analytical services
At Crawford scientific, we partner with key UK based contract laboratories to provide quality services for your analytical needs. We have built a global reputation on a professional, responsive and flexible approach designed to provide quality data, delivered on time.

Our strength is the ability to understand your analytical requirements and act as a single point of contact to ensure the data delivered meets your requirements in terms of applicability, fitness for purpose and timeliness.

We provide an extensive range of routine analysis, analytical development and expert services to clients across industry sectors at the right price and with a proven track record of success.

Our scientific staff are technically excellent, delivery-oriented, impartial and responsive. Our Study Directors strive to develop long-term relationships and close communication with all clients, including the many blue chip organisations who we count amongst our extensive client base.

Unrivalled scientific expertise, highly efficient processes and an extensive, modern, instrument base ensure a swift turnaround time and highly competitive pricing.

Detailed Study Plans, prepared with full collaboration, allow for regular review and amendment as required.

Regulatory compliance guarantees total confidence in sample handling and preparation, data acquisition, interpretation and reporting including;

- ISO 17025 approved quality system
- MHRA GLP, GMP and GCP accreditation
- UKAS accreditation in analytical chemistry

Our laboratories in Manchester, London and Ascot are well placed for sample delivery.

If you have any requirements not listed in this brochure, or if you have any questions about our analytical services please phone or e-mail us:

- 01357 522 961
- analytical@crawfordscientific.com
Delivering Quality Results

• Efficient and timely service with good project management
• Experienced staff with time and knowledge to optimise results
• Established development, optimisation and high throughput methodologies
• Unrivalled skills in Liquid and Gas chromatography with mass spectrometric detection
• On-going investment in cutting edge technology
• Fully accredited quality systems
• Milestone Based Approach – giving you a flexible / low risk approach to development projects

Application Areas

• Pharmaceutical & Biopharmaceutical
• Environmental
• Petrochemical
• Food & Beverage
• Polymer
• Foams & Textiles
• Geochemical
• Essential Oils & Fats
• Forensic / Drugs of Abuse

Expertise

• Chromatography
• Mass Spectrometry
• Data Interpretation
• Sample Analysis
• Environmental Analysis
• Method development and validation
• Technology Transfer
• Training and Consulting

Equipment (Not limited to)

• UPLC - Xevo QTOF & TQS MS/MS
• SCIEX LC-MS/MS - 5500, 5000 and 4000
• MALDI-MS
• GC-MS (EI & CI)
• GC-M5 Autospec
• GC (FID, TCD, NPD, ECD, FPD)
• Headspace GC(MS), Pyrolysis GC(MS)
• SPME / SPE
• Automated On-line SPE for LC-MS/MS
• HPLC (MSn, UV, RI, ELSD)
• Ultra Performance Liquid Chromatography, UPLC (MSn, UV, DAD)
• Gel Permeation chromatography (MALLS, RALLS, UV, TriSec)
• Capillary Electrophoresis, CE
• Capillary Electrochromatography, CEC
• Size Exclusion Chromatography, SEC
• Gel Electrophoresis, IEF, SDS–PAGE
• Dionex ICS-3000 for ion chromatography analysis
• Temperature and humidity controlled cabinets (compliant to CIPAC and ICH)
• NMR, ICP-MS, ICP-OES
• SEM, XRD, XRF,
• IR, FTIR
• And many more ...
Expert Chromatography Services

Our primary expertise is in the development and optimisation of chromatographic and mass spectrometric methods. From sample preparation to data interpretation we have hundreds of years combined experience in the development and validation of chromatographic methods across a wide range of industry and application types. Contact us for more information on the following service provisions:

- Development and validation of sample preparation protocols
- HPLC or GC column selection and screening
- Development and validation of stability indicating methods
- Impurity and degradant testing
- Cleaning validation methods
- Metabolite screening and identification methods
- LC-MS or GC-MS Method development and validation
- Assay and potency method development and validation
- Environmental screening methods
- Methods for toxological screening

Extractables and Leachables

Extractable and Leachable analysis is an area of growing regulatory significance, and provides many challenges in the development of inhalation and injectable drug products. It is concerned with the potential for compounds to migrate into the drug product from closed container system drug delivery devices i.e. pMDI, DPI, pre-filled parenterals etc., and elastomer and plastic ancillary components of the primary packaging. Such migratory compounds include:

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

Employing the published best practice recommendations of the PQRI Leachables and Extractables Working Group (2006), Crawford Scientific Analytical Services has gained an international reputation for the development of highly cost effective and efficient strategies, which deliver results fully compliant with these recommendations for the assessment of the potential for substances to migrate into the drug product.

Analytical methodology, including specific screens for compounds of particular toxicological interest i.e. Nitrosamines, PAHs, 2-Mercaptobenzothiazol etc. provide for the quantitative determination of leachable compounds enabling 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.

Extractable and leachable testing is also available for food and beverage, packaging and a host of other industries and our extensive experience in this type of testing allows us to advise you on the most appropriate and cost effective analytical approach to meet your business and regulatory requirements.
**Identification of Impurities and Degradants**

Impurity and degradant unknowns 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 identification of such species is having the right equipment, expertise and experience to generate insightful data and then interpret this data in a sensible 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.

Further structural corroboration may also be provided using our range of spectroscopic techniques, primarily, Nuclear Magnetic Resonance Spectroscopy.

**Structural Characterisation**

We use the following techniques for structural characterisation of unknowns:

R&D, GLP or cGMP Service Mass Spectrometry, MS

- Electrospray Mass Spectrometry, ESI-MS
- Matrix Assisted Laser Desorption Ionisation Time-of-flight Mass Spectrometry, MALDI-MS
- LC-MS, Liquid Chromatography Mass Spectrometry, LC-MS, LC-MS/MS
- Ultra Performance Liquid Chromatography Mass Spectrometry, UPLC-MS

Spectroscopy

- Infrared Spectroscopy FT-IR & Raman Spectroscopy
- UV/Vis, Near IR, Fluorescence Spectroscopy
- Circular Dichroism, CD
- Nuclear Magnetic Resonance, NMR
- 300, 500 MHz - A wide range of nuclei can be studied) 5 mm QN, 10 mm BB
Bio-Analysis

Comprehensive bio-analytical service for samples generated during pre-clinical and clinical trials (GLP and GCP accredited) from all around the world.

- Full method development, validation and transfer service
- Drug concentrations in both animal and human biological fluids and tissues
- Cutting edge automated high throughput systems allow very high sample numbers to be processed efficiently and economically
- Extensive and fully monitored freezer and refrigerator storage capabilities

Stability Testing

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

Physical/Chemical Testing

Analysis of raw materials, development and finished products in compliance with GLP and GMP and in accordance with ICH and VICH guidelines for pharmaceutical and veterinary medicines.

- Quality control testing
- Certificates of analysis
- Active ingredient analysis
- Residual solvents, related substances and impurities testing

Elemental Analysis

Elemental analysis and testing includes identification and quantification of elements, elemental compounds and molecular species. Sample types and matrices tested for trace elements include organic and non-organic, aqueous and non-aqueous materials. Elemental trace and ultra-trace analysis detection ranges from parts per million (ppm), to parts per billion (ppb) and parts per trillion (ppt) levels, using proven and up-to-date instruments and techniques.

Elemental trace analysis is available for a diverse range of samples and sample-matrices, using various trace level analytical techniques, such as:

- Inductively Coupled Plasma Mass Spectrometry ICP-MS and ICP-AES
- Ion Chromatography, IC (HPAEC-PAD)
- Elemental Microanalysis Techniques
- X-Ray Fluorescence Spectroscopy and X-Ray Diffraction, (XRF and XRD)
- Trace Organic and Inorganic
- Classical Organic and Inorganic Analysis, Titration
- Karl-Fischer, Kjeldahl nitrogen
- Combustion analysis (C,H,N,S, halogens, inorganic ash, residue on combustion)
- DSC analysis
Physico-Chemical Characterisation

We can provide physico-chemical property data for pharmaceutical R&D support, product development and technical support for many sample types. ‘Hazardous’ Phys-chem properties are used mainly for the purposes of safe handling and hazard communication.

Physico-chemical testing forms a significant part of the data package for REACH and the Registration of chemical substances in non-EC countries and can be vital in designing the appropriate toxicological and ecotoxicological test regimes.

We can perform the following physical chemistry tests according to the REACH Annex VII and OECD Guidelines.

- Melting Point, Boiling Point, Freezing point
- Relative Density, Viscosity, Vapour Pressure
- Surface Tension, Water Solubility, Dissolution
- Solvent Solubility, pH, Partition Coefficient
- Hydrolysis Studies, Degradation Studies
- UV/Vis Molar Extinction Coefficient
- Refractive Index, Turbidity
- Conductivity
- Transmission Electron Microscopy, TEM
- SEM (cryo and high resolution), SEM/EDX
- Light & IR Microscopy, Confocal Raman Microscopy
- Thermal Analysis (DSC and MDSC, TGA)
- Dynamic Light Scattering,
- MALLS & SEC-MALLS for Polymer
- Zeta Potential
- Bulk solid properties such as pourability
- Particle size distribution techniques, PSD
- Surface area and porosity (BET)

Summary

The inherent value of an analytical capability is well understood and assists in critical operations such as determining product quality, solving manufacturing problems and contributing to essential R&D to meet business growth expectations.

However, the unpredictable nature of analytical problem solving and analysis typically requires significant investment and maintenance of a broad scientific capability and competency. By utilising the expertise and extensive instrument base available through Crawford Scientific Analytical Services, variable-cost non-core competencies can be performed by a reliable partner as required.

With a proven track record of success Crawford Scientific Analytical Services provide a reliable, trustworthy and confidential analytical solution to your budget, timeframe, data quality and regulatory requirements.

Our people aspire to excellence and are passionate about the scientific work we perform.

Crawford Scientific Analytical Services... a trusted partner.