

## Dedicated to the analytical support and testing of the drug development pipeline

### A solution provider for your outsourced needs

At Tepnel we understand the need to have a fast reacting, flexible analytical resource, with dedicated project management which meets milestones and delivers regulatory compliant data every time. With over 25 years of dedicated analytical service provision and problem solving, Tepnel offers a wealth of experience in handling and working with small molecule and biopharmaceutical active pharmaceutical ingredients and finished products providing our customers with a value added solution.

With MHRA approved and FDA inspected facilities working under a GxP quality system, we have a dynamic and dedicated workforce providing continuity of service from start to end of every project. With experienced project managers offering a single point of contact, we can tailor our services to meet your specific quality, regulatory or scientific requirements.

#### Why choose Tepnel?

As a dedicated provider of pharmaceutical analysis, our aim is to build long-term partnerships with our customers. Each project is owned from the outset by a nominated individual who will understand your needs and deliver them to your time scale. Mutuality of benefit is of prime importance; therefore we provide a service which is cost effective, responsive and reliable, without compromising on quality.

- Reliable, confidential and cost effective extension to your in-house capabilities
- Efficient management of outsourced projects freeing-up vital in-house management and laboratory resources
- Help you to meet your own business objectives and avoid costly delays
- Fully GLP accredited/cGMP compliant laboratories
- A fully auditable quality management system ensuring premium service with complete documentation and traceability

#### Our facility

Our laboratory facility is centered in Livingston, Scotland and is spread out over 18,000 square feet of custom designed laboratories. The facility is designed and built to facilitate maximum efficiency from sample receipt through to report delivery and incorporates a Labware LIMS system for automated sample processing and data acquisition reporting.

### Testing Capabilities

- **API Development**
  - Physiochemical Characterisation
  - Storage Stability Studies (ICH)
  - Development/validation of potency and purity assays
- **Clinical Product Development**
  - Raw Materials Testing
  - IMP Release Testing
  - IMP Stability Testing (ICH)
  - Development/validation of stability indicating assays
- **Finished Product Development**
  - Batch Release Testing
  - Post Marketing Surveillance

### Project Management

Tepnel has implemented a dedicated Project Management resource, which provides a single point of contact for all your project needs resulting in continuous improved communication and focus.

### Product Experience

- API, tablets & capsules
- Syrups
- Injectables
- Creams, ointments and gels
- Large peptides
- Proteins
- MDI and DPI inhalation products
- Subcutaneous delivery
- Raw materials and excipients

## 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

### Bioanalytical Services:

- Pre-clinical Support
- Phase I-III Support
- Pharmacokinetics
- Non-proprietary Assays
- Custom ELISA development

### 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

### Tepnel Research Products & Services

Appleton Place,  
Appleton Parkway,  
Livingston,  
West Lothian.  
EH54 7EZ

T: +44 (0)1506 424 270

F: +44 (0)1506 424 280

E: [enquiries@tepnelscientific.com](mailto:enquiries@tepnelscientific.com)

[www.tepnel.com](http://www.tepnel.com)

## Our Approach & Services

### Stability Storage Capabilities

Tepnel provides analytical chemistry and quality control support for Stability Studies in accordance with the International Conference on Harmonisation (ICH) guidance documents under current Good Manufacturing Practices. With over 40m<sup>2</sup> of stability storage, in which all our conditions are mapped, qualified and validated traceable to national standards, Tepnel offers:

- Temperature and humidity ranging from ICH conditions to -20°C
- In-use stability support
- Photostability testing
- Non-ICH conditions supported

### Raw Materials Testing

Tepnel offers a rapid turnaround time on all raw and starting materials testing, using USP, EP, JP, BP and client-supplied methods. With over thirty years of experience, we have encountered most, if not all, available product types in our laboratory. We have a wealth of practical knowledge, experience and adaptability, which we believe is second to none.

### Method Development & Validation

Tepnel provides analytical chemistry and quality control support for Method Development and Validation in accordance with ICH guidance documents under current Good Manufacturing Practices. We have extensive experience and technical knowledge to provide a value added service for a large variety of techniques, materials and product types.

### IMP Testing and Release

Tepnel has been confirmed as operating in accordance with the principles of Good Manufacturing Practice 3, as a contract acceptor on authorisations issued by the MHRA and the FDA. Our experienced analytical capabilities coupled with our Qualified Person Permanent Provisions allows us to satisfy the requirements of the Clinical Trials Directive and certify both IMPs manufactured and imported from within and outside the European Union/European Economic Area.

