

#### **Data Sheet**

# Millipore Express® HPF Hydrophilic Filters

# High-capacity bioburden reduction filters

Millipore Express® HPF hydrophilic filters significantly reduce the level of bioburden and particulates across a wide range of aqueous filtration applications, including: cell culture media, media additives, buffers, process intermediates and protein-containing solutions.

Millipore Express® HPF filters are constructed with hydrophilic polyethersulfone (PES) membranes which reduce process variability and extend the filtration capacity of downstream filters by retaining large and fine particles while maintaining high flow rates. The robust design of Millipore Express® HPF filters offers broad chemical compatibility, high thermal stability, gamma stability, low extractables and exceptionally high capacity in fouling fluids for increased productivity, shortened cycle time and reduced costs.

#### Membrane

- Millipore Express® HPF hydrophilic polyethersulfone (PES) membranes
- Nominal pore size: 0.5 μm/0.3 μm

### **Filter Formats**

- OptiScale® 25 small-scale, disposable capsule filters
- Opticap® XL 150, 300, and 600 small-scale, disposable capsule filters - sterile and gamma compatible
- Opticap® XL 3, 5 and 10 disposable capsule filters—gamma compatible or presterilized
- Opticap® XLT 10, 20 and 30 disposable capsule filters—gamma compatible or presterilized
- Cartridge filters in 5, 10, 20, and 30 inch.



#### **Benefits**

- High-capacity, high-flux hydrophilic PES membranes
- Superior throughput in high-fouling streams, including media and protein-containing solutions
- Combines the dirt-holding capacity of a depth filter with the retention efficiency and cleanliness of a membrane prefilter
- Provides superior protection of downstream filters for improved process efficiency and economy
- Broad chemical and caustic compatibility across a wide pH range
- Robust devices resistant to thermal and hydraulic stress
- Available in scalable autoclavable, gamma sterilizable or presterilized disposable capsules

# **Applications**

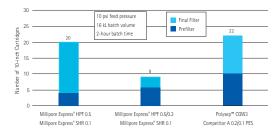
#### Cell Culture Media

Millipore Express® HPF filters extend the service life of downstream sterilizing-grade filters by removing colloidal and particulate contaminants, including lipids, without binding or obstructing the flow of vital media constituents. Millipore Express® HPF filters have a robust device construction which will withstand high operating pressures, high flow rates and multiple steam-in-place cycles of up to 135 °C (cartridges only). Millipore Express® HPF high-capacity filters absorb process variability and protect downstream filters from premature plugging.

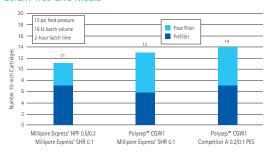
# Buffer Preparation/Column Protection/Process Intermediates

Millipore Express® HPF filters reduce particulate and bioburden before sterilizing filtration and provide excellent protection of sterilizing-grade filters in applications requiring prefiltration.

#### Serum-free CHO Perfusion Media



#### Serum-free CHO Media



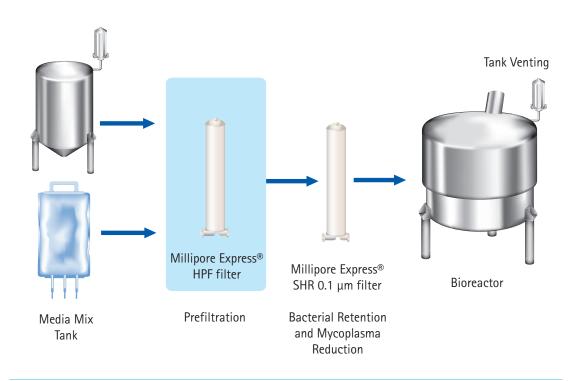
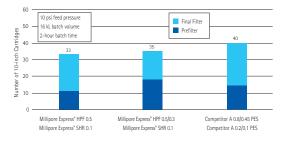
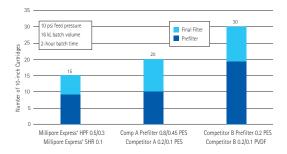


Figure 1.
Cell Culture Media Process

#### **Moderately Fouling Soy Peptone**



#### Serum-free CHO Batch Media



# Increased Throughput for Lower Filtration Costs

High-capacity polyethersulfone membranes extend filter capacity and reduce filtration surface area requirements. This benefit can deliver up to a 50 percent savings in filtration costs, improving your process economics.

# Fewer Filter Change-outs and Extended Capacity

Millipore Express® HPF filters are designed to maximize the efficiency of constrained filtration systems. Its superior dirt-holding capacity and protection of downstream filtration, can increase output while reducing capital and operating expenses.

## Reliable Performance

With the Millipore Express® HPF filter, you will benefit from:

- Higher throughput
- Consistent high capacity
- Low extractables
- High flow rates
- Multiple steam-in-place or autoclave sterilization cycles
- Gamma stable and gamma pre-sterilized devices
- Broad chemical compatibility
- Reliable performance
- High resistance to thermal and hydraulic stresses
- Superior efficiency and process economy



OptiScale® 25 disposable capsule



Small-scale Opticap® XL 150, 300, and 600 capsules and Opticap® XL 3, 5, and 10 capsules



Opticap® XLT filters



Opticap® XLT capsule stand

# OptiScale® Process Development Screening Tool

OptiScale® 25 disposable capsule filters provide a convenient small volume option for process screening and scaling. These "drop in" filters are faster and easier to set up than conventional 25 mm and 47 mm discs, and completely disposable. OptiScale® 25 capsule filters offer speed-to-market strategies for efficiently developing compounds and biotherapeutics.

# Opticap® XL and XLT Disposable Capsule Filters

#### Convenient and Easy to Use

Opticap® XL and XLT's capsule design allows unparalleled hydraulic stress resistance in a disposable filter and eliminates the time and expense associated with stainless steel housings.

Adjustable, easy-to-turn, upstream vents and drain valves with 0-ring seals and hose barb connections allow for easy process control. Other ease-of-use features include flow direction arrows and a ribbed housing for easy gripping, even with gloved hands.

#### Opticap® XL Capsule Filters

Opticap® XL disposable capsule filters have a unique capsule design that minimizes hold-up volume and reduces production losses. Opticap® XL 150, 300, 600, 3, 5 and 10 capsules are available with Millipore Express® HPF membranes in sterile and gamma compatible formats.

#### Opticap® XLT Capsule Filters

Opticap® XLT disposable T-line capsule filters with Millipore Express® HPF membrane 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 10, 20 and 30 capsules are available with Millipore Express® HPF membranes in sterile and gamma compatible formats.

# **Cartridge Filters**

Millipore Express® HPF 5, 10, 20 and 30-inch cartridge" filters provide high flow rates and extended throughput and are designed to withstand multiple steam-in-place cycles. Each cartridge is integrity tested during manufacturing. Code 0 and code 7 0-ring adaptors are available to suit your application and housing needs.



Millipore Express® HPF cartridge filters

# OptiScale® Disposable Capsules

### OptiScale® 25 Capsules

	Optiscale 25 capsures	
Nominal Dimensions Diameter Length	31 mm (1.21 in.) 39 mm (1.52 in.)	
Filtration Area	3.5 cm <sup>2</sup>	
Materials of Construction Filter membrane Structural components Vent cap	Hydrophilic polyethersulfone Polypropylene Polypropylene	
Housing Vent	Capped vent with female Luer connections on inlet side of device.	
Maximum Inlet Pressure	60 psi (4.1 bar) at 25°C	
Maximum Differential Pressure Forward	60 psi (4.1 bar) at 25°C	
Reverse	0 psi (0 bar)	
Bacterial Endotoxin	Aqueous extraction contains <0.25 EU/mL as determined by Limulus Amebocyte Lysate (LAL)	
TOC/Conductivity at 25 °C	This product exhibited less than 500 ppb TOC per USP <643> and less than 1.3 $\mu$ m per USP <645> after autoclave and WFI water flush of 15 mL.	
Sterilization	May be autoclaved for 1 cycle at 123 °C for 60 min.	
Particle Shedding	Passes USP test for particulates in injectables.	
Non-fiber Releasing	Millipore Express® HPF membranes meet 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® HPF 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.	

# Small-scale Opticap® XL Capsules

· · · · · · · · · · · · · · · · · · ·	Opticap® XL 150 Capsules	Opticap® XL 300 Capsules	Opticap® XL 600 Capsules
Nominal Dimensions			
Maximum length	3.8 in (9.7 cm)	4.7 in (11.9 cm)	6.5 in (16.5 cm)
Body diameter	2.2 in (5.6 cm)	2.2 in (5.6 cm)	2.2 in (5.6 cm)
Filtration Area	0.019 m <sup>2</sup> (0.206 ft <sup>2</sup> )	0.039 m <sup>2</sup> (0.418 ft <sup>2</sup> )	0.078 m <sup>2</sup> (0.843 ft <sup>2</sup> )
Materials of Construction Filter membrane Film edge	Hydrophilic polyethersulfone	Hydrophilic polyethersulfone —	Hydrophilic polyethersulfone —
Supports Structural components <sup>1</sup> Core Vent 0-rings <sup>2</sup>	Polyethylene Gamma Stable Polypropylene Polysulfone Silicone	Polyethylene Gamma Stable Polypropylene Polysulfone Silicone	Polyethylene Gamma Stable Polypropylene Polysulfone Silicone
Vent/Drain	1/4 in. hose barb with double O-ring s	eal	
Maximum Inlet Pressure	100 psid (6.9 bar) intermittent at 23 °C 80 psi (5.5 bar) at 23 °C 40 psi (2.8 bar) at 60 °C 15 psi (1.0 bar) at 80 °C		
Maximum Differential Pressure Forward	100 psid (6.9 bar) intermittent at 25 ° 80 psi (5.5 bar) at 25 °C 40 psi (2.8 bar) at 60 °C 15 psid (1.0 bar) at 80 °C	c	
Reverse	20 psid (1.4 bar) intermittent at 25 °C		
Bacterial Endotoxin	Aqueous extraction contains <0.25 E	U/mL as determined by the Limulus Amebocyte	Lysate (LAL) Test (per 10-inch filter)
TOC/Conductivity at 25 °C	Autoclaved filter meets the WFI requi a WFI water flush of:	rements of USP <643> for Total Organic Carbo	n and USP <645> for Water Conductivity after
	1 L	2 L	3 L
Oxidizable Substances	Meets the USP Oxidizable Substances ≤ 1000 mL	Test requirements for sterile purified water aft	er a water flush of:
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).		
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		
	Millipore Express® HPF membranes meet the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3(b)(6)		
Non-fiber Releasing	Millipore Express® HPF membranes m	neet the criteria for a non-liber releasing filter	as defined in 21 CFN 210.3(0)(6)
Non-fiber Releasing  Component Material Toxicity	Component materials were tested an	d meet the criteria for a non-noer releasing litter d meet the criteria of the USP <88> Reactivity ments of the USP <88> Safety Test, utilizing a 0	Test for Class VI plastics. Toxicity Millipore
	Component materials were tested an Express® HPF filters meet the require	d meet the criteria of the USP <88> Reactivity	Test for Class VI plastics. Toxicity Millipore .9% sodium chloride extraction

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

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

# Opticap® XL Capsules

	Opticap® XL3 Capsules	Opticap® XL5 Capsules	Opticap® XL10 Capsules
Nominal Dimensions Maximum length	6.8 in (17.3 cm)	8.5 in (21.6 cm)	13.2 in (33.5 cm)
Body diameter	4.2 in (10.7 cm)	4.2 in (10.7 cm)	4.2 in (10.7 cm)
Filtration Area	0.13 m <sup>2</sup> (1.4 ft <sup>2</sup> )	0.23 m² (2.5 ft²)	0.49 m² (5.3 ft²)
Materials of Construction Filter membrane Film edge Supports Structural components¹ Core Vent 0-rings²	Hydrophilic polyethersulfone Polyethylene Polyethylene Gamma Stable Polypropylene Polysulfone Silicone		
Vent/Drain	1/4 in. hose barb with double O-ring se	eal	
Maximum Inlet Pressure	100 psid (6.9 bar) intermittent at 25° 80 psid (5.5 bar) at 25°C 40 psid (2.8 bar) at 60°C 15 psid (1.0 bar) at 80°C	С	
Maximum Differential Pressure Forward	100 psid (6.9 bar) intermittent at 25 ° 80 psid (5.5 bar) at 25 °C 40 psid (2.8 bar) at 60 °C 15 psid (1.0 bar) at 80 °C	С	
Reverse	30 psid (2.1 bar) intermittent at 25 °C		
Bacterial Endotoxin	Aqueous extraction contains <0.25 El	U/mL as determined by the Limulus Amebocyte	Lysate (LAL) Test (per 10-inch filter).
	Autoclaved filter meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity a WFI water flush of:		
TOC/Conductivity at 25 °C		rements of USP <643> for lotal Organic Carbol	Tanu OSI (043/101 Water Conductivity after
TOC/Conductivity at 25 °C		rements of USP <643> for lotal Organic Carboi	15 L
TOC/Conductivity at 25 °C  Oxidizable Substances	a WFI water flush of:	,	15 L
Oxidizable Substances Sterilization Gamma compatible	a WFI water flush of:  4 L  Meets the USP Oxidizable Substances  Gamma compatible to 45 kGy. May be	7 L  Test requirements for sterile purified water aft on autoclaved for 3 cycles of 60 minutes at 123	15 L er a water flush of: ≤ 2000 mL °C. (Cannot be steam sterilized in-line).
Oxidizable Substances Sterilization Gamma compatible Sterile capsules	a WFI water flush of:  4 L  Meets the USP Oxidizable Substances  Gamma compatible to 45 kGy. May be	7 L  Test requirements for sterile purified water aft	15 L er a water flush of: ≤ 2000 mL °C. (Cannot be steam sterilized in-line).
Oxidizable Substances Sterilization Gamma compatible Sterile capsules	a WFI water flush of:  4 L  Meets the USP Oxidizable Substances  Gamma compatible to 45 kGy. May b  May be autoclaved for 3 cycles of 60	7 L  Test requirements for sterile purified water aft on autoclaved for 3 cycles of 60 minutes at 123	15 L er a water flush of: ≤ 2000 mL  °C. (Cannot be steam sterilized in-line). n-line).
Oxidizable Substances Sterilization Gamma compatible Sterile capsules Sterility Sterile capsules	a WFI water flush of:  4 L  Meets the USP Oxidizable Substances  Gamma compatible to 45 kGy. May b  May be autoclaved for 3 cycles of 60	7 L Test requirements for sterile purified water aft the autoclaved for 3 cycles of 60 minutes at 123 minutes at 123 °C (Cannot be steam sterilized in	15 L er a water flush of: ≤ 2000 mL  °C. (Cannot be steam sterilized in-line). n-line).
Oxidizable Substances Sterilization Gamma compatible Sterile capsules Sterility Sterile capsules USP Toxicity	a WFI water flush of:  4 L  Meets the USP Oxidizable Substances  Gamma compatible to 45 kGy. May b  May be autoclaved for 3 cycles of 60  Meets current USP and AAMI guideling	7 L Test requirements for sterile purified water aft be autoclaved for 3 cycles of 60 minutes at 123 minutes at 123 °C (Cannot be steam sterilized in the sterility utilizing a validated sterilization 3-5	15 L er a water flush of: ≤ 2000 mL  °C. (Cannot be steam sterilized in-line). n-line).
Oxidizable Substances Sterilization Gamma compatible Sterile capsules Sterility	a WFI water flush of:  4 L  Meets the USP Oxidizable Substances  Gamma compatible to 45 kGy. May b  May be autoclaved for 3 cycles of 60  Meets current USP and AAMI guidelir  Non-toxic per MEM elution ISO 1099:  Passes USP test for particulates in inj	7 L Test requirements for sterile purified water aft be autoclaved for 3 cycles of 60 minutes at 123 minutes at 123 °C (Cannot be steam sterilized in the sterility utilizing a validated sterilization 3-5	15 L er a water flush of: ≤ 2000 mL  °C. (Cannot be steam sterilized in-line). n-line).  cycle.
Oxidizable Substances  Sterilization Gamma compatible Sterile capsules  Sterility Sterile capsules  USP Toxicity Particle Shedding	a WFI water flush of:  4 L  Meets the USP Oxidizable Substances  Gamma compatible to 45 kGy. May be May be autoclaved for 3 cycles of 60  Meets current USP and AAMI guidelin  Non-toxic per MEM elution ISO 1099:  Passes USP test for particulates in injuitipore Express® HPF membranes m  Component materials were tested and	7 L  Test requirements for sterile purified water aft  be autoclaved for 3 cycles of 60 minutes at 123  minutes at 123 °C (Cannot be steam sterilized in  these for sterility utilizing a validated sterilization  3-5  ectables	15 L  er a water flush of: ≤ 2000 mL  °C. (Cannot be steam sterilized in-line).  n-line).  cycle.  as defined in 21 CFR 210.3(b)(6)  Test for Class VI plastics. Millipore Express®
Oxidizable Substances Sterilization Gamma compatible Sterile capsules Sterility Sterile capsules USP Toxicity Particle Shedding Non-fiber Releasing	a WFI water flush of:  4 L  Meets the USP Oxidizable Substances  Gamma compatible to 45 kGy. May be May be autoclaved for 3 cycles of 60  Meets current USP and AAMI guidelin Non-toxic per MEM elution ISO 1099: Passes USP test for particulates in injuice Millipore Express® HPF membranes made Component materials were tested and HPF filters meet the requirements of	7 L  Test requirements for sterile purified water aft to a autoclaved for 3 cycles of 60 minutes at 123 minutes at 123 °C (Cannot be steam sterilized in the sterility utilizing a validated sterilization 3-5 ectables the criteria for a "non-fiber releasing" filtered meet the criteria of the USP <88> Reactivity	15 L  er a water flush of: ≤ 2000 mL  °C. (Cannot be steam sterilized in-line).  n-line).  cycle.  as defined in 21 CFR 210.3(b)(6)  Test for Class VI plastics. Millipore Express®  um chloride extraction

Cage, end caps and capsule housing
 EPDM and fluorocarbon O-rings available by custom order

# Opticap® XLT Capsules

opticap ALI capsuics			
	Opticap® XLT 10 Capsules	Opticap® XLT 20 Capsules	Opticap® XLT 30 Capsules
Nominal Dimensions Maximum length	14.8 in (37.7 cm)	24.6 in (62.5 cm)	34.3 in (87.2 cm)
Body diameter	4.2 (10.7 cm)	4.2 in (10.7 cm)	4.2 in (10.7 cm)
Fitting to Fitting Sanitary flange to Sanitary flange: Sanitary flange to	6.0 in (15.2 cm)	6.0 in (15.2 cm)	6.0 in (15.2 cm)
hose barb: Hose barb to hose barb:	6.9 in (17.5 cm) 7.8 in (19.4 cm)	6.9 in (17.5 cm) 7.8 in (19.4 cm)	6.9 in (17.5 cm) 7.8 in (19.4 cm)
Filtration Area	0.49 m² (5.3 ft²)	0.98 m² (10.5 ft²)	1.47 m <sup>2</sup> (15.8 ft <sup>2</sup> )
Materials of Construction Filter membrane Film edge Supports Structural components <sup>1</sup> Core Vent 0-rings <sup>2</sup>	Hydrophilic polyethersulfone Polyethylene Polyethylene Gamma Stable Polypropylene Polysulfone Silicone		
Vent/Drain	1/4 in. hose barb with double O-ring se	al	
Maximum Inlet Pressure	100 psid (6.9 bar) intermittent at 23 °C 80 psid (5.5 bar) at 23 °C 40 psid (2.8 bar) at 60 °C 15 psid (1.0 bar) at 80 °C	C	
Maximum Differential Pressure Forward	100 psid (6.9 bar) intermittent at 25°0 80 psid (5.5 bar) at 25°C 15 psid (1.0 bar) at 80°C	C	
Reverse	30 psid (2.1 bar) intermittent at 25 °C		
Bacterial Endotoxin	Aqueous extraction contains <0.25 El	J/mL as determined by the Limulus Amebocyte	Lysate (LAL) Test (per 10-inch filter)
TOC/Conductivity at 25 °C	Autoclaved filter meets the WFI require a WFI water flush of:	rements of USP <643> for Total Organic Carbo	n and USP <645> for Water Conductivity after
,	15 L	30 L	45 L
Oxidizable Substances			
	Meets the USP Oxidizable Substances	Test requirements for sterile purified water aft	
Oxidizable Substances	Meets the USP Oxidizable Substances ≤ 2000 mL	Test requirements for sterile purified water aft ≤ 4000 mL	
Sterilization Gamma compatible	≤2000 mL		er a water flush of: ≤6000 mL
Sterilization	≤ 2000 mL  Gamma compatible to 45 kGy. May b	≤4000 mL	er a water flush of: ≤6000 mL  °C. (Cannot be steam sterilized in-line).
Sterilization Gamma compatible	≤ 2000 mL  Gamma compatible to 45 kGy. May b  May be autoclaved for 3 cycles of 60	≤ 4000 mL e autoclaved for 3 cycles of 60 minutes at 123	er a water flush of: ≤ 6000 mL  °C. (Cannot be steam sterilized in-line). n-line).
Sterilization Gamma compatible Sterile capsules Sterility	≤ 2000 mL  Gamma compatible to 45 kGy. May b  May be autoclaved for 3 cycles of 60	≤ 4000 mL  e autoclaved for 3 cycles of 60 minutes at 123 minutes at 123 °C (Cannot be steam sterilized in the sterilization of the st	er a water flush of: ≤ 6000 mL  °C. (Cannot be steam sterilized in-line). n-line).
Sterilization Gamma compatible Sterile capsules Sterility Sterile capsules	≤ 2000 mL  Gamma compatible to 45 kGy. May b  May be autoclaved for 3 cycles of 60 meets current USP and AAMI guideling	≤ 4000 mL  e autoclaved for 3 cycles of 60 minutes at 123 minutes at 123 °C (Cannot be steam sterilized in the sterilization as for sterility utilizing a validated sterilization 3-5	er a water flush of: ≤ 6000 mL  °C. (Cannot be steam sterilized in-line). n-line).
Sterilization Gamma compatible Sterile capsules Sterility Sterile capsules USP Toxicity	≤ 2000 mL  Gamma compatible to 45 kGy. May b  May be autoclaved for 3 cycles of 60 m  Meets current USP and AAMI guidelin  Non-toxic per MEM elution ISO 10993  Passes USP test for particulates in injections.	≤ 4000 mL  e autoclaved for 3 cycles of 60 minutes at 123 minutes at 123 °C (Cannot be steam sterilized in the sterilization as for sterility utilizing a validated sterilization 3-5	er a water flush of:  ≤ 6000 mL  °C. (Cannot be steam sterilized in-line).  n-line).  cycle.
Sterilization Gamma compatible Sterile capsules Sterility Sterile capsules USP Toxicity Particle Shedding	≤ 2000 mL  Gamma compatible to 45 kGy. May be May be autoclaved for 3 cycles of 60 meets current USP and AAMI guidelin Non-toxic per MEM elution ISO 10993.  Passes USP test for particulates in injumilipore Express® HPF membranes materials were tested and	≤ 4000 mL  e autoclaved for 3 cycles of 60 minutes at 123 minutes at 123 °C (Cannot be steam sterilized in the sterilization as for sterility utilizing a validated sterilization as 5-5 ectables	er a water flush of:  ≤ 6000 mL  °C. (Cannot be steam sterilized in-line).  n-line).  cycle.  as defined in 21 CFR 210.3(b)(6)  Test for Class VI plastics. Toxicity Millipore
Sterilization Gamma compatible Sterile capsules  Sterility Sterile capsules  USP Toxicity  Particle Shedding  Non-fiber Releasing	≤ 2000 mL  Gamma compatible to 45 kGy. May be May be autoclaved for 3 cycles of 60 meets current USP and AAMI guidelin Non-toxic per MEM elution ISO 10993.  Passes USP test for particulates in injumilipore Express® HPF membranes materials were tested and Express® HPF filters meet the requirer.	≤ 4000 mL  e autoclaved for 3 cycles of 60 minutes at 123 minutes at 123 °C (Cannot be steam sterilized in es for sterility utilizing a validated sterilization 3-5 ectables  eet the criteria for a "non-fiber releasing" filter in meet the criteria of the USP <88> Reactivity	er a water flush of:  ≤ 6000 mL  °C. (Cannot be steam sterilized in-line).  n-line).  cycle.  as defined in 21 CFR 210.3(b)(6)  Test for Class VI plastics. Toxicity Millipore .9% sodium chloride extraction

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

 $<sup>^{\,2}\,</sup>$  EPDM and fluorocarbon O-rings available by custom order

# **Cartridge Filters**

cartifuge Fifters			
	5-inch Cartridges	Cartridges (per 10-inch element)	
Nominal Dimensions Maximum length	5 in (12.7 cm)	10 in (25.4 cm)	
Body diameter	2.7 in (6.9 cm)	2.7 in (6.9 cm)	
Filtration Area	0.23 m² (2.5 ft²)	0.49 m <sup>2</sup> (5.3 ft <sup>2</sup> )	
Materials of Construction Filter membrane Supports Structural components <sup>1</sup> Core Vent 0-rings <sup>2</sup>	Hydrophilic polyethersulfone Polypropylene non-woven spun bound Polypropylene Polysulfone Silicone		
Maximum Differential Pressure Forward	100 psid (6.9 bar) intermittent at 4-25 °C 25 psid (1.7 bar) at 80 °C 5 psid (0.3 bar) at 135 °C		
Reverse	30 psid (2.1 bar) at 4-25 °C 1 psid (0.1 bar) at 135 °C		
Bacterial Endotoxin	Aqueous extraction contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test (per 10-inch filter)		
TOC/Conductivity at 25 °C	Autoclaved filter meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a WFI water flush of <sup>3</sup> :		
,	4.7 L	10 L	
Sterilization Autoclave	25 cycles of 60 minutes at ≤126 °C.		
In-line steam*	25 forward cycles of 30 minutes at ≤135 °C or 22 forward cycles of 30 minutes at ≤135 °C and 3 reverse cycles of 30 minutes at 135 °C		
USP Toxicity	Non-toxic per MEM elution ISO 10993-5		
Non-fiber Releasing	Millipore Express® HPF membranes meet the criteria for a "non-t	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. Toxicity Millipore Express® HPF 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 rec	quirements cited in 21 CFR 177–182.	
Good Manufacturing Practices	These products are manufactured in a facility which adheres to I	FDA Good Manufacturing Practices.	

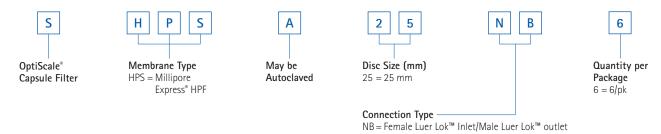
<sup>&</sup>lt;sup>1</sup> Cage, end caps and capsule housing

 $<sup>^{\</sup>rm 2}\,$  EPDM and fluorocarbon O-rings available by custom order

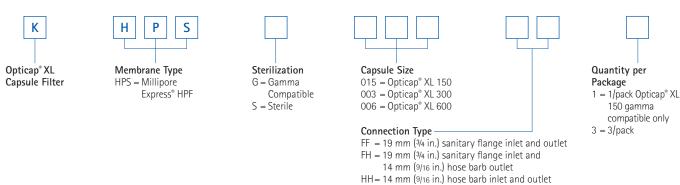
<sup>&</sup>lt;sup>3</sup> 30 inch cartridge requires 20 L flush

# **Ordering Information**

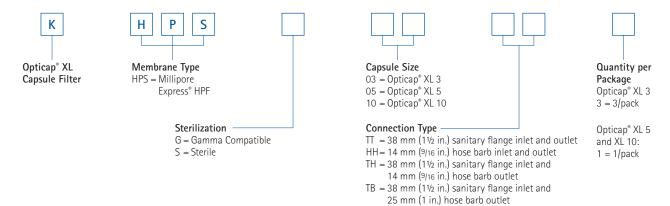
#### OptiScale® Capsule Filters



#### Small-scale Opticap® XL 150/300/600 Capsule Filters

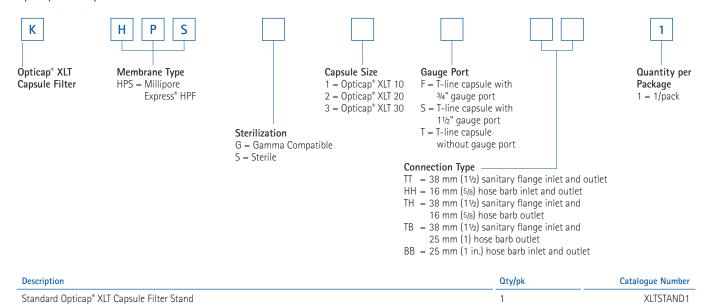


#### Opticap® XL Capsule Filters

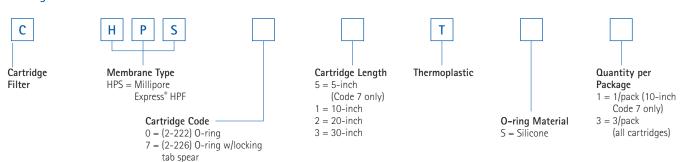


# **Ordering Information**

#### Opticap® XLT Capsule Filters



#### Cartridge Filters





www.emdmillipore.com/offices