



# hallanalytical

a Crawford Scientific company

## COMMITTED TO EXCELLENCE:

We are committed to providing assurance to our customers by operating and maintaining a quality management system based on the requirements of ISO17025, UKAS, and GLP

[www.hallanalytical.co.uk](http://www.hallanalytical.co.uk)



# because analysis is so much more than data

Hall Analytical are experts in analytical mass spectrometry and we will deliver information which can make a difference to your business

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Hall Analytical is a contract analytical laboratory which specialises in problem solving. Our extensive range of chromatographic and mass spectrometric instrumentation, combined with highly experienced and skilled scientists, mean you can have the utmost confidence in the information we deliver to your business.

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**Specialists in Mass Spectrometry**



**Extensive Range of Instrumentation**



**ISO17025, UKAS, GLP Accredited**



**Consulting, In-sourcing & Training**



# Delivering insight and understanding through collaboration and expertise

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## Welcome to Hall Analytical

Whilst most laboratories are skilled at delivering data, our analytical experts deliver answers, based on a deep understanding of chemistry, chromatography, mass spectrometry and the application areas in which we specialise.

We are highly responsive, quality focussed and always deliver results on time. We are always contactable to help you understand the meaning of the results we provide, in the context of your application area or problem.

We are experts in mass spectrometric analysis and our senior team are highly skilled in ab. initio. interpretation of mass spectrometric data obtained from hyphenated chromatographic techniques.

We specialise in the analysis of Pharmaceuticals, Tobacco and E-Cigarette products, Polyurethane Foam, Agrochemicals and Persistence Environmental Pollutants.

We have a global reputation in Extractable and Leachable analysis, Analysis of Dioxins, Furans, PCB's and PAH's, 5 Batch Agrochemical analysis and the analysis of Polyurethane foams.

Our chromatography experts undertake method development and validation work across a wide variety of HPLC and GC techniques to generate the information you require. We are experienced in technology transfer and on-site consulting which gives you the flexibility to have your critical data generated at your own facility when required.

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Malcolm Kimber  
Laboratory Operations Director



## Why work with Hall Analytical?

Our approach to working with clients is simple and well defined – understand your needs and exceed your expectations.

We achieve this using a process that has allowed us to deliver business critical data to our clients, both large and small, for the past 20 years;

- Work with you to fully understand your requirements and clearly define the analytical scope and deliverables
- Develop a study plan and have you approve the workflow
- Include Milestone exit points throughout the workflow of more complex projects to lower your overall risk
- Discuss project progress at regular intervals and consult on major project decision points
- Generate the highest quality data, on time and deliver your information in a world class report
- Ensure you fully understand the results produced and assist you to contextualise the data and use it in an appropriate way



**“ Good quality work with excellent interactions. There were a few projects with tight timelines and the Hall team were very responsive. ”**

CEO  
Global Biopharmaceutical Company

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# Accreditations

Hall Analytical Laboratories has developed their Quality Assurance procedures over a number of years to meet the stringent demands of both our clients and global regulatory programs.




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- We are a member of the Medicines and Healthcare Products Regulatory Agency (MHRA) Good Laboratory Practice (GLP) Program. For many clients it is mandatory that work is carried out to GLP standards
- We are a UKAS accredited laboratory for the analysis of Dioxins and Furans, Polychlorinated Biphenyls (PCBs) and Polycyclic Aromatic Hydrocarbons (PAHs). The schedule of analysis includes stack emissions, soils and sediments, waters, waste waters, dust and particulates
- We are the European recommended CertiPUR laboratory for the analysis of PU foams
- We are the USA recommended CertiPUR laboratory for the analysis of PU foams
- Hall Analytical Laboratories has undergone numerous client audits to provide assurance that work will be conducted to valid and recognised methods by qualified and trained staff
- We are committed to providing assurance to our customers by operating and maintaining a quality management system based on the requirements of ISO17025, UKAS and GLP

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we have an extensive range of mass spectrometric and chromatographic instrumentation

## Analytical Equipment and Instrumentation

Hall Analytical has a wide portfolio of chromatography and mass spectrometry equipment to meet your analytical challenges.

We have a variety of sampling and sample introduction techniques to deal with samples in a variety of matrices and presentations.

All of our equipment is professionally maintained and serviced, and where applicable is qualified to the levels required under the auspices of Good Laboratory Practice (GLP).

### High Resolution

- LC-TOF (Q-ToF)
- GC-MS (Magnetic sector)
- Probe MS (Magnetic sector)

### Low resolution

- LC-TOF (LCT, Ion trap)
- GC-MS (Quadrupole)
- GC-IRMS

### MSMS

- LC-MS/MS (Q-ToF, Triple Quadrupole)

### GC and LC

- GC-FID
- GC-TCD
- LC-DAD
- UHPLC-DAD

### Inlets

- Split/Splitless
- SPME
- MSSV
- PTV
- On-column
- Headspace
- Thermal desorption
- Pyrolysis

### Other Analytical Techniques

- FTIR
- Karl Fischer

### MSMS

- LC-MS/MS (Q-ToF, Triple Quadrupole, Ion trap MSn)
- GC-MS/MS (Triple Quadrupole & Magnetic Sector linked scan)

### Sub-Contracted Services (to our audited, partner laboratories)

- ICP-MS
- NMR
- ICH Stability Storage
- Chemical Synthesis

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# Mass Spectrometry

Our staff have decades of experience in the design, manufacture and use of mass spectrometry equipment, holding many patents in this field.

Our instruments can provide the full range of resolution and mass accuracy which allows us to provide the right tool to solve your analytical problems.

We have a policy of investment in equipment and technology which ensures that your data is always fit for purpose.

## Mass Spectrometry

- Electron Impact (positive)
- Chemical Ionisation (positive/negative)
- Electrospray (positive/negative)
- Atmospheric Pressure Chemical Ionisation (APCI) (positive/negative)
- MS Low and High Resolution
- MS Accurate Mass
- LC-MS/MS and GC-MS/MS
- Single Quadrupole
- Triple Quadrupole
- Ion Trap
- Quadrupole-Time of Flight
- Isotope Ratio MS
- Magnetic Sector



**“ It’s a pleasure doing business with Hall Analytical.  
Good communication and a prompt response. ”**

Site Manager, Foam Manufacturing Business



# Method Development, Validation & Technology Transfer

We undertake method development work for clients from every industry and work to the principles GLP standards as a matter of course. We can develop methods from scratch or according to your specification.

Working to our client's protocols, internal SOP's or our own state of the art method development guidelines, we can quickly and efficiently develop methods using HPLC, GC, LC-MS and GC-MS instrumentation. We use in-silico techniques to inform column choice as well as for the optimization of separations and have a robust 'platform' based approach to method screening. We undertake method development using QbD approaches where required.

Our methods can then be validated to meet FDA and MHRA standards as defined by ICH Q2(R1) guidelines by assessing the following criteria;

- Specificity and selectivity
- Analyte precision
- Intermediate precision
- Linearity and range
- Accuracy
- LOD/LOQ
- Ruggedness
- Standard and sample solution stability
- Robustness (optional)

We are experts in Technology Transfer and are highly experienced in the production and implementation of Method Transfer Protocols. We have a global consulting reputation in troubleshooting method transfer and guarantee method performance as reported in our method development and validation reports.

For each assignment we follow our tried and tested Ways of Working to ensure the highest quality work is delivered on time and according to specification.

In many cases a client may recognise that there is a need but may not be able to access the right equipment. Hall Analytical can develop a specific method to separate and identify, quantify and even isolate components.

Access to this type of information is especially valuable to Virtual, University Spin-Off and Start-Up companies and we have undertaken a significant amount of work with these types of companies.

Larger businesses are frequently unable to fulfil all of their analytical requirements due to a number of constraints including time, equipment availability or skills shortages.

This offers a very cost and time effective solution. Outsourcing of such work enables companies to keep track of real costs and to see the true financial and scientific benefit.

# Consulting & in-sourcing

We are one of the world's largest training organizations in analytical chemistry and have an established consulting business with a global reputation - so we can deliver answers where and when you need them.

Our trainers and consultants come from a wide range of industry types and have over 200 years of combined experience in analytical chemistry.

## Consulting Services

Our consultancy services provide assistance when you don't have the time or the expertise to implement new solutions, solve problems or improve laboratory performance. We will work alongside you making recommendations and advising best practices, ensuring you gain a better appreciation and understanding during the consultation and get real return on investment.

For over 28 years we have been helping clients to solve problems and improve their laboratory performance. The experience we have gained will help you to quickly and effectively navigate steep learning curves, make better informed business critical decisions and overcome problems.

We consult at our own laboratory or yours and offer in-sourcing services where your own resources are limited.

- Method Development
- Method Troubleshooting
- Improving and Transferring Methods
- Improving laboratory Productivity
- Optimising Instrument Use
- Developing Best Practice and Ways of Working
- SOP and Protocol Writing
- Audit
- Software Development
- Vendor Relationship Management / Instrument Sourcing and Demo services



# Training

The requirement for consistently high standards of competence in chromatography and analytical science is now, more than ever, a matter of priority for pharmaceutical, chemical, food and beverage, petrochemical and environmental organizations throughout the world.

Together with our sister company, Crawford Scientific, we are a recognised provider of high quality, flexible training in analytical science designed to provide maximum impact on student knowledge and effectiveness in the laboratory. Our training events are lively and enjoyable whilst ensuring that every attendee is developed to their maximum potential using modern laboratory instrumentation and cutting edge, but practically relevant, theory.

## We offer the following training courses;

### HPLC Courses

- HPLC Troubleshooting and Maintenance
- Practical HPLC Troubleshooting and Maintenance
- HPLC Method Development
- Practical HPLC Method Development
- Practical Fast HPLC / UHPLC Method Development
- Fundamental HPLC

### GC Courses

- Fundamental GC
- GC Troubleshooting and Maintenance
- Practical GC Troubleshooting and Maintenance
- Practical GC Method Development
- Practical Fast GC

### MS Training Courses

- GC-MS training
- Practical GC-MS training
- GC-MS Spectral Interpretation training
- LC-MS training
- Practical LC-MS/MS training
- LC-MS Spectral Interpretation training

### Other Training Courses

- Introduction to Analytical Validation
- Solid Phase Extraction
- Practical Dissolution Testing
- Capillary Electrophoresis
- Fundamental ICP-MS
- Basic Laboratory Skills
- Basic Chemistry
- Statistics for Scientists Introduction
- Introduction to Bio-Molecule Mass Spectrometry
- Introduction to Biopharmaceutical HPLC and LC-MS Analysis



# Application Areas

We work in specific application areas so our accumulated expertise and cutting edge technology mean you can expect a world class service

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# Polyurethane Foam Analysis

Hall Analytical is a world leader in the investigation of various polyurethane foam (PU foam) matrices for extractable organic components, e.g. prohibited additives and residual compounds such as reaction initiators.

In conjunction with Europur we have undertaken numerous development projects assessing and optimising extraction techniques for the investigation of polyurethane foams.

We are approved to undertake analyses on polyurethane foam samples under the CertiPUR™® (EuroPUR) and CertiPUR-US® product standard scheme for the assessment of analytes;

- 2,4-Toluenediamine (TDA)
- 4,4'-Diaminodiphenylmethane (4,4'-MDA)
- Tributyltin
- Phthalates
- Poly brominated flame retardants

We perform testing on the following product types;

- Conventional polyether foam
- Conventional FR polyether foam
- Super-soft foam
- High Resilience foam
- Viscoelastic (memory) foam



The Technical Guidelines contain the criteria and requirements for certification of flexible polyurethane foams through the CertiPUR-US® and CertiPUR - Europe program. The Technical Guidelines were established with guidance from the global foam industry and in conjunction with the leadership of the mattress and upholstered furniture industries. In addition, an advisory panel of scientists, academics, environmentalists and representatives of consumer groups provided invaluable input in the development process.

We have all of the requisite sampling and analytical equipment for flexible PU foam (FPF) analysis and characterisation for a variety of industries including the producers of foam stock, re-formed and molded foam and end user clients who use the foams in furniture, bedding and clothing products.



[CertiPUR-US Technical Guidelines - download »](#)



[CertiPUR Technical Paper download »](#)

# Extractables & Leachables

Extractable and Leachable analysis is an area of growing regulatory significance, and provides many challenges in the development of pharmaceutical and biopharmaceutical products and their container systems as well as components used in single use pharmaceutical devices as well as food manufacture and packaging.



It is concerned with the potential for compounds to migrate into the drug product from processing equipment, closed container system drug delivery devices or single use medical devices.

- pMDI
- DPI
- pre-filled parenterals
- elastomer and plastic ancillary components of the primary packaging
- single use medical devices (IV bags, syringes etc.)
- plastic and coated materials used in pharmaceutical and food manufacture and packaging

Our vast experience with different materials used in container/closure and packaging systems allows us to understand your requirements and in many cases we are able to offer assistance in these areas.

By performing a detailed extractable study, using a variety of appropriate methods, we can characterise and quantitate the components observed. Using a combination of gas and liquid chromatography combined with mass spectrometry we are able to provide structural information on a wide range of extractable materials. Our own, extensive, in-house library assists in identifying “unknown” components.

Typical migratory compounds include:

- Monomers and polymers i.e. elastomers, lubricants and thermoplastics
- Additives i.e. plasticisers, antioxidants, initiators and metal catalysts
- Adhesives, inks, lacquers and laminate films
- Rubber constituents

Employing the published best practice recommendations of the PQRI Leachables and Extractables Working Group (2006), we have gained an international reputation for the development of highly cost effective and efficient strategies which deliver results that are fully compliant with these recommendations. Our approach will typically include:

- Collaborative information gathering and existing data analysis
- Test protocol development for extractables and leachables studies
- Investigation of sequential extraction or alternative extraction methodologies where required according to our extensive experience
- Organic and inorganic extractables profile production
- Unknown extractable characterisation using mass spectrometric and spectroscopic techniques
- Determination of the Analytical Estimation Threshold (AET) and qualification based on the Safety Concern Threshold (SCT) using dose scaling to evaluate risk where appropriate
- Method development and validation of method(s) for the Leachables Study
- Reporting Leachable Study results within the current guideline recommendations

Analytical methods, including specific screens for compounds of particular toxicological interest i.e. nitrosamines, PAHs, 2-mercaptobenzothiazol etc., provide quantitative determination of leachable compounds which enables accurate and efficient measurements of the accumulated level of migratory species throughout the shelf life of the product.

Such data has been used to successfully support FDA and other licensing regulatory submissions.

Equipment and technology available for Extractables and Leachables testing includes:

- Soxhlet, Ultrasonic and Accelerated Solvent Extraction (ASE)
- HPLC – MS/MS, HPLC Q-Tof, HPLC-Diode Array
- Headspace GC, GC-MS, GC-HRMS
- GC-FID, GC-ECD
- FTIR

Extractables and Leachables testing is also available for food and beverage, packaging and a host of other industries. Our extensive experience in this field of testing allows us to advise you on the most appropriate and cost effective analytical approach to meet your business and regulatory requirements.

**“ Hall provided an honest and reliable service. They have good technical knowledge and are willing to discuss problems and help provide solutions. They are always contactable and friendly. ”**

**Laboratory Manager, Global Materials Manufacturing Business**

## E-Cigarette Testing Services

The E-cig marketplace has grown significantly in recent years - leading to a large increase in the number and quality of devices and liquid types available.

As the e-cigarette marketplace and regulatory frameworks develop, testing becomes more varied and detailed, and we have been involved from the start in developing and optimising extraction, collection and analytical test methods which are efficient, fit for purpose and deliver the information you need to assure and improve product quality and safety.

We recognise that the testing of e-cigarettes and their components is different from that of traditional tobacco products and our methodologies for sample collection and extraction reflect this fact. Our expertise in chromatography and mass spectrometry makes allows us to offer investigative analysis, as well as routine testing for device components, e-liquids and the aerosols created on 'vaping'.

Extractable and leachable analysis – of device components, liquid containers and container closures. Using our vast database of potential leachable compounds, we have tested and characterised cartomisers, atomisers, e-liquid bottles and mouthpieces.

We have a number of extraction methodologies available and significant experience on which extraction techniques and solvents are appropriate for e-cigarette components. We can quickly and comprehensively characterise the extractable components and highlight those of potential toxicological significance.

Once the extractable profile has been developed and established, we can also provide leachables testing to support your product development, stability testing and regulatory compliance work.

Vapour quality testing - metals analysis and the full range of aerosol carbonyls (suite of 13 carbonyl compounds).

Yield testing - using a variety of sample collection and extraction methods, we can provide nicotine, glycerol, propylene glycol, flavorings and water analysis.

Shelf Life and Degradant Testing - we can provide stability storage and analysis in support of stability studies for nicotine, leachables, related substances, menthol, glycerol, propylene glycol, water and flavourings.

E-liquid purity - screening and semi-quantitative analysis of e-liquids for composition, impurities and degradants.

Batch release testing of e-liquids - nicotine assay, water content.

Liquid label claim analysis - for nicotine, glycerol, propylene glycol, menthol, flavourings and water.





# Pharmaceutical Impurities and Degradants

Impurities and Degradants can be present in raw materials, arise during the manufacturing process, be generated during storage or evolve following sample incorporation into a closed container system.

The key to identifying such species is having the right equipment, expertise and experience to generate insightful data and interpret this data in a practical way.

Separation techniques such as HPLC and GC, when hyphenated to mass spectrometry, provide analytical platforms which are capable of generating the most defensible data for the isolation and investigation of unknowns.

Following chromatographic separation with any necessary peak purity determination, the resultant mass spectrum of an unknown may be searched and compared against established libraries or user-contributed databases to facilitate identification.



Alternatively, first principles ab. initio. mass spectral interpretation in conjunction with a proposed structure or known intermediate may elicit a proposed structure. Further structure corroboration may be provided by accurate mass determination which will yield empirical formulae proposals of the intact unknown precursor and its resultant product ions.

Our analytical laboratory has the wide variety of instrumentation required to identify unknowns. In addition to analysis alongside standards, accurate mass and MS-MS techniques provide complementary data. These techniques can also be used to complement data generated in the client's own QC laboratory.

Through our trusted out-sourcing partners we can provide environmental conditions as defined in the ICH guidelines with subsequent routine testing or the development and validation of stability indicating methods carried out at Hall Analytical. Storage stability trials to current ICH guidelines:

- 25°C/60% RH, 30°C/65% RH, 40°C/75% RH and more temperature and humidity cabinets
- Storage at -80, -20, -10, 0, 5, 10, 25, 40, 54°C
- Continuous Ice-Spy monitoring and alerts
- Photo-stability testing
- Post-marketing stability and shelf life studies

## Agrochemicals-5 Batch Analysis

For pesticide registration in the agrochemical industry a Preliminary (5-Batch) Analysis is a pre-requisite according to various Regulatory Directives;

- Europe: Regulation (EC) 1107/2009, Commission Regulation (EU) 283/2013, SANCO 3030/99
- US-EPA: OPPTS 830.1550, OPPTS 830.1700, OPPTS 830.1800
- Brasil: e.g. SINDAG, Circular Letter no 075/2007; CTA, Circular Letter Sept/2011
- Argentina: SENASA requirements
- Worldwide: FAO or IUPAC specifications on toxicological relevant impurities

This involves the analysis of five or more production batches of the pesticide. The amount of active ingredient is assayed and any impurities above a set threshold must be identified and quantified. This work is usually performed to GLP (Good Laboratory Practice) standards.

**Hall Analytical** is unique in that we can perform all the testing required for 5 batch analysis in compliance with GLP standards, as well as being able to provide Dioxins analysis to GLP standards which is an additional requisite for some pesticide materials (24 D, Dicamba, MCPP, Prochloraz and others). This saves our clients time and money as all testing is consolidated with a single supplier who can provide the complete analysis required for regulatory submission.

### **We undertake 5 batch analysis as a sequential process;**

- General semi-quantitative screen by GC or HPLC with FID or UV detection to determine all components present above the 0.1% w/w threshold
- Identify and characterise the impurities by GC-MS and/or LC-MS
- Obtain the impurities via an approved third party specialist chemical synthesis company
- Develop assay procedures for the impurities and active substances according to SANCO guidelines
- Provide a full GLP report with full client consultation, in an agreed format, for regulatory submission

Client confidentiality is assured and all results are fully discussed and explained.

**“ Answer our e-mails very quickly and helped us to solve some very tricky problems over the past few years – thank you so much! ”**

**Business Leader, Agrochemical Manufacturer**

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## Compounds which we have dealt with include;

### Impurity Profiling

- Oxyfluorfen
- Pendimethalin
- Tribenuron Methyl
- Propiconazole
- Metsulfuron Methyl
- Chlorothalonil
- Clopyralid
- Glyphosate
- Triclopyr Butoxy Ethyl Ester
- Mecoprop-P
- Flazasulfuron
- Difenoconazole
- Cypermethrin

### Full GLP 5 Batch Study

- 2,4 D 2-EHE
- Thiodicarb
- Imazethapyr
- Butoxydim
- Cyprodinil
- Tebuthiuron
- Triclopyr BEE

### GLP Testing

- Abamectin (GLP AI assay)
- Benoxacor (GLP AI assay)
- Imazethapyr (GLP Residual Toluene)
- Oxyfluorfen (GLP Nitrosamines NDMA)
- Propiconazole (GLP Nitrosamines NDMA)

### GLP Dioxin Testing

- 2,4 D
- 2,4 DB
- MCPP
- MCPA
- MCPA 2-EHE
- Dicamba
- Prochloraz and Formulations

# Environmental Analysis (Dioxins, Furans, PAHs, PCBs)

All of our environmental analysis services are driven by the following values;

- Attain accreditation to the highest national and international standards
- Use of world class technology
- Recruit, develop and retain experts in chemical analysis
- Continuous improvement of methodology, QA / QC protocols to ensure the highest data quality
- On time delivery of results in a format that suits your requirements

We are able to provide;

- International Toxicity Equivalent (ITEQ) determinations of polychlorinated dibenzo-p-dioxin (PCDD) and dibenzofuran (PCDF) compounds
- Analysis of the World Health Organisation listing of 12 polychlorinated biphenyls (PCBs) congeners (WHO 12)
- Polycyclic aromatic hydrocarbons (PAHs)

Validated methods have been developed, enabling material groups of specific environmental interest to be identified and quantified including;

- Volatile organic compounds (VOCs)
- Semi-volatiles

## Dioxins and Furans

Produced inadvertently by industrial processes such as waste incineration, chemical manufacturing and paper bleaching, dioxins and furans can be found in the air, in water and contaminated soil. As they accumulate they can become harmful to human health.

High-resolution mass spectrometry is the US EPA accepted analytical technique for quantifying dioxins and furans. Our expert staff utilise state of the art, proven techniques to accurately determine Dioxin and Furan emissions to the lowest levels, to ensure you can optimise the safety of your operations.

Stationary Source Emissions:

We undertake UKAS accredited Dioxin analysis to BS/EN 1948, the European harmonised protocol for stack measurements from hazardous waste incinerators as well as to USEPA Method 23. This includes the preparation and supply of XAD traps for sample collection.

Other Matrices:

Accredited Dioxin analysis methods to USEPA 1613 for soils, sediments, waters, waste waters, ash and dust have been developed. Other methods are also available.



Our state of the art instrumentation and sample preparation facilities combined with optimised methodology ensure the highest quality data, a swift turnaround time and highly competitive pricing, including a fast turnaround premium service for urgent samples.

We are constantly seeking ways to improve our service by reducing sample preparation time, analytical costs and detection limits. Full method blanks with each sample batch and appropriate QC sample preparation ensure confidence in our analytical results. Limits of detection are calculated separately for each targeted congener in each sample, giving a more accurate assessment of matrix interference.

Other Matrices:

Accredited Dioxin analysis methods to USEPA 1613 for soils, sediments, waters, waste waters, ash and dust have been developed. Other methods are also available.

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PCB analysis

Targeted PCB analysis in environmental samples such as soils, sediments, waste waters, stationary emission sources and foods using high resolution GCMS according to US EPA Method 23.

**“Quick turnaround with customer requirements taken into account during report preparation.”**

**Head of Department, Environmental Analysis Company**

# Pharmaceutical Analysis

Our services provide answers for the whole pharmaceutical lifecycle – from early phase, through to manufacturing and post marketing analytical support. Good laboratory Practice (GLP) compliant methods can be developed, validated and implemented from routine to high complex samples to support your Chemistry, Manufacturing and Controls (CMC) challenges.

Assay and Stability Indicating Method Development and Validation – to GLP regulations for pharmaceutical intermediates, API's, formulations and finished products (including injectable solutions, solid dose forms and a host of novel delivery systems). Methods can be developed and validated in accordance with either client-specific protocols or internal SOPs, and all methods are validated to meet MHRA, FDA and/or ICH guidelines.



Assay, Purity and Content Uniformity Testing - for the quality control of pharmaceuticals, APIs, drug substances, excipients, raw materials according to GLP requirements.

Analytical Method Evaluation, Improvement and Redevelopment – Analytical Methods associated with established pharmaceutical products should be continuously evaluated during the product lifecycle for validation status, efficacy and efficiency. In accordance with ICH guides ICH Q2(R1) we are able to evaluate existing methods to highlight performance or efficiency shortcomings. We can then re-optimize, revalidate and transfer the method back to your research or manufacturing facility.

Analysis of Counterfeit Medicines and Label Claim Analysis- We undertake chromatographic, mass spectrometric and spectroscopic analysis of counterfeit medicines to address the highly technical issues in investigating the increasingly sophisticated falsified medicines or counterfeit medicines being discovered in the supply chains. Our analytical tools allow us to determine the presence of active pharmaceutical ingredients (API's) as well the amounts of API, impurities, degradants, excipients and other ingredients such as coatings. Our data can be used in support of patent litigation.

We also undertake method development and routine testing in support of cleaning validation, comparator and stability studies.

**“Very experienced leadership and technical team.”**

**CEO, Pharmaceutical Development Company**

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## Petrochemical and Oil Analysis

Oil and oil related samples are some of the most complicated mixtures to analyse. The identification of trace components within these complex matrices requires a good understanding of the appropriate chromatographic and mass spectrometric techniques. The widely varying component concentration in these types of samples adds further complications when trying to perform quantification studies.

The use of selected ion recording (SIR) and metastable reaction monitoring (MRM) for example can enable crucial information to be gained from these complex samples. Biomarkers used for identifying the origin of oils is a typical example of the MRM work we undertake.



### Shale Gas Analysis

Shale gas can offer a lower cost and more convenient source of methane than other sources. As such there is considerable interest in finding rich sources. Environmental issues however are key in this area. Prior to exploiting the source it is necessary to take baseline readings to establish what the current levels of methane and carbon dioxide are in the local water courses. Gas composition analysis of water samples together with IRMS measurements allows this data to be obtained. Sampling from deep water courses will confirm the presence of methane together with its source (biogenic or thermogenic). Hall Analytical has been performing this type of work for several years and can also advise on the sampling methodology (which is critical if meaningful results are to be obtained).



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