

Non-Standard Bioanalytical Approaches



Valued Quality. Delivered.

GLP & GCP Bioanalysis



Intertek Pharmaceutical Services global laboratory network has extensive experience in bioanalytical method development, GLP validation and provision of analysis to support toxicology, pre-clinical and clinical studies with core strengths in bioanalytical LC-MS/MS services for small molecules and Immunochemistry for large molecules. This experience, combined with automated data capture and reporting systems, has established our laboratories as a leading centers of excellence for bioanalysis.

As the complexity of both the APIs and matrix components increase, there are some instances where other less traditional analytical techniques present a more viable option for bioanalysis.

These techniques available to GLP/GCP include:

- Inductively Coupled Plasma Spectroscopy with Mass Spectrometry (ICP-MS)
- Capillary Electrophoresis (CE)
- Nuclear Magnetic Resonance Spectroscopy (NMR)
- Gas Chromatography – Mass Spectrometry (GC-MS)
- Scanning Electron Microscopy (SEM) or Transmission Electron Microscopy (TEM)
- Chiral separation with GC-MS, NMR, CE

About our team:

Projects are assigned to and managed by experienced Principal Investigators with support from teams consisting of Project Managers, Project Coordinators, Senior Scientists and Chemists. The project teams ensure your methods are properly validated, and that study samples are accessioned, analyzed and reported in a timely and cost efficient manner.



The Intertek Solution

With recognised expertise in both large and small molecule bioanalytics and experience with a diverse array of biological matrices including plasma, blood, ocular tissues, tumour tissues and skin, Intertek pride ourselves on providing a tailor made analysis solution, chosen to best accommodate the chemistry, or biology of the analyte as well as sample matrix effects.

Our core services are based around LC-MSMS for small molecules and Immunochemistry for biologics, where each approach undoubtedly presents a unrivalled solution, in terms of sensitivity and reproducibility, for many bioanalytical applications.

However, as the complexity of both the APIs and the matrix components increase there are some instances where other less traditional analytical techniques present more viable option.

At Intertek we have become experts at adapting these traditionally chemical based techniques to meet the growing demands of the bioanalytical industry and provide our clients with the best possible solutions.

Examples of such techniques and their possible applications are presented below and can be offered to either GLP or GCP.

Technology	Bioanalysis Applications
Inductively Coupled Plasma Spectroscopy with Mass Spectrometry (ICP-MS)	Bioanalysis services to determine trace levels of inorganic materials in biological matrices, such as platinum containing anti-cancer drugs. Skin analysis (residue of topical or dermatological patch products).
Capillary Electrophoresis (CE)	Ideal for bioanalysis of oligonucleotide therapeutics.
Nuclear Magnetic Resonance Spectroscopy (NMR)	Ideal for PEGylated materials in biological matrices.

Bioanalysis Services

- Method Development & Validation
 - High Throughput GLP Sample Analysis
 - Pre-clinical Bioanalysis
 - Clinical Bioanalysis
 - Bioequivalence Studies
 - Bioavailability Studies
 - GCP Bioanalysis
- Non-GLP Discovery-Phase Bioanalysis
 - In Vitro Screening Bioanalysis
 - Tissue Bioanalysis
 - Early Pharmacokinetic (PK) Studies
- Clinical Kit Preparation, Sample Handling & Management

The Intertek Advantage

Intertek is the leading quality solutions provider to industries worldwide. From auditing and inspection, to testing, training, advisory, quality assurance and certification, Intertek adds value to customers' products, processes and assets. With a network of more than 1,000 laboratories

and offices and over 36,000 people in more than 100 countries, Intertek supports companies' success in a global marketplace. Intertek helps its customers to meet end users' expectations for safety, sustainability, performance, integrity and desirability in virtually any market worldwide.

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