User Guide

Opticap® XL Capsules and Opticap® XLT Capsules

The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the US and Canada.

Millipore®

Contents

Sterilization by Autoclave

WARNING:
DO NOT IN-LINE STEAM STERILIZE. NEVER USE A DEFORMED FILTER CAPSULE.

- Appropriate autoclave validation studies should be performed to achieve sterilizing conditions.
- For devices with filling bell, remove the protective cap from the filling bell before autoclaving.
- Remove dust cover (bag) and protective caps if present, before autoclaving.
- High and low point bleed valves must be open during autoclaving.
- Opticap® XL capsules must be oriented so that flow indicator arrows are pointing down during autoclave cycle.
- Opticap® XLT capsules must be oriented such that the t-line inlet and outlet connectors are the lowest points during the autoclave cycle to minimize condensate formation. DO NOT AUTOCLAVE OPTICAP® XLT CAPSULES IN A HORIZONTAL POSITION.
- Use plastic sanitary flange clamps or three piece stainless steel clamps to minimize stress during autoclaving. Fittings will distort if the flange or hose barb clamps are over torqued.
- For additional autoclaving information, request Technical Brief Opticap® Autoclaving Guidelines, TB072.

The following values are the maximum cycle parameters recommended for this product.

Opticap® XL and Opticap® XLT Capsule Autoclave Specifications

Membrane/Media	Catalog Number	Time (Min.)	Temp (°C)	Cycles
Aervent®	KTGRA	30	135	30
Hydrophobic Durapore®	KVGBA	30	126	20
Durapore® 0.45 µm	KPHLA	60	126	3
Durapore® 0.45 µm with prefilter	KVHLA	60	121	3
Durapore® 0.22 µm	KVGLA	60	126	3
Durapore® 0.1 µm	KVVLA	60	126	3
Multilayer Durapore®	KHGLA	60	126	3
Multimedia Durapore®	KVSSA	30	123	3
	KVSXA	30	123	3
	KVSCA	30	123	3
	KV19A	30	123	3
	KV06A	30	123	3
	KV03A	30	123	3
Millipore Express® PHF	KPGEA	60	126	3
Millipore Express® SHC	KHGEA	60	126	3
Millipore Express® SHR	KVEPA	60	126	3
Millipore Express® SHR-P	KHVEA	60	126	3
Millipore Express® SHF	KGEPA	60	126	3
Lifegard™	KP15	30	121	3
	KP20	30	121	3

Membrane/Media	Catalog Number	Time (Min.)	Temp (°C)	Cycles
Polysep™ II	KGW1	30	121	3
	KGW2	30	121	3
	KGW3	30	121	3
	KGW6	30	121	3
	KGW9	30	121	3
Milligard®	KWSS	30	121	3
	KWSC	30	121	3
	KW03	30	121	3
	KW06	30	121	3
	KW19	30	121	3
Milligard® LPB	KWLS	30	121	3
	KWLC	30	121	3
	KWL3	30	121	3
	KWL6	30	121	3
	KWL9	30	121	3
Clarigard®	K030	30	126	3
	K010	30	126	3
	K005	30	126	3
	K003	30	126	3
	K002	30	126	3
Polygard® CR	KRK1	30	126	3
	KRK3	30	126	3
	KRK5	30	126	3
	KR01	30	126	3
	KR03	30	126	3
	KR05	30	126	3
	KR10	30	126	3
	KR25	30	126	3
	KR50	30	126	3
	KR75	30	126	3
	KR99	30	126	3

Membrane/Media	Catalog Number	Time (Min.)	Temp (°C)	Cycles
Polygard® CN	KN03	30	126	3
	KN06	30	126	3
	KN12	30	126	3
	KN25	30	126	3
	KN50	30	126	3
	KN1H	30	126	3
	KN3H	30	126	3
Gamma Stable and Pre-Sterilized Capsules that can be Autoclaved:				
Hydrophobic Durapore®	KVGBG/ KVGBS	30	123	3
Durapore® 0.1 µm	KVVLG/ KVVLS	60	123	3
Durapore® 0.22 µm	KVGLG/ KVGLS	60	123	3
Durapore® 0.45 µm	KPHLG/ KPHLS	60	123	3
Multilayer Durapore®	KHGLG/ KHGLS	60	123	3
Millipore Express® PHF	KPGEA	60	123	3
Millipore Express® SHC	KHGEG/ KHGES	60	123	3
Millipore Express® SHR	KVEPG/ KVEPS	60	123	3
Millipore Express® SHR-P	KHVEG/ KHVES	60	123	3
Millipore Express® SHF	KGEPG/ KGEPS	60	123	3

Installation

- Orient the capsule in the process so that process flow follows the flow indicator arrow on the capsule label. See Figure 1.

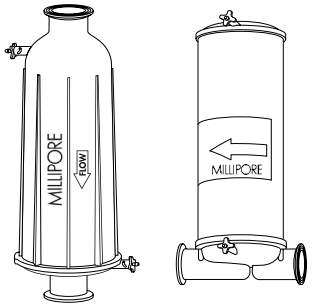

Figure 1. Flow indicator arrows

- To minimize holdup volume in the Opticap® XLT capsule, orient the capsule so that the t-line connector is at the lowest point.
- Isolation valves should be attached to the inlet and outlet ports of the capsule to allow flushing, venting and draining operations.
- If using the Opticap® XLT capsules with the optional gauge port, install gauge prior to use.

Filter Wetting

Refer to the appropriate wetting guide for more details.

NOTE: Opticap capsules with Durapore®, Multimedia Durapore® or Millipore Express® membranes MUST be wetted prior to use and integrity testing.

Close both bleed valves, and the isolation valve located downstream of the capsule.

Wet the filter capsule by slowly introducing RO, DI or WFI water or buffer through the capsule inlet port. (Product may be used, if a product-based integrity test has been validated.) Open the high point bleed valve until liquid starts flowing out of the valve. Close the valve when the flow of liquid becomes steady and free of air. Open the capsule downstream isolation valve and adjust flow to approximately 1 Lpm/ft^2 of filter surface area for a minimum of 5 minutes.

Opticap® XL 150, 300 and 600 capsules with Millipore Express® Membranes

Open the capsule downstream isolation valve and set the inlet pressure to 5 psig. Continue to flow the wetting fluid through the capsule for a total of three minutes.

Proper wetting can also be used to meet minimum flush requirements, to prevent false integrity failures, and to ensure full use of the available filtration area.

Filter Flushing—Hydrophilic Membranes

Filter flushing before product processing is strongly recommended as a preconditioning step. It will prevent adverse reactions such as excessive product binding or precipitate formation, which can occur between process fluid and dry filter material. Flushing also allows the filter to be properly wet, which is key to overall filter performance.

Flushing is beneficial to filtrate quality and will eliminate most of the filter extractable substances from the process. When the filter is subjected to autoclaving, flushing after autoclaving is highly recommended.

Capsules meet the requirements of USP Oxidizable Substances Test after a water flush as listed in the USP Oxidizable Substances Test Recommended Flush Volumes table.

Capsules meet the requirements of:

- <500 ppb TOC per USP <643>
- <1.3 µS/cm conductivity at 25 °C per USP <645>

after a water flush as listed in the TOC and Conductivity Tests Recommended Flush Volumes table.

USP Oxidizable Substances Test Recommended Flush Volumes

Membrane or Media		Recommended Flush Volume (Liters) per Opticap® Capsule									
		XL 150 XL 300 XL 600	XL1	XL2	XL3	XL4	XL5	XL 10	XLT 10	XLT 20	XLT 30
Durapore®		--	--	0.5	--	0.5	0.5	1	1	2	3
Multimedia Durapore®		--	--	--	--	--	--	5	5	10	15
Milligard®		--	--	1	--	1	2	5	5	10	15
Milligard® LPB		--	--	1	--	1	2	5	--	--	--
Polysep™		--	--	1	--	2	2	5	5	10	15
Lifegard™		--	--	--	--	--	2	5	--	--	--
Polygard® CN		--	--	--	--	--	2	5	--	--	15
Polygard® CR		--	1	--	--	--	2.5	5	--	--	--
Clarigard®		--	1	--	--	--	2	3	--	--	--
Millipore Express®	SHC	1	--	--	2	--	2	2	2	4	6
	SHF	1	--	--	1	--	1	1	1.5	3	4.5
	SHR	1	--	--	2	--	2	2	2	4	6
Multilayer Durapore®		--	--	--	--	--	--	1.5	1.5	3.0	4.5

TOC and Conductivity Tests Recommended Flush Volumes

Membrane or Media		Recommended Flush Volume (Liters) per Opticap® Capsule									
		XL							XLT		
		150	300	600	3	4	5	10	10	20	30
Gamma Compatible and Sterile											
Durapore®		--	--	--	--	<26	--	<53	--	--	--
Millipore Express®	SHC	1.0	2.0	3.0	5.0	--	9.5	21	21	42	63
	SHF	2.0	2.5	3.0	3.5	--	6.0	11.0	11	22	33
	SHR	2.0	2.5	3.0	3.5	--	6.0	11.0	11	22	33
	SHR with Prefilter	1.0	2.0	3.0	5.0	--	9.5	21.0	21	42	63
	PHF										
Multilayer Durapore®		--	--	--	--	--	--	36	36	72	108
Durapore® 0.45 µm		--	--	--	--	--	--	36	36	72	108

Membrane or Media		Recommended Flush Volume (Liters) per Opticap® Capsule									
		XL							XLT		
		150	300	600	3	4	5	10	10	20	30
Autoclaveable											
Multilayer Durapore®		--	--	--	--	--	--	16	16	32	48
Durapore® 0.1 µm											
Durapore® 0.22 µm											
Durapore® 0.45 µm with prefilter		--	--	--	--	--	--	16	16	32	48
Durapore® 0.45 µm without prefilter											
Millipore Express®	SHC	--	--	--	5.5	--	9.5	20	20	40	60
	SHF	--	--	--	3.0	--	5.5	10.0	10	20	30
	SHR	--	--	--	3.0	--	5.5	10.0	10	20	30
	SHR with Prefilter	--	--	--	5.5	--	9.5	20.0	20	40	60
	PHF										

Integrity Testing

Opticap® XL and XLT Capsules with Durapore®, Multimedia Durapore® Membrane or Millipore Express® Membranes

Pre-use, post-sterilization (autoclaving) integrity testing is recommended to identify potential problems prior to processing valuable product. Post-use integrity testing is a GMP requirement for many applications. Either a validated rinse procedure or a validated product-based integrity test is critical to minimize false failures.

Operating Conditions

Do not exceed maximum inlet pressure:

- 6.9 bar (100 psi) at 25 °C, intermittent, Millipore Express® SHF, SHC and SHR membranes only
- 5.5 bar (80 psi) at 25 °C
- 2.8 bar (40 psi) at 60 °C
- 1.0 bar (15 psi) at 80 °C

Do not exceed maximum differential pressures:

Membrane or Media Type	Maximum Pressure					
	Forward			Reverse		
	PSID	Bar	Temp °C	PSID	Bar	Temp °C
Durapore®, Multimedia Durapore® Multilayer Durapore®	80	5.5	25	50	3.4	25
	15	1.0	80			
Millipore Express® PHF	80	5.5	25	20	1.4	25
	15	1.0	80			
Millipore Express® SHF, SHC and SHR	80	5.5	25	30	2.1	25
	100*	6.9*	25			
	15	1.0	80			
Milligard®, Milligard® LPB, Polysep™ II, Lifegard™	50	3.4	25	None		
Clarigard®	70	4.8	23	None		
Polygard® CR	80	5.5	23	None		
Polygard® CN	70	4.8	25	None		

* intermittent

Opticap® capsules with filling bell attachment:

- Do not use if filling bell is cracked.
- Do not remove filling bell from capsule.
- Remove protective vinyl cap before autoclaving.

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

For technical assistance and worldwide contact information please visit:
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