

A long established, independent provider of bioanalytical services that you can rely on

Providing a quality assured and regulatory compliant service

Bioanalysis has never been as challenging as it is today. Lower limits of quantification, difficult analytes and ever decreasing timelines necessitate the need for a partnership with a flexible, responsive and experienced service organisation that is built on trust.

Tepnel has a wealth of knowledge, with over 20 years of method development and assay validation for drug substances and metabolites with an impressive and ever expanding portfolio of non-proprietary assays.

Experience

With a wealth of knowledge in the field of bioanalysis built up over the last 20 years, Tepnel offers a tailored bioanalytical service to meet your specific study requirements, which is maintained by a stable and dedicated workforce ensuring continuity in project management. With leading edge technology helping to ensure rapid data acquisition and delivery along with MHRA approved and FDA inspected facilities, fully GLP accredited and cGMP compliant, Tepnel can support your early stage discovery cassette studies through to Phase III trials.

Quality Assurance

As a GLP accredited company, Tepnel operates a fully auditable Quality Management System ensuring premium service with full documentation and traceability. All stages of our service are audited including the study plan, operational activities, data analysis, data derivation, the draft and final reports. Our QA personnel are fully conversant with GLP/GCP regulations and provide an independent and fully accountable inspection and auditing service.

Non-proprietary Assay Portfolio

We have developed and validated more than 50 generic drug substances using the FDA and GLP guidelines of the time and successfully applied them to pre-clinical and clinical trials on a range of sample types. For a full list of our assays please contact us at enquiries@tepnelscientific.com

Custom ELISA

This service offers the development of regulatory compliant monoclonal and polyclonal bioassays that can be routinely used to support pre-clinical and clinical studies. The use of ELISA technology will provide a marked increase in the level of sensitivity required for biopharmaceutical drug products and will also provide support for bio-marker identification, elucidation and anti-drug information.

Testing Capabilities

- **Pre-Clinical**
 - Drug substance analysis
 - Bioequivalence
 - Animal study support
 - Assay development & validation
 - Custom ELISA
- **Clinical**
 - PI-III human
 - Pharmacokinetics
 - DNA Extraction
 - Bioanalysis
 - Genotyping
 - Stability

Non Proprietary Assays

Alprazolam	Venlafaxine
Fentanyl	Nifendipine
Bromhexine	Thiocyanate
Hydrochlorothiazide	Loratidine
Clenbuterol	5-ASA
Alfentanyl	Valproic acid
Lansoprazol	Codeine
Captopril	Morphine-3-glucuronide
Prednisolone	Codeine6-glucuronide
Lisinopril	Tramadol
Ifenprodil	Propranolol
Losartan	Phenytoin
Morphine	Midazolam
Morphine-6-glucuronide	

Other Services from Tepnel

Tepnel Research Products & Services offers a broad range of additional services to the pharmaceutical, biotechnology and healthcare sectors including:

Microbiology Services:

- Sterility Testing
- TVC/Abs of Pathogens
- Preservative Efficacy
- Disinfectant Testing
- Bacterial Endotoxin
- Environmental Monitoring

Pharmaceutical Services:

- ICH Stability Testing
- Batch Release
- Raw Materials Testing
- Method Development & Validation
- IMP Testing/Release

Molecular Services:

- DNA/RNA Extraction
- Sample Quantification & Normalisation
- Whole Genome Amplification
- SNP Genotyping
- ELISA/ELISPOT Assay Development

Tepnel Research Products & Services specialises in the provision of regulatory services and analytical solutions in the areas of analytical chemistry, microbiology, bioanalysis and molecular services under inspection and approval of the MHRA and FDA

Contact Details

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Our Approach & Services

As an experienced provider of bioanalytical services, Tepnel prides itself on developing and promoting a successful partnership with our sponsors so we become an extension of your facility. With every new project Tepnel undertakes, the sponsor will be allocated a Project Manager to facilitate your requirements in a timely manner from start to finish. Summarised below is the key to building a successful relationship:

Discovery Support:

- Analytical support for cell culture and single/cassette dosing studies
- Generic sample preparation/chromatography for early stage development
- Pharmacokinetic and Toxicokinetic studies

Method Development:

- Full method development, feasibility and validation covering NCEs, pre-clinical and Phase I-III clinical trials. Experience with complex matrices from all major species

Method Transfer:

- Where reliable and robust methods are in place we offer a rapid, quality assured method transfer service

Method Validation:

- Study plans based on current regulatory guidelines
- Extensive range of pre-validated methods for generics

Sample Analysis:

- Sample analysis for a full range of mammalian species
- Clinical support from PI through to bioequivalence
- Large volume high throughput drug analysis capabilities
- Rapid turn around of data and sample logistics and support
- Multi-purpose semi-automated liquid handling systems
- Long-term stability studies in matrix and solution analyte
- Identical system configuration permitting redundancy for critical assays

Reporting:

- Efficient delivery of QA audited reports tailored to sponsors' specification
- Preparation of expert reports including the PK statistical analysis

