Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

our experts at your service

Discover our services portfolio supporting the Steritest™ family for sterility testing

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

Method Development Services

Optimize or simplify your method for an easy validation and cost effective testing

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 membrane filtration, 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 why we provide detailed, ready-to-validate methods (Standard Operating Procedure). Furthermore, to provide you with a complete solution, we offer detailed validation protocols (IQ/OQ) for our pumps.

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.

MERCK

Products

Method Development

Experimental study done in our application laboratory using customer samples and microbial strain(s):

- In case of compatibility issue with standard protocol or of new product to be tested
- Development of an appropriate method to overcome the interferences or improve filterability
- Service includes 1 product matrix & 5-6 strains
- Additional strains can be quoted as an option
- Duration: 4 weeks to 3 months
- Deliverables: study protocol, study report

Method Development Consultancy

Consultancy service by a our application scientist to support customer's method development:

- In case of compatibility issue with standard protocol or of new product to be tested
- 1-day training at customer site covering pump use and how to develop an appropriate method
- Customized test plan, real tests initiated on-site, then weekly follow-up calls to support customer
- Consumables charged based on consumption
- Duration: 3 months from the initial testing
- Deliverables: customized protocol, result sheets, final report

Validation Protocols and On-Site Validation Services

Get ready to start any PQ work in less 5 days!

Benefits

Proven protocols and expertise to qualify our products for use in your testing processes

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, test methods writing, formatting etc).

Estimated IQ/OQ completion time:

- Without pre-written protocol: 6 to 7 weeks.
- With our pre-written protocol: 2 to 3 weeks.
- With on-site validation service: less than a week.
- Quickly integrate equipment into your process pipeline with confidence using product specific test methods.

Products

Validation Protocols

Our validation protocols are based on our internal product qualification test methods. These extensive protocols will enable the QC/QA Lab to quickly initiate your Validation Master Plan and perform IQ, OQ and PQ (suitability of the test methodology) with ease. They follow international guidelines such as EP/USP and GMP.

On-site Validation Services

We have experienced and trained validation engineers who are skilled to assist in Validation Protocol implementation within the QC Microbiology laboratory, so the QC/QA Departments do not have to allocate resources. Technical training on your installed equipment is also provided during the validation engineer's visit. Rely on our expertise in various situations such as:

Rely on our comprehensive and ready-to-use Validation Protocols consisting of the following sections:

1. Validation Master Plan

Define structure, responsibilities for qualification

2. Installation Qualification (IQ)

- Verification and identification of the Merck product
- Verification of product's utilities and operating environment requirements
- Equipment and personnel preparation

3. Operational Qualification (OQ)

Verification of product's functionality (hardware, software, devices)

4. Performance Qualification (PQ)

Test Method suitability verification (microbiology validation procedures)

5. Final Report

Summarizes all testing performed for final approval of validation

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

We recommend to ensure regulatory compliance over time performing a periodic requalification of your pump.

IQ/OQ Service:

Support for the qualification of laboratory equipment:

- Execution of the test methods
- Furniture of calibrated tools (flow meter, stopwatch, etc.)
- IQ/OQ Section of the Final Report is completed, ready for QA approval
- Essential operator training
- Duration: 2 to 5 days depending on number of installations and consumables

Essential PQ Consultancy Service:

Consulting service for microbiological validation in order to plan and start the PQ:

- On-site support for implementation of the PQ tests
- Consumables and media calculation
- Training on recovery test techniques
- Data formatting and report finalization
- Scheduling of the tests
- Data interpretation, comments and conclusion
- Duration: 0,5 day

Advanced PQ Consultancy Service:

Close coaching all along the PQ of the consumable and test method:

- Presentation of the equipment, accessories and consumable
- Regulation overview
- Hands-on training
- Setting up the lab, equipment, consumable
- Test campaign – Supervision of the microbiological tests (several days):
  1. The Validation Engineer demonstrates the realization of the test with the first microorganism.
  2. The technician(s) repeat what has been demonstrated on the further replicates and microorganisms.
  3. Results reading and interpretation.
- Duration: customized depending on customer needs

Essential Requalification Service:

Requalification work performed on laboratory equipment after the yearly preventative maintenance:

- Requalification protocol to be ordered separately
- IQ and OQ test procedures (physical tests) + data formatting and report finalization
- Furniture of calibrated tools (flow meter, stopwatch, etc.)
- Duration: 0,5 day, recommended frequency every year

Advanced Requalification Service:

Requalification work and consulting service for laboratory equipment:

- Requalification protocol to be ordered separately
- SOP review
- Maintenance review
- IQ and OQ test procedures (physical tests) + data formatting and report finalization
- Furniture of calibrated tools (flow meter, stopwatch, etc.)
- Operators training review
- OOS results review
- Duration: 1 day, recommended frequency every 3 to 5 years

Service plans at repair center or at customer site

Rely on your pump and minimize the breakdown risk

Benefits

Ensure Optimum Performance

Preventive maintenance and pump verification ensure efficient operation of critical testing equipment. Every pump should be serviced regularly to ensure its performance remains compliant with the specifications, as per GLP 21 CFR 58.63 (FDA) and EU GMP vol.4, 3.41. We recommend checking and adjusting the pumps on an annual basis guaranteeing that your pump meets manufactured specifications and GMP/GLP requirements after every preventive maintenance and service.

cGMP require ALL equipment to be properly maintained.

21 CFR §211.67 Equipment cleaning and maintenance "(b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product."

EU GMP Vol.4, 3.41: Measuring, weighing, recording and control equipment should be calibrated and checked at define intervals by appropriate methods. Adequate records of such tests should be maintained.

Annual Preventive Maintenance

Annual preventive maintenance will reduce the risk of breakdown by ensuring the pump works within the system specifications. As part of the yearly preventive maintenance program the service engineer performs:

- Visual and functional checks
- Performance tests as found and as left
- Replacement of critical wear parts

Comprehensive Documentation

Upon completion of the service, we will provide you with a report defining the service performed on your pump as well as our recommendations. This performance report also guarantees that the pump meets system specifications. This document ensures compliance with regulations.

Products

Service Plans

We offer a variety of service plans that can be executed either in our local repair center or at customer site (where available).

	Service Essential™	Service Advanced™	Service Total™
Preventive Maintenance	Yes	Yes	Yes
Maintenance kit (quoted separately)	Yes	Yes	Yes
Number floating repair	0	1	N/A
All repairs	No	No	Yes as needed
Spare Parts	Excluded	Excluded	All inclusive
Shipment/Travel Zone 1	Yes	Yes	Yes
Options	**To be ordered separately!**		
Second Preventive Maintenance	Yes	Yes	Yes

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."

The pharmaceutical inspection authority, PIC/S, recommends that "sterility testing should only be performed by personnel who have been trained, qualified and certified to perform the various tasks and procedures related to sterility testing."
In addition, PIC/S states that, "personnel should undergo periodic recertification."

Products

Steritest™ School

Theoretical aspects of Sterility Testing:

- Regulatory aspect of sterility testing including environmental considerations
- Sample considerations
- Method development and validation
- Interpretation of results

Interactive Workshop:

- Use of Steritest™ hardware
- Use of Steritest™ units
- Demonstration of general and specific sterility testing applications
- Answers to specific user-related questions
- Duration: 1 day minimum

Steritest™ Advanced Operator Training

- This course Includes the theoretical aspects and interactive workshop in addition to a hands-on session on the best practices of use of the Steritest™ platform.
- A training certificate is delivered to each participant after evaluation.
- Duration: to be defined based on the number of participants

Which of your challenges do these courses address?

- Regulatory background
- Handling issues
- False positive test results
- Validating products with inhibitory activities - false negative test results
- Optimizing sterility testing procedures

To place an order or receive technical assistance:

Find contact information for your country at:
MerckMillipore.com/offices

For Technical Service, please visit:
MerckMillipore.com/techservice

MerckMillipore.com/biomonitoring
Merckmillipore.com/PharmaServices

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