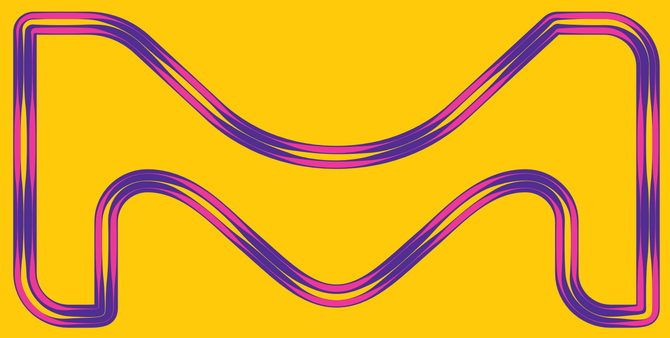
PARENTERAL PROCESS GUIDE

Formulation, Filtration, Filling

Start



The life science business of Merck operates as MilliporeSigma in the US and Canada.

SAFC®
Pharma & Biopharma Raw Material Solutions

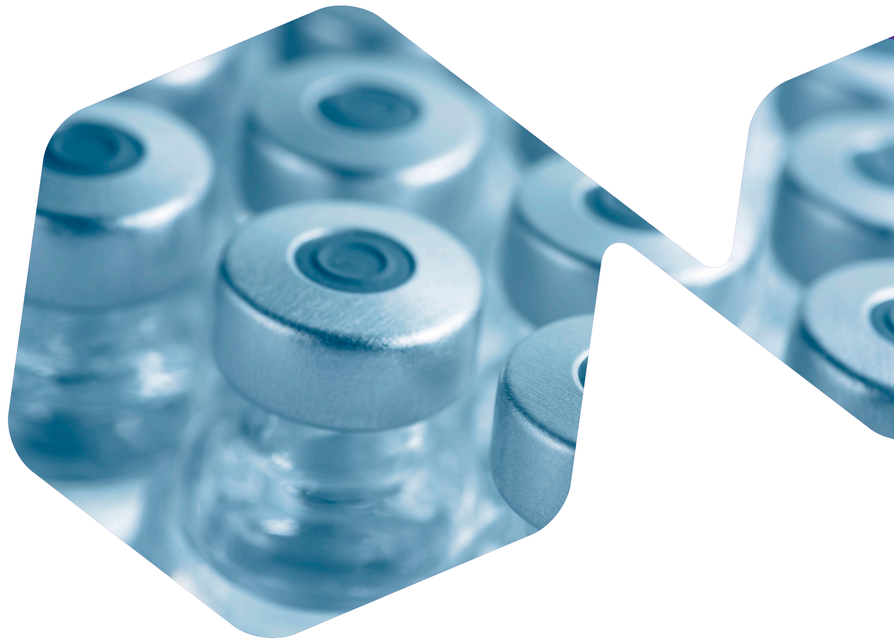
Millipore®
Preparation, Separation, Filtration & Testing Products

BioReliance®
Pharma & Biopharma Manufacturing & Testing Services

Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

Single-use components, excipients, filters and validation services



Reduce risk and increase efficiency with a fully assembled ready-to-use system:

- Let us help you design a process to meet your specific needs.
- What are the risks you are facing?
- What are your set-up and system issues to consider?

One-stop-shop to ensure component and process fit

Reduced risk of cross contamination and enhanced operator safety

Offering embedded in the Emprove® Program to facilitate regulatory compliance

Increase efficiency by reducing process and changeover time

Flexible manufacturing through:

- Reduced and flexible footprint allowing more free capacity
- Dedicated product and service offering

Quick link to technical and quality related solutions

Millipore®

The Millipore® portfolio of Merck offers an ecosystem of industry-leading products and services, spanning preparation, separation, filtration and monitoring – all of which are deeply rooted in quality, reliability and timetested processes. Our proven products, regulatory and application expertise are a strong foundation you can rely on to consistently perform at the highest level.

Denotes Millipore® products

SAFC®

The SAFC® portfolio of Merck offers customized and ready-to-use raw material solutions, backed by deep regulatory expertise. Our high-quality products and services are supported by an experienced and responsive team of raw material and regulatory experts who are committed to understand your requirements and provide tailored solutions that meet your exact needs.

Denotes SAFC® products/services

BioReliance®

The BioReliance® portfolio of Merck encompasses biopharmaceutical characterization, safety testing and process development, as well as clinical and commercial biomanufacturing. Our experienced teams and operational expertise make us the partner who supports you all the way and always has your vital goal in mind.

Denotes BioReliance® products/services

Explore our portfolio

Parenteral manufacturing process

Formulation

- Selecting high quality excipients
- Mixing of ingredients
- Monitoring critical parameters

Filtration

- Assure sterility of the drug product
- Contamination-free and closed sampling
- High recovery and low cost of goods

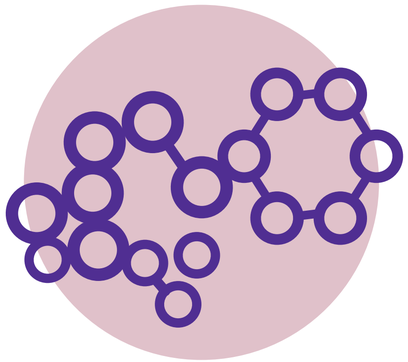
Filling

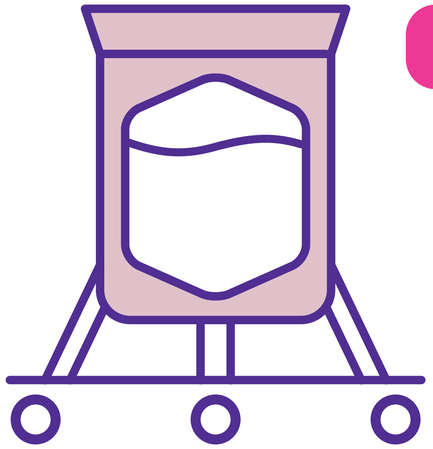
- Improve manufacturing flexibility
- Increase productivity
- Meet evolving manufacturing needs

Key steps for formulation

Select excipients

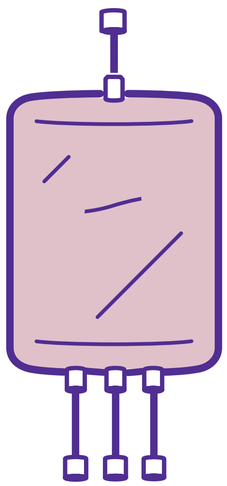
- Specifications and quality attributes designed for liquid formulations
- Reduce risk and simplify processes
- Reliable performance
- Ensure speed to market





Mixing

- Ensure mixing performance
- Gain flexibility through various working volumes and movability
- Choice for closed processing or open liners



Sterile sampling

- Improve operator safety
- Assure process sterility
- Sample representativity
- Ease of use

Denotes SAFC® products/services

Denotes Millipore® products

Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

SAFC®
Pharma & Biopharma Raw Material Solutions

View Products

Choosing the right excipients for reliable performance and quality

Considerations

Delivering State of the API | Ensuring Reliable Performance of the Final Drug Product | Market Readiness | Handling Powdered Raw Materials

Process Design	Solution
Assess delivered state of API • Aqueous • Non-aqueous • Co-solvent based Delivery system • Sustained release • Increased bioavailability, stability and solubility	• IPEC-GMP products assure consistent quality • Reliable supply • Biodegradable polymers for a sustained release profile • Lipids with optimized characteristics for pharma applications

Portfolio | Formulation | Filtration | Filling

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SAFC®
Pharma & Biopharma Raw Material Solutions

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Delivering State of the API

Ensuring Reliable Performance of the Final Drug Product

Market Readiness

Handling Powdered Raw Materials

Process Design

Choose
- Buffers
- Mineral salts & tonicity
- Preservatives
- Solvents
- Surfactants
- Antioxidants
- Stabilizers

Solution

- Comprehensive product portfolio
- Broad range of IPEC-GMP products
- Support during development, scale-up and commercial production
- Batch-to-batch consistency

Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

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Pharma & Biopharma Raw Material Solutions

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Process Design	Solution
• Meeting quality requirements • Ensuring speed to market • Documentation for regulatory approval	• Reduce risk and simplify processes through the Emprove® Program • Low Bioburden, Endotoxins and Reducing Sugars • IPEC-GMP Manufacturing • Multicompendial

Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

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Delivering State of the API | Ensuring Reliable Performance of the Final Drug Product | Market Readiness | **Handling Powdered Raw Materials**

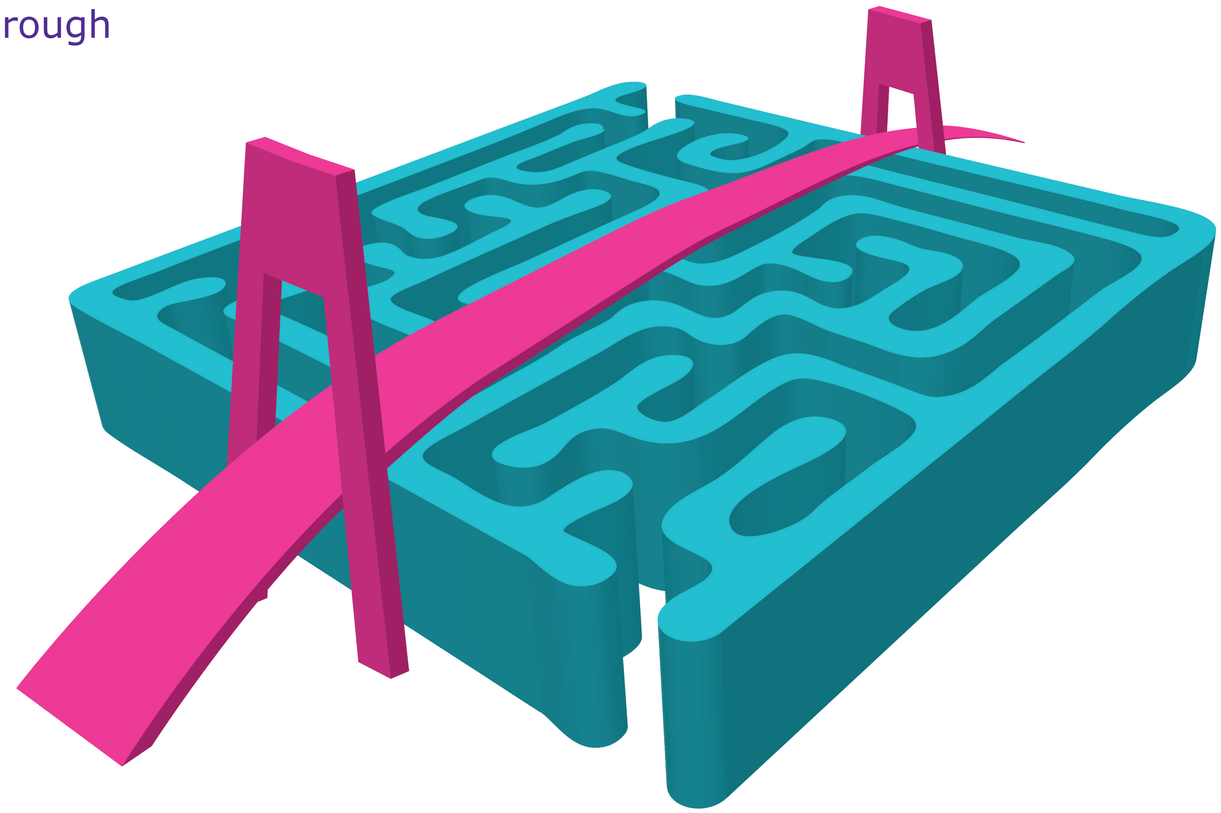
Process Design	Solution
• Minimized product contamination risk • Increased personnel and facility safety	• Paper free packaging to control the particulate matter • Packaging system to minimizes product caking • Granulated excipients for better processing and handling

How does the Emprove® Program help you

Qualification, risk assessment, and process optimization

The Emprove® Program contains over 400 raw and starting materials as well as 20 filter and single-use product families. Each product portfolio is supported with Emprove® Dossiers which provide comprehensive and up-to-date documentation to help you navigate regulatory challenges, manage risks, and improve your manufacturing processes.

Emprove® Dossiers are available exclusively through the Emprove® Suite subscription.



Emprove® Dossiers

- Material Qualification
- Quality Management
- Operational Excellence

Click here for more information on the Emprove® Program

Exemplary specification parameters of two of our stabilizers

Sucrose
low in endotoxins
≤ 0.3 I.U./g

Reducing sugars are normally incompatible with the primary amine. That leads to discoloration of the solution and reduction of the potency.

Endotoxins are the most significant pyrogens in parental drugs and the cause of strong immune responses.

To control the reducing sugars and the endotoxin levels in the raw materials, we offer lower limits than Pharmacopeia specifications.

	Endotoxins (I.U./g)		Reducing Sugars (%)	
	SAFC®	Ph Eur, USP	Merck	Ph Eur, USP
Sorbitol	≤ 1	< 2.5	≤ 0.11	≤ 0.2
Mannitol	≤ 1	< 2.5	≤ 0.05	≤ 0.1

Packaging

Handling

DRYPOUR™ – offers triple protection of the material: against moisture and contamination from outside and absorption of moisture present in the material

- Polyethylene (PE) drum with tamper-evident seal
- Polyethylene inliner with integrated desiccant bags
- Tyvek® inliner

Dispense

Increase product and operator safety with bulk powder transfer packaging

- Direct dispense solution
- Customizable quantity
- Ergonomic design

Packaging

Most raw materials are available in paper-free packaging including

- Pails
- Drums
- Pre-packs
- Double PE bags
  - Specially-designed for clean-room manufacturing
  - Removal of the outer bag outside of the clean room
  - Labelled inner bag to minimize handling risks

SAFC®
Pharma & Biopharma Raw Material Solutions

Excipients

- **Buffers**, to ensure best pH for physiological tolerance, solubility and stability
- **Mineral salts & tonicity** adjustment, to ensure the osmolarity for physiological tolerance
- **Preservatives**, to ensure microbial purity and sterility by inhibiting microbial growth
- **Solvents & surfactants**, to enhance solubility and stability of the API
- **Antioxidants**, to ensure the stability of oxidation prone APIs
- **Stabilizers**, to stabilize the finished drug product

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Millipore®
Preparation, Separation,
Filtration & Testing Products

View Products

Choosing the right mixers for homogenous and effective formulations

Considerations

Application Requirements | Operator Friendly Solutions | Facility Needs | Validation

Process Design	Solution
• Sensitive formulation – Small molecule: cytotoxic and hormonal drugs – Peptides and protein solutions • Low to high concentrations • Difficult to mix solutions – Polymers – Oil-based formulation	• Low shear gentle mixing (liquid-liquid mixing) • High mixing strength creating vortex (solid-liquid mixing) • Optimization, technical and process support by team available • Live demonstration in the M Lab™

Millipore®
Preparation, Separation,
Filtration & Testing Products

View Products

Choosing the right mixers for homogenous and effective formulations

Considerations

Application Requirements	Operator Friendly Solutions	Facility Needs	Validation

Process Design	Solution
Plant specific requirements • Convenient powder delivery • In-process measurement options • Representative sampling • Direct filtration	• In process measurements parameters: pH, weight, temperature, conductivity • Powder delivery system • Closed, sterile, zero-dead-leg sampling system

Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

Millipore®
Preparation, Separation,
Filtration & Testing Products

View Products

Choosing the right mixers for homogenous and effective formulations

Considerations

Application Requirements | Operator Friendly Solutions | **Facility Needs** | Validation

Process Design	Solution
The conceptual design • Process economics • Flexibility for product change-over • Purpose of facility • Ease of process validation	Benefits of single use mixing systems: • Decreased risk of contamination • Reduced downtime and costs for cleaning validation • Reduced capital • Faster turn-around • Flexibility to change scale or process • Closed processing for critical applications or open liners for lower value applications

Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

BioReliance®
Pharma & Biopharma
Manufacturing &
Testing Services

View Products

Choosing the right mixers for homogenous and effective formulations

Considerations

Application Requirements | Operator Friendly Solutions | Facility Needs | **Validation**

Process Design	Solution
Equipment coming in contact with the product assembly must not be • Additive • Reactive • Absorptive	• Validation team experts – To help you choose and conduct the appropriate validation services for your mixing process – To accelerate and simplify your path to market • Documentation support to meet your compliance needs

Millipore®
Preparation, Separation, Filtration & Testing Products

How is the Mobius® Power MIX different than the Mobius® MIX?

Mobius® MIX

Gentle mixing of drug products throughout entire process.

Mobius® Power MIX

Forms a vortex for powerful mixing of difficult-to-mix solutions.

Mobius® MIX

Levitating, magnetically driven impeller

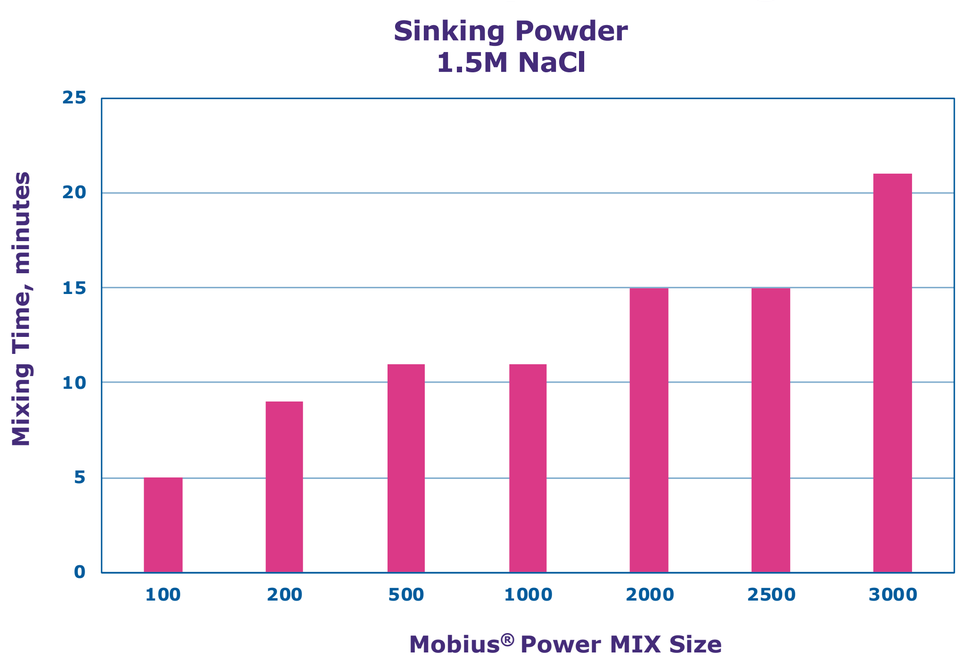
- Low shear impeller design
- No particle shedding
- Mixing from 10 L – 1000 L

Mobius® Power MIX

Magnetically driven impeller (NovAseptic technology)

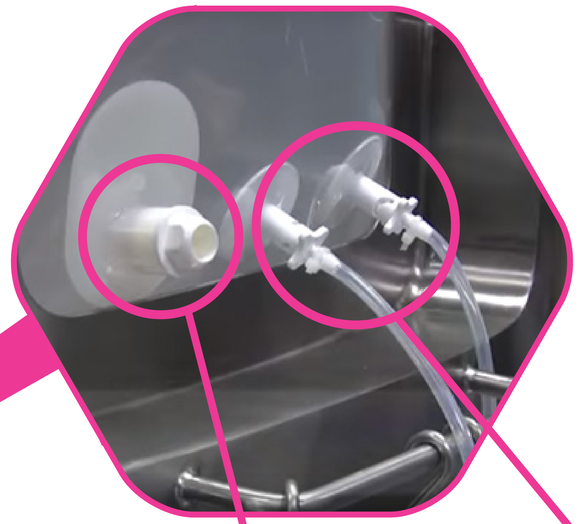
- More efficient powder/liquid mixing
- Viscous solutions
- Mixing capabilities from 100 L – 3000 L

Scalability of mixing



Millipore®
Preparation, Separation,
Filtration & Testing Products

Inline measurement and sampling



Closed, sterile, zero-dead-leg system

Convenient in-process measurement

BioReliance®
Pharma & Biopharma Manufacturing & Testing Services

Validation services for mixing bags

Chemical compatibility

Assess the chemical compatibility based on key characteristics, after prolonged exposure with the drug product. Provide evidence that the process fluids and conditions do not adversely impact the structure of the mixing bag.

Extractables

Identify and quantify the extractables which may be extracted out from the mixing bag by employing the Model Solvent Stream Approach and worst case test conditions. Analytical methods used are:

NVR: Non-Volatile Residue

TOC: Total Organic Carbon

FTIR: Fourier Transform Infrared Spectroscopy

RP-HPLC: Reverse-Phase High-Performance Liquid Chromatography

GC-MS: Gas Chromatography/ Mass Spectrometry

Patient safety

Assess the potential impact of the substances that have been detected, identified and quantified on patient safety. This assessment is done by a toxicologist.

Click here for more information on the BioReliance® Validation Services

Millipore®
Preparation, Separation,
Filtration & Testing Products

Mobius® Mixer

Mobius® Power Mix

Stainless Steel Carrier
- 100 L
- 200 L
- 500 L

Plastic Carrier

- 1000 L
- 2000 L
- 2000 L + 500 L Extension
- 2000 L + 2x 500 L Extension

Mobius® Mix

Plastic Carrier
- 10 L
- 50 L
- 100 L
- 200 L
- 500 L

Stainless Steel Carrier

- 1000 L

Millipore®
Preparation, Separation,
Filtration & Testing Products

Mobius® Mixer

Mobius® Power Mix

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Preparation, Separation,
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Preparation, Separation,
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Stainless Steel Carrier

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Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

Millipore®
Preparation, Separation,
Filtration & Testing Products

View Products

View Products

Choosing the right sampling systems to monitor critical parameters across each step

Considerations

Ease of Use | Facility Needs | Meeting Regulation Requirements | Validation

Process Design	Solution
• Flexibility and speed • Safety of operators • Secure disconnection of sample	• Solutions for all process steps • Wide range of sampling containers, available pre-sterilized and pre-assembled • Preconfigured or configure on site • No operator training needed

Portfolio | Formulation | Filtration | Filling

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Preparation, Separation,
Filtration & Testing Products

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View Products

Choosing the right sampling systems to monitor critical parameters across each step

Considerations

Ease of Use | **Facility Needs** | Meeting Regulation Requirements | Validation

Process Design	Solution
• No need for additional utilities (pressure, steam, …) • Option of sampling from SU and SS • Limited investment – Maintenance – Spare parts	• Utilities: only need of crimping tool to disconnect taken sample • **Sampling from single-use and stainless steel tank possible** • Reduced cleaning needs

Portfolio | Formulation | Filtration | Filling

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Filtration & Testing Products

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Choosing the right sampling systems to monitor critical parameters across each step

Considerations

Ease of Use | Facility Needs | Meeting Regulation Requirements | Validation

Process Design	Solution
• Right specifications • Representative samples • Process risk mitigation • Accelerate speed to market	• Process integrity • No dead leg, flush or sample dilution • Closed and validated sampling system

Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

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Pharma & Biopharma Manufacturing & Testing Services

View Products

View Products

Choosing the right sampling systems to monitor critical parameters across each step

Considerations

Ease of Use | **Facility Needs** | **Meeting Regulation Requirements** | **Validation**

Process Design	Solution
Equipment coming in contact with the product must not be • Additive • Reactive • Absorptive	• Validation team experts - to help you choose and conduct the appropriate validation services for your sampling system - to accelerate and simplify your path to market • Documentation support to meet your compliance needs

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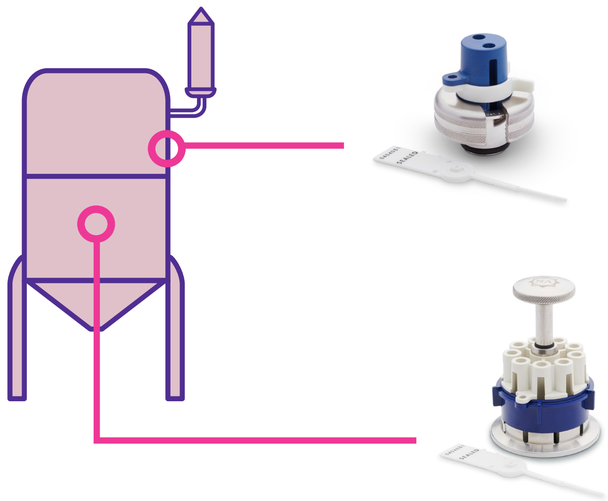
Preparation, Separation, Filtration & Testing Products

Process step options

Connector for stainless steel tank



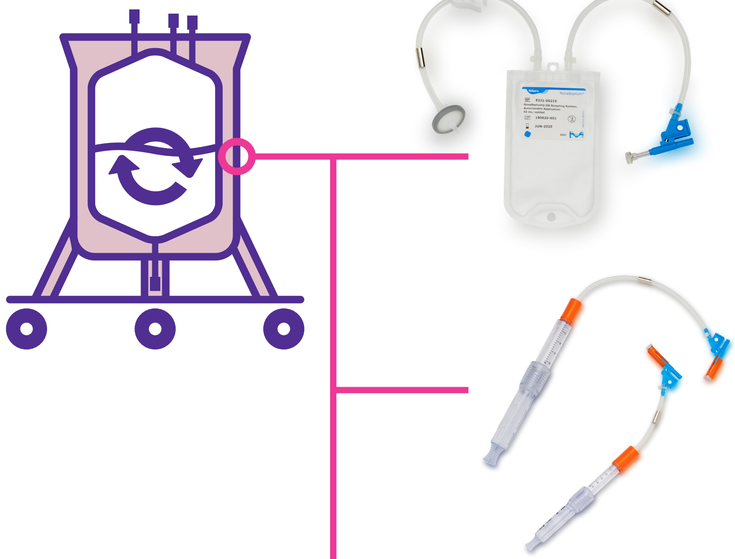
Ingold connectors

- Available in any length
- 2 independant points of access

TC connectors

- 1/2” to 2” size with up to 10 independent access points
- Also available in single-use format, pre-assembled with the containers of your choice

Sampling containers



Autoclave containers

- Bags and syringes ideal for small portable tanks that are fully autoclaved
- Vented to withstand the most aggressive autoclave cycles

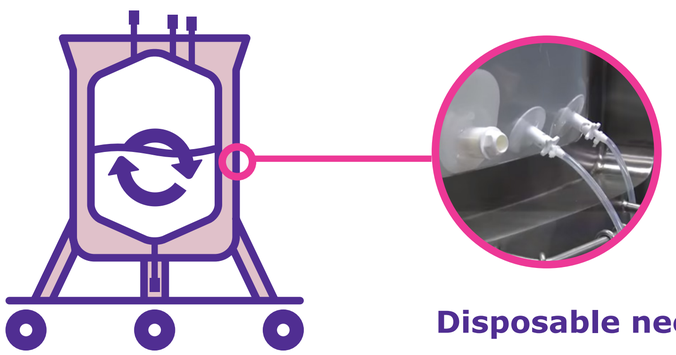
Sterile syringes

- Contamination free with patented design
- Ideal to save and store high value product

Bottles

- Bio-neutral plastic bottles ideal for all tests
- Offered in multiple sizes

Connector for single-use tank



Disposable needle-free valve

- Ideal for sampling from disposable bags
- Welded any place needed

Millipore®
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Process step options

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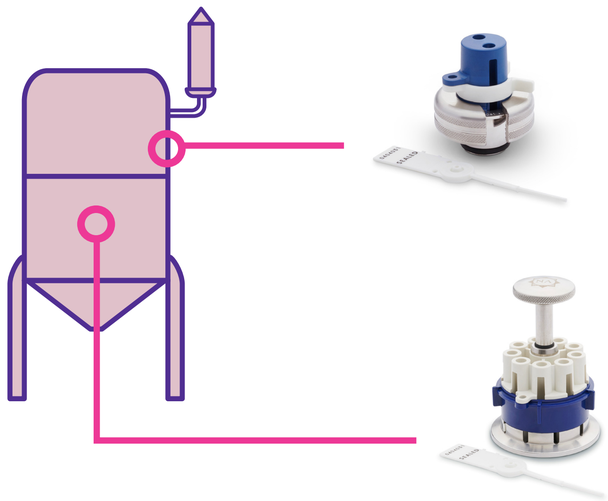

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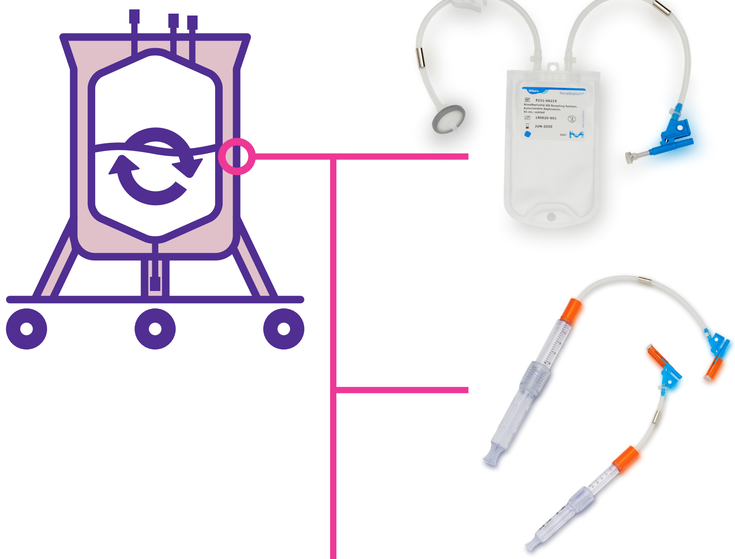

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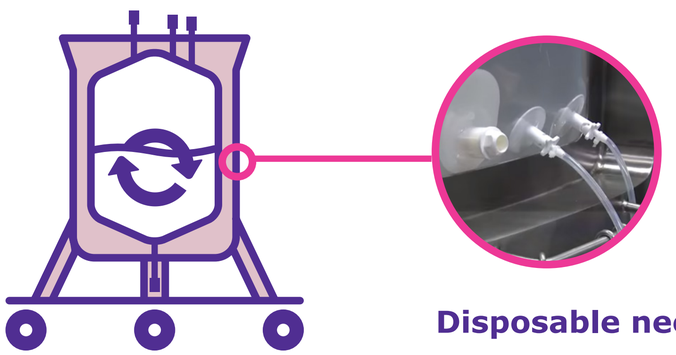

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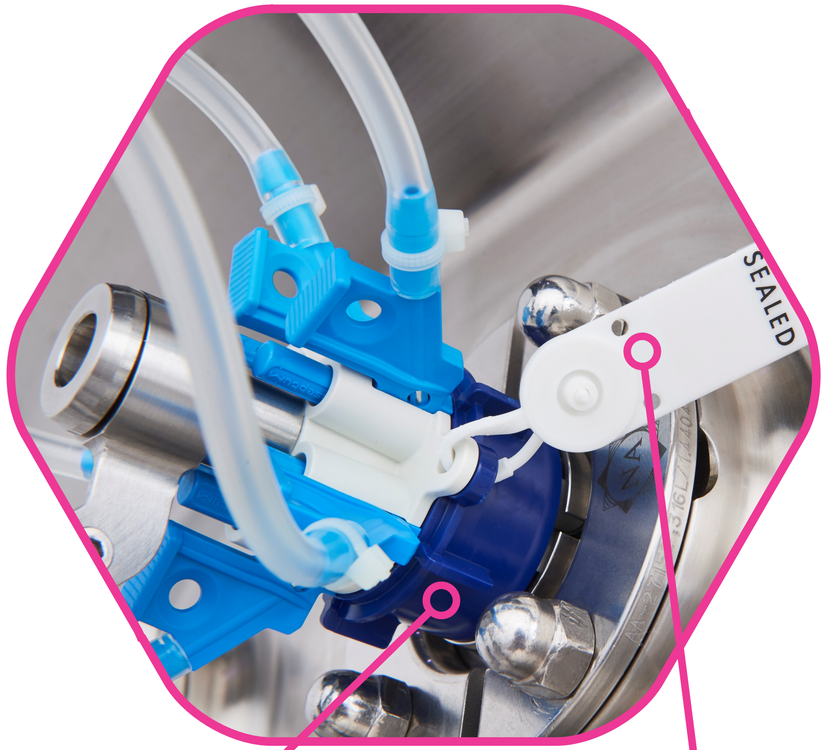
Millipore®
Preparation, Separation, Filtration & Testing Products

Maximum security and reliability

- Eliminating high heat/pressure and glass bottle safety risks
- No steam condensate to dilute sample, avoid requirement for flushing
- “Neutral” containers for accurate testing and storage
- Simple procedure eliminates complexity of training, reducing risk of operator bias
- Eliminating time of steam sterilization and cooling between samples



The safety ring prevents accidental actuation during processing

System locking tag, to demonstrate that no actuation occurred prior to use

BioReliance®
Pharma & Biopharma
Manufacturing &
Testing Services

Validation services for sampling system

Chemical compatibility

Assess the chemical compatibility based on key characteristics, after prolonged exposure with the drug product. Provide evidence that the process fluids and conditions do not adversely impact the structure of the Sampling System

Functionality test

Verify that the sampling element is within the qualified acceptance criteria after product contact & process conditions simulation.

Non permeation test for bag

Demonstrate that the bag is not permeable to disinfectant/ decontamination agent

Click here for more information on the BioReliance® Validation Services

Millipore®
Preparation, Separation, Filtration & Testing Products

NovaSeptum® GO sterile sampling holders and connectors

Multi-Use holders for stainless steel

- A fast and easy connection of the sampling solution to the manufacturing process available.

Ingold® Holder

TC Holder

Single-use holder for stainless steel

- Available pre-loaded with high purity or autoclavable bags, bottles or AV syringe

Single-Use connectors for single-use assemblies

- Reduce labor associated with cleaning or handling.
- with NovaSeptum® single-use connectors.
- The needle-free sampling valve brings capabilities for NovaSeptum® sampling integration into your larger single-use bag assemblies.

Needle-free sampling port

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Needle-free sampling port

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Filtration & Testing Products

NovaSeptum® GO sterile sampling system

The NovaSeptum® GO high purity bag single and multi-sampling systems are available from 50 mL to 1000 mL.

The NovaSeptum® GO autoclavable bag single sampling system is available in 50 mL, 100 mL, 250 mL and 1000 mL.

The NovaSeptum® GO bottle single and multi-sampling systems are available in 60 mL to 500 mL.

The NovaSeptum® GO transfer unit is available in different tubing materials (Thermoplastic Silicone, and C-Flex®).

The NovaSeptum® GO AV single and multi-sampling units are available from 5 mL to 20 mL syringe sizes.

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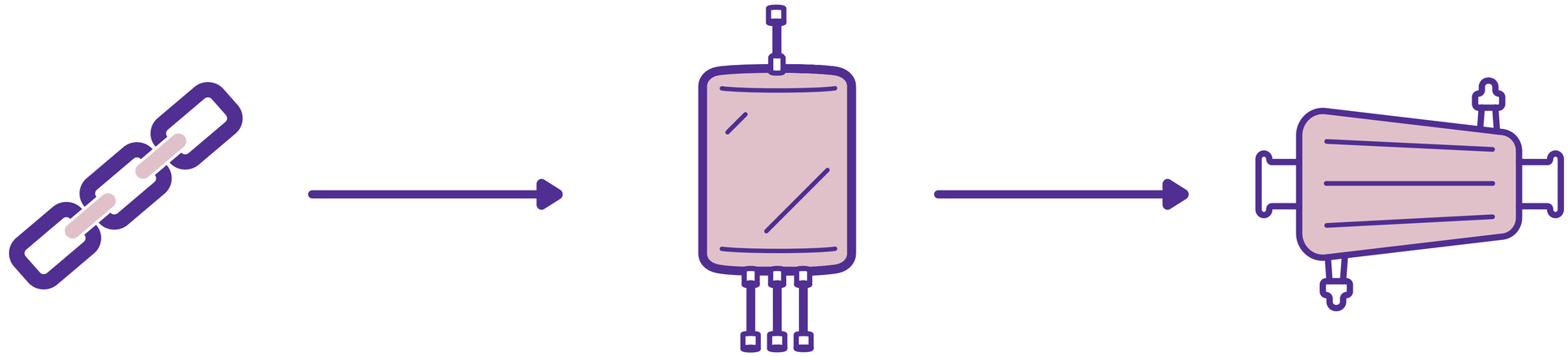
Key steps for filtration



Sterile connection

- Assure the fluid path is not compromised between process steps
- Transition between multi-use and single-use systems

Sterile sampling

- Improve operator safety
- Maintain process sterility
- Assure representative sampling
- Ease of use

Sterile filtration

- Filters designed for critical sterile filtration steps
- Expertise in single-use filtration system design

Portfolio | Formulation | Filtration | Filling

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Chosing the right sterile connectors to maintain an aseptic fluid path

Considerations

Handling | Sterility Assurance | Application | Validation

Process Design	Solution
• Quick and easy connectivity • Maintain sterile flow-path • Avoid operator mistakes	• Robust design delivers consistent and reliable performance • Operator handling training

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Chosing the right sterile connectors to maintain an aseptic fluid path

Considerations

Handling | **Sterility Assurance** | Application | Validation

Process Design	Solution
• Completely closed fluid path • Sterile connection could be made in both non-classified and classified area • Eliminate contamination risk associated with aseptic connections	• 100% air-integrity tested in manufacturing • Aerosolized microbial challenge test – worst case simulation for validation

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Chosing the right sterile connectors to maintain an aseptic fluid path

Considerations

Handling | Sterility Assurance | **Application** | Validation

Process Design	Solution
• Sterile fluid transfer • Connect sterilized fluid paths, integrate steamable hard-piped connections to disposable fluid paths • Single and multiple actuations	• Sterile-to-sterile connection • Steamable hard-piped connection to disposable fluid path • Multiple connections/disconnections

Portfolio | Formulation | Filtration | Filling

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Chosing the right sterile connectors to maintain an aseptic fluid path

Considerations

Handling | Sterility Assurance | Application | Validation

Process Design	Solution
Equipment coming in contact with the product must not be • additive • reactive • absorptive	• Validation team experts - to help you choose and conduct the appropriate validation services for your sterile connectors - to accelerate and simplify your path to market • Documentation support to meet your compliance needs

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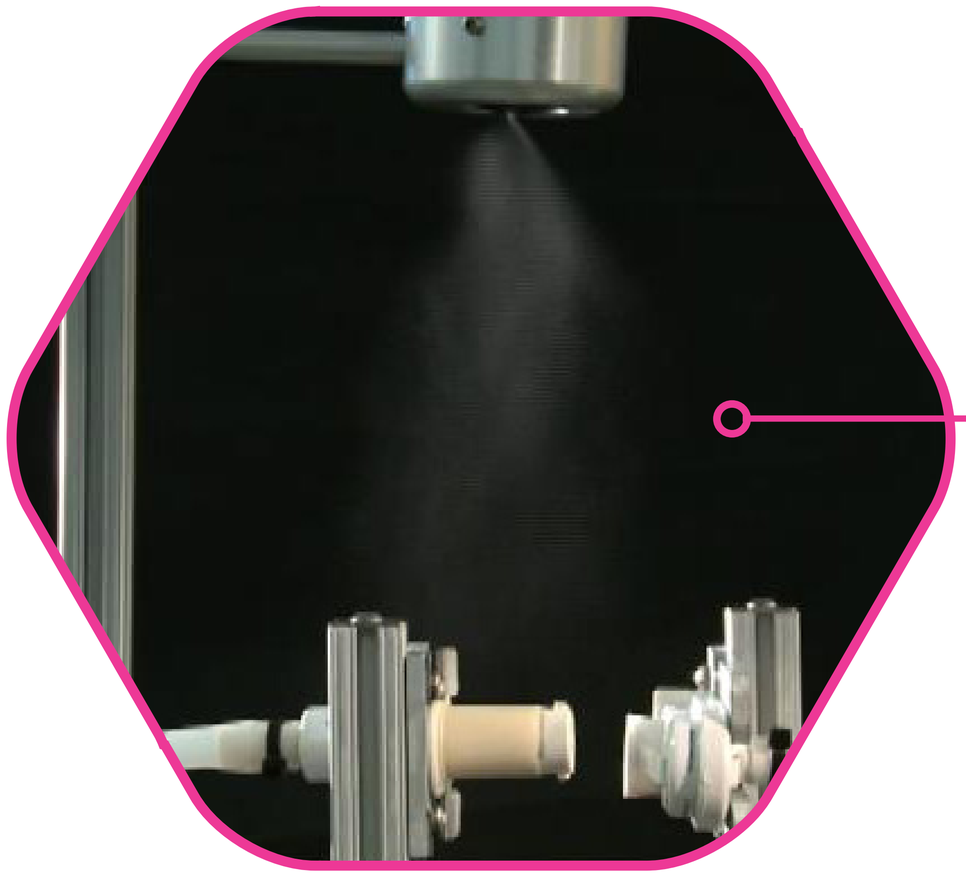

Brevundimonas diminuta, >4 x 10^6 cfu per connector set

Sterility assurance during actuation

Two tests were conducted to challenge the ability of Lynx® S2S connectors to prevent ingress of microorganisms in a non-classified area.

Tests were performed to confirm that the Lynx® S2S connectors showed no ingress of the challenge organism, *B. diminuta*.

Bacterial aerosol

The connector was connected and actuated in the presence of a bacterial aerosol at a minimum concentration of 1 x 10^6 cfu/connector.

Direct bacterial soiling

B. diminuta was applied to the mating surfaces of the male and female Lynx® S2S connector lumen plugs, followed after a setting time, by connection and actuation.

All Lynx® S2S connectors met the acceptance criteria for the Bacterial Aerosol Test and the Direct Bacterial Soiling test, assuring a sterile connection can be made in non-classified areas.

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Validation services for sterile connectors

Chemical compatibility

Assess the chemical compatibility based on key characteristics, after prolonged exposure with the drug product. Provide evidence that the process fluids and conditions do not adversely impact the structure of the connectors.

Extractables

Identify and quantify the extractables which may be extracted out from the connectors by employing the Model Solvent Stream Approach and worst case test conditions. Analytical methods used are NVR, TOC, FTIR, RP-HPLC and GC-MS (when applicable).

Patient safety

Assess the potential impact of the substances that have been detected, identified and quantified on patient safety. This assessment is done by a toxicologist.

Click here for more information on the BioReliance® Validation Services

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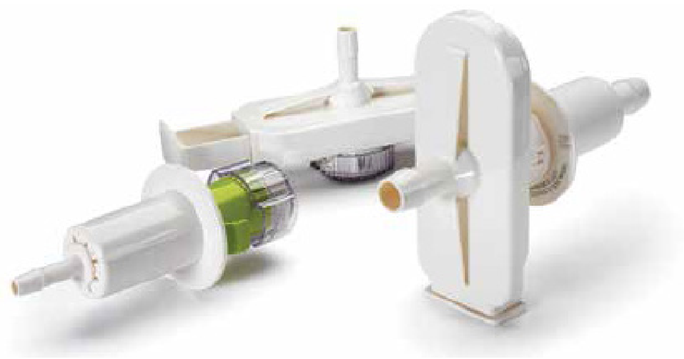
Lynx® product family



Lynx® S2S
Sterile-to-Sterile Connector

A single actuation, disposable device for connecting sterilized disposable flow paths

Lynx® ST
Steam-To Connector

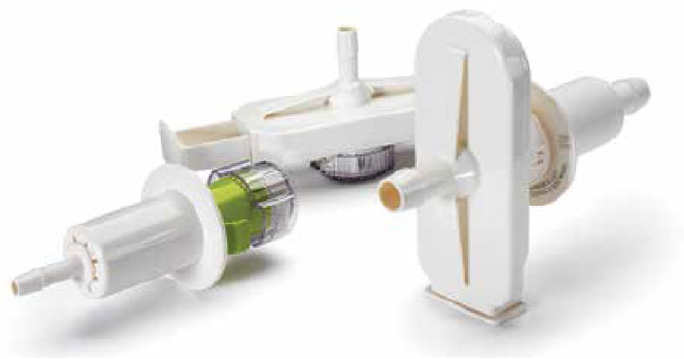
Designed to connect steamable hard-piped processing systems to sterilized disposable flow paths

Lynx® CDR
Connect, Disconnect, Reconnect

Offers multiple sterile connections, disconnections, and reconnections wet, and under pressure

Millipore®
Preparation, Separation,
Filtration & Testing Products

Lynx® product family



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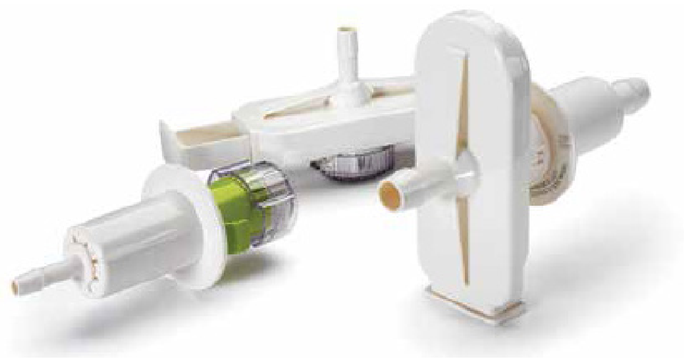

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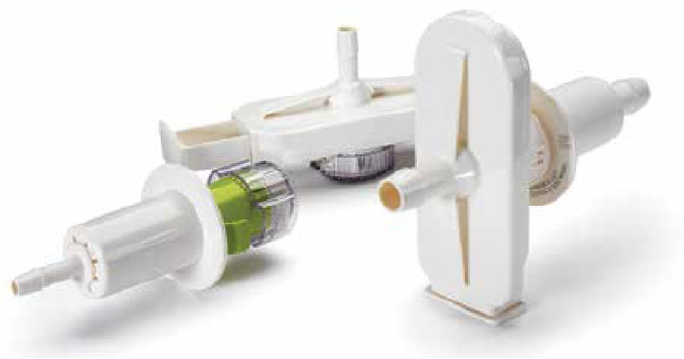

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Choosing the right filters to sterilize your product

Considerations

Filter design | Filtration System Setup | Line Flushing Integrity Testing | Validation

Process Design	Solution
• Maximizing yield, minimize loss • Ease of use • Membrane selection (sterility assurance level, low adsorption, flow rates, capacity, chemical compatibility) • Maintain sterility of flow path	• Streamlined single-use assembly • Truly closed systems • Reliable sterile filtration of small volume and high value solutions

Portfolio | Formulation | Filtration | Filling

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Choosing the right filters to sterilize your product

Considerations

Filter design | **Filtration System Setup** | **Line Flushing Integrity Testing** | **Validation**

Process Design

- Single - Dual - Redundant Filtration
- Line orientation (vertical, sloped, or horizontal)
- Sterile Filter placement (inside or outside of the isolator)
- PUPSIT implementation (Pre-use-post-sterilization-integrity-test)

Solution

- Support in risk evaluation
- Expertise in filtration system design equipment characterization
- Dedicated Mlab Collaboration Center to meet with our experts

Portfolio | Formulation | Filtration | Filling

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Choosing the right filters to sterilize your product

Considerations

Filter design | Filtration System Setup | **Line Flushing Integrity Testing** | Validation

Process Design	Solution
• Maintain a closed system • Optimum flushing volume (to mitigate E&L risk and adsorption phenomenon) • Filter integrity test method	• Certification training for operators • Options to maintain a closed system through flush bags or barrier filter • Single-use system design expertise to simplify PUPSIT implementation

Portfolio | Formulation | Filtration | Filling

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Choosing the right filters to sterilize your product

Considerations

Filter design | Filtration System Setup | Line Flushing Integrity Testing | Validation

Process Design	Solution
Equipment coming in contact with the product must not be • additive • reactive • absorptive	• Validation team experts - to help you choose and conduct the appropriate validation services for your aseptic filtration - to accelerate and simplify your path to market • Documentation support to meet your compliance needs

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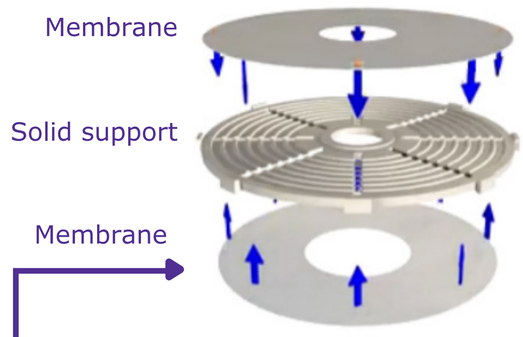
Minimize hold-up volume with stacked disc design

Support layer

Membrane

Drainage layer

Pleated:
Membrane is placed between supporting layers



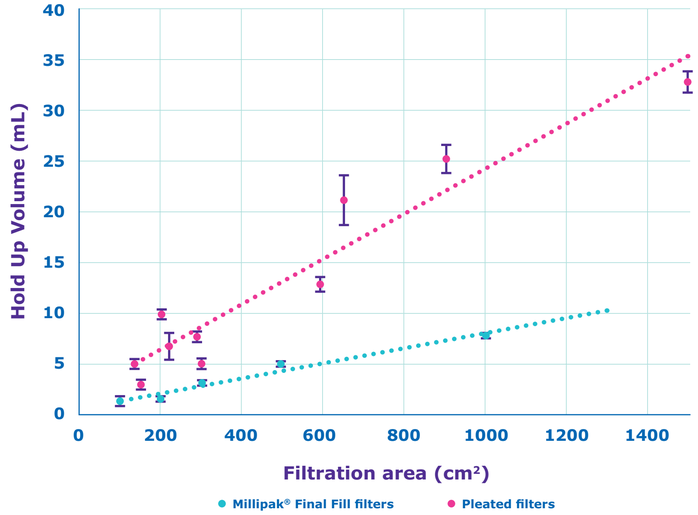
Membrane

Solid support

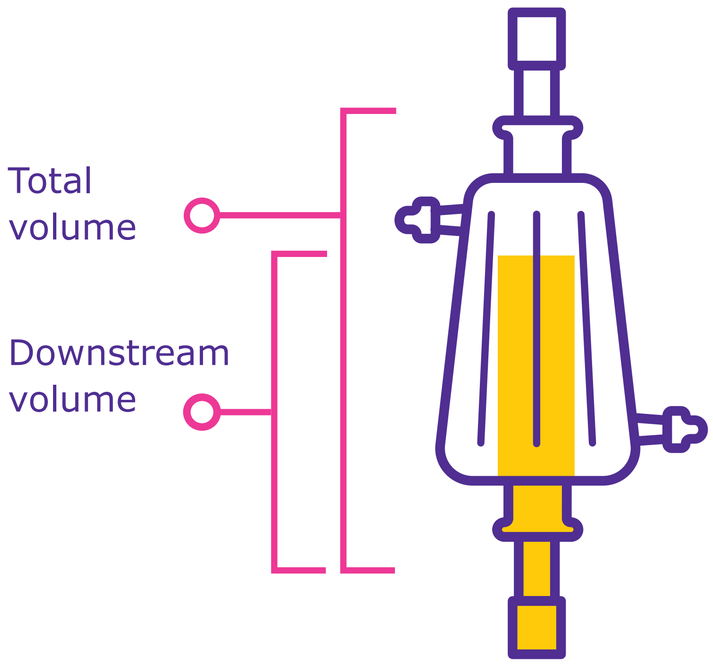
Membrane

Stacked discs:
Membrane is bonded to solid discs

Flat disc filters minimize hold-up volume



	Filtration area	Total void volume	Downstream volume	Hold up volume
Millipak® FF 20 filter	100 cm²	38 mL	6.4 mL	1.1 mL
Millipak® FF 200 filter	1,000 cm²	145 mL	38 mL	7.7 mL
Opticap® XL 2 capsule	900 cm²	225 mL	30 mL	15 mL



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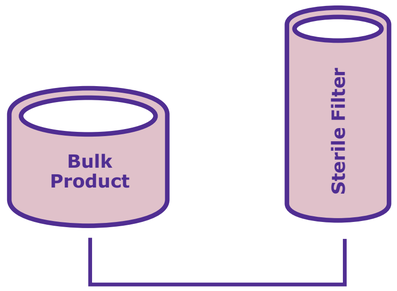
Design options



Filter Configurations

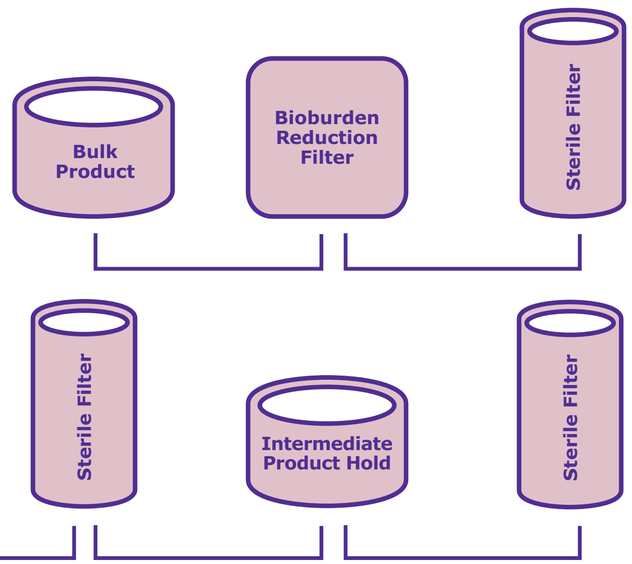
Single Filter
Sterile Filtration

Single filter

Sterile Filtration

Advantages
- Minimum hold-up volume
- Minimum flushing requirements
- Ease of handling and operation
- Lower filter cost

Disadvantages
- No back-up in the event of primary filter failure
- Filter plugging



Dual Filters
Bioburden/Sterile Filtration

Dual Filters
Sterile Filtration - Hold - Sterile Filtration

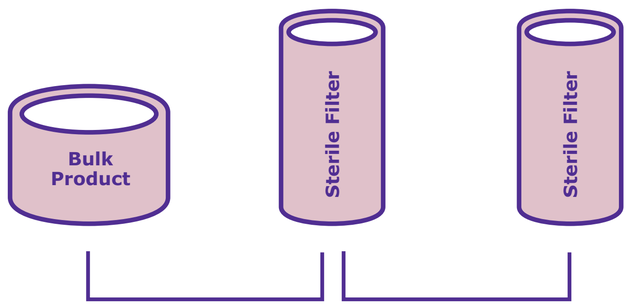
Dual filter

Bioburden / Sterile Filtration

Sterile – Hold - Sterile Filtration

Advantages
- Compliance with regulatory guidance for <10 cfu/100 mL
- Very low plugging risk for primary filter

Disadvantages
- No back-up in the event of primary filter failure
- Higher hold up volume
- Higher cost than single filter
- Higher system complexity than single filter



Redundant Filters
Sterile Filtration

Redundant

Sterile Filtration

Advantages
- Compliance with regulatory guidance for <10 cfu/100 mL
- Very low plugging risk for primary filter
- Potential batch recovery if one filter fails IT

Disadvantages
- Higher hold up volume
- Higher cost than single filter
- Higher system complexity than single filter

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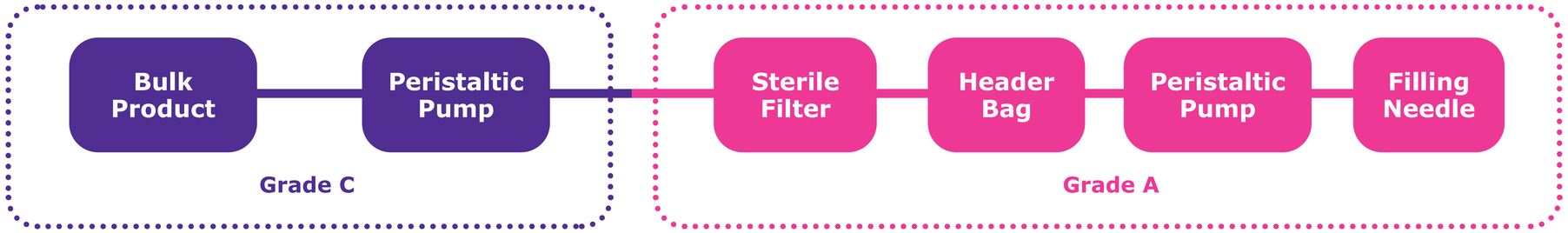
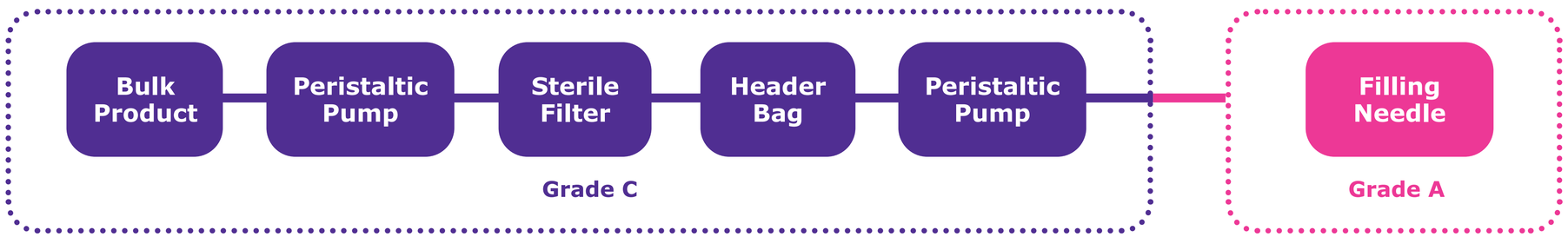
Sterile filter placement

Sterile filter placement considerations: Inside or Outside the Isolator/RABS

Sterile filter in Grade A/ISO 5/Class 100 space



Sterile filter in Grade C/ISO 7/Class 10,000 space



Complete SUS transferred to Grade A

Benefits

- Low risk of fluid path contamination with majority of operations (venting, connections, etc.) occurring inside isolator/RABS

Considerations

- Sterile environment risk if performing open venting

Handling challenges

- Large number of components to transfer from Grade C into Grade A
- Pre-use integrity testing challenge

Only filling needles transferred to Grade A

Benefits

- Majority of operations (instability, flushing, etc.) occur outside isolator/RABS
- Potential to replace filter if integrity test fails

Considerations

- More potential points for microbial ingress
- Demonstration of assembly integrity more critical

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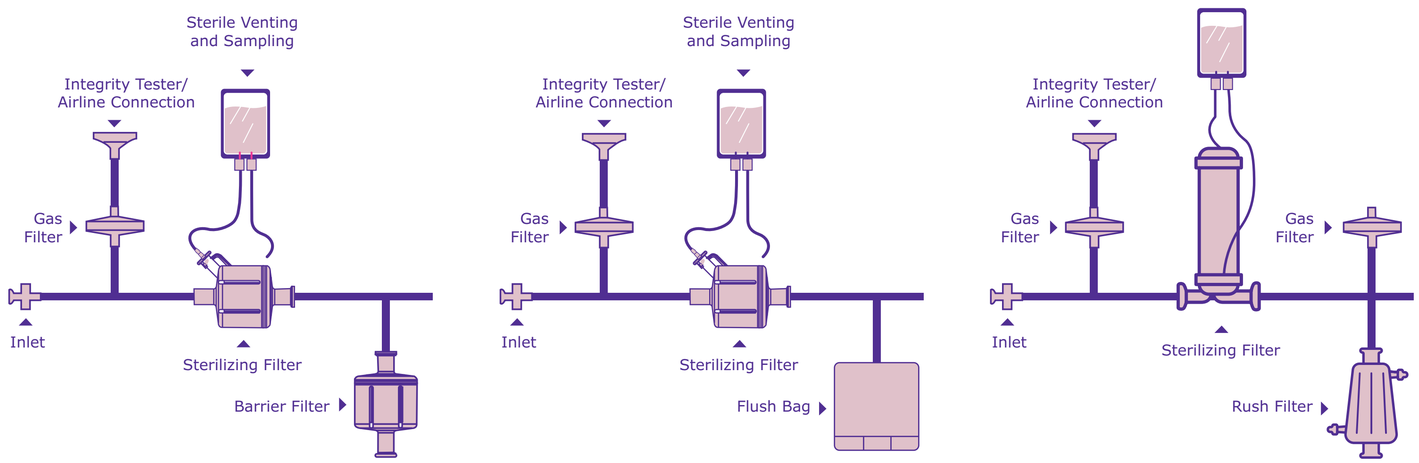
Maintaining a closed system

Details about barrier filter

- Millipak® Barrier filters simplify in-line pre-use, post-sterilization integrity testing (PUPSIT) of single or redundant liquid filtration systems.
- Separate layers of hydrophobic and hydrophilic 0.22 µm Durapore® sterilizing-grade membranes allow the sterile flow of liquid and gas.
- Simplify wetting, flushing and integrity testing of upstream sterile filters in filtration assemblies while removing the constraint of a flush bag or can.



	Barrier Filter	Flush Bag	Downstream Filter
Ability to Retest	Yes	No	Yes
Ability to Dry the Product Filter	Yes	No	Yes
Simple Design	Yes	Yes	No

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Validation services for filtration

Extractables
Identify and quantify the extractables which may be extracted out from the filter by employing the Model Solvent Stream Approach and worst case test conditions.

Bacterial retention validation
Validate the performance of your sterilizing grade filter by simulating your product and process conditions. *B. diminuta* is used as the standard challenge microorganism.

Bubble point/diffusion determination
Provide a product-specific bubble point/diffusion value.

Patient safety assessment
Assess the potential impact of the substances that have been detected, identified and quantified on patient safety.

Leachables
Identify and quantify the leachables which leach out from the filter with the use of your actual product under normal processing conditions.

Particle shedding
Provide particle shedding data with the drug product and using actual and scale-down customer worse-case filtration conditions.

Binding study
Show that the filter does not remove unacceptable amounts of stream compounds.

Compatibility study
Assess the chemical compatibility based on key characteristics and provide evidence that the process fluids and conditions do not adversely impact the structure of the filter device.

Click here for more information on the BioReliance® Validation Services

Millipore®
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Filters

Opticap® Capsules

- Eliminates time and expense associated with stainless steel housings
- Pleated filter membrane

Millipak® Final Fill

- Designed for small volume, high value solutions
- Stacked disc design
- Multi-purpose port that simplifies venting, integrity testing and sampling, and is validated to maintain an aseptic flow path

Millipore Express® Membrane

- Polyethersulfone (PES) membranes
- Broad chemical compatibility, pH 1-14
- Exceptionally high flow rates

Durapore® Membrane

- Polyvinylidene fluoride (PVDF) membrane
- Broad chemical compatibility
- High flow rates

Millipore®
Preparation, Separation, Filtration & Testing Products

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Millipore®
Preparation, Separation,
Filtration & Testing Products

Automated integrity tester

- Verifying the integrity of your filters and processing equipment
- Portable, easy to implement, and automated
- Delivering a simple and intuitive user experience
- Providing optional depth of flexibility to fit your process

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View Products

Choosing the right sampling systems to monitor critical parameters across each step

Considerations

Ease of Use | Facility Needs | Meeting Regulation Requirements | Validation

Process Design	Solution
• Flexibility and speed • Safety of operators • Secure disconnection of sample	• Solutions for all process steps • Wide range of sampling containers, available pre-sterilized and pre-assembled • Preconfigured or configure on site • No operator training needed

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View Products

Choosing the right sampling systems to monitor critical parameters across each step

Considerations

Ease of Use | **Facility Needs** | Meeting Regulation Requirements | Validation

Process Design	Solution
• No need for additional utilities (pressure, steam, …) • Option of sampling from Single-Use and Stainless Steel • Limited investment • Maintenance & spare parts	• Utilities: only need of crimping tool to disconnect taken sample • **Sampling from Single-Use and Stainless Steel tank possible** • No cleaning needs

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View Products

Choosing the right sampling systems to monitor critical parameters across each step

Considerations

Ease of Use | Facility Needs | **Meeting Regulation Requirements** | Validation

Process Design	Solution
• Right specifications • Representative samples • Process risk mitigation • Accelerate speed to market	• Process integrity • No dead leg, flush, or sample dilution • Closed and validated sampling system • Sampling actuation evidence and control

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Testing Services

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Choosing the right sampling systems to monitor critical parameters across each step

Considerations

Ease of Use | Facility Needs | Meeting Regulation Requirements | Validation

Process Design	Solution
Drug Product shall not be affected by the process conditions and equipment	• Validation team experts - to help you choose and conduct the appropriate validation services for your sampling system - to accelerate and simplify your path to market • Documentation support to meet your compliance needs

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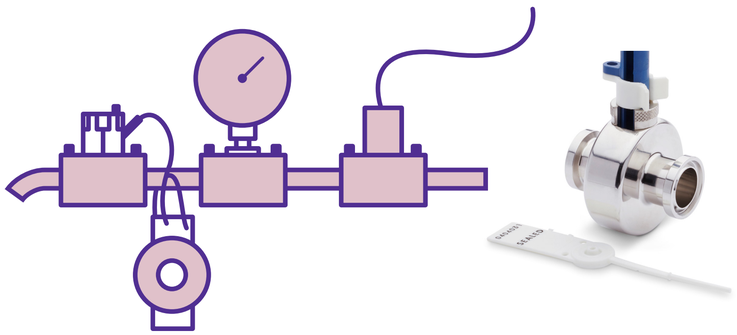
Process step options for sampling before sterilizing filtration

Connector for Stainless Steel tank



In-line connectors

- Ideal to collect numerous samples between equipment
- Yields a representative sample from your process stream

Without Connector

- Directly at the filtration assembly
- Directly at the Final Fill Filter

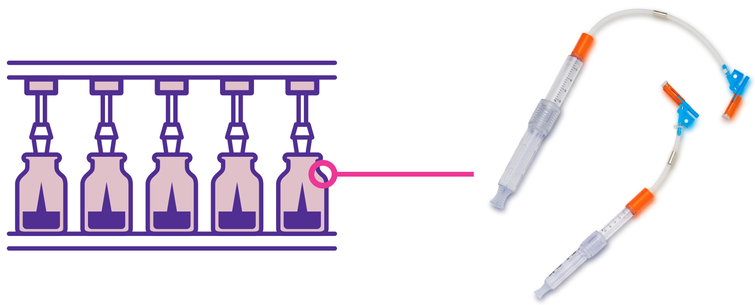
Sampling containers

Bottles

- Bio-neutral plastic bottles ideal for all tests
- Offered in multiple sizes

Autoclave containers

- Bags and syringes ideal for small portable tanks that are fully autoclaved
- Vented to withstand the most aggressive autoclave cycles



Sterile syringes

- Contamination free with patented design
- Ideal to save and store high value product

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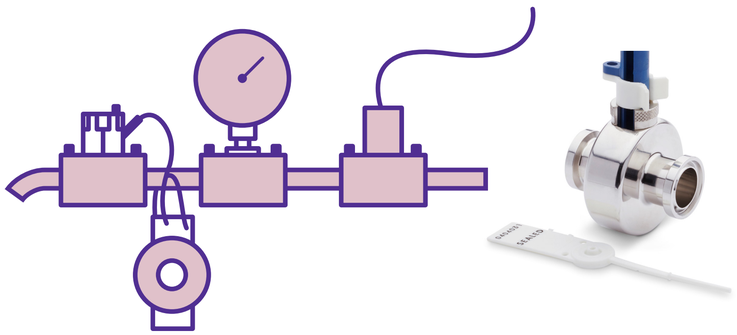
Process step options for sampling before sterilizing filtration

Connector for Stainless Steel tank



In-line connectors

- Ideal to collect numerous samples between equipment
- Yields a representative sample from your process stream

Without Connector

- Directly at the filtration assembly
- Directly at the Final Fill Filter

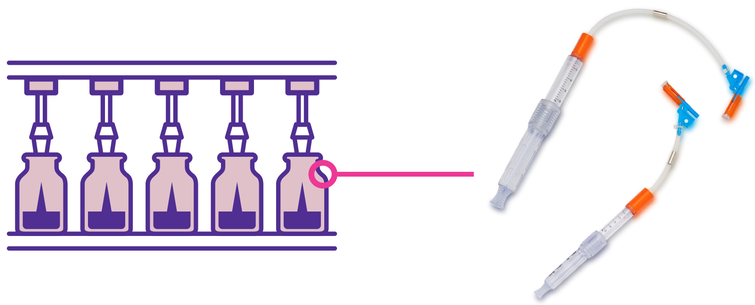
Sampling containers

Bottles

- Bio-neutral plastic bottles ideal for all tests
- Offered in multiple sizes

Autoclave containers

- Bags and syringes ideal for small portable tanks that are fully autoclaved
- Vented to withstand the most aggressive autoclave cycles



Sterile syringes

- Contamination free with patented design
- Ideal to save and store high value product

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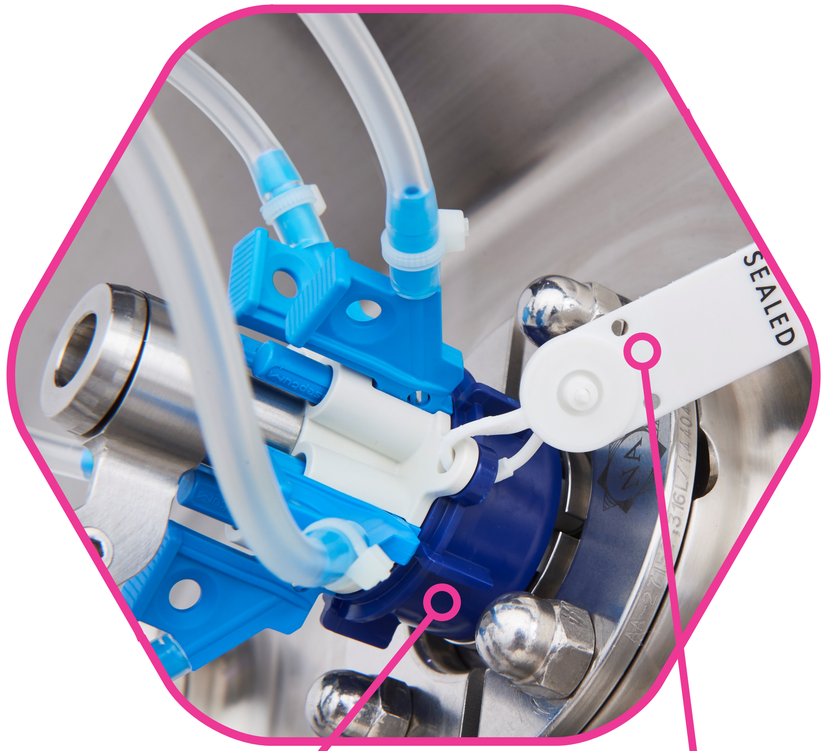
Preparation, Separation, Filtration & Testing Products

Maximum security and reliability

- Eliminating high heat/pressure and glass bottle safety risks
- No steam condensate to dilute sample, avoid requirement for flushing
- “Neutral” containers for accurate testing and storage
- Simple procedure eliminates complexity of training, reducing risk of operator bias
- Eliminating time of steam sterilization and cooling between samples



The safety ring prevents accidental actuation during processing

System locking tag, to demonstrate that no actuation occurred prior to use

BioReliance®
Pharma & Biopharma
Manufacturing &
Testing Services

Validation services for sampling system

Chemical compatibility

Assess the chemical compatibility based on key characteristics, after prolonged exposure with the drug product. Provide evidence that the process fluids and conditions do not adversely impact the structure of the Sampling System

Functionality test

Verify that the Sampling element is within the qualified acceptance criteria after product contact & process conditions simulation.

Non permeation test for bag

Demonstrate the bag is not permeable to disinfectant/ decontamination agent

Click here for more information on the BioReliance® Validation Services

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NovaSeptum® GO sterile sampling system

Multi-Use holders

- A fast and easy connecting of the sampling solution to the manufacturing process.
- Available in various designs

In-line

Custom

The NovaSeptum® GO high purity bag single and multi-sampling systems are available from 50 to 1000 mL.

The NovaSeptum® GO autoclavable bag single sampling system is available in 50, 100, 250 and 1000 mL.

The NovaSeptum® GO bottle single and multi-sampling systems are available in 60 to 500 mL.

The NovaSeptum® GO transfer unit is available in different tubing materials (Thermoplastic Silicone, and C-Flex®).

The NovaSeptum® GO AV single and multi-sampling units are available from 5 mL and 20 mL syringe sizes.

Millipore®
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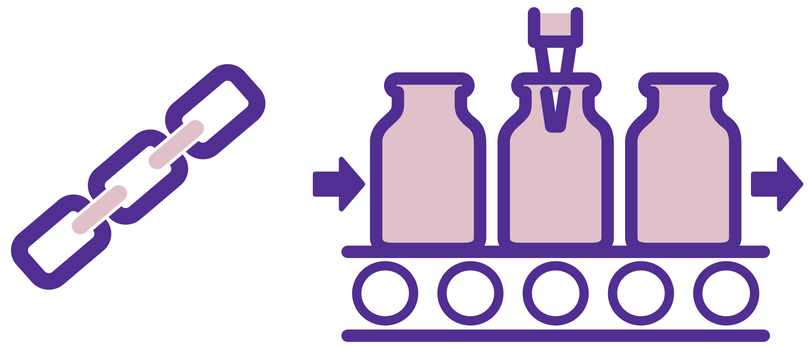
Filtration & Testing Products

Key steps for filling

Sterile connection

- Robust design delivers consistent, reliable performance
- Completely closed flow path 100% air-integrity tested in manufacturing



Final fill assemblies

- Extensive library of prequalified components providing flexibility for customized assembly design
- Easy integration with different filling machines
- Extensive technical support in design, risk assessment and testing services

Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

Millipore®
Preparation, Separation,
Filtration & Testing Products

View Products

Chosing the right sterile connectors to maintain an aseptic fluid path

Considerations

Handling | Sterility Assurance | Application | Validation

Process Design	Solution
Quick and easy connectivity to avoid operator mistakes	Robust design delivers consistent, reliable performance

Millipore®
Preparation, Separation,
Filtration & Testing Products

View Products

Chosing the right sterile connectors to maintain an aseptic fluid path

Considerations

Handling | **Sterility Assurance** | Application | Validation

Process Design	Solution
• Completely closed flow path • Sterile connection could be made in both non-classified and classified area • Eliminate contamination risk associated with aseptic connections	• 100% air-integrity tested in manufacturing • Aerosolized microbial challenge test – worst case simulation for validation

Portfolio | Formulation | Filtration | Filling

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Millipore®
Preparation, Separation,
Filtration & Testing Products

View Products

Chosing the right sterile connectors to maintain an aseptic fluid path

Considerations

Handling | Sterility Assurance | **Application** | Validation

Process Design	Solution
• Sterile fluid transfer • Connect sterilized fluid paths, integrate steamable hard-piped process equipment with disposable sterile fluid paths • Single and multiple actuations	• Sterile to sterile connection • Steamable hard-piped connection to disposable flow path • Multiple connections/disconnections

BioReliance®
Pharma & Biopharma
Manufacturing &
Testing Services

View Products

Chosing the right sterile connectors to maintain an aseptic fluid path

Considerations

Handling | Sterility Assurance | Application | Validation

Process Design	Solution
Drug Product shall not be affected by the process conditions and equipment	• Validation team experts - to help you choose and conduct the appropriate validation services for sterile connectors - to accelerate and simplify your path to market • Documentation support to meet your compliance needs

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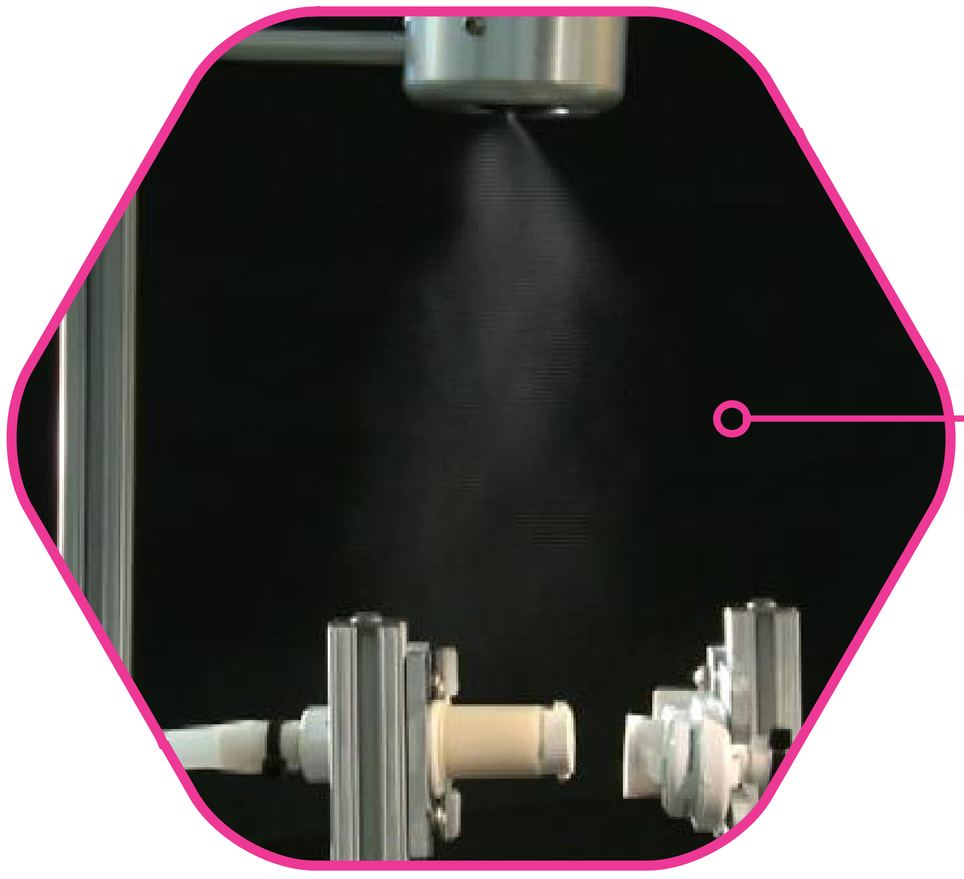

Brevundimonas diminuta, >4 x 10^6 cfu per connector set

Sterility assurance during actuation

Two tests were conducted to challenge the ability of Lynx® S2S connectors to prevent ingress of microorganisms in a non-classified area.

Tests were performed to confirm that the Lynx® S2S connectors showed no ingress of the challenge organism, *B. diminuta*.

Bacterial aerosol

The connector was connected and actuated in the presence of a bacterial aerosol at a minimum concentration of 1 x 10^6 cfu/connector.

Direct bacterial soiling

B. diminuta was applied to the mating surfaces of the male and female Lynx® S2S connector lumen plugs, followed after a setting time, by connection and actuation.

All Lynx® S2S connectors met the acceptance criteria for the Bacterial Aerosol Test and the Direct Bacterial Soiling test, assuring a sterile connection can be made in non-classified areas.

BioReliance®
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Validation services for sterile connectors

Chemical compatibility

Assess the chemical compatibility based on key characteristics, after prolonged exposure with the drug product. Provide evidence that the process fluids and conditions do not adversely impact the structure of the connectors.

Extractables

Identify and quantify the extractables which may be extracted out from the connectors by employing the Model Solvent Stream Approach and worst case test conditions. Analytical methods used are NVR, TOC, FTIR, RP-HPLC and GC-MS (when applicable).

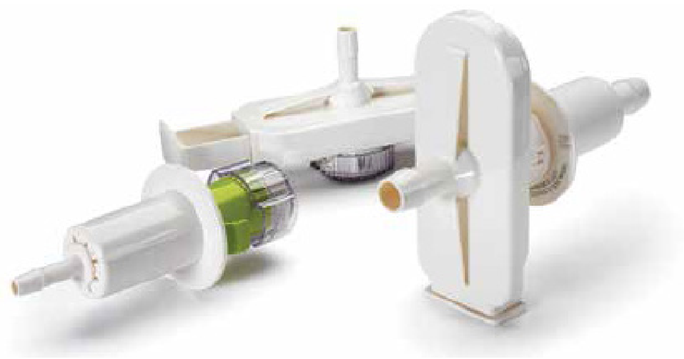
Patient safety

Assess the potential impact of the substances that have been detected, identified and quantified on patient safety. This assessment is done by a toxicologist.

Click here for more information on the BioReliance® Validation Services

Millipore®
Preparation, Separation,
Filtration & Testing Products

Lynx® product family



Lynx® S2S
Sterile to Sterile Connector

A single actuation, disposable device for connecting sterilized disposable flow paths

Lynx® ST
Steam-To Connector

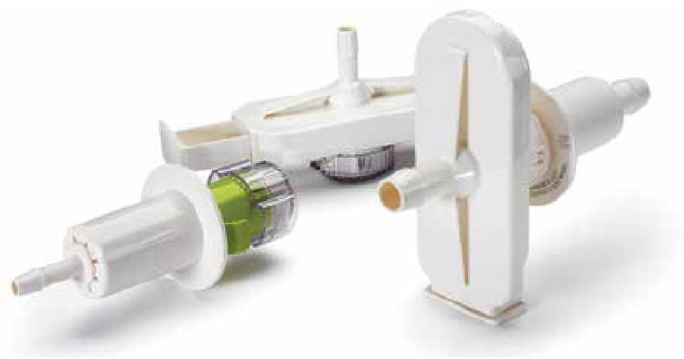
Designed to connect steamable hard-piped processing systems to sterilized disposable flow paths

Lynx® CDR
Connect, Disconnect, Reconnect

Offers multiple sterile connections, disconnections, and reconnections wet, and under pressure

Millipore®
Preparation, Separation,
Filtration & Testing Products

Lynx® product family



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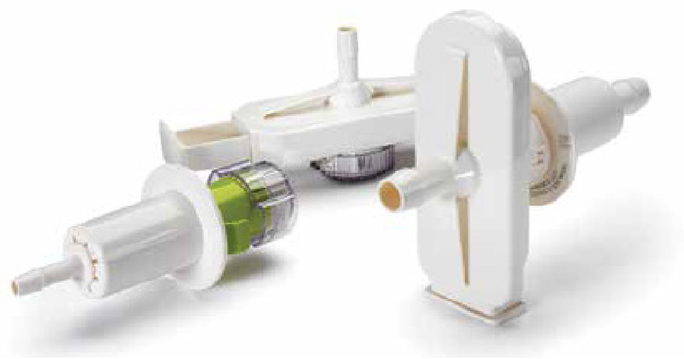

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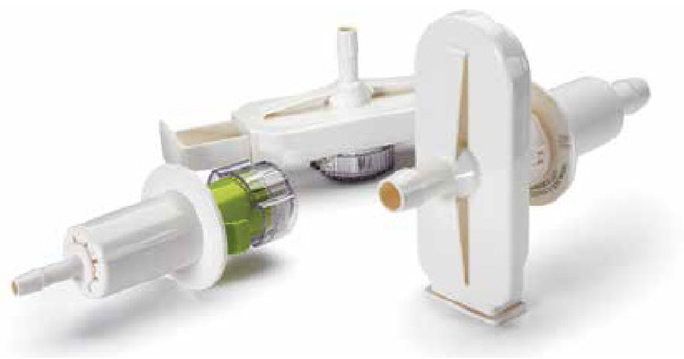

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Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

Millipore®
Preparation, Separation,
Filtration & Testing Products

View Products

Filling assemblies are designed to fit for purpose

Considerations

Customization | Risk Mitigation | Quality | Validation | Enhanced Economics

Process Design	Solution
• Full single-use system • Integrating into various filling machines • Integrating with isolator / RABS (restricted access barrier system) filling machines	• Extensive single-use component-library • Pre-qualified components • Flexibility for customized assembly design • Expertise to collaborate with machine vendors, to design, integrate and validate single-use assemblies for your filling process

Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

Millipore®
Preparation, Separation,
Filtration & Testing Products

View Products

Filling assemblies are designed to fit for purpose

Considerations

Customization | Risk Mitigation | Quality | Validation | Enhanced Economics

Process Design	Solution
• Components placement (pump tubing, header bag, filter) inside/outside of isolator • Operator’s handling and installation challenges	• Expertise to refine system design • Designed and packaged for ease-of-use • On-site support during machine qualification steps

Portfolio | Formulation | Filtration | Filling

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Filtration & Testing Products

View Products

Filling assemblies are designed to fit for purpose

Considerations

Customization | Risk Mitigation | **Quality** | Validation | Enhanced Economics

Process Design	Solution
• No particle risks • Sterility assurance • Integrity Testing	• Fully sterile assemblies, manufactured in dedicated clean room areas • Various material and release testing and claims

Portfolio | Formulation | Filtration | Filling

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Pharma & Biopharma
Manufacturing &
Testing Services

View Products

Filling assemblies are designed to fit for purpose

Considerations

Customization | Risk Mitigation | Quality | Validation | Enhanced Economics

Process Design	Solution
Drug Product shall not be affected by the process conditions and equipment	• Validation team experts - to help you choose and conduct the appropriate validation services for your final fill assemblies - to accelerate and simplify your path to market • Documentation support to meet your compliance needs

Portfolio | Formulation | Filtration | Filling

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Millipore®
Preparation, Separation, Filtration & Testing Products

View Products

Filling assemblies are designed to fit for purpose

Considerations

Customization | Risk Mitigation | Quality | Validation | Enhanced Economics

Process Design	Solution
• Increase efficiency and minimize downtime • Cost effectiveness • Reduce cleaning time	Partnership from initial specification to optimization to validation of your single-use system

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Material and release testing claims

Criteria:

Gamma compatibility >40kGy

Functional testing

Regulatory statements (Animal Origin, Latex, BPA, etc.)

USP <88> Class VI

USP <85> Endotoxin

USP <788> Particulates

USP <661> Physiochemical

Shelf life > 2 years

Sterility per ANSI/AAMI/ISO 11737

Bacteriostasis/Fungistasis

Bioburden

Mobius® assembly leak testing

- Gold certified assemblies are 100% tested
- Testing performed using pressure decay method

Packaging and transport validation

Mobius® packaging protects assemblies from the rigors of typical shipping conditions. Representative Mobius® Final Fill assemblies have been proven to be integral after being subjected to a packaging validation per the International Safe Transit Association (ISTA) 2A Procedure.

BioReliance®
Pharma & Biopharma Manufacturing & Testing Services

Validation service for final fill assemblies

Chemical compatibility

Assess the chemical compatibility based on key characteristics, after prolonged exposure with the drug product. Provide evidence that the process fluids and conditions do not adversely impact the structure of the connectors.

Extractables

Identify and quantify the extractables which may be extracted out from the connectors by employing the Model Solvent Stream Approach and worst case test conditions. Analytical methods used are NVR, TOC, FTIR, RP-HPLC and GC-MS (when applicable).

Patient safety

Assess the potential impact of the substances that have been detected, identified and quantified on patient safety. This assessment is done by a toxicologist.

Click here for more information on the BioReliance® Validation Services

Millipore®
Preparation, Separation,
Filtration & Testing Products

Efficient and cost effective

Customer case study:

A filling campaign setup, installation and production time was reduced from 36 to 12 hours by using a Mobius® single-use final fill solution versus a traditional stainless steel system.

Features and Benefits:

- Reduced upfront capital investment
- Reduced risk of cross contamination and enhanced operator safety
- Flexibility and increased filling productivity
- Advanced single-use filtration technologies to maximize yields

	Traditional	SU Solution
Clean and Set-up	14 Hours	<1 Hour
Cleaning Validation	Extensive	Zero
Filling Time	24 hours	10 Hours
Average Vials per Hour	3,000	10,000
Aseptic Connections	50	0
Operator Training	2 Weeks	2 Days
Equipment Utilization	35%	82%
CAMPAIGN FILL TIME	36 Hours	12 Hours

Assembly product page

Example of a final fill assembly:

In close collaboration, discussion and review with our technical experts, final fill assemblies are full custom designed, depending on your filling machine design and process needs.

Examples of customization are:

- Header bag design and size
- Tubing lengths and materials
- Flush bag / barrier filter
- Various types of sterile connectors
- Various filling needle styles
- RTP (rapid transfer port) bag and tri-clamp manifold pass-through
- Unique needle packaging and tubing management solution

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Portfolio | Formulation | Filtration | Filling

Emprove® Program | BioReliance® Validation Services

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SAFC®
Pharma & Biopharma Raw Material Solutions

Your fast track through regulatory challenges

Example of a final fill assembly:

High-quality products, comprehensive documentation, and superior customer support facilitate your efforts in qualification, risk assessment, and process optimization.

Confidently speed your way through the regulatory maze and fast track your new drug to market.

Emprove® Dossiers for Chemicals ▶

Emprove® Dossiers for Chemicals provide three levels of Information Supporting Quality Risk Assessment and Regulatory Requirements

Emprove® Chemicals Portfolio: Starting and Raw Materials ▶

Simplifying the selection process
Our Emprove® Chemicals portfolio contains over 400 raw materials. To address different levels of risk, and to simplify and streamline the selection process, the Portfolio is divided into four categories: Emprove® Evolve, Emprove® Essential, Emprove® Expert, Emprove® API

Emprove® Dossiers for Filtration and Single-Use ▶

Emprove® Dossiers for Filters are grouped according to product families with the same materials of construction, production processes, and packaging components.

Emprove® Dossiers for Single-Use Components are available beginning with the most commonly used components in the process. Assembly level information can be developed from the individual dossiers available for components forming the part of the single use assemblies.

SAFC®
Pharma & Biopharma Raw Material Solutions

Emprove® Dossiers for chemicals

Emprove® Material Qualification Dossier

Material Qualification Dossier

Supports raw material qualification and speeds up drug filing preparation.

In line with CTD chapter 3 quality (adapted for excipients)

- General information
- Manufacturer
- Characterization
- Control of drug substance
- Reference standard
- Materials
- Container closure system
- Stability summary

Emprove® Quality Management Dossier

Quality Management Dossier

Answers questions during quality risk assessment according to ICH Q9 and EU 2015/C95/02.

- Supply chain information
- Product quality self-assessment
- Audit report summary
- Stability data**

***Available for Emprove® Evolve™, Emprove® Essential and Emprove® Expert products only*

Emprove® Operational Excellence Dossier

Operational Excellence Dossier

Supports process optimization and safety risk assessment activities.

- Elemental impurities information
- Product quality report
- Analytical procedure
- Technically Unavoidable Particle Profile (if applicable)

Emprove® Suite Subscription

Unlock Full Access to all dossiers today with the Emprove® Suite Subscription

- 1, 2, or 5-year subscriptions
- 24/7 full online access
- Constantly updated
- Optimized searches

Millipore®
Preparation, Separation, Filtration & Testing Products

Emprove® Dossiers for filtration and single-use

Material Qualification Dossier

Supports product qualification and speeds up regulatory filing preparation. Includes content on the manufacturing process, product specifications and various qualification criteria (product validation data), regulatory statements, and more.

- General information
- Manufacturing flow chart
- Product validation and qualification
- Specifications (design and release criteria)
- Materials of construction
- Extractables summary**
- Regulatory statements (Animal origin, e.g. Animal Origin, BPA etc.)

Quality Management Dossier

Answers questions during quality risk assessment. Provides valuable information on how quality variability attributes are controlled.

- Quality Self-assessments
- Chain of custody
- Supplier and CMO management
- Shelf life testing and results
- Packaging and Sterilization Validation

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Unlock Full Access to all dossiers today with the Emprove® Suite Subscription

- 1, 2, or 5-year subscriptions
- 24/7 full online access
- Constantly updated
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Operational Excellence Dossier

Support process optimization and safety risk assessment with detailed extractables profile (BPOG extractables protocol and USP <665> draft chapters and information on elemental impurities (ICH Q3D)).

- Extractables Report**
- Elemental impurities summary
- Analytical procedure

SAFC®
Pharma & Biopharma Raw Material Solutions

Emprove® chemicals portfolio

Starting and Raw Materials

Emprove® Evolve

For early stage or (bio-)pharmaceutical manufacturing

Fills the gap between lab-grade and GMP compliant raw and starting materials. This product line provides detailed and transparent supply chain information and documentation to support risk assessments for critical raw materials used in manufacturing processes.

Emprove® Essential

Moderate Risk Applications

Designed for moderate risk applications, Emprove® Essential products offer compliance to IPEC PQG GMP Guide and/or EXiPACT™ Certification Standard, supply chain transparency and regulatory support designed to assist drug manufacturers' formalized risk assessments. They are produced according to controlled manufacturing processes. Critical parameters such as elemental impurities and residual solvents are characterized by using validated analytical techniques.

Emprove® Expert

High Risk Applications

Addresses higher risk applications where the lowest microbiological and endotoxin levels are of utmost importance. Along with the risk management features of Emprove® Essential, the Emprove® Expert line goes even further: The cGMP manufacturing processes are designed to yield products with specified low microbiological and endotoxin levels, thus supporting the overall risk mitigation strategy.

Emprove® API

Support Final Drug Product Compliance with International Standards

Manufactured in Europe to meet the quality and regulatory requirements of active pharmaceutical ingredients, according to ICH Q7 GMP. In order to support final drug product compliance with international standards, our Regulatory Affairs team offers dedicated support with access to extensive documentation including DMFs, CEP and ASMF.

BioReliance®
Pharma & Biopharma
Manufacturing &
Testing Services

BioReliance® Validation Services

Details to each test

Extractables evaluation*

Leachables testing

Patient safety evaluation*

Bacterial retention testing*

Integrity testing*
(Diffusion, Bubble Point, Rinsing)

Compatibility evaluation*

Binding studies

Particle shedding studies

*Validation Requirements for Regulatory Submissions

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Pharma & Biopharma
Manufacturing &
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(Diffusion, Bubble Point, Rinsing)

Compatibility evaluation*

Binding studies

Particle shedding studies

*Validation Requirements for Regulatory Submissions

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BioReliance® Validation Services - details

Extractables
Identify and quantify the extractables which may be extracted out from the filter by employing the Model Solvent Stream Approach and worst case test conditions.

Leachables
Identify and quantify the leachables which may be leached out from the filter with the use of your actual product under normal processing conditions.

Patient safety assessment
Assess the potential impact of the substances that have been detected, identified and quantified on patient safety.

Bacterial retention validation
Validate the performance of your sterilizing grade filter by simulating your product and process conditions. *B. diminuta* is used as the standard challenge microorganism.

Bubble point / diffusion determination
Provide a product-specific bubble point/diffusion value.

Compatibility study
Assess the chemical compatibility based on key characteristics and provide evidence that the process fluids and conditions do not adversely impact the structure of the filter device.

Binding study
Show the filter does not remove unacceptable amounts of stream compounds.

Particle shedding
Provide particle shedding data

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