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 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 you a comprehensive range of professional, best-in-class services for each of the different platform usage stages:

1. Evalution phase

2. Implementation phase

3. Routine use phase

1. During platform evaluation phase

Training

Understand good practices in sterility testing

Benefits

Develop your expertise

- Being always “up to date“ on the best testing procedures and regulatory requirements is fundamental to be able to implement good practices in your laboratory.

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

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

2. During platform implementation phase

STEP 1: Method Development

Develop an optimized test 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.

Products

Method Development at our lab

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 Consulting at customer site

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

Remote Method Development Consulting

Consultancy service by our application scientist to support customer's method development provided via a visio-conferencing system:

- Theoretical presentation of the different parameters to consider when developing a sterility test method (filterability assessment, antimicrobial activity assessment, pre-wetting and rinsing strategy, selection of the right device, fluids and test strains)
- Customized test protocol allowing the assessment of the parameters seen above.
- Demo of the Steritest® system
- Phone and e-mail support
- Duration: minimum 1/2 day, customized depending on your needs

Visit our dedicated webpage:
SigmaAldrich.com/Microbio-Services-Method-Validation

STEP 2: Hardware, consumables, media and method validation

Get ready to start any PQ work in less than 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.

Benefit from our validation expertise and best practices

We have experienced and trained field 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. They will perform the actual qualification activities using our Val@MTM Application. Technical training on your installed equipment is also provided during the validation engineer’s visit. Rely on our expertise in various situations such as:

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

Products

Digital Validation Protocols

Our digital validation protocols are based on our internal product qualification test methods and are available for a fully digital execution workflow on our Val@M™ Application. These extensive protocols will enable the QC/QA lab to quickly initiate your Validation Master Plan. They follow international guidelines such as EP/USP and GMP. They must be completed by an on-site IQ & OQ execution service.

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 our 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)

IQ/OQ Execution Service at customer site

Support for the qualification of laboratory equipment:

- Execution of the test methods
- Calibration tools provided (flow meter, stopwatch, etc.)
- IQ & OQ protocols are completed in the Val@M™ Application, ready for QA approval
- Essential operator training
- Duration: 2 to 5 days depending on number of installations and consumables

Remote IQ & OQ Consulting

Support for the qualification of laboratory equipment provided via a video-conferencing system:

- Preparation call upfront to agree on topics and schedule of the consultancy
- Preliminary discussion about our Customer Validation Protocol: roles and responsibilities, list of tools, list of consumables needed, relevant tests
- Calls during and after the validation work to help with data formatting and protocol finalization
- Duration: minimum 1 day, customized depending on your needs

Essential PQ Consulting Service at customer site

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

PQ Execution Service at customer site

Execution of the performance qualification tests for one sterility test method, with the 6 strains given by the Pharmacopeia (Chapter 2.6.1, Pharmacopoeia EU).

It is recommended, but not mandatory, that at least one laboratory technician attends full-time.

- Performance qualification of one sterility test method.
- Execution and coaching for the tests of the performance qualification:
- Sterility for 2 Steritest® media
- Growth promotion for 2 Steritest® media
- Absence bacteriostasis and fungistasis activity for 1 Steritest® Device and 2 rinse fluids
- Tips and tricks for every test: handling, time and consumables management.
- Implementation of the PQ tests: design of experiments, number of replicates, controls, which strains to test etc. A preparation call before the service is mandatory.
- Intermediate reading during incubation for sterility test.
- SOP review.
- Coaching for the verification of the adequacy of the existing test methods for the relevant applications/ products (one microorganism, one product). Could have additional cost depending on the work.
- Test protocol and test report writing (methodology, appendices, deviation management, conclusion, summary) using our Digital Validation Protocol.

Visit our dedicated webpages:

SigmaAldrich.com/ValatM

SigmaAldrich.com/Microbio Services-Method-Validation

SigmaAldrich.com/Microbio-Services-Qualification

STEP 3: Training

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

Benefits

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

Advanced Operator Training

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

- Presentation of the equipment, accessories, and consumables
- Regulation overview: pharmacopoeia chapter(s) about the application, qualification of critical equipment, method validation, training, and maintenance (life-cycle management)
- Hands-on training: assembling the equipment, 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: 0,5 day

Visit our on-line training platform:
LearnAtM.EMDGroup.com/global/learn

3. During routine use phase

STEP 1: Yearly preventative maintenance and service plans

Rely on your equipment 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).

		Protection level		Risk level
Service	**Details**	**Total Service Plan[3]**	**Advanced Service Plan**	**Essential Service Plan**
System eligibility		**< 10 years**	**All ages**	**All ages**
Preventive maintenance (PM) visit	1 PM visit (labor and travel fees[1] or return shipment[2] included)	✓	✓	✓
Preventive maintenance (PM) service kit	System specific PM service kit	✗	✗	✗
Software & firmware updates	Last updates implementation	✓	✓	✓
Traceable and auditable documentation	PM performance service report	✓	✓	✓
Access to technical support	Remote support on system and software by phone and email	✓	✓	✓
Repair visits	Labor and travel fees or return shipment[2]	Unlimited	One per year	✗
Spare parts	Spare parts for repair	✓	✗	✗

[1] According to the region, travel fees might be quoted separately

[2] For workshop service plan only

[3] Not applicable to detection tower

STEP 2: Periodic requalification

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

Benefits

Stay qualified over time

Periodic requalification or after a major change helps maintaining regulatory compliance over time and optimal performance of your QC testing system.
It allows the management of changes around the equipment and the testing method.

Products

Essential Requalification Service at customer site

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 at customer site

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

Visit our dedicated webpage:
SigmaAldrich.com/Microbio-Services-MR

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

Learn more at **SigmaAldrich.com/Product-Services**

To place an order or receive technical assistance

Order/Customer Service: **SigmaAldrich.com/order**
Technical Service: **SigmaAldrich.com/techservice**

MK_DS1425EN Ver. 3.0
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09/2024