honeyman LABORATORIES

Analytical Services

More than results

THE QUEEN'S AWARDS FOR ENTERPRISE

honeyman GROUP

Assuring Compliance in Life Science

Operating extensively within the global pharmaceutical, biotech, medical device and related healthcare industries, the Honeyman Group has a well-earned and highly regarded reputation for technical problem solving, knowledge transfer and successful project delivery.

Whether it be manufacturing process issues, equipment and process upgrades, design and engineering, analytical support, audit preparation and responses, or simply an independent review of facility projects and operations, we have the technical expertise and knowledge to provide unbiased and regulatory compliant solutions and advice.

Honeyman's unique position in the market as a holistic service, product and knowledge provider, is built on decades of close alliances with clients, suppliers and industry experts.

honeyman WATER

Water and Steam: Purified Water & WFI generation and storage, URS consultancy, IQ/OQ and PQ validation, Maintenance and troubleshooting, Consultancy.

honeyman LABORATORIES

Contract Laboratory: Water and clean steam testing, Finished Products QC release Microbiology, and Finished Product QC release Chemistry, Clean room validation support (e.g. DET, Environmental Monitoring).

honeyman VALIDATION

Validation Services: Thermal mapping, Cycle development, Control system upgrades, Service and maintenance, Environmental monitoring.

honeyman TRAINING

Training: Public Courses, Onsite Courses both generic and bespoke, e-Learning (generic or bespoke solutions), Consultation.

www.linkedin.com/company/honeyman-group-limited/

www.facebook.com/honeymangrouplimited

www.twitter.com/honeymangroup

A TRANSPARENT & FRIENDLY APPROACH

As a valued client of Honeyman Laboratories, you will have regular interaction with your appointed account manager and dedicated laboratory contacts.

We pride ourselves in being close to our clients, and are often regarded as an extension of their own organisation.

Our proactive. approachable team is continually seeking to improve the customer experience whilst ensuring compliance and timely delivery.

Contact us for one-off projects, regular testing or if you need help with an urgent problem, we are always happy to hear from you.

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WHY HONEYMAN LABORATORIES?

Quality

- ☑ Fully GMP Compliant: Consistency, reliability and traceability
- ☑ MHRA Regulatory body inspected
- ☑ Testing in accordance with BP, Ph. Eur., JP, USP, ISO and Client Specifications as required
- ☑ Independent quality department performing regular self-inspection
- ☑ We welcome clients visiting and auditing our first-class Laboratory facilities and systems

Cost

- Competitive pricing
- Bespoke pricing solutions to suit your required level of support

Expertise

Our expert team of highly qualified Chemists, Microbiologists, Engineers, Validation & Regulatory Professionals have been delivering industry leading laboratory services here for 28 years.

Communication

- ☑ Strong, client led relationships
- ☑ Passionate and friendly laboratory staff, available to answer any queries
- ☑ Dedicated laboratory contact, expert in their testing requirements
- ☑ Direct contact to staff by email and telephone for prompt communication and consistency

Delivery

- ☑ Fast-track testing service
- ☑ Quick sample turn-around
- ☑ Delivery of results to clients is a KPI for Honeyman Laboratories

Easy to do business with

- Support and guidance on regulatory testing requirements
- Flexible weekend and out-of-hours analysis
- Onsite sampling & troubleshooting
- One-stop-shop for analytical services
- Simplifying materials testing

SAMPLE COLLECTION

Honeyman Laboratories offers a collection courier service throughout the UK and Ireland.

Our specialist GPS tracked vehicles collect and transport your samples in a reliable, timely, compliant and controlled manner.

We also provide all inclusive solutions where our trained samplers can visit site and carry out sampling on your behalf.

honeyman LABORATORIES

MORE THAN RESULTS

Honeyman delivers world-class analytical services for leading global Pharmaceutical Manufacturers and UK specialist clients from our MHRA approved cGMP labs. Performing expert microbiological and chemical tests, on a contract basis, covering raw materials, pharmaceutical grade water, API's, intermediates and finished products.

Our Biological Indicator Evaluation Resistometer (BIER) Vessel, one of the largest in the world, provides independent biological indicator studies.

Water & Steam Testing

Testing high purity water and steam for pharm manufacture

Microbiology Laboratory

Microbial analysis of pharmaceutical products, processes and cleanrooms

Chemistry Laboratory

Chemical analysis of pharmaceutical water, raw materials and finished products

Biological Indicator Testing

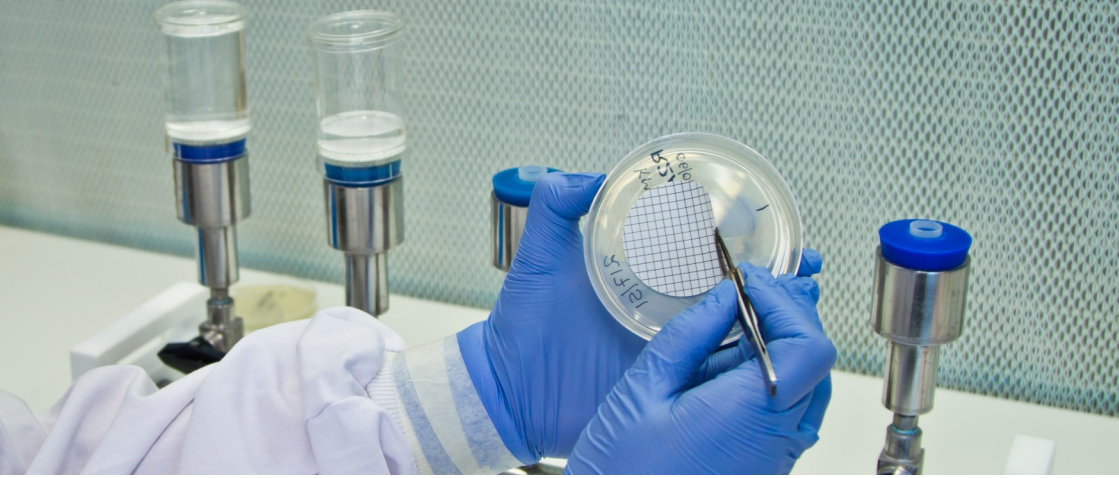
One of the world's largest BIER Vessels, BI Stability Studies, D-value Verification, Direct Inoculations, Survival/Kill Time

More than results, our technical ability and experience enables trend analysis, data interpretation and remedial action plans to improve performance and address compliance issues.

Test Us

GMP GOOD MANUFACTURING PRACTICE PRODUCT

MHRA Regulating Medicines and Medical Devices



WATER AND STEAM TESTING

Experts in Pharmaceutical Water, WFI and Steam

Honeyman Laboratories offer Chemical analysis, Physio-Chemical analysis, Microbiological and Quantitative Endotoxin testing for all types of pharmaceutical water and steam. From feed water to WFI to pure steam. IQ, OQ, PQ and service maintenance testing.

Our specialist water quality knowledge enables us to interpret water analysis results in terms of plant performance and provide advice.

- ☑ Compendial Analysis to the current EP/USP/JP for bulk Purified Water/ WFI and other grades
- ☑ Non-Compendial Chemical Analysis of samples from water systems
- ☑ Non-Compendial Microbiological Analysis of samples from water systems

Submission Form:

Samples Form for Water Testing
Honeyman PW/WFI Water Systems Guide

Routine Testing Includes:

- Total Organic Carbon (TOC) Analysis
- Conductivity
- Wet Chemical Tests for Pre-Treatment and Purification Assessment
- Endotoxin (LAL) Analysis
- Total Viable Count (TVC)
- Absence of Objectionable Organisms
- HTM 2030
- HTM 2031 for Dishwasher Disinfector Water and Clean Steam Samples
- Condensate analysis to HTM 2010, EN 285 or Water For Injection (WFI) specifications

MICROBIOLOGY TESTING

Microbial Analysis of Pharmaceutical Products, Processes and Cleanrooms

Our expert team of Microbiologists, Validation and Regulatory Professionals are here to help. Working closely with clients we advise, develop and validate analytical methods of new or non-pharmacopoeial test methods to ensure product safety.

From Environmental Analysis, practical advice and guidance in establishing an environmental monitoring programme within any cleanroom or production environment to the supply of quality controlled plates, incubation and analysis of samples and identification of organisms.

Testing to al major pharmacopoeial or client-defined specifications.

We undertake analytical testing and analysis for a wide variety of materials and products for batch release into European and international markets.

Submission Forms:

Samples Form - Raw Materials & Product
Samples Form - Water & Environmental Monitoring

Routine Testing Includes:

- Microbial Limit Testing
- Endotoxin Testing
- Bioburden Testing
- Preservative Efficacy Testing
- Antibiotic Assays
- Disinfectant Efficacy Testing
- Environmental Monitoring
- Microbiological / Mycological Species Identification, Bacteria and Fungi
- Ongoing assessment of trending data to assess the significance of bio-contamination
- Method Development & Validation

BIER VESSEL

Biological Indicator Evaluation Resistometer (BIER) Vessel Services

With one of the world's largest Biological Indicator Evaluation Resistometer (BIER) vessels, Honeyman is one of the few independent contract laboratories with the capability to perform D-Value analysis and other associated thermal studies by direct inoculation of product or equipment using Biological Indicator Organisms (BI's).

Specialists in the validation of sterilisation processes, we offer a wide range of BI formats including; spore ampoules, strips, discs, metal discs, suspensions, threads and wires.

Independent D-Value verification of Manufacturer's Certificate Values ensures no significant difference in accordance with USP and ISO11138 acceptance criteria.

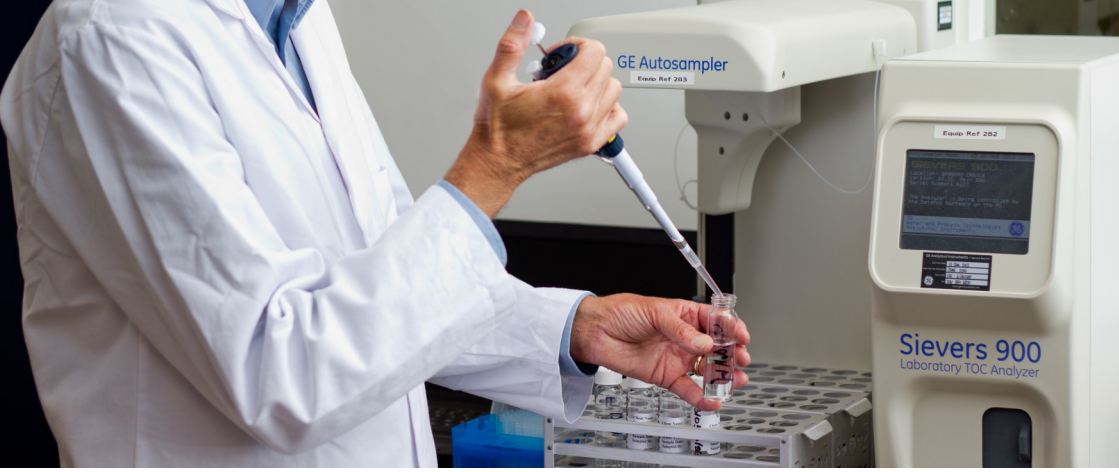
For further information and advice on BI's please see our online knowledge hub featuring: BI Preparation Method Download

Submission Form:

Samples Form for Biological Indicator Testing

Routine Testing Includes:

- Biological Indicator (BI) Stability Studies
- D-Value Determination
- BI Population Verification
- BI Population Identification
- BI Spore Counts
- BI Direct Inoculation Studies - On products, components (e.g. bung or stopper washing sterilisation) and critical equipment
- EP/USP Survival / Kill Time - Verification applying either EP/Ph Eur and USP Acceptance Criteria
- Biological Indicator use and application for the Validation of Sterile Processes



CHEMISTRY TESTING

Chemical Analysis of Water, Raw Materials and Finished Products

Honeyman laboratories provide expertise in chemistry analysis for product, process and cleanroom.

Finished Product and Raw Material Testing and Analysis provides

⇒ QC analysis for batch release (EU)

⇒ EP, BP, USP, JP and bespoke testing

Pharmacopoeial analysis of Purified Water

⇒ WFI and Potable Water, Water from Steam Sterilisers and Washer Disinfectors (HTM 2030 and 2031)

We undertake Method Validation of Analytical procedures, ensuring fit for purpose methods meeting regulatory requirements

⇒ Method development

Submission Forms:

Samples Form - Water & Environmental Monitoring

Samples Form - Raw Materials & Product

Routine Testing Includes:

- Product and Raw Material Quality Testing
- Water Testing and Analysis of Pharmaceutical Water
- Total Organic Carbon (TOC) Analysis
- High Performance Liquid Chromatography (HPLC)
- Spectroscopy
- Dissolution Testing
- Cleaning Validation Testing
- Gas Chromatography
- Disintegration Testing
- Uniformity Assurance
- Determination Studies
- Limit Testing

LABORATORY CONSULTANCY

Honeyman Laboratories offers expert industry advice and guidance through Microbiology and Chemistry Laboratory Consultation Services.

⇒ Consultation staff with specialised knowledge of your testing requirements.

⇒ Raw material, API and FP testing requirements

⇒ Validation of processes and methods

⇒ Environmental Monitoring, Programme design and risk assessment

⇒ Disinfectant and Cleaning validation support and advice

⇒ Trending and interpreting client's facility Data.

⇒ Current legislation pertaining to cGMP

All consultation services are documented to cover all items reviewed and our advice on actions required.

We can provide telephone, email and on-site support as required to suit your need.

Consultancy Services:

- Audits & Risk Assessments
  - On-site Quality Audits and Risk Assessments
- Troubleshooting
  - Site Specific and Emergency Response
- CAPA Corrective and Preventative Action Plans
- LEAN Lab Improvement
  - Efficiently streamlining laboratory processes
- On-site Training
  - Pharmaceutical Industry training for all levels
- Bespoke Laboratory Testing
  - Method Development and Validation
- All disciplines: Microbiology, Chemistry and BIER.

PHARMACEUTICAL TRAINING

Honeyman offers professional level training programs on the following:

- Biotechnology and the Future
- Cleaning Validation
- Cleanrooms: Principles in Practice®
- Microbiology for Non-Microbiologists
- Sterilisation: Principles in Practice®
- Pharmaceutical Water Systems: Principles in Practice®
- Microbial Risk Management During Cleanroom Operations
- Critical Factors for Sterile Product Manufacture

Accredited Specialist

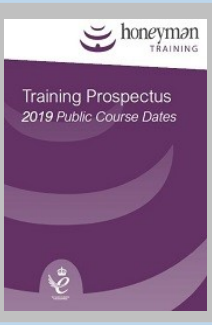
University Certificate for Professional Development (UCPD)

Delegates have the option, on selected courses, to become an

Accredited Specialist

Download our Public Training Course Prospectus at:

www.honeymantraining.com



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