Millipore®
Filtration, Separation
& Preparation

Data Sheet

Our Experts at your Service

Discover our services portfolio supporting the PyroMAT™ Kit for pyrogen detection

Microbiological monitoring and testing in the pharmaceutical industry is a highly regulated and thus very complex field. In our long history of serving the pharmaceutical industry by pioneering and refining groundbreaking solutions, we have gained the regulatory and technological expertise to offer our customers a comprehensive range of professional, best-in-class services.

Application Services

Benefit from our expertise and support to implement the monocyte activation test (MAT) in your lab and overcome sample related challenges.

Benefits

A name you know

We are known for the quality of our products. We apply these same high standards to our method development assignments and keep the same strict attention to regulatory compliance.

People you can trust

Depending on the scope of your project, we can assemble a team of our experienced scientists with expertise in molecular biology, biochemistry, microbiology, pharmacology or regulatory affairs.

Methods you can validate

Whatever the assignment is, we know that the ultimate goal is validation. This is why we provide detailed, ready-to-validate methods (Standard Operating Procedure).

Ready when you need us

It can take weeks or even months to develop a new test method in-house, especially in today's busy QC or QA laboratories where time and technicians are often in short supply. Our team of experts is available around the globe to help you develop the methods you need, when you need them.

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Products

Feasibility Study

Experimental study carried out in our application laboratory using customer samples:

- Assessment of the compatibility of customer sample with the PyroMAT™ system using the short ELISA protocol and the Gen5 software protocol
- Service includes 1 product matrix
- Duration: 2 to 3 weeks
- Deliverable: study report

Method Development

Experimental study carried out in our application laboratory using customer samples:

- Assessment of the product compatibility with the PyroMAT™ system using the long ELISA protocol and the Gen5 software protocol
- Development of an appropriate method to overcome interference
- Service includes 1 product matrix
- Duration: 4 weeks to 3 months
- Deliverables: study protocol, study report

Software Data Analysis for Product Specific Validation Service

Consulting service to support with the analysis of the raw data generated at customer site during the Product Specific Validation with the PyroMAT™ system:

- Agreement with customer on the target Contaminant Limit Concentration (CLC) and the chosen method
- Detailed plate setup to be followed during Product Specific Validation to be sent upfront
- Calculation of the Maximum Valid Dilution (MVD)
- Detailed analysis and interpretation of raw data using the Gen5 software protocol
- Duration: 8 hours
- Deliverables: complete report for 4 plates including compilation of test results, interpretation, and conclusion of the best dilution

Software Data Analysis Service

Consulting service to support with the analysis of the raw data from a routine test generated at customer site with the PyroMAT™ system:

- Detailed analysis and interpretation of raw data using the Gen5 software protocol
- Available for all MAT test methods (Methods A, B or C)
- Calculation of Endotoxin Standard Curve, Maximum Valid Dilution (MVD) and pyrogenicity level of the tested product based on the Contaminant Limit Concentration (CLC)
- Duration: 4 hours
- Deliverables: complete report for 1 plate including test results analysis and interpretation, conclusion on pyrogenicity of sample

Validation Protocols and On-Site Validation Services

Get ready to start using your new kit in a few weeks

Benefits

Proven protocols and expertise to qualify our products for use with your samples

cGMPs/cGLPs require equipment and test methods to be validated before routine use. This can be time consuming and delay the start of critical QC procedures. Receive prepared protocols and have your new QC systems validated quickly and efficiently by our experts and save time with this process.

Reduce the Development Time & Cost of the Validation

Your protocol preparation may require around 4 weeks of development (research on applicable regulations, acceptance criteria definition, writing of test methods, formatting, etc).

Products

Product Specific Validation protocols and related software protocols

Our validation protocols are based on existing regulations and guidelines. These extensive protocols will enable the QC/QA Lab to quickly initiate your Product Specific Validation and perform the data analysis thanks to the software protocols we provide through the service. They follow international guidelines such as EP/USP and GMP.

With the limited resources of many QA/QC departments, why not ease the burden and rely on our expertise such as:

- New technology
- New product or reformulated product to be tested
- Compliance with updated regulations: EP, USP, JP, etc.

Product Specific Validation Consultancy Service:

- Consulting activity to support the Product Specific Validation in compliance with EP using PyroMAT™ system and based on the method targeted for routine use
- On-site theoretical and hands-on training on the PyroMAT™ system, including assessment of the different parameters to verify during the Product Specific Validation
- Customized test protocol
- Guidelines for further tests to be performed
- Phone and e-mail support: follow-up of tests, analysis of data, interpretation of results, planning of next tests, practical recommendations, technical guidance, tips and tricks, sharing of our knowledge and expertise of the PyroMAT™ system
- Duration: 1 day at customer site for training + 3 months remote support following the on-site visit

Product Specific Validation Execution Service:

- On-site or In-house theoretical and practical training on the PyroMAT system including assessment of the different parameters to verify during the PDV execution
- Execution of the PSV in-house on 3 product lots
- Customized test protocol
- Method transfer support
- Duration: 3-4 weeks upon protocol approval

Training Services

Ensure your lab team can make the best out of your equipment

Benefits

Benefit from Decades of Expertise

According to the United States Pharmacopeia's guidelines, "training curricula should be established for each laboratory staff member… They should not independently conduct a microbial test until they are qualified to run the test."

Our training packages include an in-depth review of regulatory requirements, their validation and practical implementation. The courses are based on the most recent editions of international pharmacopeias and international guidelines.

Products

Operator Training

In-depth training on pyrogen detection for up to 5 participants. Each participant receives a customized handout:

- Presentation of the kit
- Regulation overview: pharmacopoeia chapter(s) about the application, method validation, training (life-cycle management)
- Hands-on training: usage (with customer's products in their final containers), cleaning, troubleshooting and common mistakes
- Question session
- Final examination and grading of the attendees with certificate of training
- Duration: 2 day

On-Site BEST Microbiology Training

- BEST is a 3 day innovative, interactive educational program designed specifically for you. This program will focus on both in-process and product release quality control, including Bioburden, Endotoxin, Sterility
- Testing and Environmental Monitoring. The training will provide an overview of relevant methods in each area; however, basic technical laboratory skills are assumed as a prerequisite for participation. The course will consist of class presentations and demonstrations of laboratory applications
- Understand the current requirements of pharmacopoeias and be familiar with good testing procedures from method development / validation through to routine test result interpretation
- Take preventive actions to avoid false positive or false negative test results
- Develop and optimize testing procedures
- Understand and identify root causes for common issues

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