



Flexel[®] Pre-Designed Solutions for Mixing

Intelligent, Powerful and Intuitive Mixing
for your cGMP Biomanufacturing

Simplifying Progress

SARTORIUS

Flexel® Mixer Pre-Designed Solutions

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Digital Selection Map

Please click on the box that matches your process need

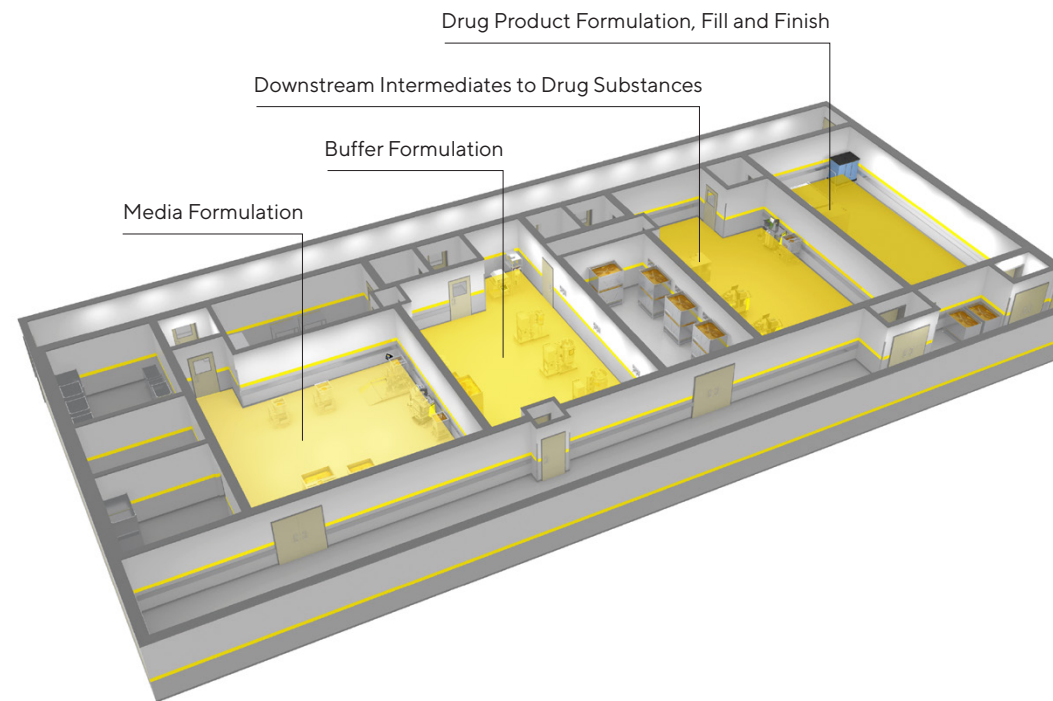


Flexel® Mixer Pre-Designed Solutions

Powerful, Intuitive and Intelligent Mixers from 50 L up to 3000 L

Building on 20 years of experience in designing single-use fluid management solutions, we have established Pre-designed Solutions (PDS) for all process steps where either powerful or low shear mixing performances are required.

Flexel® for Magnetic Mixer offers powerful mixing performances for media and buffer formulation. The strong vertical vortex combined with the baffle effect of the cubical design allows instant downward movement and efficient dissolution of floating powders such as media powders or diatomaceous earth powder used in dynamic body feed filtration applications. In addition, the impeller high torque offers efficient mixing of high concentration or viscous powders such as buffer powders. Flexel® for LevMixer® for downstream intermediates, drug substances and drug product offers low shear mixing performances for homogenization, viral inactivation and formulation of sensitive drug substances and drug products. The levitated impeller eliminates shear effects that can affect product quality and yield premature fouling of sterilizing grade filters by degrading sensitive proteins and generating particles and aggregates.



Media Formulation

Pre-designed Solutions for media formulation



Buffer Formulation

Pre-designed Solutions for buffer formulation



Downstream Intermediates

Pre-designed Solutions for downstream intermediates



Drug Substance Purification

Pre-designed Solutions for drug substance purification



Drug Product Formulation

Pre-designed Solutions for drug product formulation

When you select a Flexel® Mixer PDS, you get assurance of best mixing performance for every specific process step and robust change control with at least 24 months of change notification.

Flexel® Mixer Pre-Designed Solutions

Assurance of Supply for Fluid-Contact Components

Component quality and change control

Fluid-contact components used for Flexel® for Magnetic Mixer and Flexel® for LevMixer® PDS are secured by long term contracts and quality agreements to offer the best assurance of supply.

Our supply contracts and quality agreements ensure at least a 24-month change notification on fluid-contact components thus providing robust change control and business continuity.

Fluid-contact components are also available off-the-shelf to offer the best delivery ability.

Material qualification

Flexel® for Magnetic Mixer and Flexel® for LevMixer® PDS components are evaluated for conformity against the EP and USP standards after reviewing technical documentation and certificates of quality available from our suppliers. Additional internal qualification tests are performed to establish extractable profiles, post gamma sterilization shelf life and consistent functional properties.

Criteria for component selection	Reference
Biological safety (USP Class VI)	USP<87> & USP<88>
TSE-BSE questionnaire	Compliance with EMA/410/01 and E.P 5.2.8
Endotoxin	USP<85> or EP 2.6.14
Bioburden	ISO 11737
Sub-visible particulates	USP<788> or EP 2.9.19
Visible particulates	Internal reference
Others	Bisphenol A free, REACH compliance

Our core expertise in plastics and polymers enables the selection of the cleanest and most inert materials to minimize chemical interactions with biopharmaceutical fluids, and leachable substances.

Design qualification

Component designs are selected to maximize tubing engagement tensile strength and tightness. Test samples are visually inspected for absence of defect and tested for leak, burst pressure, traction and compression.

Using a Flexel® for Magnetic Mixer and Flexel® for LevMixer® Pre-designed Solution in all your process steps provide you with the best quality, change control, business continuity and delivery performances.

Flexel® for Magnetic Mixer and Flexel® for LevMixer® PDS

Components	Biocompatibility USP <87> or USP<88> Class VI	Endotoxin sub-visible particulates	TSE-BSE EMA/410/01 & REACH	Notification period time
Flexel® bags	Yes	Yes	Yes	24 months
Impellers	Yes	Yes	Yes	24 months
Top ports	Yes	Yes	Yes	24 months
TuFlux® tubes	Yes	Yes	Yes	24 months
Opta® sterile connectors	Yes	Yes	Yes	24 months
Fittings	Yes	Yes	Yes	24 months
Connectors	Yes	Yes	Yes	24 months
Sensors (conductivity, pH, thermowell)	Yes	Yes	Yes	24 months

Flexel® Mixer Pre-Designed Solutions

Validation and Quality Assurance

Flexel® for Magnetic Mixer and Flexel® for LevMixer® PDS are qualified against extensive biological, chemical, physical, extractable and functional testing. Sartorius Stedim Biotech Quality Systems for single-use products follow applicable ISO 9001 and ISO 13485 for Medical Devices. Design, manufacture, quality control and sterilization of PDS are conducted under conditions that mirror biopharmaceutical operations and meet cGMP like requirements to ensure they are supplied clean, pure, non-pyrogenic fluid path and sterile. PDS are validated and routinely controlled to provide consistent performance for:

Robustness

- Qualification of the bag manufacturing process capabilities following recommendations from standards (ASTM F-2097, ISO15747) and other publications (PDA,FDA-CBER)
- Internal standardized methods for connection tests and functional qualification in real process conditions
- ASTM D882, D1004, F392 for tensile properties, tear resistance and flex durability

Gas transmission (Film)

- ASTM F1927, F1249, F2476: Oxygen, Water Vapor Transmission Rate and Carbon Dioxide.

Biocompatibility and chemical compatibility

- USP<87> and ISO 10993-5: Biological reactivity tests, in Vitro
- USP<88>: Biological reactivity tests, in Vivo
- USP<661> and EP 3.1.5: Containers, physico-chemical tests – Plastics
- ASTM D543-06: resistance of plastic to chemical reagents

Purity, extractable and leachable

- Extractable data
- TSE/BSE: EMA/410/01 and EP 5.2.8

Cleanliness, particles and sterilization

- USP<788> and EP 2.9.19: Particulate Matter in Injections Endotoxin
- USP<85> and E.P. 2.6.14: Bacterial endotoxins Sterility
- ISO 11737 Sterilization of medical devices – Microbiological methods: Bioburden
- ISO 11137 Sterilization by irradiation of Medical Devices: Sterilization of Medical Devices
- ISO 14644: Cleanroom environmental controls
- Gamma radiation dose mapping

PDS for media, buffer, harvest & downstream intermediates and drug substance process steps are released on the basis of a weekly quality control for bioburden, sub-visible particulates and endotoxin performed on representative samples.

Media, Buffer, Downstream Intermediates & Drug substance

Weekly testing of bioburden, sub-visible particles and endotoxin on representative sample

Drug Product¹

Lot release testing of bioburden, sub-visible particles and endotoxin on actual product sample

¹ None of the PDS for Drug Product are yet released on the basis of a lot release testing

Certificate of Release

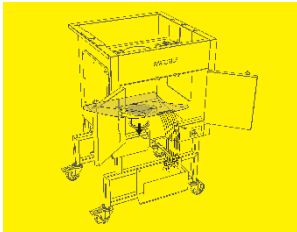
Statement	Monitoring*	100% Batch testing
USP Class VI USP<87> and ISO 10993-5: Biological reactivity tests, in Vitro USP<88>: Biological reactivity tests, in Vivo	Bioburden ISO 11737	Gamma radiation Dose
Physico-chemical testing USP<661> and EP 3.1.5	Endotoxin: USP<85> and E.P. 2.6.14	Visual inspection Film, bag, seal and packaging
	Sub-visible Particulates USP<788> and EP 2.9.19	Technical Drawing conformity Batch record review

* performed weekly on representative samples

Flexel® Mixer Pre-Designed Solutions

Universal and Intelligent Mixing Solutions

Universal



Front door and cubical shape for an easy bag installation



Front access to sensors and tubing for easy manipulation



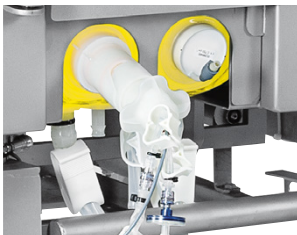
8 inches top opening for easy powder addition

Easy to Use and Intuitive for All Process Steps

The front door and the cubical shape provide convenient installation, deploying and folding of the bag during filling and draining. The front access to sensors and tubing lines facilitates the filling, sampling and draining manipulations. The large 8" diameter top port allows easy and contained powder transfer into the mixing bag. The sided windows allow for visual check of the mixing process.

Flexel® for Magnetic mixing provides powerful and fast powder dissolution for buffer and media process steps. Flexel® for LevMixer® offers low shear mixing for downstream intermediates, drug substance and drug product process steps.

Intelligent



Single-use pH probe and conductivity sensor



Weight control



Heat exchange jacket and temperature control

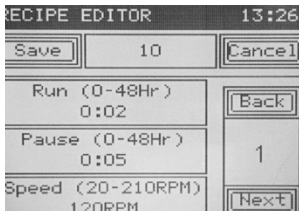
Intelligent Mixing for your cGMP Biomanufacturing

Intelligent Mixers are designed for monitoring and controlling all critical mixing parameters required for cGMP processes.

In-line control and monitoring of pH, conductivity and temperature are performed with pre-assembled single-use pH probe, conductivity sensor and thermowell. In-line sensors meet the PAT and cGMP requirements, eliminate the risk of contamination present with insertion of re-usable probes and reduce operator time.

Palletank for Intelligent Mixers are available with weighing functions and heat exchange jacket for integrated control of the volume and temperature.

The LevMixer® features an automated control of the mixing parameters by reading the real impeller speed, offering mixing recipes and password management.



LevMixer® Drive unit touchscreen

Flexel® Mixer Pre-Designed Solutions

Pre-designed Solutions for All Process Steps

Top lines

- pH adjustment lines with CPC Quick coupler or Opta® SFT female or when using drain valves on the bottom lines:
- top addition lines with CPC Quick coupler or Opta® SFT female
- and | or sampling line withclave needleless sampling port

Single-Use Sensors for in line measurement

- pH sensor with 2 calibration points
- Pre-calibrated conductivity sensor
- Thermowell for temperature measurement

Bottom Port

- Drain valve (2 lines possible)
- UPS 4 ports allowing 4 lines

Large 8" diameter Top Port

- Opened Top Port for powder transfer
- Closed Top Port for sterile or low bioburden application

Mixing Technology

- Magnetic Mixer for Buffer, Media, Harvest and Downstream Intermediates
- LevMixer® for Downstream Intermediates, Drug substance and Drug product

Bottom Lines

- Filling line with Tri-Clamp connector or Opta® SFT female
- Draining line with Tri-Clamp connector or Opta® SFT male
- Addition lines with CPC Quick coupler or Opta® SFT female
- Sampling line usingclave needleless sampling port

Inlet and Outlet Connectors

- Tri-Clamp 1½" sanitary flange are used for either sanitary connection or aseptic connection under ISO5 laminar air flow to stainless steel systems
- CPC quick couplers are used for either sanitary connection or aseptic connection under ISO5 laminar air flow to single-use systems
- Opta® SFT Female enables sterile connections to other single-use systems
- Clave needleless sampling port enables sterile sampling

Tubes

- TuFlux® silicone tubing enables safe and fast pumping
- Clear C-Flex® tubing allows for sterile weld connection with BioWelder® TC and sterile seal disconnection with BioSealer®

Sensors

Single-use pH sensor:

- Electrochemical pH electrode with integrated Pt-1000
- Pre-installed and pre-sterilized single-use pH sensor
- Large measurement range pH2 - pH11, 4 - 50°C
- High accuracy after 2 points calibration: pH2 - pH11: ±0.08
- Retractable probe: 3 activations (insertion-removal-insertion) validated with maintained sterility

Single-use conductivity sensor:

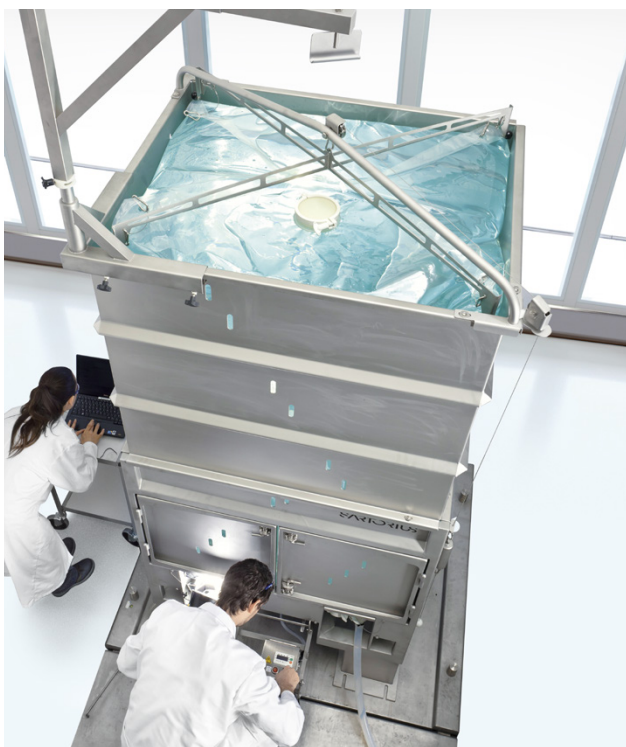
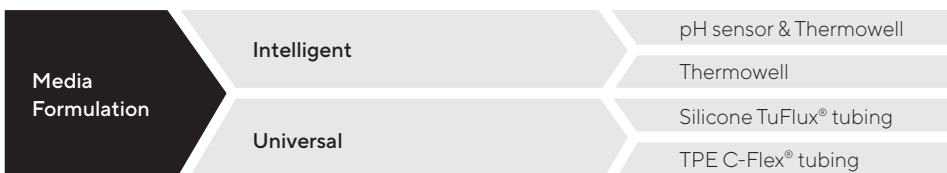
- Pre-installed and pre-sterilized single-use conductivity sensor
- Pre-calibrated single-use conductivity sensor and ready to use
- Large measurement range 100µS/cm up to 200 mS/cm
- Accuracy:
 - <100 mS/cm: 2%
 - 100 - 200 mS/cm: 5%

Thermowell:

- 3.2 mm ID for reusable temperature sensor insertion

Flexel® Mixer Pre-Designed Solutions for

Media Formulation



PDS for media formulation are designed with a bottom mounted Magnetic Mixer for easy, intuitive and rapid media powder dissolution.

An optimized media formulation process involves filling the mixer with water for injection (WFI) up to 60% to 80% of the final volume. WFI can be heated up with the heat exchange jacket to accelerate the dissolution. The mixing drive unit is started and the media powder or a concentrated liquid media is added during mixing.

Once the dissolution is complete, WFI is added to adjust to the final volume. Volume adjustment can be automatically performed using weighing control. Temperature and pH can be monitored and adjusted in-line. Process samples are taken off-line for other QC tests. When the formulation is complete, the media is filtered for sterilization and mycoplasma removal and stored before further transfer to the bioreactor.

Flexel® for Magnetic Mixer PDS for media are available in:

- Intelligent version using single-use and integrated sensors for in-line pH and temperature monitoring and adjustment required for your cGMP biomanufacture.
- Universal version using either reusable sensors via the 8" top opening for in-line controls or sampling in single-use bags for off-line controls.

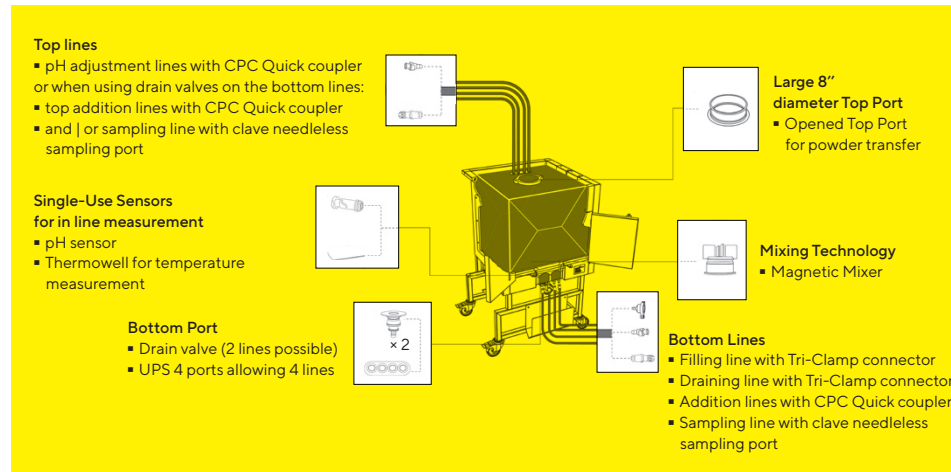
Filling and draining lines are available with Silicone TuFlux®, TPE C-Flex® tubing and Tri-Clamp 11" sanitary flange. Samples can be taken via an additional Silicone TuFlux® line equipped with a clave needleless sampling port.

The following options are also available:

- lines for other liquid additions with Silicone TuFlux® tubing and quick coupler connector
- drain valves to prevent powder accumulation in bottom tubing lines

Flexel® Mixer Pre-Designed Solutions for

Media Formulation

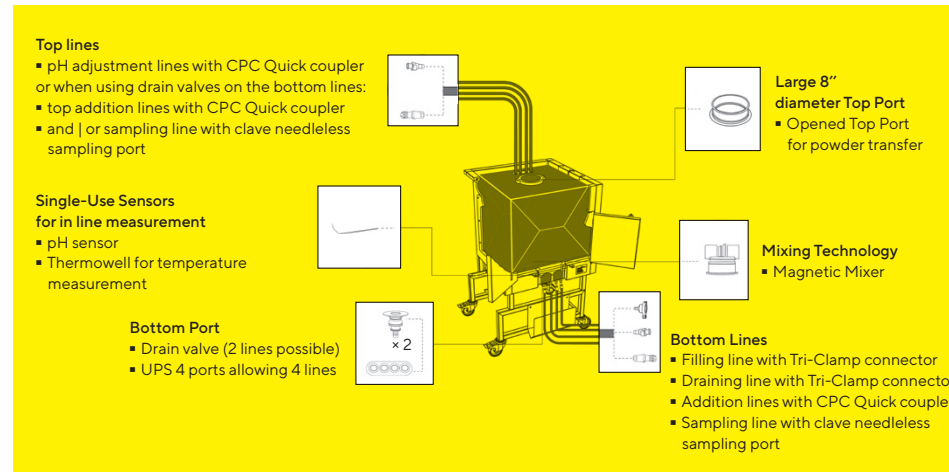


Intelligent Flexel® for Magnetic Mixer with pH Sensor & Thermowell

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB128161	2		½" ID Silicone TuFlux® 1.5 m (60")	½" ID Silicone TuFlux® 1.5 m (60")	¼" ID Silicone TuFlux® 0.1 m (4")	When a drain valve is used: 1 top line: ⅜" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4") + MPC female + sealing cap
100 L	FMB127650	2	■	+ ½" Tri-Clamp	+ ½" Tri-Clamp	+ Clavé needleless sampling port		
	FMB128162	2		1½" sanitary flange with gasket, cap & union	1½" sanitary flange with gasket, cap & union			
200 L	FMB127651	2	■					
	FMB128163	2						
400 L	FMB127652	2	■				When no drain valve is used: 1 bottom line addition: ⅜" ID Silicone TuFlux® 1.5 m (60") + MPC female + sealing cap	
	FMB128164	2						
650 L	FMB127653	1	■					
	FMB128165	1						
1,000 L	FMB127654	1	■					
	FMB128166	1						

Flexel® Mixer Pre-Designed Solutions for

Media Formulation

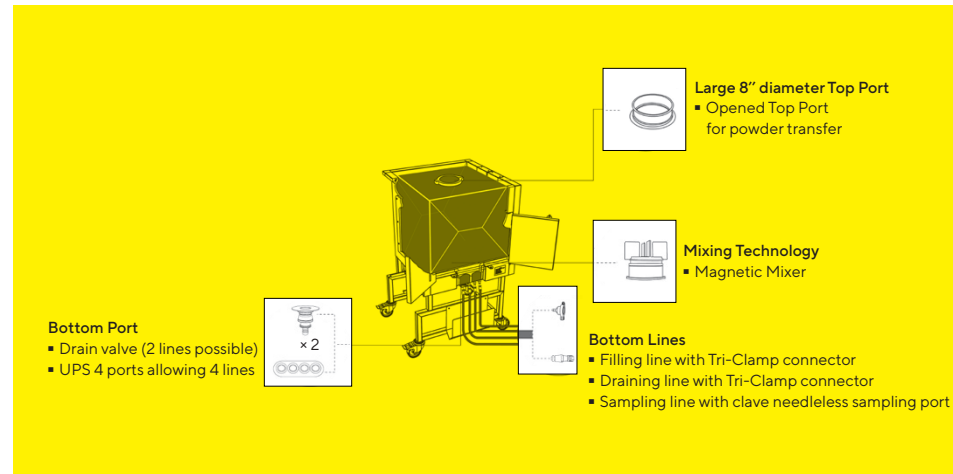
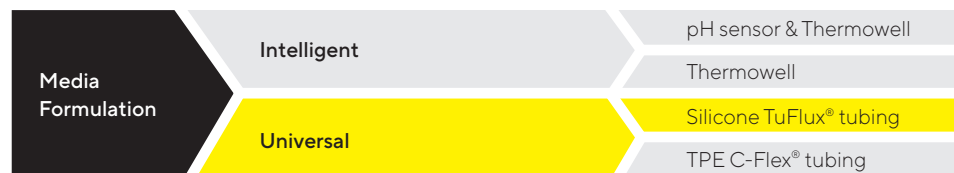


Intelligent Flexel® for Magnetic Mixer & Thermowell

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB127630	2	■	½" ID Silicone TuFlux® 1.5 m (60") +	½" ID Silicone TuFlux® 1.5 m (60") +	¼" ID Silicone TuFlux® 0.1 m (4") +	When a drain valve is used: 2 top lines: ¾" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4") + MPC female + sealing cap
	FMB128179	2						
100 L	FMB127631	2	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	When no drain valve is used: 1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") + MPC female + sealing cap	
	FMB128180	2						
200 L	FMB127632	2	■				When no drain valve is used: 1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") + MPC female + sealing cap	
	FMB128181	2						
400 L	FMB127633	2	■				When no drain valve is used: 1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") + MPC female + sealing cap	
	FMB128182	2						
650 L	FMB127634	1	■				When no drain valve is used: 1 top line: ¾" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	
	FMB128183	2						
1,000 L	FMB127635	1	■				When no drain valve is used: 1 top line: ¾" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	
	FMB128184	2						
1,500 L	FMB128175	1		¾" ID Silicone TuFlux® 3 m (119") +	¾" ID Silicone TuFlux® 3 m (119") +	¼" ID Silicone TuFlux® 0.5 m (20") +	1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") +	
2,000 L	FMB128176	1		¾" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¾" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	¾" Tri-Clamp 1½" sanitary flange with gasket, cap & union	

Flexel® Mixer Pre-Designed Solutions for

Media Formulation

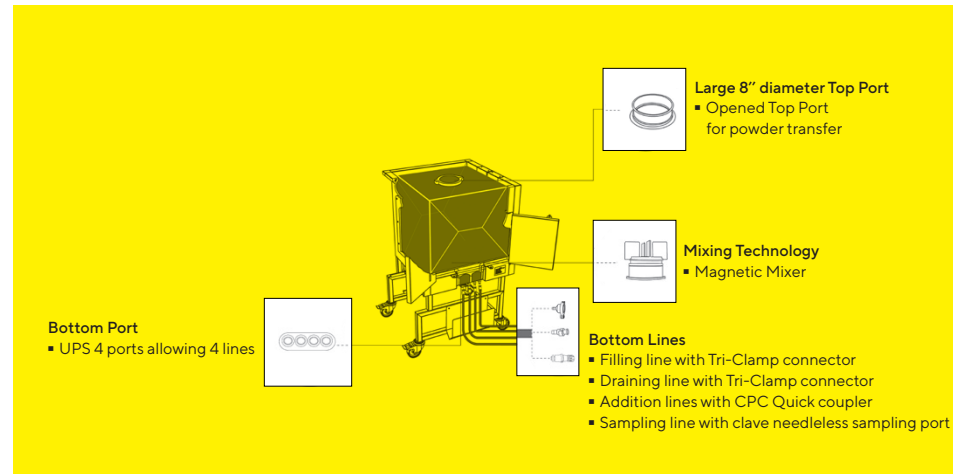
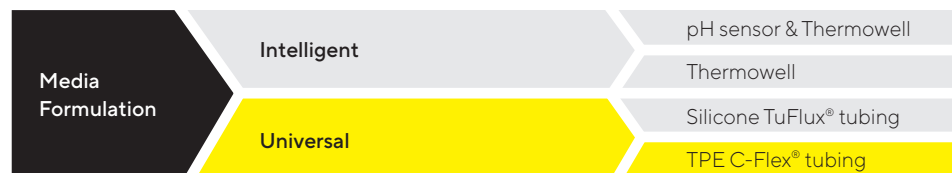


Intelligent Flexel® for Magnetic Mixer with Silicone TuFlux® Tubing

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB127637	2	■	½" ID Silicone TuFlux® 1.5 m (60") + ½" Tri-Clamp	½" ID Silicone TuFlux® 1.5 m (60") + ½" Tri-Clamp	¼" ID Silicone TuFlux® 0.1 m (4") + Clave needleless sampling port	NA	NA
	FMB127643	2	■					
100 L	FMB127638	2	■	1½" sanitary flange with gasket, cap & union	1½" sanitary flange with gasket, cap & union			
	FMB127644	2	■					
200 L	FMB127639	2	■					
	FMB127645	2	■					
400 L	FMB127640	2	■					
	FMB127646	2	■					
650 L	FMB127641	1	■					
	FMB127647	2	■					
1,000 L	FMB127642	1	■					
	FMB127648	2	■					

Flexel® Mixer Pre-Designed Solutions for

Media Formulation

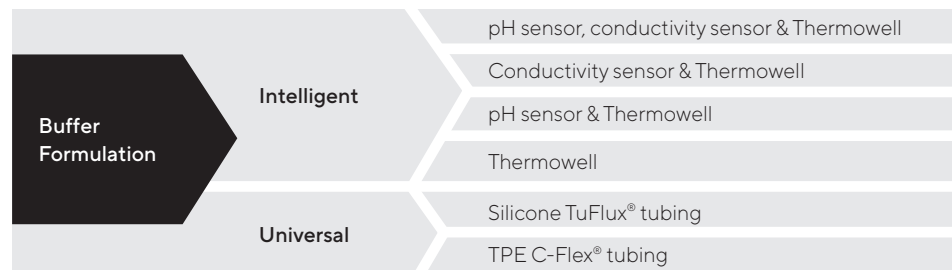


Intelligent Flexel® for Magnetic Mixer with Silicone TuFlux® Tubing

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB114867	2	NA	½" ID Silicone (Dow Corning) 1 m (40")	½" ID Silicone (Dow Corning) 1 m (40")	¼" ID Silicone (Dow Corning) 0.15 m (6")	1 bottom line: ½" ID Silicone (Dow Corning) 1 m (40")	NA
100 L	FMB114870	2		½" ID Silicone (Dow Corning) 1 m (40")	½" ID Silicone (Dow Corning) 1 m (40")	¼" ID Silicone (Dow Corning) 0.15 m (6")	1 bottom line: ½" ID Silicone (Dow Corning) 1 m (40")	
200 L	FMB114893	2		½" ID Silicone (Dow Corning) 1 m (40")	½" ID Silicone (Dow Corning) 1 m (40")	¼" ID Silicone (Dow Corning) 0.15 m (6")	1 bottom line: ½" ID Silicone (Dow Corning) 1 m (40")	
400 L	FMB114894	2		½" ID Clear C-Flex® 0.5 m (20")	½" ID Clear C-Flex® 0.5 m (20")	⅛" ID Clear C-Flex® 0.5 m (20")	½" ID Clear C-Flex® 0.5 m (20")	
650 L	FMB114895	2		½" ID Clear C-Flex® 0.5 m (20") + ½" Tri-Clamp	½" ID Clear C-Flex® 0.5 m (20") + ½" Tri-Clamp	⅛" ID Clear C-Flex® 0.5 m (20") + Clave needleless sampling port	½" ID Clear C-Flex® 0.5 m (20") + MPX male + sealing cap	
1,000 L	FMB114896	2		½" ID Clear C-Flex® 0.5 m (20") + 1½" sanitary flange	½" ID Clear C-Flex® 0.5 m (20") + 1½" sanitary flange	⅛" ID Clear C-Flex® 0.5 m (20") + Clave needleless sampling port	½" ID Clear C-Flex® 0.5 m (20") + MPX male + sealing cap	

Flexel® Mixer Pre-Designed Solutions for

Buffer Formulation



PDS for buffer formulation are designed with a bottom mounted Magnetic Mixer impeller for easy, intuitive and rapid buffer powder dissolution. An optimized buffer formulation process involves filling the mixer with water for injection (WFI) up to 60% to 80% of the final volume. WFI can be heated up with the heat exchange jacket to accelerate the dissolution. The mixing drive unit is started and the buffer powder or a concentrated liquid buffer is added during mixing.

Once the dissolution is complete, WFI is added to adjust to the final volume. Volume adjustment can be automatically performed using weighing control. Temperature, conductivity, and pH can be monitored and adjusted in-line. Process samples are taken off-line for other QC tests.

When the formulation is complete, the buffer is sterile filtered and stored before further use for drug substance purification or final drug product formulation. Flexel® for Magnetic Mixer PDS for buffer are available in:

- Intelligent version using single-use and integrated sensors for in-line pH, conductivity and temperature monitoring and adjustment required for your cGMP biomanufacture
- Universal version using either reusable sensors via the 8" top opening for in-line controls or sampling in single-use bags for off-line controls

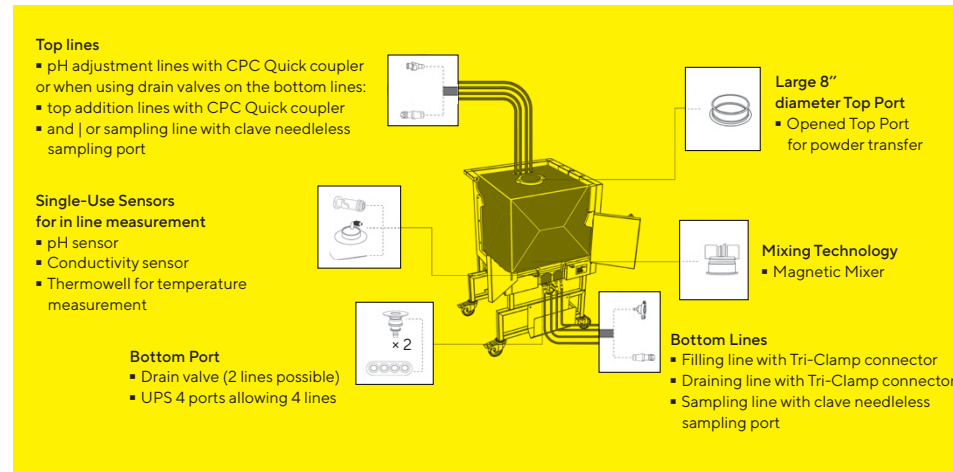
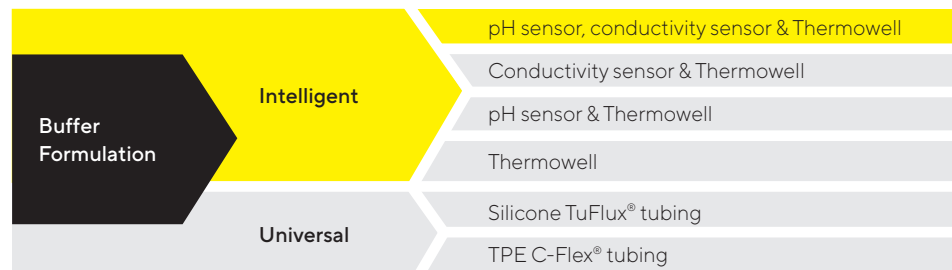
Filling and draining lines are available with Silicone TuFlux®, TPE C-Flex® tubing and Tri-Clamp 11" sanitary flange. Samples can be taken via Silicone TuFlux® line equipped with aclave needleless sampling port.

The following options are also available:

- lines for liquid additions with Silicone TuFlux® tubing and quick coupler connector
- drain valves to prevent powder accumulation in bottom mounted tubing

Flexel® Mixer Pre-Designed Solutions for

Buffer Formulation

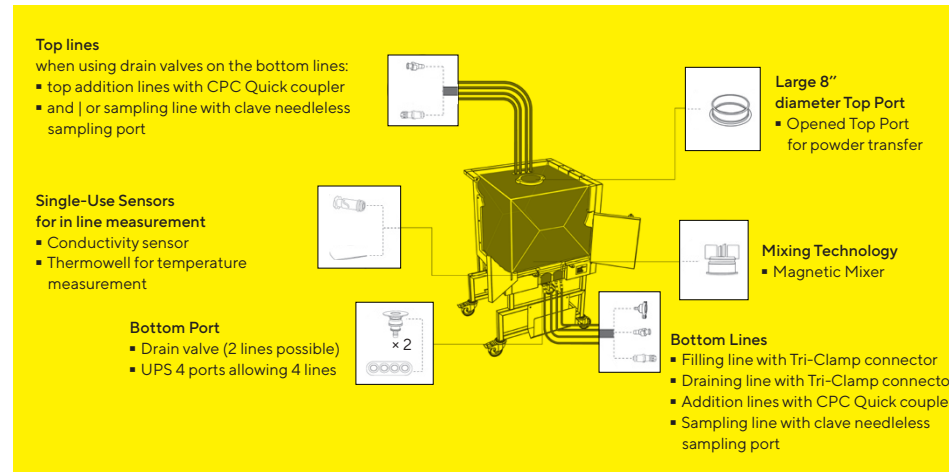
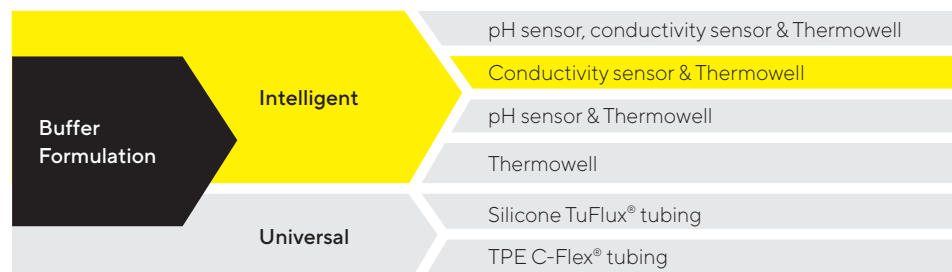


Intelligent Flexel® for Magnetic Mixer with pH sensor, conductivity sensor & Thermowell

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB128518	2		½" ID Silicone TuFlux® 1.5 m (60")	½" ID Silicone TuFlux® 1.5 m (60")	¼" ID Silicone TuFlux® 0.1 m (4")	When a drain valve is used: 2 top lines: ¾" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4") + MPC female + sealing cap
100 L	FMB128513	2	■	+ ½" Tri-Clamp	+ ½" Tri-Clamp	+ Clave needleless sampling port		
	FMB128519	2		1½" sanitary flange with gasket, cap & union	1½" sanitary flange with gasket, cap & union			
200 L	FMB128514	2	■				When no drain valve is used: No addition line	
	FMB128520	2						
400 L	FMB128515	2	■					
	FMB128521	2						
650 L	FMB128516	1	■					
	FMB128522	1						
1,000 L	FMB128517	1	■					
	FMB128523	1						

Flexel® Mixer Pre-Designed Solutions for

Buffer Formulation

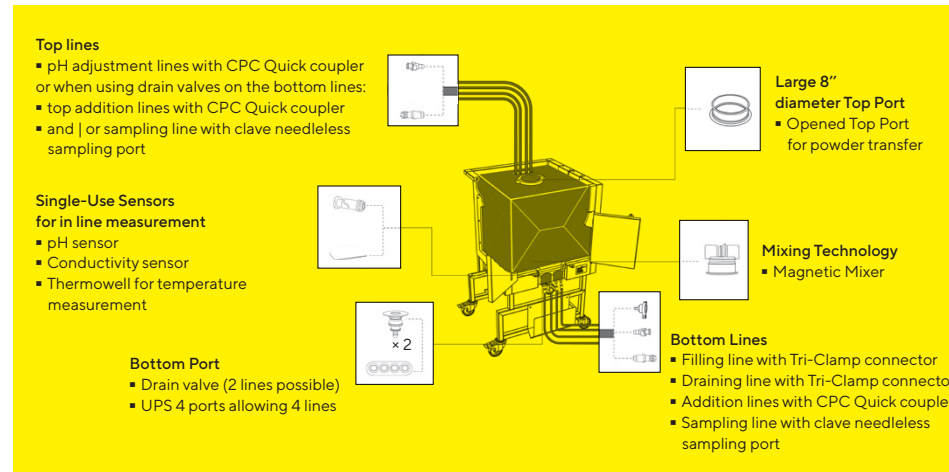
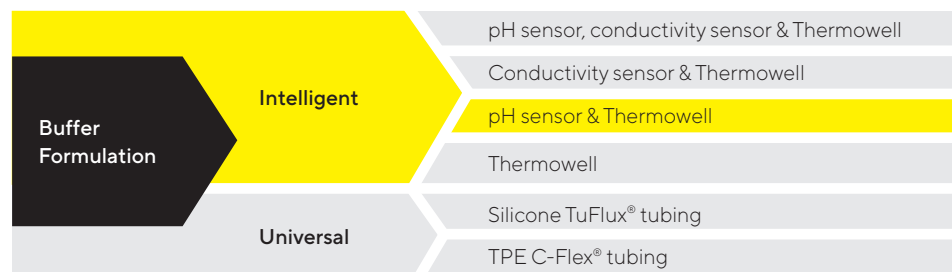


Intelligent Flexel® for Magnetic Mixer with conductivity sensor & Thermowell

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB128190	2		½" ID Silicone TuFlux® 1.5 m (60")	½" ID Silicone TuFlux® 1.5 m (60")	¼" ID Silicone TuFlux® 0.1 m (4")	When a drain valve is used: 1 top line: ⅜" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	NA
100 L	FMB128185	2	■	+ ½" Tri-Clamp	+ ½" Tri-Clamp	+ Clave needleless sampling port		
	FMB128191	2		1½" sanitary flange with gasket, cap & union	1½" sanitary flange with gasket, cap & union			
200 L	FMB128186	2	■					
	FMB128192	2						
400 L	FMB128187	2	■					
	FMB128193	2						
650 L	FMB128188	1	■					
	FMB128194	1						
1,000 L	FMB128189	1	■					
	FMB128195	1						

Flexel® Mixer Pre-Designed Solutions for

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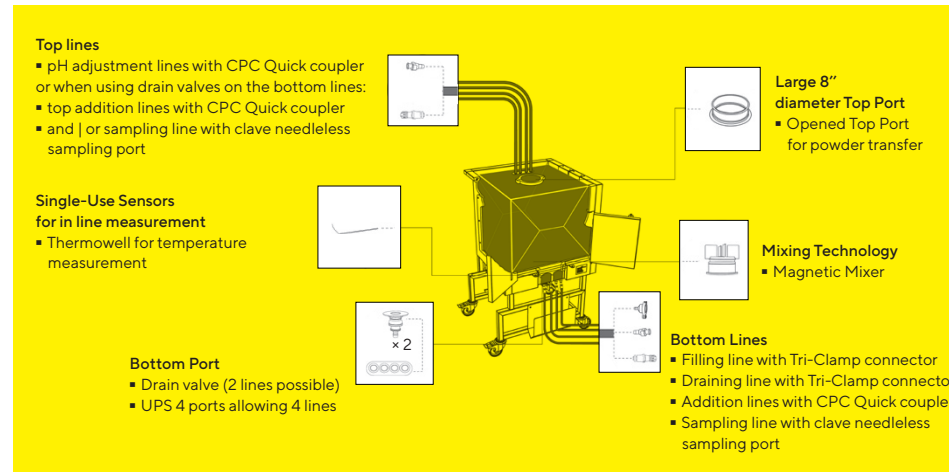
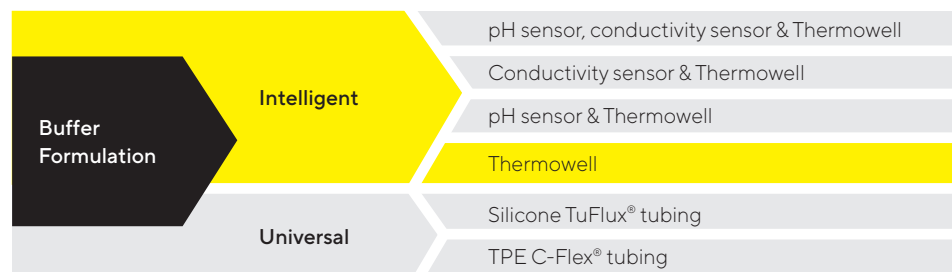


Intelligent Flexel® for Magnetic Mixer with pH sensor & Thermowell

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB128161	2		½" ID Silicone TuFlux® 1.5 m (60")	½" ID Silicone TuFlux® 1.5 m (60")	¼" ID Silicone TuFlux® 0.1 m (4")	When a drain valve is used: 1 top line: ⅜" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4") + MPC female + sealing cap
100 L	FMB127650	2	■	+ ½" Tri-Clamp	+ ½" Tri-Clamp	+ Clavette needleless sampling port		
	FMB128162	2		1½" sanitary flange with gasket, cap & union	1½" sanitary flange with gasket, cap & union			
200 L	FMB127651	2	■					
	FMB128163	2						
400 L	FMB127652	2	■					
	FMB128164	2						
650 L	FMB127653	1	■					
	FMB128165	1						
1,000 L	FMB127654	1	■					
	FMB128166	1						

Flexel® Mixer Pre-Designed Solutions for

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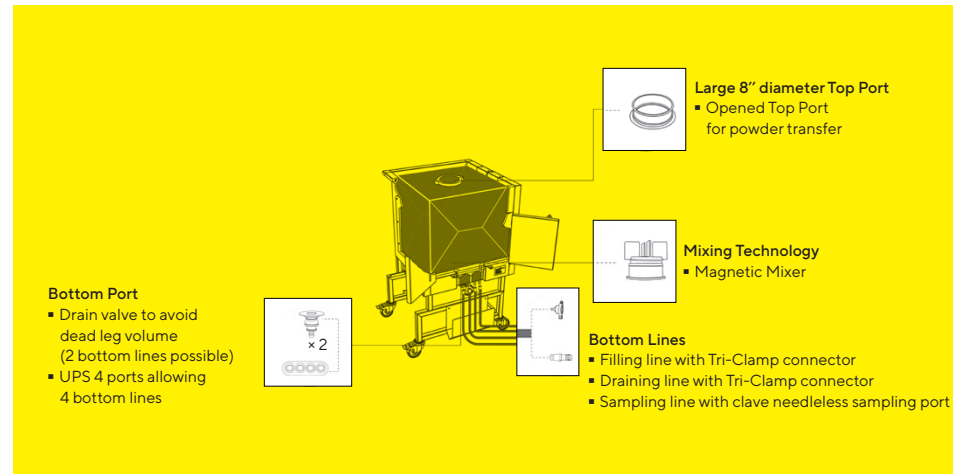
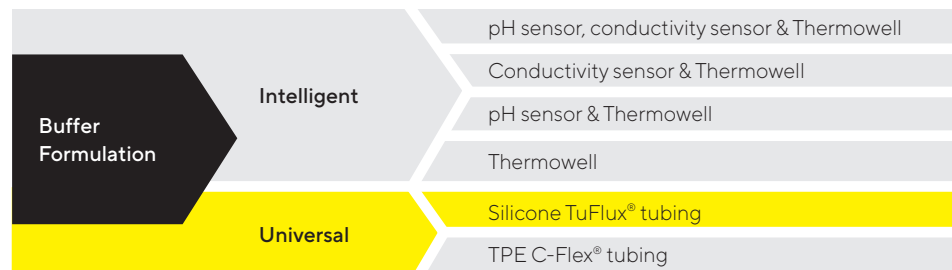


Intelligent Flexel® for Magnetic Mixer with Thermowell

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB127630	2	■	½" ID Silicone TuFlux® 1.5 m (60") + ½" Tri-Clamp	½" ID Silicone TuFlux® 1.5 m (60") + ½" Tri-Clamp	¼" ID Silicone TuFlux® 0.1 m (4") + Clave needleless sampling port	When a drain valve is used: 2 top lines: ¾" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4") + MPC female + sealing cap
	FMB128179	2	1½" sanitary flange with gasket, cap & union					
100 L	FMB127631	2	■	½" Tri-Clamp	½" Tri-Clamp	Clave needleless sampling port	When no drain valve is used: 1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") + MPC female + sealing cap	MPC female + sealing cap
	FMB128180	2	1½" sanitary flange with gasket, cap & union					
200 L	FMB127632	2	■	½" Tri-Clamp	½" Tri-Clamp	Clave needleless sampling port	When no drain valve is used: 1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") + MPC female + sealing cap	MPC female + sealing cap
	FMB128181	2	1½" sanitary flange with gasket, cap & union					
400 L	FMB127633	2	■	½" Tri-Clamp	½" Tri-Clamp	Clave needleless sampling port	When no drain valve is used: 1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") + MPC female + sealing cap	MPC female + sealing cap
	FMB128182	2	1½" sanitary flange with gasket, cap & union					
650 L	FMB127634	1	■	¾" ID Silicone TuFlux® 3 m (119") + ¾" Tri-Clamp	¾" ID Silicone TuFlux® 3 m (119") + ¾" Tri-Clamp	¼" ID Silicone TuFlux® 0.5 m (20") + Clave needleless sampling port	When no drain valve is used: 1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") + ¾" Tri-Clamp	MPC female + sealing cap
	FMB128183	2	1½" sanitary flange with gasket, cap & union					
1,000 L	FMB127635	1	■	¾" ID Silicone TuFlux® 3 m (119") + ¾" Tri-Clamp	¾" ID Silicone TuFlux® 3 m (119") + ¾" Tri-Clamp	¼" ID Silicone TuFlux® 0.5 m (20") + Clave needleless sampling port	When no drain valve is used: 1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") + ¾" Tri-Clamp	MPC female + sealing cap
	FMB128184	2	1½" sanitary flange with gasket, cap & union					
1,500 L	FMB128175	1		¾" ID Silicone TuFlux® 3 m (119") + ¾" Tri-Clamp	¾" ID Silicone TuFlux® 3 m (119") + ¾" Tri-Clamp	¼" ID Silicone TuFlux® 0.5 m (20") + Clave needleless sampling port	1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") + ¾" Tri-Clamp	1½" sanitary flange with gasket, cap & union
2,000 L	FMB128176	1		¾" ID Silicone TuFlux® 3 m (119") + ¾" Tri-Clamp	¾" ID Silicone TuFlux® 3 m (119") + ¾" Tri-Clamp	¼" ID Silicone TuFlux® 0.5 m (20") + Clave needleless sampling port	1 bottom line: ¾" ID Silicone TuFlux® 1.5 m (60") + ¾" Tri-Clamp	1½" sanitary flange with gasket, cap & union

Flexel® Mixer Pre-Designed Solutions for

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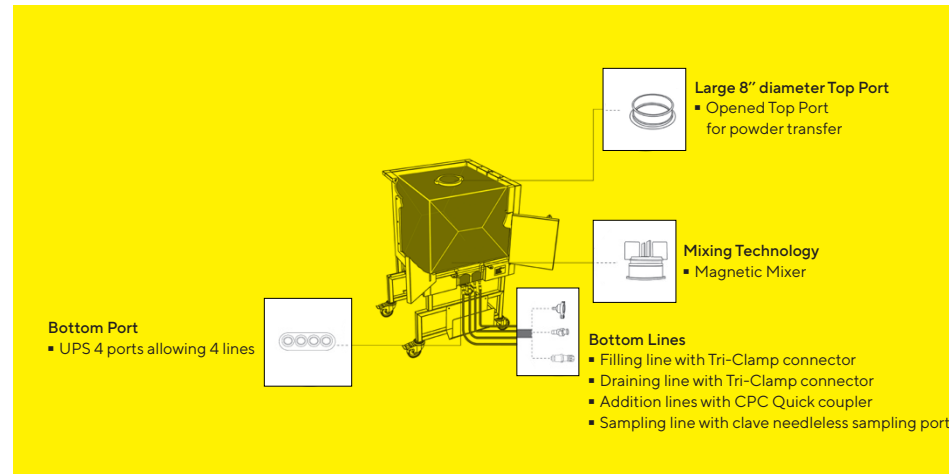
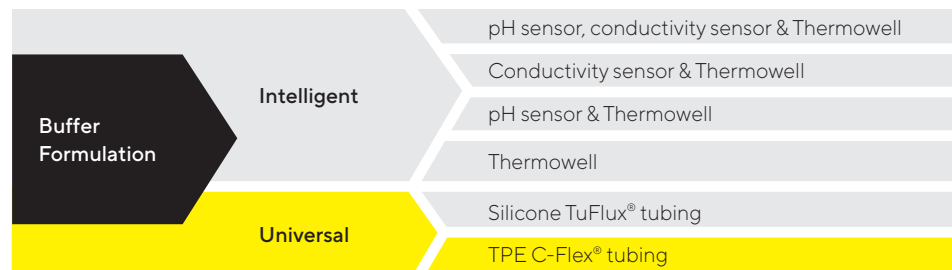


Universal Flexel® for Magnetic Mixer with Silicone TuFlux® Tubing

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment																																																						
50 L	FMB127637	2	■	½" ID Silicone TuFlux® 1.5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" ID Silicone TuFlux® 1.5 m (60") + ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	¼" ID Silicone TuFlux® 0.1 m (4") + Clave needleless sampling port	NA	NA																																																						
	FMB127643	2							100 L	FMB127638	2	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127644	2		200 L	FMB127639	2	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127645	2		400 L	FMB127640	2	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127646	2		650 L	FMB127641	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127647	2		1,000 L	FMB127642	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union
100 L	FMB127638	2	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA																																																						
	FMB127644	2							200 L	FMB127639	2	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127645	2		400 L	FMB127640	2	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127646	2		650 L	FMB127641	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127647	2		1,000 L	FMB127642	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127648	2							
200 L	FMB127639	2	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA																																																						
	FMB127645	2							400 L	FMB127640	2	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127646	2		650 L	FMB127641	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127647	2		1,000 L	FMB127642	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127648	2																			
400 L	FMB127640	2	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA																																																						
	FMB127646	2							650 L	FMB127641	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127647	2		1,000 L	FMB127642	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127648	2																															
650 L	FMB127641	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA																																																						
	FMB127647	2							1,000 L	FMB127642	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA	FMB127648	2																																											
1,000 L	FMB127642	1	■	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	Clave needleless sampling port	NA	NA																																																						
	FMB127648	2																																																												

Flexel® Mixer Pre-Designed Solutions for

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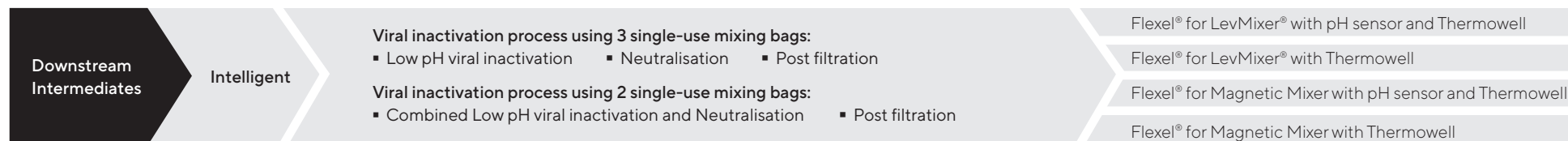


Universal Flexel® for Magnetic Mixer with C-Flex® TPE Tubing

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB114867	2	NA	½" ID Silicone (Dow Corning) 1 m (40")	½" ID Silicone (Dow Corning) 1 m (40")	¼" ID Silicone (Dow Corning) 0.15 m (6")	1 bottom line: ½" ID Silicone (Dow Corning) 1 m (40") +	NA
100 L	FMB114870	2		½" ID Clear C-Flex® 0.5 m (20")	½" ID Clear C-Flex® 0.5 m (20")	½" ID Clear C-Flex® 0.5 m (20")	½" ID Clear C-Flex® 0.5 m (20")	
200 L	FMB114893	2		+ ½" ID Clear C-Flex® 0.5 m (20")	+ ½" ID Clear C-Flex® 0.5 m (20")	+ ½" ID Clear C-Flex® 0.5 m (20")	+ ½" ID Clear C-Flex® 0.5 m (20")	
400 L	FMB114894	2		+ ½" Tri-Clamp 1½" sanitary flange	+ ½" Tri-Clamp 1½" sanitary flange	+ Clave needleless sampling port	+ MPX male + sealing cap	
650 L	FMB114895	2						
1,000 L	FMB114896	2						

Flexel® Mixer Pre-Designed Solutions for

Downstream Intermediates



PDS are designed for safe and reliable viral inactivation process steps. They include both Flexel® for LevMixer® and Magnetic Mixer options and are available with integrated single-use sensors. Low pH viral inactivation of downstream process intermediates consists of 3 steps: The pH of the downstream intermediate is first reduced and maintained at low pH for a validated period of time, usually at pH 3 – 4 for an hour, until the virus is totally inactivated. The low pH inactivation is followed by a neutralisation step where the pH is increased, usually up to pH 7 – 8 and a final filtration.

All three steps require mixing for inactivation, neutralization and homogenization.

To ensure that the entire content of the first mixer is inactivated, including droplets on the mixer wall or dead volume inside tubing, some processes are operated using 3 single-use mixing bags:

- 1 for low pH viral inactivation
- 1 for neutralisation
- 1 for homogenization of the filtered drug substance.

Some processes are operated with two single-use mixing bags by combining the 2 mixers for low pH inactivation and neutralisation in one mixer.

PDS for Low pH virus inactivation and neutralisation are designed with:

- Fully closed 8" diameter top port for a safe mixing
- Integrated single-use pH sensor and thermowell for in-line monitoring and control of the inactivation process
- Top lines with silicone TuFlux® tubing and quick coupler connector for pH adjustment
- Bottom lines with silicone TuFlux® tubing and Tri-Clamp 11" sanitary flange for filling and draining
- Bottom lines with silicone TuFlux® tubing and clave needleless port for sterile sampling

The following options are also available:

- lines for other liquid additions with Silicone
- TuFlux® tubing and quick coupler connector
- drain valves to avoid hold up volumes into the tubes.

PDS for post filtration are designed with:

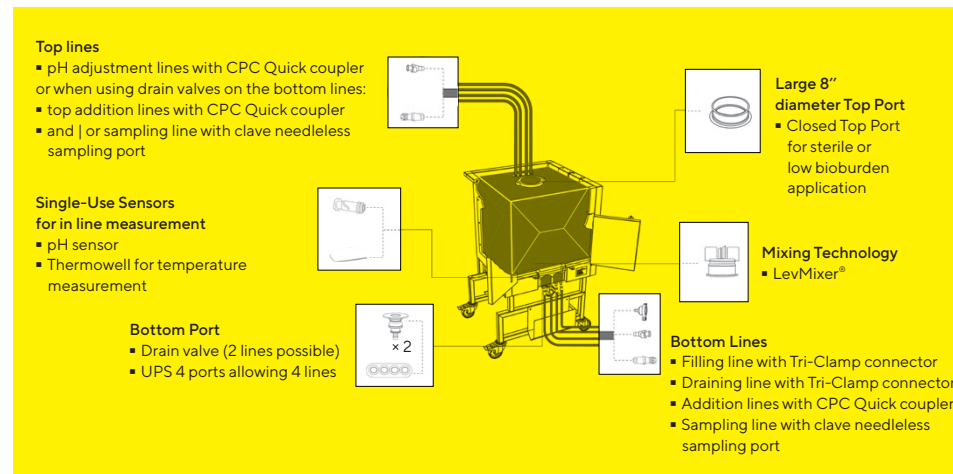
- Integrated thermowell for temperature monitoring and control
- A combined Silicone TuFlux® + C-Flex® tubing ended by an Opta® SFT female to allow sterile connection and disconnection of the adequate filter line
- A combined Silicone TuFlux® + C-Flex® tubing ended by a Tri-Clamp 1 ½" sanitary flange for draining
- Bottom line with silicone TuFlux® tubing and clave needleless port for sterile sampling
- Bottom line with Silicone TuFlux® tubing and quick coupler connector for liquid additions

Flexel® for LevMixer® is the preferred mixing technology for all downstream process intermediate purification steps due to its low shear.

PDS are also available with the Magnetic Mixer technology for those intermediates substance processes that are not sensitive to shear effects.

Flexel® Mixer Pre-Designed Solutions for

Downstream Intermediates

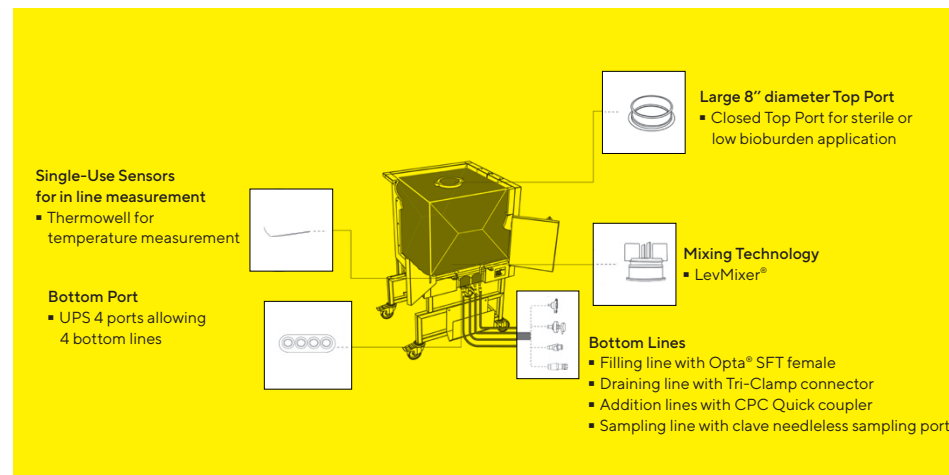
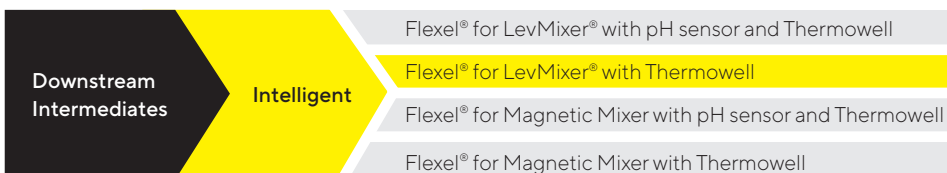


Flexel® for LevMixer® with with pH sensor and Thermowell for Low pH viral inactivation and Neutralisation

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB127411	2		½" ID Silicone	½" ID Silicone	¼" ID Silicone	When a drain valve is used: 1 top line: ⅜" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4") + MPC female + sealing cap
100 L	FMB127448	2	■	TuFlux® 1.5 m (60") +	TuFlux® 1.5 m (60") +	Clave needleless sampling port		
	FMB127412	2		½" Tri-Clamp	½" Tri-Clamp			
200 L	FMB127449	2	■	1½" sanitary flange with gasket, cap & union	1½" sanitary flange with gasket, cap & union		When no drain valve is used: 1 bottom line: ⅜" ID Silicone TuFlux® 1.5 m (60") + MPC female + sealing cap	
	FMB127413	2						
400 L	FMB127450	2	■					
	FMB127414	2						
650 L	FMB127451	1	■					
	FMB127415	1						
1,000 L	FMB127452	1	■					
	FMB127416	1						

Flexel® Mixer Pre-Designed Solutions for

Downstream Intermediates

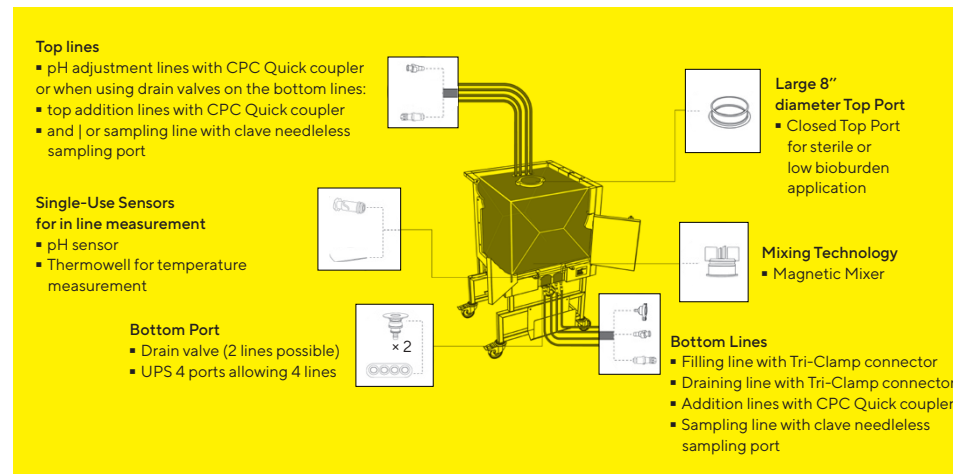
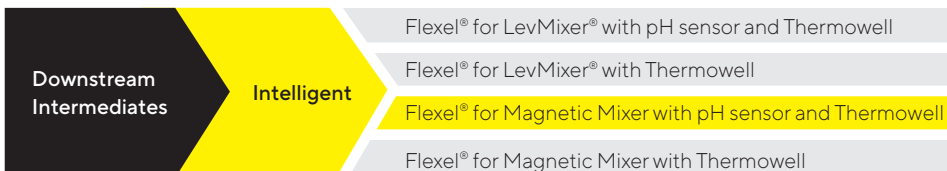


Flexel® for LevMixer® with Thermowell for Post Filtration

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB127482	2	NA	½" ID Silicone TuFlux® 1 m (40")	½" ID Silicone TuFlux® 1 m (40")	¼" ID Silicone TuFlux® 0.1 m (4")	1 bottom line:	NA
100 L	FMB127483	2		+ ½" ID Clear C-Flex® 0.5 m (20")	+ ½" ID Clear C-Flex® 0.5 m (20")	+ Clave needleless sampling port	¾" ID Silicone TuFlux® 1.5 m (60")	
200 L	FMB127484	2		+ ½" Opta® SFT female	+ ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union		MPC female + sealing cap	
400 L	FMB127485	2						
650 L	FMB127486	2						
1,000 L	FMB127487	2						

Flexel® Mixer Pre-Designed Solutions for

Downstream Intermediates

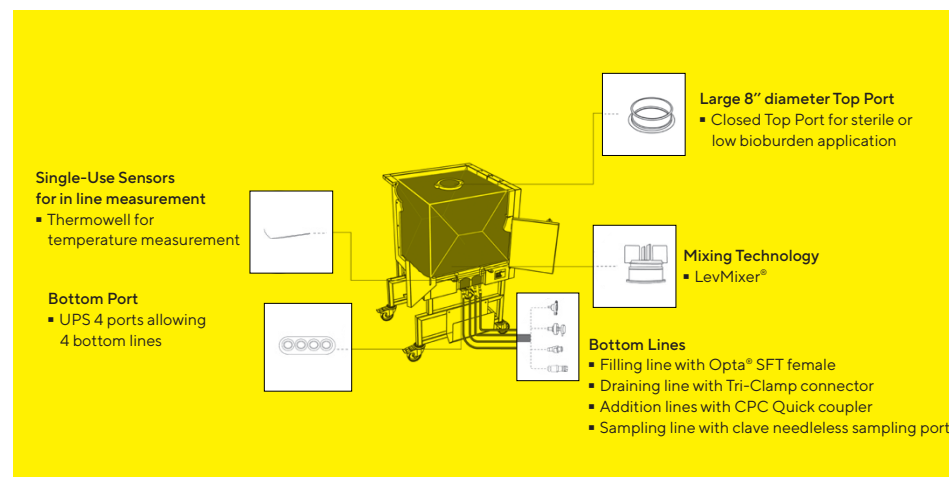


Flexel® for Magnetic Mixer with pH sensor and Thermowell for Low pH viral inactivation and Neutralisation

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB127429	2		½" ID Silicone	½" ID Silicone	¼" ID Silicone	When a drain valve is used: 1 top line: ⅜" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4") + MPC female + sealing cap
100 L	FMB127457	2	■	TuFlux® 1.5 m (60") +	TuFlux® 1.5 m (60") +	Clave needleless sampling port		
	FMB127430	2		½" Tri-Clamp	½" Tri-Clamp			
200 L	FMB127458	2	■	1½" sanitary flange with gasket, cap & union	1½" sanitary flange with gasket, cap & union			
	FMB127431	2						
400 L	FMB127459	2	■				When no drain valve is used: 1 bottom line: ⅜" ID Silicone TuFlux® 1.5 m (60") + MPC female + sealing cap	
	FMB127432	2						
650 L	FMB127460	1	■					
	FMB127433	1						
1,000 L	FMB127461	1	■					
	FMB127434	1						

Flexel® Mixer Pre-Designed Solutions for

Downstream Intermediates



Flexel® for LevMixer® with Thermowell for Post Filtration

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB127611	2	NA	½" ID Silicone TuFlux® 1 m (40")	½" ID Silicone TuFlux® 1 m (40")	¼" ID Silicone TuFlux® 0.1 m (4")	1 bottom line:	NA
100 L	FMB127612	2		+ ½" ID Clear C-Flex® 0.5 m (20")	+ ½" ID Clear C-Flex® 0.5 m (20")	+ Clave needleless sampling port	¾" ID Silicone TuFlux® 1.5 m (60")	
200 L	FMB127613	2		+ ½" Opta® SFT female	+ ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union		MPC female + sealing cap	
400 L	FMB127614	2						
650 L	FMB127615	2						
1,000 L	FMB127616	2						

Flexel® Mixer Pre-Designed Solutions for

Drug Substance Purification



PDS are designed for safe and reliable mixing during drug substance purification steps. They feature the Flexel® for LevMixer® low shear homogenization and integrated single-use pH sensor and thermowell for in-line monitoring and control. Process samples are taken off-line for other QC tests such as product quality attributes and bioburden prior to sterile filtration.

The Opta® SFT connector or the BioWelder® TC are used for respectively sterile connection or sterile weld.

Tri-Clamp or quick coupler connectors are used for aseptic connections under ISO laminar air flow.

Sterile disconnection is done using the BioSealer®.

PDS for mixing during drug substance purification are designed for

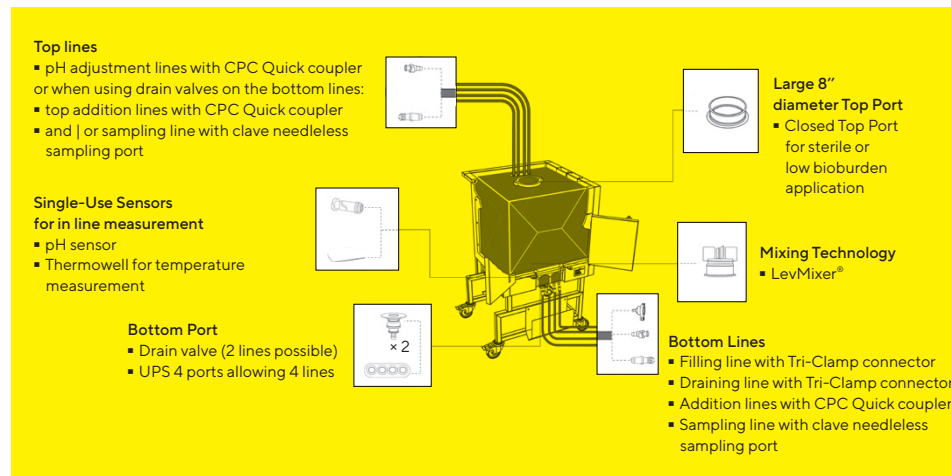
- Aseptic filling and draining operations under ISO laminar air flow: bottom lines with silicone TuFlux® tubing and Tri-Clamp 1 ½" sanitary flange
- Sterile filling and draining operations: bottom filling line with a combined Silicone TuFlux® + C-Flex® tubing ended by an Opta® SFT female; bottom draining line with a combined Silicone TuFlux® + C-Flex® tubing ended by a Tri-Clamp 1 ½" sanitary flange
- Integrated single-use pH sensor and | or thermowell for in-line monitoring and control
- Top lines with silicone TuFlux® tubing and quick coupler connector for pH adjustment
- Bottom line with silicone TuFlux® tubing andclave needleless port for sterile sampling
- Bottom or top line with Silicone TuFlux® tubing and quick coupler connector for liquid additions
- Fully closed 8" diameter top port for a safe mixing

Options with drain valves to avoid hold up volumes into the tubes are also available.



Flexel® Mixer Pre-Designed Solutions for

Drug Substance Purification

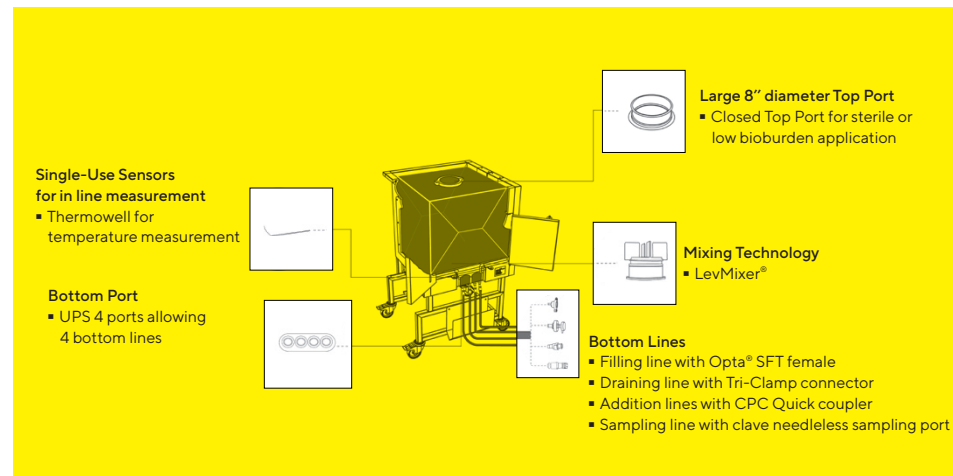


Flexel® for LevMixer® with pH sensor and Thermowell

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB127411	2		½" ID Silicone	½" ID Silicone	¼" ID Silicone	When a drain valve is used: 1 top line: ⅜" ID Silicone TuFlux® 0.15 m (6") + MPC female + sealing cap	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4") + MPC female + sealing cap
100 L	FMB127448	2	■	TuFlux® 1.5 m (60") +	TuFlux® 1.5 m (60") +	Clave needleless sampling port		
	FMB127412	2		½" Tri-Clamp	½" Tri-Clamp			
200 L	FMB127449	2	■	1½" sanitary flange with gasket, cap & union	1½" sanitary flange with gasket, cap & union			
	FMB127413	2						
400 L	FMB127450	2	■				When no drain valve is used: 1 bottom line: ⅜" ID Silicone TuFlux® 1.5 m (60") + MPC female + sealing cap	
	FMB127414	2						
650 L	FMB127451	1	■					
	FMB127415	1						
1,000 L	FMB127452	1	■					
	FMB127416	1						

Flexel® Mixer Pre-Designed Solutions for

Drug Substance Purification

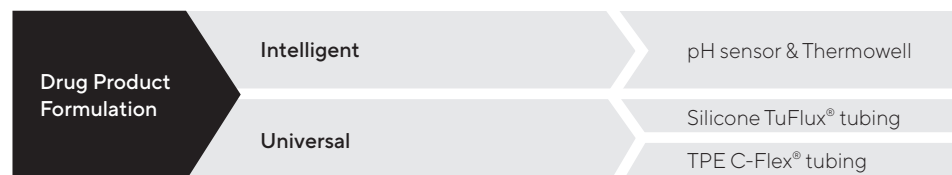


Flexel® for LevMixer® with Thermowell

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB127482	2	NA	½" ID Silicone TuFlux® 1 m (40")	½" ID Silicone TuFlux® 1 m (40")	¼" ID Silicone TuFlux® 0.1 m (4")	1 bottom line:	NA
100 L	FMB127483	2		+ ½" ID Clear C-Flex® 0.5 m (20")	+ ½" ID Clear C-Flex® 0.5 m (20")	+ Clave needleless sampling port	¾" ID Silicone TuFlux® 1.5 m (60")	
200 L	FMB127484	2		+ ½" Opta® SFT female	+ ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union		MPC female + sealing cap	
400 L	FMB127485	2						
650 L	FMB127486	2						
1,000 L	FMB127487	2						

Flexel® Mixer Pre-Designed Solutions for

Drug Product Formulation



PDS are designed for safe and reliable drug product formulation. They feature the Flexel® for LevMixer® low shear homogenization and integrated single-use pH sensor and thermowell for in-line monitoring and control.

The drug product formulation involves a mixing step where the product is formulated before final filtration, fill and finish in its final container. During this step, the drug substance is mixed with other buffers and excipients to obtain the final drug product concentration and composition.

pH is monitored and | or adjusted in-line and samples are taken off-line for other QC tests such as product quality attributes and bioburden prior to sterile filtration.

Flexel® for LevMixer® PDS for final formulation are available in:

- Intelligent version using single-use and integrated sensors for in-line pH and temperature monitoring and adjustment required for your cGMP biomanufacture
- Universal version where sterile samples are taken for off-line controls

PDS are designed for either sterile or aseptic connections and sterile disconnections.

The Opta® SFT connector or the BioWelder® TC are used for respectively sterile connection or sterile weld.

Tri-Clamp or quick coupler connectors are used for aseptic connections under ISO laminar air flow.

Sterile disconnection is done using the BioSealer®.

Intelligent PDS for final formulation are designed with:

- Bottom lines with a combined Silicone TuFlux® + C-Flex® tubing ended by an Opta® SFT connector to allow pumping and sterile weld and | or seal
- Integrated single-use pH sensor and thermowell for in-line monitoring and control
- Top lines with silicone TuFlux® tubing and Opta® SFT connector for sterile pH adjustment
- Bottom line with silicone TuFlux® tubing and clave needleless port for sterile sampling
- Bottom or top line with Silicone TuFlux® tubing and Opta® SFT connector for sterile liquid additions
- Fully closed 8" diameter top port for a safe mixing

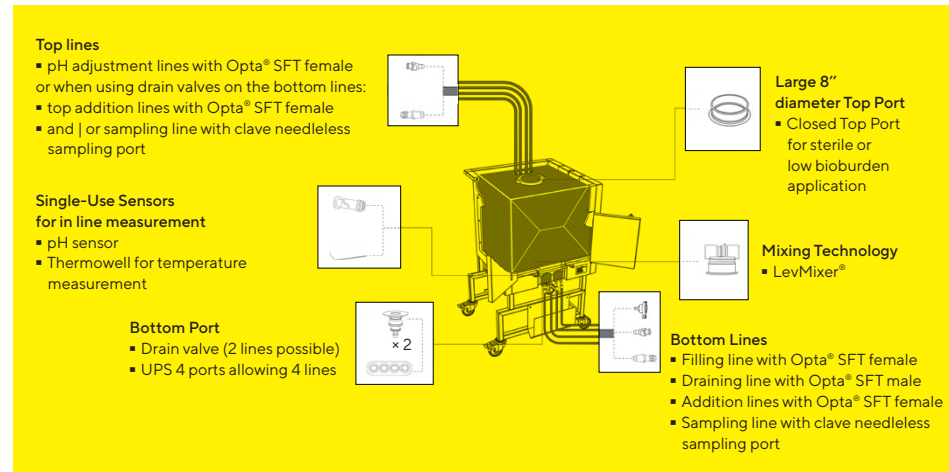
Universal PDS for final formulation are designed for:

- Aseptic operations under ISO laminar air flow:
 - filling and draining lines with silicone
 - TuFlux® tubing and Tri-Clamp 1 ½" sanitary flange
 - additions and pH adjustment lines with Silicone TuFlux® tubing and quick coupler connector
 - sampling line with TuFlux® tubing and clave needleless port
- For sterile operations:
 - filling and draining lines with a combined Silicone + C-Flex® tubing ended by an Opta® SFT connector or ended by a Tri-Clamp 1 ½" sanitary flange
 - pH adjustment top lines with Silicone TuFlux® tubing ended by Opta® SFT connector
 - sampling line with a clave needleless port
 - liquid addition lines either with a combined Silicone + C-Flex® tubing ended by a quick coupler connector or with Silicone TuFlux® tubing ended by Opta® SFT connector
- The large 8" diameter top port is either
 - opened or fully closed for sterile mixing
 - applications.

Options with drain valves to avoid hold up volumes into the tubes are also available.

Flexel® Mixer Pre-Designed Solutions for

Drug Product Formulation

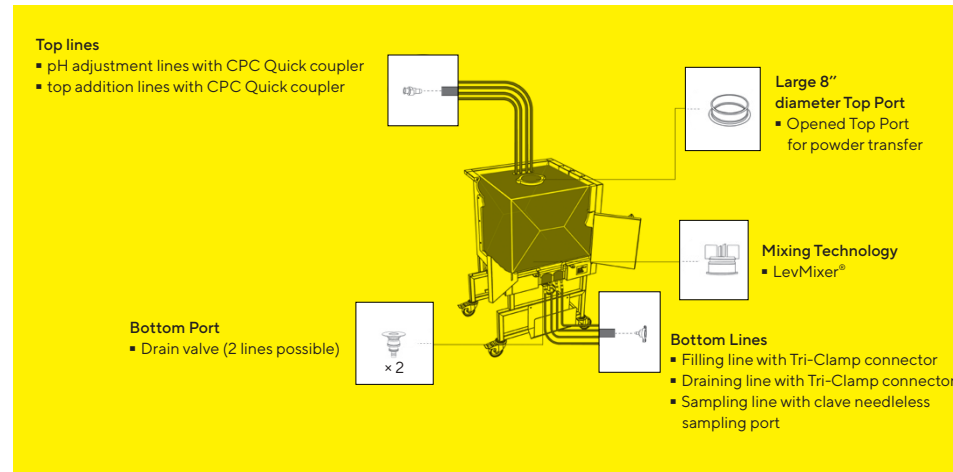
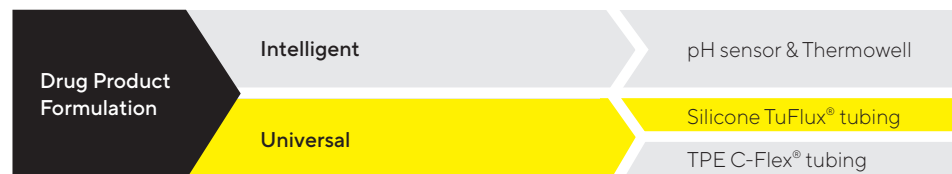


Intelligent Flexel® for LevMixer® with pH sensor & Thermowell

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB128691	2		½" ID Silicone TuFlux® 1 m (40")	½" ID Silicone TuFlux® 1 m (40")	¼" ID Silicone TuFlux® 0.1 m (4")	When a drain valve is used: 1 top line: ⅜" ID Silicone TuFlux® 0.15 m (6")	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4")
100 L	FMB128697	2	■	+	+	+	+	+
	FMB128692	2		½" ID Clear C-Flex® 0.5 m (20")	½" ID Clear C-Flex® 0.5 m (20")	Clave needleless sampling port	⅜" Opta® SFT female	⅜" Opta® SFT female
200 L	FMB128698	2	■	+	+			
	FMB128693	2		½" Opta® SFT female	½" Opta® SFT female		When no drain valve is used: 1 bottom line: ⅜" ID Silicone TuFlux® 1.5 m (60")	
							+	⅜" Opta® SFT female

Flexel® Mixer Pre-Designed Solutions for

Drug Product Formulation

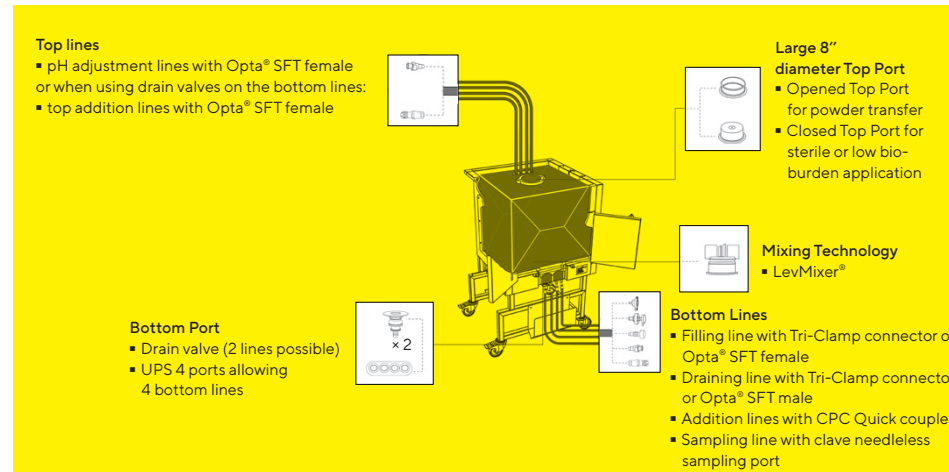
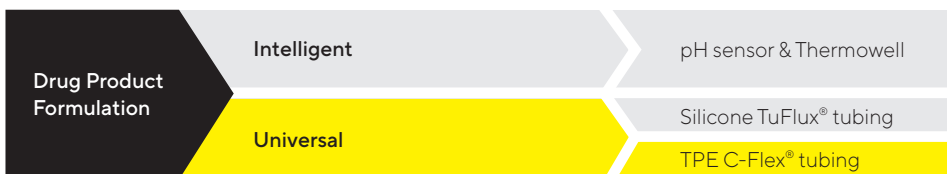


Universal Flexel® for LevMixer® for Drug Product Formulation with Silicone TuFlux® Tubing

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
50 L	FMB128677	2	■	½" ID Silicone TuFlux® 1.5 m (60")	½" ID Silicone TuFlux® 1.5 m (60")	¼" ID Silicone TuFlux® 0.1 m (4")	2 top lines: ¾" ID Silicone TuFlux® 0.15 m (6")	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4")
100 L	FMB128678			+ ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	+ ½" Tri-Clamp 1½" sanitary flange with gasket, cap & union	+ Clave needleless sampling port	+ MPC female + sealing cap	+ MPC female + sealing cap
200 L	FMB128679							

Flexel® Mixer Pre-Designed Solutions for

Drug Product Formulation



Universal Flexel® for LevMixer® for Drug Product Formulation with TPE C-Flex® tubing

Bag Volume	Part Number	Units per box	Drain Valves	Inlet	Outlet	Sampling	Addition	pH Adjustment
Aseptic connections under ISO laminar air flow								
50 L	FXB111567	2	NA	½" ID Silicone (Dow Corning®) 1 m (40")	½" ID Silicone (Dow Corning®) 1 m (40")	¼" ID Silicone TuFlux® 0.15 m (6")	1 bottom line: ½" ID Silicone (Dow Corning®) 1 m (40") + ½" ID Clear C-Flex® 0.5 m (20")	NA
100 L	FXB111568			+ ½" ID Clear C-Flex® 0.5 m (20")	+ ½" ID Clear C-Flex® 0.5 m (20")	+ ½" ID Clear C-Flex® 0.5 m (20")	+ ½" ID Clear C-Flex® 0.5 m (20")	
200 L	FXB111420			+	+	+	+	
400 L	FXB111421			½" Tri-Clamp	½" Tri-Clamp	Clave needleless sampling port	MPC female + sealing cap	
650 L	FXB111565			1½" sanitary flange	1½" sanitary flange			
1,000 L	FXB111569							
Sterile connections								
50 L	FMB128671	2	■	½" ID Silicone TuFlux® 1 m (40")	½" ID Silicone TuFlux® 1 m (40")	¼" ID Silicone TuFlux® 0.1 m (4")	2 top lines: ⅜" ID Silicone TuFlux® 0.15 m (6") + ⅜" Opta® SFT female	2 top lines: ¼" ID Silicone TuFlux® 0.1 m (4") + ¼" Opta® SFT female
100 L	FMB128672			+	+	+	+	+
200 L	FMB128673			½" ID Clear C-Flex® 0.5 m (20") + ½" Opta® SFT female	½" ID Clear C-Flex® 0.5 m (20") + ½" Opta® SFT female	Clave needleless sampling port		

Hardware

Standard Palletank for Magnetic Mixer | LevMixer[®]

Palletank for Mixing

Description	Volumes	Technical Specification
Volumes		50 L 100 L 200 L 400 L 650 L 1,500 L 2,000 L 2,500 L 3,000 L
Main construction materials	50 L to 3,000 L 50 L to 1,000 L	Stainless Steel 304L Windows made of PC and EPDM sealing
Surface finish	50 L to 3,000 L	Acid cleaned, stainless steel bead blasted and passivated
Door	50 L to 400 L 650 L and 1,000 L 1,500 L to 3,000 L	Front hinged door and PC windows Front hinged doors and PC windows Front and lateral hinged doors
Bag tubing gate	50 L to 3,000 L	Front bottom port for bag lines sensor access
Port	50 L to 3,000 L	Railed port for drive unit coupling
Mobility	50 L to 1,000 L 1,500 L to 3,000 L	Mounted on stainless cart with four clean room wheels and push handles Mounted on stainless cart with four clean room fixed feet
Minimum door height	1,500 L to 3,000 L	1,550 mm
Minimum ceiling height	1,500 L 2,000 L 2,500 L 3,000 L	3,000 mm 3,500 mm 4,000 mm 4,500 mm
Operating temperature	50 L to 3,000 L	0°C to 50°C

Integrated Weighing

Description	Technical Specification
Scale Indicator	Minebea Combics 1
Material of construction	Stainless Steel 304
Keyboard	6 keys
Display	14 segments 20 mm weight readout
Interface	RS232
Connection to printer	Additional cable available as an option
IP protection rate	IP69K
Operating temperature range	-10°C to 40°C
Integrated load cells	Minebea Novego
Material of construction	304 and 4418 (sensor)
IP protection rate	IP68 + IP69
Overload	High overload protection
Vibration resistance	Resistance against oscillations (IEC 68-2-6 Fc); 20 g, 100 h, 10 to 150 Hz
Design	In accordance with European Hygienic Engineering and Design Group (EHEDG) guidelines
Lift-off	Lift-off protector and anti-wobbling mechanism

Weighing Characteristics

Volumes	Maximum net capacity	Resolution	Accuracy
50 L	60 kg	20 g	60 g
100 L	110 kg	20 g	60 g
200 L	220 kg	20 g	60 g
400 L	450 kg	50 g	150 g
650 L	750 kg	50 g	150 g
1,000 L	1,100 kg	100 g	300 g
1,500 L	1,750 kg	100 g	300 g
2,000 L	2,200 kg	200 g	600 g
2,500 L	2,750 kg	200 g	600 g
3,000 L	3,300 kg	200 g	600 g

Hardware

Standard Palletank for Magnetic Mixer | LevMixer®

Palletank for Mixing

Dimensions & Weight

Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC301951	50 L	785 × 705 × 989 mm	78 kg
FXC301952	100 L	785 × 705 × 1,094 mm	86 kg
FXC301953	200 L	785 × 705 × 1,194 mm	105 kg
FXC301954	400 L	1,031 × 873 × 1,344 mm	142 kg
FXC301955	650 L	1,181 × 1,008 × 1,454 mm	175 kg
FXC301956	1,000 L	1,296 × 1,157 × 1,654 mm	256 kg
FXC301958	1,500 L	1,733 × 1,076 × 2,444 mm	465 kg
FXC301959	2,000 L	1,733 × 1,076 × 2,944 mm	528 kg
FXC301960	2,500 L	1,733 × 1,076 × 3,445 mm	592 kg
FXC301961	3,000 L	1,733 × 1,076 × 3,945 mm	656 kg

Palletank for Mixing with Weighing

Dimensions & Weight

Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC301962	50 L	878 × 705 × 1,018 mm	81 kg
FXC301963	100 L	921 × 705 × 1,115 mm	90 kg
FXC301964	200 L	981 × 705 × 1,194 mm	108 kg
FXC301965	400 L	1,159 × 873 × 1,344 mm	145 kg
FXC301966	650 L	1,311 × 1,008 × 1,454 mm	178 kg
FXC301967	1,000 L	1,426 × 1,157 × 1,654 mm	259 kg
FXC301968	1,500 L	1,860 × 1,076 × 2,444 mm	469 kg
FXC301969	2,000 L	1,860 × 1,076 × 2,944 mm	533 kg
FXC301970	2,500 L	1,860 × 1,076 × 3,445 mm	596 kg
FXC301971	3,000 L	1,860 × 1,076 × 3,945 mm	660 kg



Hardware

Standard Palletank for Magnetic Mixer | LevMixer®

Palletank Jacketed

Description	Volumes	Technical Specification	
Version		PED (for Europe, Asia and NEMA)	ASME (for North America)
Volumes		50 L 100 L 200 L 400 L 650 L 1,500 L 2,000 L 2,500 L 3,000 L	
Main construction materials	50 L to 3,000 L	Stainless Steel 304L, Perlit Balls (insulation)	Stainless Steel 304L, Foam Glass and Ceramic Fiber (insulation)
Surface finish	50 L to 3,000 L	Acid cleaned, stainless steel bead blasted and passivated	
Door	50 L 100 L 200 L 400 L 650 L to 3,000 L	No door Front insulated hinged door Front insulated hinged doors	
Bag tubing gate	50 L to 3,000 L	Hinged PTFE bottom door	Hinged UHMW bottom door
Port	50 L to 3,000 L	Railed port for drive unit coupling	
Mobility	50 L to 1,000 L 1,500 L to 3,000 L	Mounted on stainless cart with four clean room wheels and push handles Mounted on stainless cart with four clean room fixed feet	
Minimum door height	1,500 L to 3,000 L	2,070 mm	
Minimum ceiling height	1,500 L 2,000 L 2,500 L 3,000 L	3,000 mm 3,500 mm 4,000 mm 4,500 mm	
Operating temperature	50 L to 3,000 L	0°C to 50°C	
Inlet pressure maximum	50 L to 3,000 L	6 bar	10 bar
Pressure loss maximum	50 L to 3,000 L	0,4 bar	0,4 bar
Test pressure	50 L to 3,000 L	9 bar	13 bars
Compliance	50 L to 3,000 L	PED	Heat exchanger ASME certified From heat exchanger : designed and build under ASME code
Insulated	50 L to 3,000 L	On all sides, the bottom and the lids	
Jacketed	50 L and 100 L 200 L to 1,000 L 1,500 L to 3,000 L	4 sides and bottom 3 sides and bottom 3 sides and bottom for 1,500 L base, module and top insulated only	
Inlet outlet of heat transfer fluid	50 L to 3,000 L	DN20 with flange nozzles 50.5 mm Ball valve DN20 PN64	Connector Male NPT

Hardware

Standard Pallettank for Magnetic Mixer | LevMixer®

Pallettank for Mixing Jacketed

Dimensions & Weight PED Version (for Europe, Asia and NEMA)

Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC301930	50 L	847 × 817 × 1,045 mm	118 kg
FXC301931	100 L	878 × 817 × 1,150 mm	178 kg
FXC301932	200 L	949 × 969 × 1,250 mm	238 kg
FXC301933	400 L	1,158 × 1,186 × 1,399 mm	347 kg
FXC301934	650 L	1,242 × 1,319 × 1,509 mm	456 kg
FXC301935	1,000 L	1,376 × 1,435 × 1,710 mm	592 kg
FXC301936	1,500 L	1,822 × 1,135 × 2,530 mm	791 kg
FXC301937	2,000 L	1,822 × 1,135 × 3,050 mm	933 kg
FXC301938	2,500 L	1,822 × 1,135 × 3,570 mm	1,076 kg
FXC301939	3,000 L	1,822 × 1,135 × 4,090 mm	1,218 kg

Dimensions & Weight ASME Version (North America)

Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC301994	50 L	847 × 817 × 1,045 mm	118 kg
FXC301995	100 L	878 × 817 × 1,150 mm	178 kg
FXC301996	200 L	949 × 969 × 1,250 mm	238 kg
FXC301997	400 L	1,158 × 1,186 × 1,399 mm	347 kg
FXC301998	650 L	1,242 × 1,319 × 1,509 mm	456 kg
FXC301999	1,000 L	1,376 × 1,435 × 1,710 mm	592 kg
FXC302000	1,500 L	1,822 × 1,135 × 2,530 mm	791 kg
FXC302001	2,000 L	1,822 × 1,135 × 3,050 mm	933 kg
FXC302002	2,500 L	1,822 × 1,135 × 3,570 mm	1,076 kg
FXC302003	3,000 L	1,822 × 1,135 × 4,090 mm	1,218 kg



Hardware

Standard Pallettank for Magnetic Mixer | LevMixer[®]

Pallettank for Mixing Jacketed with Weighing

Dimensions & Weight PED Version (for Europe, Asia and NEMA)

Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC301940	50 L	970 × 817 × 1,058 mm	121 kg
FXC301941	100 L	1,013 × 817 × 1,150 mm	181 kg
FXC301942	200 L	1,112 × 969 × 1,250 mm	241 kg
FXC301943	400 L	1,287 × 1,186 × 1,399 mm	350 kg
FXC301944	650 L	1,412 × 1,319 × 1,509 mm	459 kg
FXC301945	1,000 L	1,511 × 1,435 × 1,710 mm	595 kg
FXC301946	1,500 L	1,949 × 1,135 × 2,530 mm	794 kg
FXC301947	2,000 L	1,949 × 1,135 × 3,050 mm	936 kg
FXC301948	2,500 L	1,949 × 1,135 × 3,570 mm	1,079 kg
FXC301949	3,000 L	1,949 × 1,135 × 4,090 mm	1,221 kg

Dimensions & Weight ASME Version (North America)

Part Number	Volume	Dimensions (approx.) W × D × H	Weight
FXC302004	50 L	970 × 817 × 1,058 mm	121 kg
FXC302005	100 L	1,013 × 817 × 1,150 mm	181 kg
FXC302006	200 L	1,112 × 969 × 1,250 mm	241 kg
FXC302007	400 L	1,287 × 1,186 × 1,399 mm	350 kg
FXC302008	650 L	1,412 × 1,319 × 1,509 mm	459 kg
FXC302009	1,000 L	1,511 × 1,435 × 1,710 mm	595 kg
FXC302010	1,500 L	1,949 × 1,135 × 2,530 mm	794 kg
FXC302011	2,000 L	1,949 × 1,135 × 3,050 mm	936 kg
FXC302012	2,500 L	1,949 × 1,135 × 3,570 mm	1,079 kg
FXC302013	3,000 L	1,949 × 1,135 × 4,090 mm	1,221 kg



Hardware

Standard Palletank for Magnetic Mixer | LevMixer®

Powder Bag Holders

Description	Powder bag holder 50 L to 200 L	Powder bag holder 400 L to 1,000 L	Powder bag holder 1,500 L to 3,000 L
Part Number	FXA304216	FXA304217	FXA304218
Construction material	Stainless Steel 304 and Nylon		
Surface finish	Bead Blasted		
Dimensions	660 × 1,360 mm	960 × 1,360 mm	860 × 1,360 mm
Weight	14 kg	16 kg	14 kg
Height above Palletank®	1,349 mm	1,349 mm	1,349 mm
Filling weight, maximum	30 kg	30 kg	30 kg
Ambient Conditions	+2°C - +30°C	+2°C - +30°C	+2°C - +30°C



Hardware

Standard Palletank for Magnetic Mixer | LevMixer[®]

Tubing Holder

Description	Part number	Type	Outer tube diameter	Material	Surface finish	Dimensions	Weight
Tubing Holder Single 5/8"	FXC301562	Single	5/8"	Stainless Steel 304 and TPE	Bead Blasted	139 × 68 mm	423 g
Tubing Holder Twin 5/8"	FXC301563	Twin	5/8"			150 × 113 mm	465 g
Tubing Holder Triple 5/8"	FXC301564	Triple	5/8"			150 × 158 mm	506 g
Tubing Holder Quattro 5/8"	FXC301565	Quattro	5/8"			150 × 205 mm	546 g
Tubing Holder Single 3/4"	FXC301566	Single	3/4"			139 × 77 mm	427 g
Tubing Holder Twin 3/4"	FXC301567	Twin	3/4"			150 × 132 mm	474 g
Tubing Holder Triple 3/4"	FXC301568	Triple	3/4"			150 × 188 mm	518 g
Tubing Holder Quattro 3/4"	FXC301569	Quattro	3/4"			150 × 243 mm	559 g
Tubing Holder Single 1"	FXC301570	Single	1"			139 × 86 mm	434 g
Tubing Holder Twin 1"	FXC301571	Twin	1"			160 × 151 mm	510 g
Tubing Holder Triple 1"	FXC301572	Triple	1"			160 × 216 mm	571 g
Tubing Holder Quattro 1"	FXC301573	Quattro	1"			160 × 281 mm	626 g
Tubing Holder Single 1 1/8"	FXC301574	Single	1 1/8"			146 × 86 mm	445 g
Tubing Holder Twin 1 1/8"	FXC301575	Twin	1 1/8"			160 × 151 mm	510 g
Tubing Holder Triple 1 1/8"	FXC301576	Triple	1 1/8"			160 × 216 mm	570 g
Tubing Holder Quattro 1 1/8"	FXC301577	Quattro	1 1/8"			160 × 281 mm	627 g
Tubing Holder Single 1 3/8"	FXC301578	Single	1 3/8"			156 × 89 mm	454 g
Tubing Holder Twin 1 3/8"	FXC301579	Twin	1 3/8"			171 × 157 mm	527 g
Tubing Holder Triple 1 3/8"	FXC301580	Triple	1 3/8"			171 × 225 mm	595 g
Tubing Holder Quattro 1 3/8"	FXC301581	Quattro	1 3/8"			171 × 293 mm	657 g



Hardware

Standard Palletank for Magnetic Mixer | LevMixer[®]

Filter Holder

Description	Part number	Type	Filter diameter	Material	Surface finish	Dimensions	Weight
Filter Holder Short 55 mm	FXC301582	Short	55 mm	Stainless Steel 304 and TPE	Bead Blasted	100 × 55 mm	596 g
Filter Holder Long 55 mm	FXC301583	Long	55 mm			500 × 55 mm	1519 g
Filter Holder Short 75 mm	FXC301584	Short	75 mm			100 × 75 mm	672 g
Filter Holder Long 75 mm	FXC301585	Long	75 mm			500 × 75 mm	1596 g
Filter Holder Short 100 mm	FXC301586	Short	100 mm			100 × 100 mm	735 g
Filter Holder Long 100 mm	FXC301587	Long	100 mm			500 × 100 mm	1658 g
FT HOLDER SHORT H 75 mm	FXA304200	Short	75 mm			100 × 75 mm	672 g
FT HOLDER SHORT H 55 mm	FXA304201	Short	55 mm			100 × 55 mm	596 g
FT HOLDER SHORT H 100 mm	FXA304202	Short	100 mm			100 × 100 mm	735 g



Hardware

Standard Palletank for Magnetic Mixer | LevMixer[®]

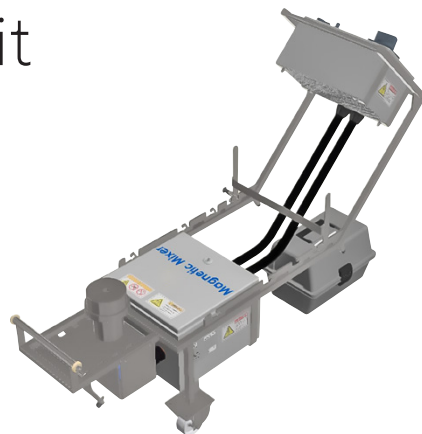
pH Reader Holder and pH Bag Holder

Description	Part number	Material	Surface finish	Dimensions	Weight
Palletank [®] for Mixing pH Reader Holder	FXA304214	Stainless Steel 304 and elastomer	Bead Blasted	245 × 170 × 181 mm	1,499 g
Palletank [®] for Mixing pH Bag Holder	FXA304215			160 × 181 × 212 mm	1,519 g



Hardware

Magnetic Mixer Drive Unit



Part Number	Description
DU010	Magnetic Mixer drive unit, 200 - 240 V, without plug
DU011	Magnetic Mixer drive unit, 100 - 120 V, US plug
LT-SVSP365	US Power cord
LT-SVSP366	European Power cord
LT-SVSP367	Australian Power cord
LT-SVSP368	Swiss Power cord
LT-SVSP369	UK Power cord

General Category	Parameter	Technical Specifications
Facility	Dimensions (W × L × H)	Docking position: 426 mm × 1245 mm × 888 mm; 17" × 49" × 34.9" Storage position: 426 mm × 1291 mm × 515 mm; 17" × 50.8" × 20.3"
	Weight	DU010: approx. 32.2kg 70.99 lbs; DU011: approx. 32.4 kg; [~71.4 lbs]
	Materials of Construction	Control box, cart & drive unit cabinets: 304 Stainless Steel
	Surface finish	Control box, cart & drive unit cabinets: Brushed at least 0.89 µm Ra / 35 µin Ra
	Operational footprint	Max. 426 mm × 1245 mm; 17" × 49"
	IP Rating	Control box: IP55; Motor: IP66
	Noise (at operator position):	<70dB
	Max humidity	85%, avoid condensation
	Ambient temperature	0 - 35°C
	Electrical supply	DU010: Single phase 200V-240V AC, 50 Hz DU011: Single phase 100V-120V AC, 60 Hz
Utilities	Amperage	DU010: 1.7A DU011: 2.7A
	Motor power	Less than 180 Watts

General Category	Parameter	Technical Specifications
Control system	Control architecture	Local: Speed Control Potentiometer and Speed Display Unit. Remote: Speed Control Signal and Speed Feedback Signal.
	Plug type options	DU010: Bulgin connector for 230V, (bulgin cable available for EU, UK, AU, CN, CH, to be ordered separately) DU011: Fixed US poxer cable
	Remote Control Connector	Hummel M23, 12-pin. Remote/Local; Start/Stop; Speed In: 4 - 20mA; Speed Out: 4 - 20mA; Alarm Out.
Mixing	Impeller type	Vertical bladed 'Rushton' type impeller
	Speed range (rpm)	20 to 300 RPM
Electrical safety	CE	EC in accordance with: Machinery Directives: 2006/42/EC; EMC Directive: 2014/30/EU
	UL	UL 61010-1: 2012 and 61010-2-051:2019 Standard for Safety Electrical Equipment For Measurement, Control and Laboratory

Hardware

LevMixer® Drive Unit



Part Number	Description
LT-DBTL300	Superconducting drive machine on cart with universal latch for 8", 15" and 23" ports. Control panel (100-230 V) and lifting mechanism on handle and welded body. 304 L Stainless Steel with 35 µin. Ra 0.89 µm Ra surface finish. Includes tool box with accessories.
LT-SVSP402	Remote control cable - Analog I O Cable, 6 m (20 ft.)
LT-SVSP403	Remote control cable - Digital I O Cable, 6 m (20 ft.)

Description	Technical Specifications
Footprint in mm (inches) W x L x H	Collapsed configuration: 407 x 1,118 x 915 mm (16 x 44 x 36 in.) Expanded configuration: 407 x 1,311 x 915 mm (16 x 51.6 x 36 in.)
Weight	123 lbs (56 kg)
Control box, cart & mixer enclosure material	304 L Stainless Steel
Control box, cart & mixer enclosure surface finish	At least 35 µin. Ra 0.89 µm Ra
Control box ingress rating	IP 65
Enclosure ingress rating	IP 23
Voltage	100 - 230 VAC, 50 60 Hz
Input Wattage	Less than 350 W
Amperage	100 V 3.0 A; 110 V 2.5 A; 230 V 1.5 A
Voltage fluctuation	+/- 10%
Altitude rating	1,000 m (3,280 ft)
Max humidity	85%, avoid condensation
Ambient temperature	4 - 40°C
Motor horsepower	1/8 hp
Power cord length	6 m (20 ft)
E-stop (present, yes no, location)	Yes, face of control box

Description	Technical Specifications
Min and Max impeller speed	20 to 210 RPM
Connections for remote output control	TURCK RSFPV61, RSFPV579
Functions available from remote control panel	Motor - start, stop Speed - adjustment, indication Alarm - indication Mode of control (remote local) - indication
Signal type(s) for remote output control	Impeller speed out 4-20 mA, motor control in 0-10 VDC, discrete I O signals relay contact type
Mixer charge time	35 minutes
Operator interface type	Touchscreen PLC
Method for RPM measurement	Direct measurement of impeller speed via non-contact magnetic sensor
Noise level at operator position	67 dB
Mobility	Mounted on stainless cart with four clean room wheels and push Handles - 2X swivel (front), 2X stationary (rear)
Wheel material	Polyurethane
Recipe storage	Up to 10 recipes can be stored
Password protection	Operator, Supervisor, Maintenance levels
CE Mark	Compliant
UL	Compliant

Hardware

Accessories

Accessories

Powder Transfer System



Part Number	Description	Bag Port 1	Qty. Box
FMA300221	STD Powder Bag 15 L (PWD Port) with pinch clamp	4-inch triclamp	5
FMA300222	STD Powder Bag 30 L (PWD Port) with pinch clamp	4-inch triclamp	5
FMA114007	8-inch to 4-inch triclamp reducer	NA	1
FMA114179	Component Plug Gasket Union for TC4"	NA	5

Powder Transfer Bags

Description	Technical Specifications
Bag Chamber	Multiple layer film construction, (mLLDPE MDPE-LDPE mLLDPE)
Fittings	4-inch triclamp
Accessory	Pinch clamp
Volumes	15 L and 30 L
Number of Port	1 port
Irradiation	25 – 45 kGy

Triclamp Reducer

Description	Technical Specifications
Triclamp Reducer	8-inch to 4-inch triclamp reducer with a 4-inch triclamp plug, 4-inch triclamp gasket and 4-inch triclamp union
Material of Construction	Reducer: polyethylene, Plug: polyethylene, Gasket: platinum cured silicone, 4-inch triclamp union: glass reinforced polyamide
Sterility	Non sterile

Cap | Gasket | Union

Description	Technical Specifications
Cap Gasket Union	4-inch triclamp plug, 4-inch triclamp gasket, 4-inch triclamp union
Material of Construction	Plug: polyethylene, Gasket: platinum cured silicone, 4-inch triclamp union: glass reinforced polyamide
Sterility	Non sterile

Flexel® Mixer Pre-Designed Solutions

Design, Application Development and Validation Services

Design Configuration Options

Should our Pre-designed Solutions need to be adjusted to more specific requirements, they can serve as a base for adjusting your specific design using our Corporate Configurator and configure to Order (CTO) solutions.

Our Engineered to order (ETO) solutions allows the selection of a larger variety of solutions with added features, lines, manifolds, filters, connectors and sampling systems.

Please contact our sales representatives and application specialist to support you with the selection and design of your best solution for your specific process and application.

Application Support

Our expert FMT Application Specialists provide global support for:

- Single-use process URS definitions and application development
- Process design with standard and custom solutions
- Filter selection and sizing optimization study
- SOP development, process validation and operator training
- Technology transfer and process optimization

Validation Service

Our global validation services network offers:


- Installation start up, FAT, IQ & OQ, calibration and maintenance
- Consultancy service and process specific validation studies including
- Extractables | leachables,
- Chemical compatibility
- Bacterial challenge test
- Particle shedding

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