiry dating, and periodic requalification to support reliable analytical testing.

Cleaning Validation Support
Cleaning validation testing helps identify and quantify residual contaminants associated with pharmaceutical manufacturing equipment and processes. Intertek supports the assessment of API residues, degradation products, detergents, and solvents using analytical techniques such as HPLC-MS, ion chromatography, ICP-MS, and ICP-OES.

Analytical Capabilities
Our laboratory utilizes a range of analytical technologies to support pharmaceutical testing, method development, and product quality assessments, including:

- HPLC and UPLC
- GC/MS and LC-MS/MS
- Ion chromatography
- ICP-MS and ICP-OES
- UV-visible spectroscopy
- Dissolution testing
- Total organic carbon (TOC) analysis
- Moisture analysis
- Particle size analysis

Products & Formulations Supported
Our analytical services support small-molecule drug products, biologics, active pharmaceutical ingredients, solid dosage forms, liquid formulations, gels, ointments, patches, and nanoparticle-based formulations.

Proteins & Peptides Analytical Testing

Peptide and protein therapeutics present unique analytical challenges that require specialized characterization strategies, advanced instrumentation, and phase-appropriate regulatory support. Intertek Whitehouse provides analytical testing services for synthetic peptides, recombinant proteins, biosimilars, and complex therapeutic molecules throughout development and commercialization.

Whether supporting early-stage development, IND-enabling studies, clinical manufacturing, or commercial release programs, our scientists develop customized analytical approaches addressing identity, purity, potency, stability, and impurity characterization requirements.

Identification & Molecular Characterization

We establish molecular identity and characterize structural attributes using advanced analytical techniques. Our scientists support intact mass verification, primary sequence confirmation, molecular fingerprinting, and reference standard comparisons to provide a comprehensive understanding of product identity.

Assay & Purity Testing

Accurate determination of assay and purity is essential to evaluate product quality and consistency. We support assay determination, purity profiling, quantitative analysis, and counterion analysis through tailored analytical methods, including method qualification, validation, and transfer to meet development and regulatory needs.

Related Substances & Stability Assessment

We conduct forced degradation studies and impurity identification to evaluate degradation pathways and support the development of stability-indicating analytical methods. These studies help assess product stability and support ongoing stability monitoring programs throughout the product lifecycle.

Process Impurity & Residual Analysis

Our scientists provide synthesis-related impurity profiling, truncated sequence analysis, residual solvent testing, and process contaminant assessment. These services help manufacturers understand process-related risks and support manufacturing process development and control.

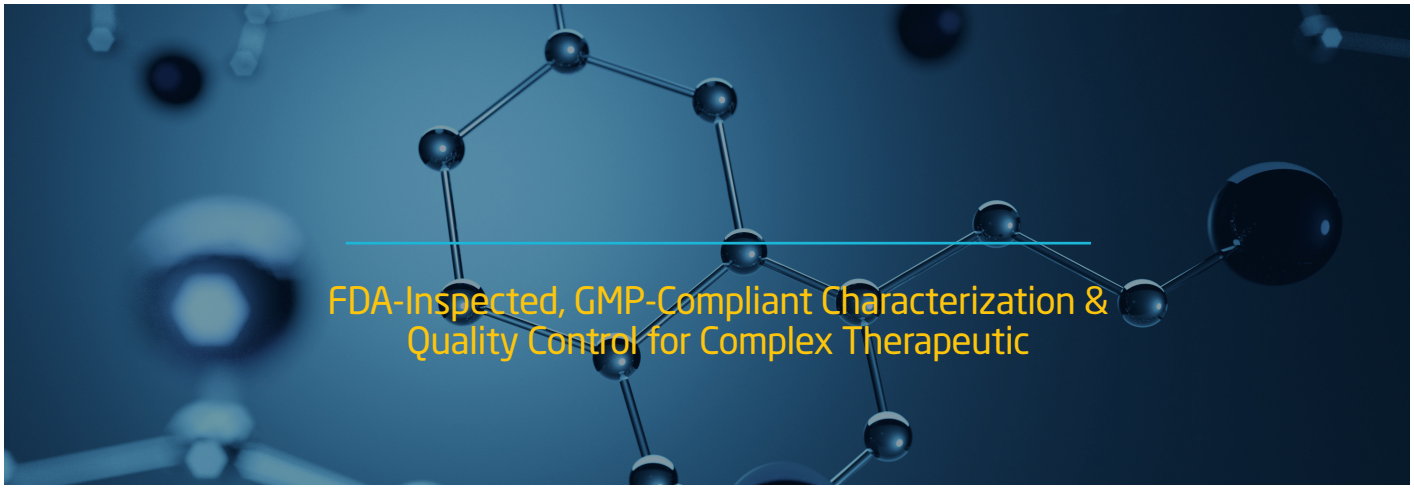
Analytical Capabilities

Our laboratories use a range of advanced technologies to support characterization and testing of peptide and protein therapeutics, including:

- LC-MS
- Intact mass spectrometry
- HPLC and UPLC
- SEC-UV
- Ion chromatography (IC)
- GC-MS
- ICP-MS and ICP-OES

Development Phase Support

Our analytical strategy supports programs from early development and IND-enabling studies through clinical manufacturing and commercial release. Services include structural confirmation, initial purity profiling, method qualification and validation, method transfer, release testing, stability testing programs, and regulatory submission support.

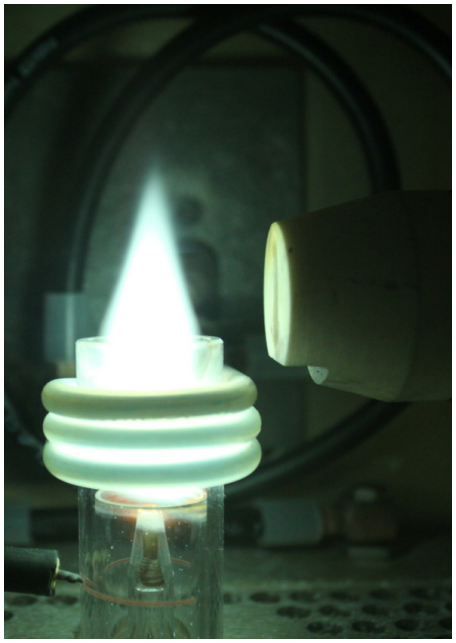


Trace Metals & Elemental Impurities Testing

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.

Elemental impurities can originate from raw materials, manufacturing processes, processing equipment, packaging components, and environmental sources. Intertek provides trace element and elemental impurity testing services to support product development, regulatory compliance, manufacturing investigations, and ongoing quality control programs for pharmaceutical and biologic products.

Our scientists develop practical testing strategies that support product quality objectives while meeting global regulatory requirements. Services range from routine USP/ICH compliance testing to complex investigations involving contamination sources, process changes, and supplier qualification activities.



Given the potential toxicity of certain trace metals and the complexity of pharmaceutical products, elemental analysis plays an important role in assessing product quality and safety. Our scientists use advanced analytical techniques to identify and quantify trace elements, supporting manufacturers in evaluating impurity levels and addressing potential contamination concerns.

Our analytical capabilities include:

- Inductively coupled plasma–mass spectrometry (ICP-MS)
- Inductively coupled plasma–optical emission spectroscopy (ICP-OES)
- Ion chromatography (IC)

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

Elemental impurities such as lead, arsenic, cadmium, and mercury require careful evaluation due to their potential toxicity. Testing helps manufacturers determine impurity concentrations and assess compliance with applicable regulatory limits.

Intertek Whitehouse supports elemental impurity testing in accordance with USP <232> (Elemental Impurities Limits), USP <233> (Elemental Impurities Procedures), and ICH Q3D guidelines.

Our services include routine elemental analysis, semi-quantitative screening, analytical method development, and validation to support pharmaceutical quality and regulatory requirements.
Additional services include:

- Quality control testing
- Reference materials certification
- Stability testing
- GMP batch release testing
- Manufacturing investigations and contamination assessments
- Supplier qualification and process change support

Organic Volatile Impurity Analysis

Residual solvents may be introduced during the manufacture of active pharmaceutical ingredients (APIs) and drug products. Because certain solvents can pose potential safety risks, their presence must be evaluated against established limits, including applicable permitted daily exposure (PDE) values.
Intertek Whitehouse provides residual solvent testing in accordance with USP <467>, supporting manufacturers in identifying and quantifying residual solvents and assessing their levels against applicable requirements.

Organic Volatile Impurity Analytical Capabilities

- Headspace gas chromatography
- Gas chromatography–mass spectrometry (GC-MS)
- Gravimetric techniques
- Analytical method development in accordance with applicable ICH guidelines

Extractables & Leachables (E&L) Studies

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.

Materials used in packaging, manufacturing systems, and drug delivery devices can interact with pharmaceutical products over time. Intertek provides extractables and leachables studies to help manufacturers understand these interactions and assess potential risks.

Our teams work with pharmaceutical, biologic, and combination product developers to build testing strategies aligned with the product, packaging system, route of administration, and stage of development. Support extends from early material characterization through commercial lifecycle management.

E&L Study Services

We tailor our studies to your materials, product requirements, and stage of development.

- **Material Characterization & Extractables Studies:** Characterization of packaging, manufacturing, and device materials to identify potential extractables and support material selection.
- **Leachables Assessment**: Product-specific studies to identify and evaluate compounds that may migrate into a drug product during storage and use.
- **Single-Use Systems Qualification**: Testing programs for tubing, filters, bags, and fluid-path components used in bioprocessing and pharmaceutical manufacturing.
- **Combination Product Support**: E&L support for prefilled syringes, autoinjectors, cartridges, wearable systems, and other drug-device combination products.

Analytical Capabilities

Our analytical techniques support the detection and characterization of extractables and leachables across packaging, manufacturing systems, and drug delivery devices.

- GC-MS and headspace GC-MS
- LC-MS/MS and high-resolution mass spectrometry
- ICP-MS and ICP-OES
- TOC analysis and FTIR spectroscopy
- Non-targeted screening, compound identification, and structural elucidation

Applications Supported

Packaging & Container Closures
Vials, syringes, cartridges, flexible bags, closures, and stoppers.

Bioprocessing & Manufacturing
Single-use systems, bioreactor assemblies, and process fluid paths

Drug Delivery Systems
Injection devices and wearable devices.



Container Qualification & Packaging Systems Evaluation

Pharmaceutical packaging systems play a critical role in maintaining product quality, safety, efficacy, and regulatory compliance throughout the product lifecycle. Intertek provides container qualification programs that establish material identity, evaluate packaging-system suitability, and support risk-based packaging control strategies from development through commercialization.

Our experts help clients connect material characterization, packaging performance, supplier controls, and lifecycle management into a qualification strategy that evaluates the complete packaging system in the context of its intended pharmaceutical use.



Material Characterization & Packaging Qualification

Intertek Whitehouse provides analytical characterization and qualification testing aligned with USP <661.1> and <661.2>. Our services establish polymer identity, assess material composition, and evaluate finished packaging systems for suitability in their intended pharmaceutical applications.

Supplier & Change Control Programs

Changes to packaging materials, suppliers, manufacturing processes, or component formulations can affect packaging-system performance and consistency.

Our experts support supplier qualification, resin and additive changes, manufacturing transfers, and comparability assessments. These evaluations help manufacturers understand the potential impact of changes and maintain appropriate packaging controls throughout the product lifecycle.

Failure Investigation & Root Cause Analysis

Packaging-related concerns may arise from material inconsistencies, particulate contamination, discoloration, surface defects, or unexpected performance changes.

Intertek provides analytical investigation support to help identify potential causes, characterize affected materials, and assess differences between packaging components. These findings support corrective actions, process improvements, and ongoing quality control activities.

Analytical Capabilities

Intertek Whitehouse applies a range of analytical technologies to support material identification, physicochemical characterization, extractables risk assessment, and packaging-system evaluation.

Capabilities include:

- FTIR spectroscopy and differential scanning calorimetry (DSC)
- UV-visible spectroscopy and total organic carbon (TOC)
- ICP-MS and ICP-OES
- HPLC, UHPLC, and LC-MS
- GC, headspace GC, and GC-MS
- XRF screening and SEM-EDS analysis
- XRPD and XPS
- Microscopy and imaging techniques

Packaging Systems Supported

Our qualification programs support a variety of pharmaceutical packaging components and systems, including bottles and closures, vials, prefilled syringes, cartridges, films and flexible packaging, blow-fill-seal systems, molded plastic components, drug delivery devices, combination products, and integrated container closure systems.

Container Closure Integrity Testing (CCIT)

Container Closure Integrity Testing is critical to maintaining sterility, product quality, and patient safety throughout the lifecycle of pharmaceutical and biologic products. Intertek Whitehouse provides CCIT solutions using deterministic technologies aligned with USP <1207> principles to support development, validation, manufacturing, stability studies, investigations, and regulatory submissions.

Our experts help clients develop and implement risk-based container closure integrity strategies tailored to the specific product, package system, and regulatory objective. Programs consider package configuration, formulation characteristics, closure design, assembly processes, storage conditions, transportation stresses, and intended product use.

Package Systems Supported

Our CCIT capabilities support a range of parenteral packaging systems, including vials, prefilled syringes, and flexible packaging such as IV bags. Our experts tailor testing approaches to the package design, material characteristics, and intended use.

Deterministic CCIT Technologies

Intertek Whitehouse provides deterministic testing methods to evaluate container closure integrity and support scientifically justified method selection.

- **Vacuum Decay:** Non-destructive leak detection for a range of sealed pharmaceutical packaging systems.
- **High-Voltage Leak Detection (HVLD):** Sensitive testing for liquid-filled, non-conductive containers.
- **Helium Leak Detection:** Highly sensitive testing using helium as a tracer gas to identify small leak pathways.
- **Residual Seal Force:** Evaluates the compressive force retained in stoppered and capped container systems.

Method Development & Validation

Our experts develop and optimize CCIT methods based on product-package characteristics, test sensitivity, and intended use. Validation studies assess method suitability, accuracy, precision, repeatability, robustness, and detection capability in alignment with applicable USP <1207> principles.

Root Cause Investigation & Packaging Optimization

Intertek supports investigations into closure compression, crimp quality, stopper fit, syringe or cartridge assembly, material defects, and process-related packaging failures. Findings help guide corrective actions, component optimization, and manufacturing improvements.

Stability & Lifecycle Support

CCIT studies help evaluate packaging integrity under aging, storage, shipping, temperature cycling, and other relevant conditions. Testing can also support manufacturing controls, change assessments, and ongoing package integrity verification.



Typical Testing Scope & Workflow

Our workflow is designed to be seamless, moving from initial scoping to the delivery of submission-ready data.

1. **Scope Definition**
2. **Risk Assessment**
3. **Strategy Building**
4. **Execution**
5. **Delivery**

Medical Device Performance & Functionality Testing

An integrated, lifecycle-based approach supports consistent dose delivery, usability, and compliance for combination products.

cGMP-ready testing programs and ISO/IEC 17025-accredited scope where applicable

Design Verification
Mechanical and functional testing to confirm device and package-system performance meets defined design inputs and acceptance criteria.

ISO Syringe Testing
Prefilled syringes, syringe components, glass/polymer barrels, plungers, closures, and needle-shield delivery interfaces.

Investigation & CAPA
Complaint investigations, CAPA support, supplier/process change investigations with traceable technical conclusions.

Method Development & Validation
Risk-based method development using defined fixtures, calibrated equipment, controlled sample preparation, and statistical suitability tools.

Ongoing Support
Support across early-stage development, commercial manufacturing, method transfer, process changes, aging/stability, and post-market investigations.

Integrated Services
Integration of robustness studies utilizing advanced technologies and services across our team of multidisciplinary experts.

Medical devices, drug delivery systems, and combination products must demonstrate reliable performance throughout development, regulatory review, commercialization, and lifecycle management. Intertek Whitehouse provides mechanical, functional, and performance testing services to evaluate device integrity, usability, durability, and product performance under real-world and simulated-use conditions.

Our multidisciplinary teams support pharmaceutical, medical device, and combination-product manufacturers through development studies, device verification programs, quality investigations, supplier qualification activities, and regulatory support testing.

Testing & Support	Capabilities
Injection & Delivery	Break-loose and glide force; needle shield and tip cap removal; plunger and stopper performance
Mechanical Performance	Flange and barrel strength; Luer and connector robustness; tensile, compression, peel, adhesion and torque testing
Simulated Use	Simulated-use evaluations and environmental conditioning studies
Devices Supported	Prefilled syringes, autoinjectors, injection systems, wearable drug delivery devices, combination products, connectors, closures and sterile barrier systems
Analytical Support	Optical microscopy, FTIR, Raman spectroscopy, SEM/EDS and thermal analysis for material characterization and failure investigations



The Intertek Advantage

Intertek Whitehouse combines analytical development, GMP testing, packaging science, container integrity, and device-performance expertise within one laboratory organization. This connected approach helps clients coordinate testing across the product, package, and delivery system while maintaining clear technical ownership throughout the program.

- **Integrated lifecycle support:** Services span development, characterization, qualification, validation, stability, investigations, and commercial quality programs.
- **Multidisciplinary scientific expertise:** Analytical chemists, packaging specialists, and mechanical testing teams can collaborate to take an intregrated approach to programs.
- **Program-specific study design:** Testing strategies are built around the product, materials, package configuration, intended use, and regulatory objective.
- **Practical problem solving:** Whitehouse supports routine testing as well as supplier changes, comparability studies, deviations, complaints, and root cause investigations.
- **Clear, decision-ready reporting:** Programs are designed to produce data and technical conclusions that support development, quality, and regulatory decisions.

intertek
Total Quality. Assured.



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