

When it comes to Microbiological determination, Tepnel can support your development needs

A leading provider of microbiological support

The demands on the Pharmaceutical Manufacturing Industry to comply with the growing requirements for safe product manufacture and handling are becoming increasingly rigorous. More and more companies are turning to experienced Contract Research Organisations for advice as well as outsourced microbiological solutions. Tepnel is at the forefront of regulatory compliant Microbiological analysis and offers access to industry experienced staff as well as cutting edge technology in the battle against the ever intrusive microbe.

Experience

With over 30 years of dedicated pharmaceutical microbiology service provision, Tepnel offers a wealth of experience in handling a wide range of sample types from raw materials through finished products to medical devices.

- MHRA approved and FDA inspected with facilities working under a GxP quality system
- Highly trained, qualified and dedicated workforce ensuring customer requirements are met within agreed timescales
- Tailored services to meet your specific quality, regulatory or scientific requirements
- Proactive in our Project Management with open channels of communication through a single point of contact
- Based around a Labware LIMS which maximises efficiency and effectiveness

With extensive experience of chemical, physical and microbiological analysis in the pharmaceutical, biotechnology and healthcare industry, Tepnel provides a reliable and cost effective extension to your in-house capabilities.

Harmonised Regulations Update

Global harmonisation of the pharmacopoeial chapters on general microbiology will be implemented on the 1st May 2009. The harmonisation process will see a consistency in the microbiological strategies used by pharmaceutical companies on a global platform bringing together the methods of the USP, EP and the JP for the first time.

The harmonisation process will see the USP affected the most with a change in the title of the Microbial Limits Test to a new Microbial Enumeration Test and the separation of the Absence of Specified Microorganisms into a new chapter.

This may have an effect on products and materials previously validated under the old pharmacopoeial methods. Tepnel will provide re-validation in conjunction with existing sample analysis free for all current customers and at a significantly reduced rate for new customers.

Testing Capabilities

Tepnel has invested in technology which meets customers' expectations all along the drug development pipeline:

- **Pre-Clinical**
 - Raw materials Testing
 - Formulation Stability
 - Batch Release Testing
 - ICH Stability Testing
- **Clinical**
 - Safety Testing
 - Manufacturing Support
 - Process Development
- **Post-Approval**
 - Batch Release
 - Post Marketing Surveillance
 - Manufacturing Support

Product Experience

- API, tablets & capsules
- Syrups, creams, ointments and gels
- Injectables
- Medical Devices
- Antibiotics
- Cell banks
- Fermentation cycle support
- MDI and DPI inhalation products
- Subcutaneous delivery products
- 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:

Bioanalytical Services:

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

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

The Microbiology Group has extensive experience in performing microbiological analysis on behalf of the pharmaceutical, biotechnology and healthcare industries. All work undertaken at Tepnel is performed under our GxP quality umbrella and complies with current Good Manufacturing Practice (cGMP).

Our range of microbiological testing and analytical services includes:

- Microbiological method development and validation (sterile and non-sterile products)
- Sterility Testing using isolator technology with gaseous sterilisation:
 - Membrane Filtration
 - Direct Inoculation
- Disinfectant Efficacy to EN standards
- Preservative Efficacy Testing
- Microbiological antibiotic assay to Ph.Eur and USP
- Microbial identification:
 - DNA
 - API System
 - API lab Software
- Bioburden Analysis (Total Viable Counts & Absence of Specific Pathogens)
- Micro-organism Identification
- Bacterial Endotoxin (LAL) Testing:
 - Gel Clot
 - Kinetic Turbidimetric with 21CFR Part 11 compliant software
 - Kinetic Chromogenic with 21CFR Part 11 compliant software
- Environmental Monitoring Services
- Stability testing including storage facilities conforming to ICH guidelines (25°C/60%RH, 30°C/60%RH & 40°C/75%RH with continuous monitoring, data security & 24hr call out)
- Ph.Eur., USP and JP Pharmacopoeia testing plus TGA, CFR guidelines, in-house and customer-specified methods
- Consultancy services including QP release testing service

