

## LENNTECH

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Data Sheet

## Millipore Express<sup>®</sup> SHF Hydrophilic Filters

# Sterilizing-Grade PES membrane for fast, efficient, economical buffer filtration



- High-flux hydrophilic PES sterilizing-grade membrane
- Faster flow, up to 2.5 times faster than most other sterilizing grade membranes
- Increased output without increasing filtration area
- Lower cost from improved process economics
- Optimized for buffer filtration which requires sterility assurance and high flow rates
- Broad chemical compatibility across a wide pH range—NaOH compatible

Millipore Express SHF (Sterile High-Flux) devices are the choice for optimal buffer filtration. A sterilizing grade, 0.2  $\mu$ m hydrophilic polyethersulfone (PES) membrane, Millipore Express SHF filters provide sterility assurance, broad chemical compatibility, and exceptionally high flow rates for buffers at the high and low range of pH, 1–14.

The high flow rate of the Millipore Express SHF membrane cuts your filtration time in half, dramatically improving filtration economics and extending production capacity. The membrane is caustic compatible and offers high-flux performance with a full range of buffer chemistries. Its low extractables and non-fiber releasing properties contribute to clean processes. With Millipore Express SHF filters, you increase productivity, shorten cycle-time and reduce costs.

### Superior Performance, Speed and Value

For biotech and pharmaceutical customers seeking fast, efficient and economical sterile buffer filtration, no PES membrane delivers more than Millipore Express SHF.

- Fast filtration with sterility assurance
- Broad chemical compatibility even at high pH
- Low filtration costs reduced up-front filter and overall filtration costs.

Membrane Types	Filter Formats
<ul> <li>Millipore Express SHF</li> <li>PES membranes</li> </ul>	OptiScale® small-scale disposable capsule filters
	Opticap <sup>®</sup> XL and XLT disposable capsule filters – autoclavable, sterile and gamma compatible Cartridge filters

### **Developed to Enhance Buffer Filtration**

Millipore Express SHF filters use a fast flowing process membrane specifically developed for the filtration of buffers, pH adjusters and other aqueous intermediate pharmaceutical and biotech process solutions. Designed to offer high-flux performance and improved economics, Millipore Express SHF membrane is compatible with a wide range of buffer chemistries, including acids and sodium hydroxide.

### More than Twice as Fast

Millipore Express SHF filters have flow rates that are up to two to two-and-a-half times faster than other sterilizing grade membranes for lower filtration costs and increased production capacity. You get fast flowing filters with broad chemical compatibility, especially at the high pH of caustic and buffer solutions.

#### **Reduced Surface Area and Lower Costs**

Because Millipore Express SHF filters feature flow rates faster than most other membranes, you can maintain batch volume while reducing filtration surface area. This high-flux benefit has been shown to deliver greater than 50 percent savings in filtration costs, improving your process economics.

## Reduced Process Time and Extended Capacity

Millipore Express SHF filters are ideal for maximizing the capacity of constrained buffer filtration systems. With its superior flux, you can reduce processing time by half, doubling your output without significant capital expense.

### **Reliable Performance**

Millipore Express SHF membrane delivers all the benefits you'd expect from a quality Millipore membrane. Reliable sterilizing performance. Multiple steam-in-place or autoclave sterilization cycles. Broad chemical compatibility. Easy integrity testing. And fast flow to help you fill your buffer filtration tank quickly—now with the added benefits of improving efficiency and economics.

#### **Regulatory Compliance**

Millipore Express SHF filters are designed, developed and manufactured in accordance with a Quality Management System approved by an accredited registering body of an ISO<sup>®</sup> 9000 Quality Systems Standard. Each device is shipped with a Certificate of Quality. All cartridge filters are 100% integrity tested during manufacture and supported by a Validation Guide for compliance with regulatory requirements. For traceability and easy identification, each filter is identified with product name and other characteristics.

## SUPERIOR FLUX





Millipore Express SHF Membrane Flux Relative to Competitors (n=2)



Competitor B2

\*Includes 0.2 M Arginine-HCl, 0.5 M Sodium Phosphate





From process development to fullscale production, Millipore has the right solution for all of your process needs.



OptiScale Filters

## OptiScale Process Development Screening Tool

OptiScale disposable capsule filters provide a convenient small-volume option for process screening and scaling. These "drop in" filters are ideal for evaluating biopharmaceuticals. OptiScale capsule filters offer speed-to-market strategies for efficiently developing compounds and biotherapeutics.

The OptiScale capsule is ideally suited for process development and screening. OptiScale capsules are faster and easier to set-up than conventional 25 mm and 47 mm discs, and completely disposable.



Cartridge Filters

## **Cartridge Filters**

Millipore Express SHF 5- 10-, 20-, and 30-inch cartridge filters provide very high flow rates. Cartridges are robust, strong, resilient and designed to withstand multiple steam-in-place cycles. Each cartridge is integrity tested during manufacturing.

Code O and code 7 O-ring adaptors are available to suit your application and housing needs.

## **Opticap XL and XLT Disposable Capsule Filters**



Opticap XL Filters

## Convenient and Easy to Use

Opticap XL and XLT capsule filters eliminate the time and expense



associated with assembling, cleaning, and validating stainless steel housings.

Adjustable, easy-to-turn, upstream vents and drain valves with O-ring seals and hose barb connections allow for easy process control. Other ease-of-use features include flow direction arrows and ribbed housing for easy gripping even with gloved hands.



Opticap XLT Filters

### The Right Size

Opticap XLT 10, 20 and 30 capsules are available to fit all of your application needs and to allow easy scale-up of your small volume filtration steps to larger, full-scale filtration processes.

### **The Right Connections**

Designed to optimize your filtration process, Opticap XL and XLT disposable capsule filters are available with a choice of inlet and outlet connections, including sanitary flanges, fractional sanitary flanges as well as hose barbs.

### **Proven Integrity**

Each capsule is integrity tested during the manufacturing process to ensure reliable performance in your process.

## **Robust Construction**

Opticap XL and XLT capsules' design allows unparalleled hydraulic stress resistance in a disposable filter.

## Opticap XL Capsule Filters

Opticap XL disposable capsule filters have a unique design to minimize hold-up volume and reduce production losses.

## Opticap XLT 10, 20 and 30 Capsule Filters

Opticap XLT disposable T-line capsule filters are available with or without a pressure gauge port for ease in monitoring process conditions. The T-line design accommodates series or parallel filtration to match your application needs, and a specially-designed stand enables quick and easy integration into your existing process.



Opticap XLT Capsule Stand

## **SPECIFICATIONS** Cartridge Filters and OptiScale Disposable Capsules

		Optiscale 25 Capsules	Optiscale 47 Capsules	5-inch Cartridge	Per 10-inch Cartridge		
S	Diameter:	31 mm (1.21 in.)	69 mm (2.75 in.)	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)		
sion	Length:	39 mm (1.52 in.)	82 mm (3.24 in.) w/flange inlet/hose	12.5 cm (5 in.) 25.4 cm (10			
lominal Dimen			74 mm (2.91 in.) w/flange inlet/flange outlet		111.7		
			94 mm (3.70 in.) w/hose barb inlet/ hose barb outlet				
Ž	Weight	5.5 g (0.19 oz)	67 g (2.3 oz)	—			
Filtratio	on Area	3.5 cm <sup>2</sup>	17.7 cm <sup>2</sup>	0.29 m <sup>2</sup> (2.5 ft <sup>2</sup> )	0.54 m <sup>2</sup> (5.3 ft <sup>2</sup> )		
Ę	Filter membrane:	Hydrophilic polyethersulfone	Hydrophilic polyethersulfone	Hydrophilic polyethersulfone			
ictic	Film edge:	—	—	Polypropylene			
stru	Supports:	—	Polypropylene	Polypropylene			
Cage and end caps:		—	Polycarbonate	Polypropylene			
of	Core:	—	Polycarbonate	Polysulfone			
rials	Structural components:	Polypropylene	Polycarbonate	_			
late	Vent cap:	Polypropylene	Polyvinylidene fluoride (PVDF)	_			
≥	O-rings:	Fluorocarbon rubber	Fluorocarbon rubber	Silicone, EPDM or fluoroca	rbon rubber		
Housing	l Vent	Capped vent with female Luer connections on inlet side of device.	Adjustable vent with male Luer and female Luer-Lok® connections on inlet side of the device	—			
Maximu	m Inlet Pressure	4136 mbar (60 psi) at 25 °C	5516 mbar (80 psi) at 25 °C				
Forward:		4136 mbar (60 psi) at 25°C	5516 mbar (80 psi) at 25 °C	6895 mbar (100 psi) at 25 ℃			
iffer sur(				1700 mbar (25 psi) at 80 °	С		
m D res				340 mbar (5 psi) at 135 °C			
cial	5		700 1 (10 1) 105 00				
May ent	Reverse:	U mbar (U psi)	700 mbar (10 psi) at 25 °C	2068 mbar (30 psi) at 25 °C			
Bubble	Point at 23 °C			≥ 4000 mbar (58 psi) air with water			
Air Diffusion at 23 °C				Through a water wet mem	brane at 2758 mbar (40 psi):		
				< 16.4 cc/min	< 30 cc/min		
Bacterial Retention			_	Quantitative retention of	10 <sup>7</sup> CFU/cm <sup>2</sup> Brevundimonas		
				diminuta ATCC® 19146 per ASTM® methodology			
Bacterial Endotoxin		Aqueous extraction contains < 0.25 EU/mL as determined by Limulus Amebocyte Lysate (LAL) Test	—	Aqueous extraction contains <0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.			
TOC/Conductivity		This product exhibited less than 500 ppb TOC per USP <643> and less than 1.3 um per USP<645> after autoclave and WFI water	_	Autoclaved cartridges meet the WFI of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a WFI water flush of:			
		flush of 15 mL.		5.5 L at 25 °C	10 L at 25 °C		
Oxidizal	ble Substances	—	Effluent meets the USP Oxidizable Substance Test requirements for sterile purified water after a water flush of ≤100 mL.	Effluent meets the USP Oxidizable Substance Test requirements for sterilepurified water after a water flush of: 1000 mL.			
Sterilization		May be autoclaved for 1 cycle at 123 °C for 60 min.	May be autoclaved for 3 cycles of 60 min at 126 °C.	Autoclave: May be autoclaved 25x, 60 min cycles at 126 °C			
				In-line Steam: 25x (forward), 30 min cycles at 135 °C, or 22x (forward) and 3x (reverse), 30 min cycles at 135 °C			
USP Toxicity		-	-	Non-toxic per MEM elution	ISO® 10993-5.		
Particle Shedding Passes USP test for p in injectables.		Passes USP test for particulates in injectables.	-	Passes USP test for partic	ulates in injectables.		
Non-fib	er Releasing	Millipore Express SHF membrane m	eet the criteria for a "non-fiber releasing	" filter as defined in 21 CFR	210.3(b)(6).		
Compon	ent Material Toxicity	Component materials were tested a filters meet the requirements of the	and meet the criteria of the USP <88> R USP <88> Safety Test, utilizing a 0.9% so	eactivity Test for Class VI pl dium chloride extraction.	astics. Millipore Express SHF		
Indirect	Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.					
Good M	anufacturing Practices	These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.					

## SPECIFICATIONS

## **Opticap XL and XLT Disposable Capsules (Autoclavable)**

	Opticap XL 3	Opticap XL 5	Opticap XL 10	Opticap XLT 10	Opticap XLT 20	Opticap XLT 30	
Nominal Dimensions							
Maximum length:	17.3 cm (6.8 in.)	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)	37.6 cm (14.8 in.)	62.5 cm (24.6 in.)	87.1 cm (34.3 in.)	
Body diameter:	10.7 cm (4.2 in.) 10.7 cm (4.2 in.) 10.7 cm (4.2 in.) — — — —						
Fitting to Fitting							
Sanitary flange to							
sanitary flange:	—			15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	
Sanitary flange to							
hose barb:	—			17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	
Hose barb to hose barb:	—			19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	
Filtration Area	0.16 m <sup>2</sup> (1.7 ft <sup>2</sup> )	0.29 m <sup>2</sup> (3.1 ft <sup>2</sup> )	0.54 m <sup>2</sup> (5.8 ft <sup>2</sup> )	0.54 m <sup>2</sup> (5.8 ft <sup>2</sup> )	1.08 m <sup>2</sup> (11.6 ft <sup>2</sup> )	1.62 m <sup>2</sup> (17.4 ft <sup>2</sup> )	
Materials of Construction							
Filter membrane:	Hydrophilic polye	thersulfone					
Film edge:	Polypropylene						
Supports:	Polypropylene						
Structural components <sup>1</sup> :	Polypropylene						
Core:	Polysulfone						
Vent O-rings	Silicone						
Vent/Drain	¼ in. hose barb w	vith double O-ring s	seal				
Maximum Differential							
Pressure							
Forward:	5516 mbar (80 p	si) at 25 °C					
	6895 mbar (100	psi) intermittent a	t 25 °C				
Deveneer	1034 mbar (15 p	si) at 80 °C					
Reverse:	2000 mbar (50 p	si) intermittent at	25 L				
Air Diffusion at 23 °C	Z4000 IIIDal (30	wot mombrano at	2758 mbar (10 pci):				
Air Diffusion at 23 °C		wel memprane at	2730 mbar (40 psi).	< 30 cc/min	<60 cc/min	< 90 cc/min	
Bactorial Potention	$\leq$ 9.1 cc/min. $\leq$ 10.4 cc/min. $\leq$ 30 cc/min. $\leq$ 30 cc/min. $\leq$ 00 cc/min. $\leq$ 90 cc/min.						
Bacterial Endotoxin	Quantitative retention of 10° CFU/clif <i>Drevunuinionas aiminuta</i> ATCL° 19140 per ASTM° methodology						
	filter)						
TOC/Conductivity	Autoclaved filter meets the WEI requirements of USP <643> for Total Organic Carbon and USP <645> for						
	Water Conductivity after a WFI water flush of 10L at 25 °C (per 10-inch filter)						
Oxidizable Substances	Meets the USP Oxidizable Substances Test requirements for sterile purified water after a water flush of:						
	≤1000 mL ≤1000 mL ≤1000 mL ≤1000 mL ≤3000 mL						
Sterilization	May be autoclaved for 3 cycles of 60 minutes at 126 °C. (Cannot be steam sterilized in-line).						
Non-Fiber Releasing	Component materials meet criteria for a "non fiber releasing" filter as defined in 21 CFR 210.3 (b)(6).						
<b>Component Material</b>	Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics.						
Toxicity	Millipore Express SHF filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride						
	extraction.						
USP Toxicity	Non-toxic per MEM Elution ISO 10993-5						
Good Manufacturing	These products a	are manufactured	in a facility which ac	lheres to FDA Good	Manufacturing Prac	tices.	
Practices							
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.						

<sup>1</sup> Cage, end caps and capsule housing

## TYPICAL CLEAN WATER FLOW RATES

### Cartridge Filters with Millipore Express SHF Hydrophilic Membrane



### **Opticap XL and XLT Disposable Capsules (Autoclavable)**





Opticap XL 5 Capsule Filters with 0.2  $\mu m$  Millipore Express SHF Membrane



Opticap XL 10 Capsule Filters with 0.2 µm Millipore Express SHF Membrane



Opticap XLT 10 Capsule Filters with 0.2  $\mu m$  Millipore Express SHF Membrane







## Opticap XLT 30 Capsule Filters with 0.2 $\mu m$ Millipore Express SHF Membrane



#### Opticap XL Capsule Legends Refer to Connection Type

- TT = 38 mm (1  $\frac{1}{2}$  in.) Sanitary Flange Inlet and Outlet
- HH = 14 mm (  $^{9\prime}\!\prime_{\rm 16}$  in.) Hose Barb Inlet and Outlet
- TH = 38 mm (1  $\frac{1}{2}$  in.) Sanitary Flange Inlet and 14 mm ( $\frac{9}{16}$  in.) Hose Barb Outlet
- TB = 38 mm (1 ½ in.) Sanitary Flange Inlet and 25 mm (1 in.) Hose Barb Outlet

### Opticap XLT Capsule Legends Refer to Connection Type

- TT = 38 mm (1  $\frac{1}{2}$  in.) Sanitary Flange Inlet and Outlet
- TH = 38 mm (1  $\frac{1}{2}$  in.) Sanitary Flange Inlet and
- 16 mm ( <sup>5</sup>/<sub>8</sub> in.) Hose Barb Outlet
- HH = 16 mm ( $\frac{5}{8}$  in.) Hose Barb Inlet and Outlet
- $\mathsf{BB}$  = 25 mm (1 in.) Hose Barb Inlet and Outlet
- TB = 38 mm (1 ½ in.) Sanitary Flange Inlet 25 mm (1 in.) Hose Barb Outlet

## SPECIFICATIONS

## Opticap XL 150, 300 and 600 Disposable Capsules (Sterile and Gamma Compatible)

	Opticap XL 150	p XL 150 Opticap XL 300 Optic						
Nominal Dimensions Maximum length: Body diameter:	9.7 cm (3.8 in.) 5.6 cm (2.2 in.)							
Fitting to Fitting Sanitary flange to Sanitary flange: Sanitary flange to hose barb: Hose barb to hose barb:								
Filtration Area	0.022 m <sup>2</sup> (0.240 ft <sup>2</sup> )	0.048 m <sup>2</sup> (0.514 ft <sup>2</sup> )	0.097 m <sup>2</sup> (1.046 ft <sup>2</sup> )					
Materials of Construction Filter membrane: Film edge: Supports: Structural components <sup>1</sup> : Core: Vent O-rings <sup>2</sup> :	Hydrophilic polyethersulfone — Polyethylene Gamma stable polypropylene Polysulfone Silicone							
Vent/Drain	¼ in. hose barb with d	ouble O-ring seal						
Maximum Inlet Pressure	6895 mbar (100 psi) ii 5515 mbar (80 psi) at 2758 mbar (40 psi) at 1035 mbar (15 psi) at	6895 mbar (100 psi) intermittent at 23 °C 5515 mbar (80 psi) at 23 °C 2758 mbar (40 psi) at 60 °C 1035 mbar (15 psi) at 80 °C						
Maximum Differential Pressure Forward: Reverse:	6895 mbar (100 psi) intermittent at 25 °C 5515 mbar (80 psi) at 25 °C 1035 mbar (15 psi) at 80 °C 2068 mbar (30 psi) intermittent at 25 °C							
Bubble Point at 23 °C	≥4000 mbar (58 psi) air with water							
Air Diffusion at 23 °C	Through a water wet membrane at 2758 mbar (40 psi): $\leq 1.4 \text{ cc/min.}$ $\leq 2.8 \text{ cc/min.}$							
Bacterial Retention	Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> Brevundimonas diminuta ATCC <sup>®</sup> 19146 per ASTM <sup>®</sup> methodology							
Bacterial Endotoxin	Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test							
TOC/Conductivity at 25 °C	Gamma Sterilized filter meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645>for Water Conductivity after a WFI water flush of:2 L2.5 L3 L							
Oxidizable Substances								
<b>Sterilization</b> Gamma compatible: Sterile capsules:	Gamma compatible to 45 kGy. May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line). May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line.)							
Sterility Sterile capsules:	Meets current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.							
USP Toxicity	Non-toxic per MEM elution ISO 10993-5.							
Particle Shedding	Passes USP test for particulates in injectables.							
Non-Fiber Releasing	Millipore Express SHF membrane meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3(b)(6).							
Component Material Toxicity	Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics. Millipore Express SHF filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction.							
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.							
Good Manufacturing Practices	These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.							

<sup>1</sup> Cage, end caps and capsule housing

<sup>2</sup> EPDM and fluorocarbon O-rings available by custom order

Filters were tested post gamma radiation at 25-65  $\rm kGy$ 

## **TYPICAL CLEAN WATER FLOW RATES**

### **Opticap XL and XLT Disposable Capsules (Sterile and Gamma Compatible\*)**

## Opticap XL 150 with 0.2 $\mu m$ Millipore Express SHF Membrane



#### Opticap XL 300 with 0.2 µm Millipore Express SHF Membrane



Opticap XL 600 with 0.2  $\mu m$  Millipore Express SHF Membrane



#### Opticap XL 150, 300 & 600 Capsule Connection Type

- FF = 19 mm ( $^{3}/_{4}$  in.) sanitary flange inlet and outlet
- FH = 19 mm ( $^{3}\!\prime_{4}$  in.) hose barb inlet and and 14 mm ( $^{9}\!\prime_{16}$  in.) hose barb outlet
- HH = 14 mm ( $\%_{16}$  in.) hose barb inlet and outlet

\*Filters were tested post gamma radiation at 45-65kGy and autoclave at 123 °C for 60 minutes.

## SPECIFICATIONS

## **Opticap XL and XLT Disposable Capsules (Sterile and Gamma Compatible)**

	Opticap XL 3	Opticap XL 5	Opticap XL 10	Opticap XLT 10	Opticap XLT 20	Opticap XLT 30		
Nominal Dimensions								
Maximum length:	17.3 cm (6.8 in.)	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)	37.6 cm (14.8 in.)	62.5 cm (24.6 in.)	87.1 cm (34.3 in.)		
Body diameter:	10.7 cm (4.2 in.) 10.7 cm (4.2 in.) 10.7 cm (4.2 in.) — — — —							
Fitting to Fitting								
Sanitary flange to								
sanitary flange:	—			15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)		
Sanitary flange to								
hose barb:	—			17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)		
Hose barb to hose barb:	—			19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)		
Filtration Area	0.17 m <sup>2</sup> (1.8 ft <sup>2</sup> )	0.31 m <sup>2</sup> (3.3 ft <sup>2</sup> )	0.57 m² (6.1 ft²)	0.57 m² (6.1 ft²)	1.14 m <sup>2</sup> (12.3 ft <sup>2</sup> )	1.71 m <sup>2</sup> (18.4 ft <sup>2</sup> )		
Materials of Construction								
Filter membrane:	Hydrophilic polye	thersulfone						
Film edge:	Polyethylene							
Supports:	Polyester							
Structural components <sup>1</sup> :	Gamma stable po	lypropylene						
Core:	Polysulfone							
Vent O-rings	Silicone							
Vent/Drain	¼ in. hose barb w	vith double O-ring s	seal					
Maximum Differential								
Pressure								
Forward:	5.5 bar (80 psi) a	t 25 °C						
	6.9 bar (100 psi)	intermittent at 25						
D	1.0 bar (15 psi) a	t 80 °C						
Reverse:	2.1 bar (30 psi) ir	itermittent at 25						
Buddle Point at 23 °C	≥4000 mbar (58	psi) air with water						
Air Diffusion at 23 °C	Inrough a water	wet membrane at	2/58 mbar (40 psi):	227.00/min <4		2		
Bacterial Retention	≤ 9.5 cc/mm.	$\leq$ 17.4 CC/IIIII.	s 32.7 cc/mm. s	$diminuta$ $\Delta T \cap (^{\circ} 191)$	JS.S CC/IIIII. ≤ 90 16 per ΔSTM® meth			
Bacterial Endotoxin	Quantitative recention of TO' CFU/CIIP <i>Dievunuinionas unninuta</i> ATCC° 19140 per ASTM° methodology							
TOC/Conductivity	Autoclayed filter meets the WEI requirements of LISP <6/3> for Total Organic Carbon and LISP <6/45> for							
	Mater Conductivity after a WEI water flush of 11 L at 25 °C (ner 10-inch filter)							
Oxidizable Substances	Meets the LISP Oxidizable Substances Test requirements for sterile purified water after a water flush of							
	> 1000 mL	>1000 mL	≤1500 mL	≤1500 mL	≤ 3000 mL	≤4500 mL		
Sterilization								
Gamma compatible:	Gamma compatible to 45 kGy. May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized							
	in-line.)							
Sterile capsules:	May be autoclaved for 3 cycles of 60 minutes at 123 °C. (Cannot be steam sterilized in-line.)							
Sterility								
Sterile capsules:	Meets current USP and AAMI guidelines for sterility utilizing a validated sterilization cycle.							
Non-Fiber Releasing	Component materials meet criteria for a "non fiber releasing" filter as defined in 21 CFR 210.3 (b)(6).							
Component Material	Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI plastics.							
Toxicity	Millipore Express SHF filters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride							
	extraction.							
USP Toxicity	Non-toxic per ME	M Elution ISO 109	93-5					
Good Manufacturing	These products are manufactured in a facility which adheres to FDA Good Manufacturing Practices.							
Practices								
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.							

<sup>1</sup> Cage, end caps and capsule housing

Filters were tested post gamma radiation at 25-45 kGy  $\,$ 

## **TYPICAL CLEAN WATER FLOW RATES**

### **Opticap XL and XLT Disposable Capsules (Sterile and Gamma Compatible)**

Opticap XL 3 Capsule Filters with 0.2  $\mu m$  Millipore Express SHF Membrane



Opticap XL 5 Capsule Filters with 0.2 µm Millipore Express SHF Membrane



Opticap XL 10 Capsule Filters with 0.2  $\mu m$  Millipore Express SHF Membrane



Opticap XLT 10 Capsule Filters with 0.2  $\mu m$  Millipore Express SHF Membrane



Opticap XLT 20 Capsule Filters with 0.2  $\mu m$  Millipore Express SHF Membrane



Opticap XLT 30 Capsule Filters with 0.2  $\mu m$  Millipore Express SHF Membrane



### Filter Sizing



Testing with the Millipore Express SHF filters across a range of commonly used buffers and cleaning solutions (pH = 1 - 14) showed an average permeability of 450 liters per hour per psi per 10-inch cartridge.

### Opticap XL 150/300/600 Filters



HH = 14 mm ( $\Re_6$  in.) hose barb inlet and outlet

13

## **ORDERING INFORMATION**

### **Cartridge Filters**



TB = 38 mm (1½ in.) sanitary flange inlet and 25 mm (1 in.) hose barb outlet

## **ORDERING INFORMATION**

### **Opticap XLT Filters**



15

### Go Mobius®

Millipore Express SHF hydrophilic filters are part of the Mobius integrated, disposable bioprocess solution. No matter what your application step or scale, Mobius can help you achieve greater process efficiency and productivity with the right combination of single-use products, application solutions, and expert validation support. From disposable process containers to Millipore patented capsule filters and connectors, to validated, gamma-compatible turnkey assemblies, Mobius solutions provide faster turnaround time and reliable performance, right out of the box.





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## Millipore-Express-SHF-Hydrophilic-Filters

KGEPG015FF1	CGEP01TP1	SGEPA25HH3	KGEPA05TT1	KGEPA1TTT1
KGEPG015FH1	CGEP01TE1	SGEPA25FF3	KGEPA05HH1	KGEPA1TTH1
KGEPG015HH1	CGEP01TF1	SGEPA25FH3	KGEPA05TH1	KGEPA1THH1
KGEPG003FF1	CGEP02TP1	SGEPA25NB3	KGEPA05TB1	KGEPA1TBB1
KGEPG003FH1	CGEP02TE1	SGEPA47HH3	KGEPA10TT1	KGEPA1TTB1
KGEPG003HH1	CGEP02TF1	SGEPA47FF3	KGEPA10HH1	KGEPA2TTT1
KGEPG006FF1	CGEP03TP1	SGEPA47FH3	KGEPA10TH1	KGEPA2TTH1
KGEPG006FH1	CGEP03TE1	SGEPA47NB3	KGEPA10TB1	KGEPA2THH1
KGEPG006HH1	CGEP03TF1		KGEPG05TT1	KGEPA2TBB1
KGEPS015FF1	CGEP75TP1		KGEPG05HH1	KGEPA2TTB1
KGEPS015FH1	CGEP75TE1		KGEPG05TH1	KGEPA3TTT1
KGEPS015HH1	CGEP75TF1		KGEPG05TB1	KGEPA3TTH1
KGEPS003FF1	CGEP01TP3		KGEPG10TT1	KGEPA3THH1
KGEPS003FH1	CGEP01TE3		KGEPG10HH1	KGEPA3TBB1
KGEPS003HH1	CGEP01TF3		KGEPG10TH1	KGEPA3TTB1
KGEPS006FF1	CGEP02TP3		KGEPG10TB1	KGEPG1TTT1
KGEPS006FH1	CGEP02TE3		KGEPS05TT1	KGEPG1TTH1
KGEPS006HH1	CGEP02TF3		KGEPS05HH1	KGEPG1THH1
	CGEP03TP3		KGEPS05TH1	KGEPG1TBB1
	CGEP03TE3		KGEPS05TB1	KGEPG1TTB1
	CGEP03TF3		KGEPS10TT1	KGEPG2TTT1
	CGEP75TP3		KGEPS10HH1	KGEPG2TTH1
	CGEP75TE3		KGEPS10TH1	KGEPG2THH1
	CGEP75TF3		KGEPS10TB1	KGEPG2TBB1
			KGEPA03TT3	KGEPG2TTB1
			KGEPA03HH3	KGEPG3TTT1
			KGEPA03TH3	KGEPG3TTH1
			KGEPA03TB3	KGEPG3THH1
			KGEPG03TT3	KGEPG3TBB1
			KGEPG03TT3	KGEPG3TTB1
			KGEPG03TT3	KGEPS1TTT1
			KGEPG03TT3	KGEPS1TTH1
			KGEPS03TT3	KGEPS1THH1
			KGEPS03TT3	KGEPS1TBB1
			KGEPS03TT3	KGEPS1TTB1
			KGEPS03TT3	KGEPS2TTT1
				KGEPS2TTH1
				KGEPS2THH1
				KGEPS2TBB1
				KGEPS2TTB1
				KGEPS3TTT1
				KGEPS3TTH1
				KGEPS3THH1
				KGEPS3TBB1
				KGEPS3TTB1

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