



Your Contract Laboratory Partner

2018 Services Guide

UK & Ireland Operations

Part of Honeyman Group Limited



Founded in 1991, Honeyman Group Ltd operates from facilities in the UK & Ireland offering a range of products and services to the Pharmaceutical, Biotech, Healthcare and Medical Device industries.

The Laboratories Division, along with Engineering, Validation, Training & Consultancy Divisions offer a range of industry support services.

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.

Our pro-active and approachable Operations Directors are always available to deal with any queries or questions that you may have. They are continually seeking to improve the customer experience whilst ensuring compliance and timely delivery of projects.



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James Dean

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WHY Honeyman Laboratories? honeyman



Quality

- Fully GMP compliant: Consistency, reliability and traceability.
- Regulatory body inspected.
- Qualified Person (QP) for contract consultation and batch release
- Independent quality department which performs regular self-inspection
- We welcome clients to visit or audit our first class Laboratory facilities and systems.

Cost

- Competitive pricing
- Bespoke pricing solutions to suit your required level of support
- World-class quality of service

Expertise

- An expert team of highly qualified Chemists, Microbiologists, Engineers, Validation & Regulatory Professionals.
- Leading industry experts for 26 years.

Communication

- Honeyman prides itself on our strong, client led relationships.
- Passionate and friendly laboratory staff who are always available to answer any queries
- Each client has a dedicated laboratory contact who is an expert in their testing requirements
- Each member of staff has a direct email and telephone number for prompt communication and consistency

Delivery

 Industry leading sample turn-around time

- Delivery of results to our clients is a major KPI for Honeyman Laboratories.
- Consistently achieve or better our targets
- Fast-track testing service

Easy to do business with.

- Simple and straight forward
- Support and guidance on regulatory testing requirements
- Flexible weekend/Out of hours analysis
- Onsite sampling and troubleshooting
- "One stop shop" for analytical services
- Simplifies the materials testing process

NEW SERVICE!!

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

Utilising a fleet of specialist GPS tracked collection vehicles, Honeyman will collect and transport your samples in a reliable, timely, compliant and controlled manner.

Additionally, we can provide all inclusive solutions where our trained samplers can visit site and carry out sampling on your behalf.

Whether you have one sample per month or require a twice daily collection, talk to us about how we can help you!

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honeyman MICROBIOLOGICAL SERVICES

Testing carried out to all major pharmacopoeial or client defined specifications!

Water Testing and Analysis

- Total Viable Count (TVC) to Pharmacopoeial, HTM2030 or Client defined specs.
- Absence of Specified Organisms.

Bioburden Testing and Analysis

 Product, process, medical device and customer specific Bioburden testing and analysis.

Microbial Limit Testing and Analysis

 Total Viable Count (TVC), Fungi and absence of specified Organisms for Finished Product, Raw materials, excipients, API's and Intermediates.

Preservative Efficacy Testing and Analysis

 Preservative Efficacy Testing (PET) across a wide range of product types including Oral, Topical, Ophthalmic and Parenterals.

Endotoxin Testing and Analysis

 LAL Testing by turbidimetirc kinetic method on water, finished product and raw materials.

Antibiotic Assays

- Method development &
- Zone interpretation
- Dissolution



Kirsty, Senior Microbiology Analyst, carrying out membrane filtrations as part of a client purified water PQ

MICROBIOLOGICAL SERVICES honeyman





Disinfectant Efficacy Testing and Analysis

- Disinfectant Efficacy Testing (DET) both for Disinfectant suspensions and disinfectant efficacy on hard surfaces using compendial organisms and client specific in house flora.
- Tailored specifically for Client Requirements
- Method development & validation

Environmental Monitoring Testing

- Design, Validation and implementation of Environmental monitoring Programs
- Receipt, Processing, enumeration and interpretation of Clients Environmental monitoring Plates.
- Trending, alert and action limit setting and justification
- Fully outsourced solutions

<u>Microbiological / Mycological Identification Services</u>

Bacteria and fungi Identification

BIER VESSEL SERVICES

Biological Indicator Testing and Analysis

- D-value determination
- Population verification & Identification
- EP/USP Survival time / kill time
- Direct inoculations

" A unique team of industry experienced Chemists, Microbiologists, Engineers, Validation and Regulatory Professionals means that in the event of an out of specification result, we can undertake a full investigation and provide compliant and effective solutions"

Further tests and techniques available - Contact us, we might be able to help!



CHEMISTRY SERVICES

Testing carried out to all major pharmacopoeial or client defined specifications!

Finished Product and Raw Material Testing and Analysis

- QC analysis for batch release (EU)
- EP, BP, USP, JP & bespoke testing

Water Testing and Analysis

- Pharmacopoeial analysis of Purified Water, WFI and Potable Water
- Water from steam sterilisers and washer disinfectors (HTM 2030 and 2031)

High Performance Liquid Chromatography

HPLC with UV detection

Thin Layer Chromatography (TLC) **Gas Chromatography**

- FID
- Headspace to USP467
- Residual solvent testing
- Organic volatile impurity testing

Dissolution Testing

- For testing of solid dose forms
- USP 1 and 2 testing methodologies/ apparatus

Disintegration testing

- Tablets and capsules
- Enteric coated tablets

Uniformity assurance

- Uniformity of weight and weight variance
- Uniformity of content

Spectroscopy

FTIR

- **UV-Vis**
- AAS flame/furnace

Determination studies

- Melting point
- Refractive index
- Weight per millimetre, density, relative density and apparent density
- Ash/Sulphated Ash
- Loss on drying
- Water content



Bernie, Chemistry Consultant

CHEMISTRY SERVICES



Method Validation of Analytical procedures

- Ensuring fit for purpose methods meeting **Particle sizing** regulatory requirements
- Method development

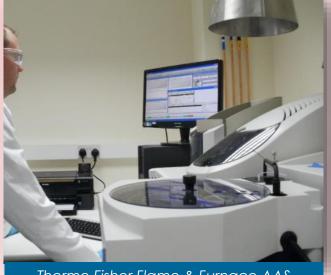
Laser Particle sizing (Malvern)

Cleaning Validation Testing and Analysis

Total Organic Carbon (TOC)/HPLC analysis for cleaning samples

Autotitrator Techniques

- Karl Fischer
- **Ampometric**
- Potentiometric
- Compleximetric
- Precipitimetric
- Acid-Base
- Oxidation-reduction
- Non-Aqueous titrations



Thermo Fisher Flame & Furnace AAS

Conductivity

pH testing

Limit testing

- Chloride
- Arsenic
- Iron
- Heavy metals
- Sulphate



Clarity & Colour of Solution

Further tests and techniques available - Contact us, we might be able to help!



honeyman TRAINING & CONSULTANCY

Microbiology and Chemistry Consultation

- Guidance and advice from industry experts
- Consultation staff with specialised knowledge of your testing requirements

Contract Analytical Resource

- We can address Short and long term resource issues on behalf of clients
- QP available for batch release

Bespoke Laboratory Testing and Analysis

- Client specific methodology
- Method Development
- All laboratory disciplines covered: Microbiology, Chemistry and BIER

LEAN Lab solutions

- Training and advice on installing lean tools in the Laboratory
- Increase efficiency and streamline your processes

On-site training

- Microbiology training catered to all levels of required understanding.
- Risk-assessment courses
- Clean room development advice

E-Learning

 Developed and managed in-house, Honeyman eLearning software provides a new, engaging and consistent way to train staff within an organisation



Screen shot of Honeyman e-Learning software which can be tailored to your specific operating procedures/requirements and integrated with your LMS. The software features tutorial slides, videos, interactive exercises and assessments.

PW & WFI SOLUTIONS



Honeyman offers a unique formula of full lifetime support for your new or existing quality water system.

Our laboratories provide a flexible service to clients validating new or upgraded systems and routine analysis. In addition to testing, the laboratory can provide:

- Protocols,
- Reports
- Trending
- Troubleshooting
- Sampling Resource
- Sampler Transportation

The wider Honeyman Group offers support in:

- Engineering (Design, Build, Install, Troubleshooting, Service/Maintenance)
- Validation (IQ/OQ/PQ)
- Training,
- Consultancy & Troubleshooting

This support allowing Honeyman to be the only company to offer lifecycle support for your quality water system

HYDROGIENIC® is Honeyman Groups range of Purified Water & Water For Injection systems. Offering significant benefits over competing systems, HYDROGIENIC® will provide a compliant, cost effective solution to your on site quality water needs.



A HydroGienic® purified water system installed at Dechra Manufacturing in the UK



honeyman VALIDATION & THERMAL MAPPING

Sterility Assurance with Honeyman

The Honeyman Group has been supporting its clients to achieve and maintain sterility assurance objectives for over 25 years. We have extensive experience in aseptically manufactured products and terminally sterilised products including:-

- Pre Filled Syringes
- Blow Filled Sealed Products
- Lyophilised powders
- Sterile creams, gels and ointments
- Finished pharmaceuticals in sealed containers & medical devices

Our team of leading industry experts have assisted our clients on projects during all life cycle phases from initial start-up and qualification, through production optimisation and supported them during investigation and remediation activities.



A Honeyman Engineer calibrating a client temperature probe

We enjoy working with challenging or novel products and processes where standards may not be developed or where limited industry experience is available. When working with the Honeyman Group you can be assured of effective knowledge transfer, supported by sound scientific rationales, clear concise documentation and regulatory compliance.

We understand the sensitive nature of your process or product. Therefore, to discuss your requirements with one of our experts in a confidential manner, please contact us with your details and a brief introduction, so we can arrange a call back at a time convenient to you. The Honeyman Group offers a variety of validation activities encompassing equipment qualification (laboratory, packaging and manufacturing), process validation (API, product and utilities), cleaning validation, shipping/transportation studies and revalidation/re-qualification exercises.

EQUIPMENT MAINTENANCE



Equipment maintenance matched to the exact requirements of each individual system or piece of equipment.

Our cost effective, flexible service and maintenance plans can be tailored to include a range of routine and breakdown services as required.

As the industry's leading, independent specialists in high purity water systems and sterilisation processes we can provide comprehensive service and maintenance cover for a range of quality critical utility processes and equipment including:

- PW/WFI Purification, Storage and Distribution (including Elga/Veolia, Stilmas, Bram-Cor, Purite, BCD, BWT, Bosch, Telstar)
- Pure/Clean Steam Generators (including Telstar, Stilmas, BWT, Spirax Sarco, Steris)
- Autoclaves (including Getinge, Fedegari, Denley, Boxer, Tuttnauer, BMT, BMM Weston)
- Ovens
- Disinfectors
- Washers

There are a number of advantages to using a third party provider such as Honeyman Group Ltd:

- 1. Lower maintenance prices
- 2. Support for multiple manufacturers all in a single contract
- 3. Support for older systems no longer handled by the OEM
- 4. Support backed up by our team of industry leading team of consultants and engineers.

Our strength is the range of specialist in-house expertise we bring to each project. We can provide the combination of design, engineering, technical, microbiological, regulatory and project management expertise which is essential to meet quality –as well as time and cost criteria.



Part of Honeyman Group Limited

SETTING NEW STANDARDS

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