Data Sheet

Durapore® 0.45 µm Hydrophilic Filters

The superior solution for extending the life of downstream sterilizing filters by removing colloidal and particulate contaminants

Hydrophilic 0.45 µm Durapore polyvinylidene fluoride (PVDF) membrane provides low protein binding, high flow rates and high throughputs. Durapore 0.45 µm membrane contributes to clean processes due to low extractables, broad chemical compatibility, and its non-fiber releasing properties.

Durapore 0.45 µm hydrophilic filters remove particles and microorganisms from aqueous liquid streams. These filters are ideally suited for large volume parenteral or ophthalmics manufacturing, where prefiltration is either unnecessary or already present at an earlier point in the process, or where protein binding must be minimized.

Benefits

- Low protein binding membrane yields high protein recovery with minimal loss of valuable product
- Superior membrane for filtration processes requiring high flow rates and throughputs
- Ideal for bioburden reduction before final sterilization
- Ideal for designing scalable solutions from bench top to full-scale manufacturing

Membrane Types	Filter Formats
Durapore 0.45 µm hydrophilic	○ OptiScale® small scale disposable capsule filters ○ Millipak® low-volume capsule filters ○ Opticap® XL 2 disposable capsule filters

Fisher Scientific

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

MILLIPAK LOW-VOLUME CAPSULE FILTERS

Millipak filters with 0.45 µm hydrophilic Durapore membranes are uniquely designed for the removal of particles and microorganisms. The stacked disc design allows minimal hold-up volume and no particle shedding, making Millipak units ideally suited for high value-added applications. Each Millipak filter is integrity tested during the manufacturing process.

Millipak filters are available in two different stack sizes. Adjustable, easy-to-turn, upstream vents and drain valves with O-ring seals and hose barb connections allow for easy process control.

OPTICAP XL 2 DISPOSABLE CAPSULE FILTERS

The patented Opticap XL capsule design allows unparalleled thermal and hydraulic stress resistance in a disposable filter, resulting in reliability, high confidence in the sterility process and improved cleanliness. The unique capsule design with pleated Durapore membrane minimizes hold-up volume and reduces production losses.

Convenient and Easy to Use

Opticap XL 2 capsule filters eliminate the time and the 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 directional arrows and ribbed edges for easy gripping even with gloved hands.

The Right Size

The Opticap capsule product family provides a wide range of filtration areas 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

Self-contained and disposable, Opticap XL 2 capsule filters are supplied with a choice of inlet and outlet connections to optimize your filtration process, including sanitary flanges which provide a higher flow rate, fractional sanitary flanges, and hose barbs.

REGULATORY COMPLIANCE

Filters with hydrophilic Durapore membrane are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to an ISO® 9000 Quality Systems Standard and are shipped with a Certificate of Quality. Each Millipak® and Opticap® XL 2 filter is integrity tested during manufacturing and is supported by a Validation Guide for compliance with regulatory requirements.

For traceability and easy identification, each device is marked with the product name and identifying characteristics.

MULTIPLE FORMATS AVAILABLE

Hydrophilic Durapore membranes are available in multiple formats and configurations that vary by filtration area and type of inlet/outlet connection. We have a format to meet your application needs.

SPECIFICATIONS (OptiScale and Millipak Capsule Filters)

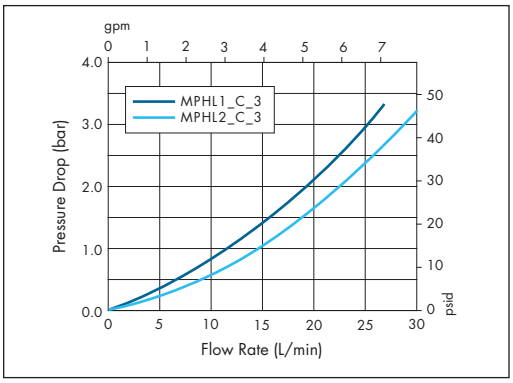
	OptiScale			Millipak-100	Millipak-200
Nominal Dimensions					
Inlet/outlet:	Flange/hose barb	Flange/flange	Hose barb/hose barb	—	—
Maximum length:	82 mm (3.24 in.)	74 mm (2.91 in.)	94 mm (3.70 in.)	13 cm (5.1 in.)	15.5 cm (6.1 in.)
Diameter:	69 mm (2.75 in.)	69 mm (2.75 in.)	69 mm (2.75 in.)	7.6 cm (3.0 in.)	7.6 cm (3.0 in.)
Weight:	2.3 oz (67 g)	2.3 oz (67 g)	2.3 oz (67 g)	—	—
Filtration Area	17.7 cm^2			500 cm^2 (0.54 ft^2)	1000 cm^2 (1.08 ft^2)
Materials of Construction					
Filter membrane:	Hydrophilic PVDF			Hydrophilic PVDF	
Structural components:	Polycarbonate			Polycarbonate	
Suppports:	Polypropylene			Polycarbonate	
Vent caps:	PVDF			PVDF	
Internal seal rings:	Viton® fluoroelastomers			—	
Housing Vent	Adjustable vent with male luer and female Luer-Lok™ connections on inlet side of device.				
Maximum Inlet Pressure	5.5 bar (80 psig) at 25 °C			5.2 bar (75 psi) at 25 °C	
Maximum Differential Pressure					
Forward:	—			4.1 bar (60 psid) at 25 °C 1.7 bar (25 psid) at 80 °C 345 mbar (5 psid) at 123 °C	
Reverse:	—			690 mbar (10 psid) at 25 °C	
Bubble Point at 23 °C	—			≥ 1790 mbar (26 psig) air with water	
Gravimetric Extractables	—			After autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade waterat controlled room temperature:	
				≤ 2.5 mg	≤ 5.0 mg
Bacterial Endotoxin	—			Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.	
Oxidizable Substances	Meets the requirements of the USP Oxidizable Substance Test after a water flush of:				
	≤100 mL			200 mL	200 mL
Sterilization	May be autoclaved for 3 cycles of 60 minutes at 126 °C			May be autoclaved for 3 cycles of 90 minutes at 123 °C. Capable of 45 kilogray (4.5 Megarad) gamma exposure. (Cannot be steam sterilized in-line)	
Good Manufacturing Practices	These products are manufactured in a Millipore facility which adheres to FDA Device Good Manufacturing Practices.				
Non-Fiber Releasing	Durapore 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. Sterilizing-grade Durapore Filters are non-toxic per the current USP <88> Safety Test.				
Indirect Food Additive	The Durapore membrane used in these products meets the FDA Indirect Food Additive requirements cited in 21 CFR 177.2910. All other components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.				

SPECIFICATIONS (Opticap XL 2 Capsule Filters)

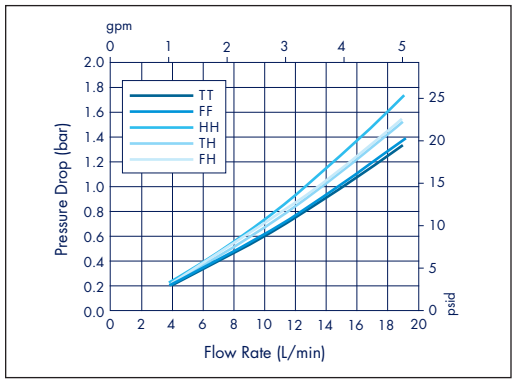
Nominal Dimensions	
Maximum length:	14.2 cm (5.6 in.)
Diameter:	8.4 cm (3.3 in.)
Filtration Area	0.09 m^2 (0.93 ft^2)
Materials of Construction	
Filter membrane:	Hydrophilic PVDF
Film edge:	—
Structural components:	Polypropylene
Supports:	Polypropylene
Vent O-rings:	Silicone
O-rings:	—
Vent/Drain	¼ in. hose barb with double O-ring seal
Maximum Inlet Pressure	5.5 bar (80 psi) at 23 °C 2.8 bar (40 psi) at 60 °C 1.0 bar (15 psi) at 80 °C
Maximum Differential Pressure	
Forward:	3.4 bar (50 psid) at 25 °C
Reverse:	3.4 bar (50 psid) at 25 °C, intermittent
Bubble Point at 23°C	≥ 1930 mbar (28 psig) air with water
Gravimetric Extractables	After autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade water at controlled room temperature: ≤ 10 mg
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.
Oxidizable Substances	Meets the requirements of the USP Oxidizable Substance Test after a water flush of: 500 mL
Sterilization	May be autoclaved for 3 cycles of 60 minutes at 126 °C. (Cannot be steam sterilized in-line)
Good Manufacturing Practices	These products are manufactured in a Millipore facility which adheres to FDA Good Manufacturing Practices.
Non-Fiber Releasing	Durapore 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. Sterilizing-grade Durapore Filters are non-toxic per the current USP <88> Safety Test.
Indirect Food Additive	Durapore membrane meets the FDA Indirect Food Additive requirements cited in 21 CFR 177.2910. All other component materials also meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.
European Pressure Equipment Directive	Millipore Corporation certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has beendesigned and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.

TYPICAL CLEAN WATER FLOW RATES

Millipak 100/200 Filter with 0.45 µm Durapore Membrane (MPHL)



Opticap XL 2 Capsule Filters 0.45 µm Durapore Membrane (KPHL)

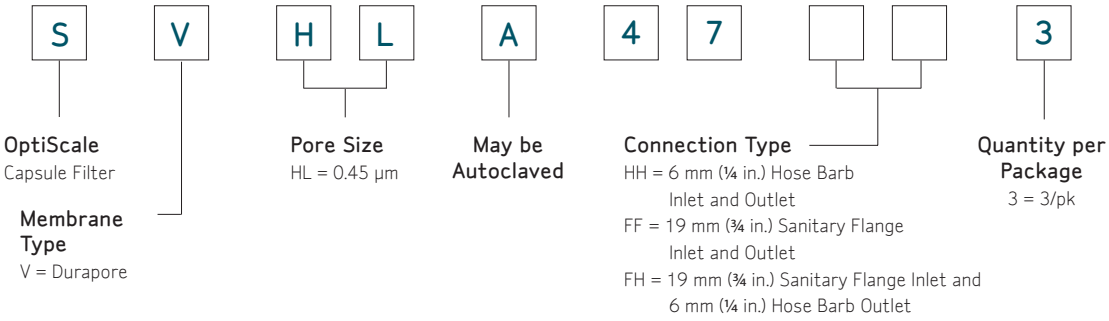


Legends Refer to Capsule Connection Type

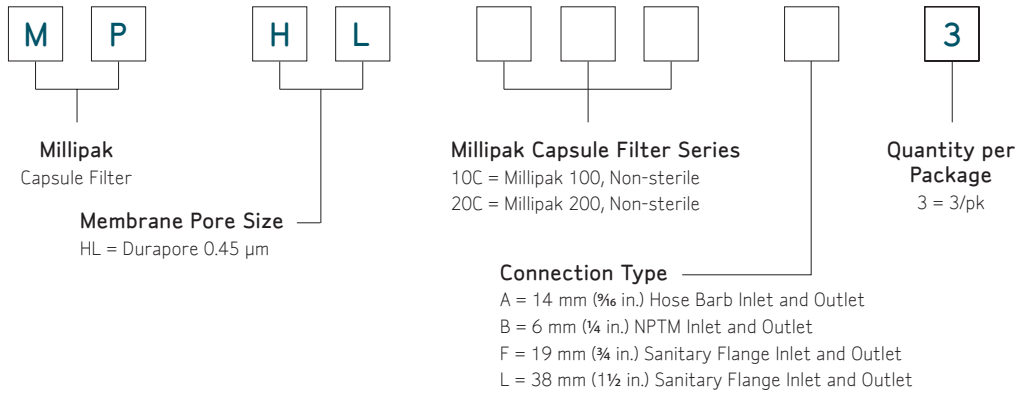
TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
HH = 14 mm (⅝ in.) Hose Barb Inlet and Outlet
TH = 38 mm (1½ in.) Sanitary Flange Inlet and 14 mm (⅝ in.) Hose Barb Outlet
FH = 19 mm (¾ in.) Sanitary Flange Inlet and 14 mm (⅝ in.) Hose Barb Outlet

ORDERING INFORMATION

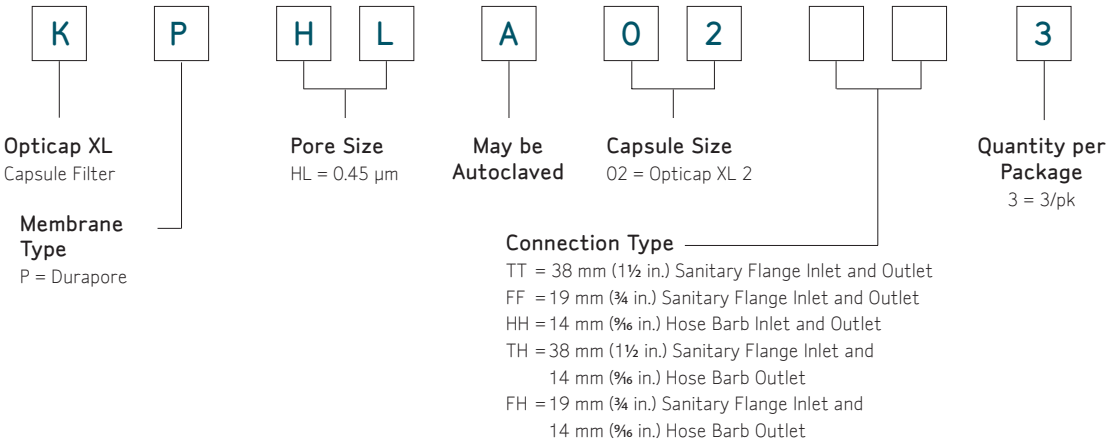
OptiScale Capsule Filters



Millipak Capsule Filters



Opticap XL 2 Capsule Filters



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