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 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.

Method Development Services

Optimize or simplify your method for 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 is 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.

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Method Development

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

- In case of any compatibility issues with standard protocols or new products that need to be tested
- Development of an appropriate method to overcome any interference 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

Validation Protocols and On-Site Validation Services

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 and 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.

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 Steritest™ 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)

Verification of test method suitability (microbiology validation procedures)

5. Final Report

Summarizes all testing performed for final approval of validation

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. Complete 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
- Testing new or reformulated products
- Compliance with updated regulations: EP, USP, JP, etc.

IQ/OQ Service:

Support for the qualification of laboratory equipment:

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

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

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 to guarantee 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 defined 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.

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Service Plans

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

	Service Essential™	Service Essential™ + Advanced™	Service Essential™ + Total™
Preventive Maintenance	Yes	Yes	Yes
Maintenance kit (quoted separately)	Yes	Yes	Yes
Number of repairs included	0	1	As required
Spare Parts	Excluded	Excluded	All inclusive
Return shipment	Yes	Yes	Yes
Options	**To be ordered separately!**		
Second Preventive Maintenance	Yes	Yes	Yes

*Where available

Training Services

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

Benefits

Benefit from Decades of Expertise

According to the United States Pharmacopeia 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.”

MilliporeSigma 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.

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BEST and On-site BEST Microbiology Training

BEST is a 3 day on-site innovative, interactive educational program designed specifically for you. This program will focus on both in-process and product release quality control, including bioburden, endotoxin, and 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
- Hands-on training

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