Membrane Technologies

Data Sheet

0.2µm *AseptiCap® VK-γ*

Gamma Irradiatable Hydrophilic Polyethersulfone (PES) and Hydrophobic PVDF Membrane Capsule Filters

mdi *AseptiCap® VK-γ* capsule filters incorporate a specially designed combination of validated sterilizing grade hydrophobic PVDF as well as hydrophilic Polyethersulfone (PES) membrane to facilitate and provide unique performance advantages in pre-use integrity testing of aseptic filtration systems.

AseptiCap® VK-γ capsule filters help carry out critical functions such as filter wetting and integrity testing while maintaining sterility of the aseptic filtration system.

mdi produces a wide range of Gamma compatible Sterilizing grade *AseptiCap® VK-γ* devices to meet filtration requirements of biopharmaceutical processing. These filter devices are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as absolute retention, high flow rates and throughputs.

With the advantages linear scalability of filter area for smooth transitions from lab scale to pilot to process scale and widest range of end connections for quick and reliable connections to the existing fittings, **mdi** *AseptiCap® VK-γ* filters offer a universal solution for process filtration.

Advantages

- Allows unlimited water for injection (WFI) flushing of sterilizing grade product filter for easy wetting
- Allows fast drying of the filtration system necessary for processes involving oily solutions
- Acts as a sterile barrier against inadvertent ingress of environmental air

AseptiCap® VK-γ

Datasheet

AseptiCap® VK-γ 0.2 micron capsule filters use **mdi** hydrophilic PES membrane and hydrophobic PVDF membrane in Gamma compatible Polypropylene housing. No adhesives or glue are used in the manufacturing process and all bonding is done by heat welding.

Key Features

- Absolute retention
- 100% integrity tested
- Very low hold up volume in filters
- High flow rates
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Widest range of end connections
- Products available for total scalability
- Total traceability through unique serial number for each filter
- Sterilizable by Gamma irradiation

Quality Assurance

Datasheet

mdi quality management system emphasizes on quality by design rather by end product testing. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each *AseptiCap® VK-γ* is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Flow Rate

Each lot is tested for water and air flow rates to ensure that flow rates are within the specifications.

Pressure, Temperature Endurance

AseptiCap® VK-γ filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

These filters are also validated for high burst pressure to ensure user safety in case of inadvertent pressure build-up.

Bioburden Testing

Device bioburden is tested as per ISO 117 37-1 and assured to be <1000 cfu/device.

Endotoxin Testing

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>.

Total Traceability

AseptiCap® VK-γ filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot and identification numbers are laser etched on each filter device.

Other Regulatory Compliance

- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics
- Complies with Biological Reactivity Tests, In-vitro, USP <87> for Cytotoxicity

Easy Connect

Datasheet

Widest Range of End Connections

Biopharmaceutical processes involve transfer of high value fluids through multiple process steps. Making high quality, reliable, flexible and functionally convenient connectivity with filters is of utmost value to the bio-processors.

mdi *AseptiCap® VK-γ* filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

Validated for Performance

These end connections are manufactured with tight dimension tolerance and are validated for strength and connection integrity under extreme use conditions as well as for their ability to withstand gamma irradiation.

½" HB

½" Single Stepped Hose Barb

1/4" MNPT

¼" SHB

Quick Connector

Male Luer Slip

3/8" Hose Barb

Female Luer Lock

1½" Sanitary Flange

¾" Sanitary Flange

½" MNPT

1" Hose Barb

Variety of end connections

Customized Connectivity

mdi *AseptiCap® VK-γ* filters are available in a wide range of end connections and are also customized to offer different inlet-outlet combinations to meet the unique connectivity needs in biopharmaceutical process assemblies where, for example, stainless steel components with sanitary flange connections are sometimes required to be connected to single use disposable systems through quick-connectors or hose barb connections.

1½" Sanitary Flange to ½"Barb Hose

1½" Sanitary Flange to ¾" Sanitary Flange

AseptiCap® with HighSecurity ½" hose barb connection

Linear Upscaling from R&D to Production Process

Datasheet

mdi offers a wide range of *AseptiCap® VK-γ* filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to required flush volumes.

Filter Devices	EFA* (Nominal)	Hold up Volume
AseptiCap® VK-γ 1″	250cm²	< 5ml
AseptiCap® VK-γ 2″	500cm²	< 25ml
AseptiCap® VK-γ 5″	1000cm²	< 45ml
AseptiCap® VK-γ 8″	2000cm²	< 60ml
AseptiCap® VK-γ 5″ Large	3000cm²	< 80ml
AseptiCap® VK-γ 10″	6000cm²	< 150ml

***EFA: Effective Filtration Area**

AseptiCap® VK-γ
1″, 250cm²

AseptiCap® VK-γ
2″, 500cm²

AseptiCap® VK-γ
5″, 1000cm²

AseptiCap® VK-γ
8″, 2000cm²

AseptiCap® VK-γ
5″, 3000cm²

Specifications

Small Capsule Filters

Datasheet

Construction					
Membrane	Hydrophobic PVDF and Hydrophilic PES				
Support Layers	Polyester				
Plastic Parts	Gamma Stable Polypropylene				
Integrity Testing / Retention					
Bubble Point	≥ 18 psi (1.26 Kg/cm^2) with 50% IPA/water solution				
Microbial Retention	LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2				
Size					
Size		1″	2″	5″	8″
Effective Filtration Area (Nominal)		250cm^2	500cm^2	1000cm^2	2000cm^2
Operational Radius (with Vent/ Drain)		40 mm	65 mm	65 mm	65 mm
Vent and Drain	¼″ Hose Barb with Silicone "O" ring				
Operational					
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm^2)				
Max. Differential Pressure	60 psi (4 Kg/cm^2) @ 30 °C				
Sterilization By Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters should not be autoclaved or in-line steam sterilized.				
Shelf Life	2 years after gamma sterilization				
Assurance					
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics				
Cytotoxicity	Passes Biological Reactivity tests, In Vitro, USP <87> for cytotoxicity				
Bacterial Retention	LRV> 7 for *B. diminuta* (ATCC 19146) per cm^2 of filter area as per ASTM F 838				
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>				
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release				
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520				
Oxidizable Substances	Passes test as per USP <1231>				
Quality Management System	ISO-9001 Certified				
USFDA	DMF No. 015554				

Specifications

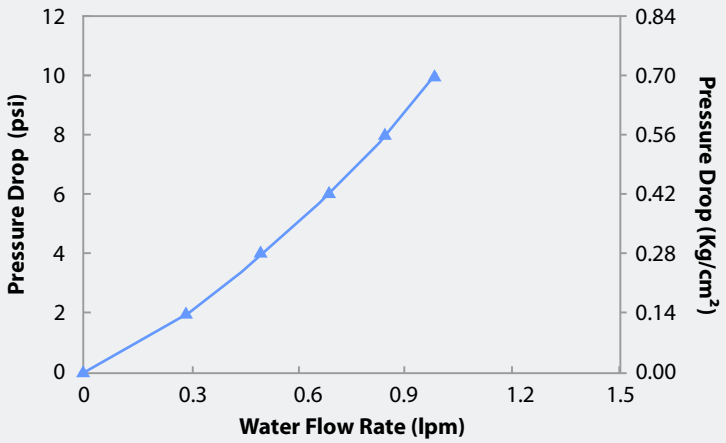
Large Capsule Filters

Datasheet

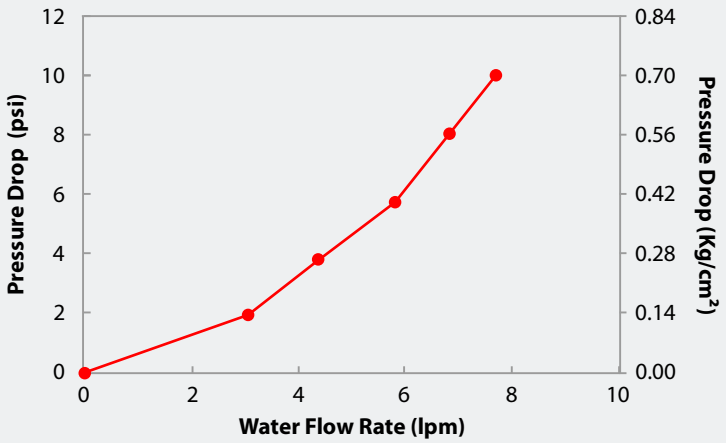
Construction		
Membrane	Hydrophobic PVDF and Hydrophilic PES	
Support Layers	Polyester	
Plastic Parts	Gamma Stable Polypropylene	
Integrity Testing / Retention		
Bubble Point	≥ 18 psi (1.26 Kg/cm^2) with 50% IPA/water solution	
Microbial Retention	LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2	
Size		
Size	5″	10″
Effective Filtration Area (Nominal)	3000 cm^2	6000 cm^2
Operational Radius (with Vent/ Drain)	80 mm	80 mm
Vent and Drain	¼″ Hose Barb with Silicone "O" ring	
Operational		
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm^2)	
Max. Differential Pressure	60 psi (4 Kg/cm^2) @ 30 °C	
Sterilization By Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters should not be autoclaved or in-line steam sterilized.	
Shelf Life	2 years after gamma sterilization	
Assurance		
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics	
Cytotoxicity	Passes Biological Reactivity tests, In Vitro, USP <87> for cytotoxicity	
Bacterial Retention	LRV> 7 for *B. diminuta* (ATCC 19146) per cm^2 of filter area as per ASTM F 838	
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>	
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release	
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520	
Oxidizable Substances	Passes test as per USP <1231>	
Quality Management System	ISO-9001 Certified	
USFDA	DMF No. 015554	

Typical Water Flow Rates

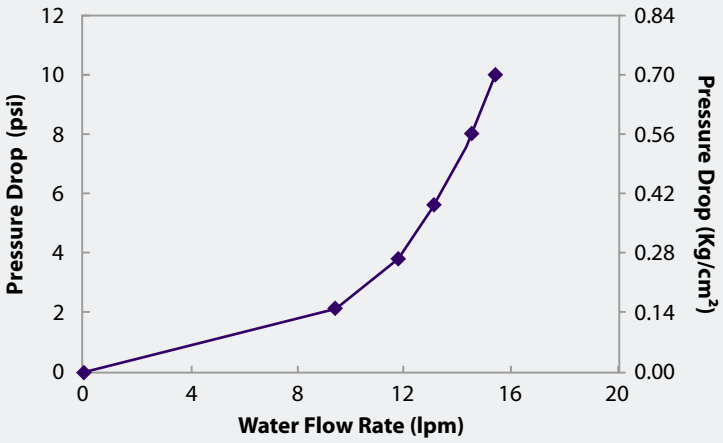
1" Capsule Filters, DD Connection



5" Capsule Filters, DD Connection



10" Capsule Filters, QQ Connection



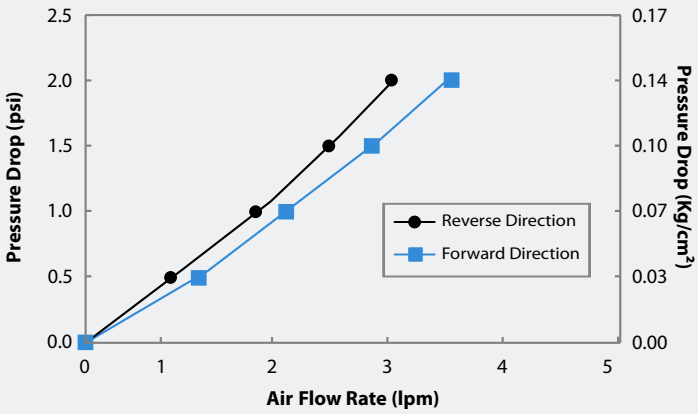
End Connection Type:

DD: ½" Hose Barb

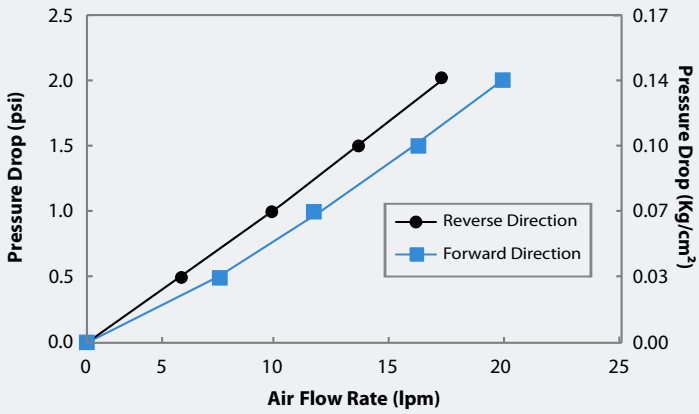
QQ: ½" Single Step Hose Barb

Typical Air Flow Rates in Wet Condition

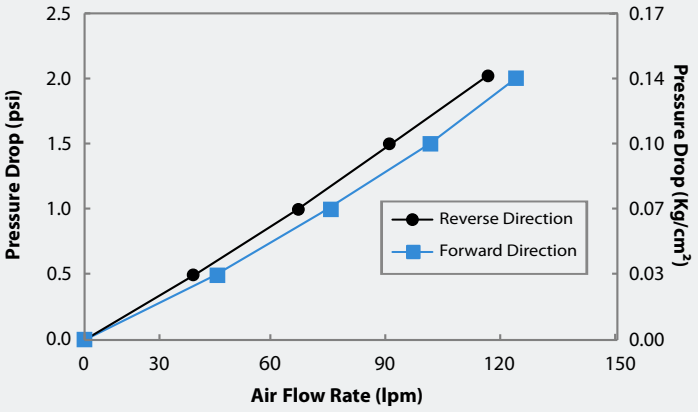
1" Capsule Filters, DD Connection



5" Capsule Filters, DD Connection



10" Capsule Filters, QQ Connection



End Connection Type:

DD: ½" Hose Barb

QQ: ½" Single Step Hose Barb

Inlet/Outlet Connections and Dimensions

Datasheet

0.2 µm *AseptiCap® VK-γ* Small Capsule filter

Inlet/Outlet Connections

Inlet/Outlet	Size/Length			
	1″	2″	5″	8″
¼″ Stepped Hose Barb	√	√	√	√
½″ Single Step Hose Barb	X	√	√	√
½″Hose Barb	√	√	√	√
1½″ Sanitary Flange	√	√	√	√
¾″ Sanitary Flange	√	√	√	√
Quick Connector	√	√	√	√
Female Luer Lock	√	√	√	√
Male Luer Slip	Outlet Only	X	X	X
3⁄16″ Hose Barb	√	√	Outlet Only	X
3⁄8″ Hose Barb	X	√	√	√

Dimensions (in mm)

End Connections	1″	2″	5″	8″
¼″ SHB I/O	94	122	172	223
¾″ Sanitary Flange Inlet I/O	85	104	155	206
Quick Connector	100	113	164	218
1½″ Sanitary Flange I/O	92	112	164	216
½″ Hose Barb I/O	90	112	162	214
½″ Single Step Hose Barb I/O	-	115	165	218
1½″ Sanitary Flange Inlet ½″ Single Step Hose Barb Outlet	-	112	165	216
3/8″ Hose Barb I/O	-	115	167	217
Operational Radius	40	65	65	65

0.2 µm *AseptiCap® VK-γ* Large Capsule filter

Inlet/Outlet Connections

Inlet/Outlet	Inline		T-Line
	5″	10″	10″
½″ Single Step Hose Barb	√	√	X
1½″ Sanitary Flange	√	√	√
¾″ Sanitary Flange	√	√	X
3⁄8″ Hose Barb	√	√	X
1″ Hose Barb	X	√	X

Dimensions (in mm)

	Inline		T-line
End Connections	5″	10″	10″
1½″ Sanitary Flange I/O	205	330	340
¾″ Sanitary Flange I/O	214	335	x
½″ Single Step Hose Barb I/O	218	336	x
1½″ Sanitary Flange Inlet ½″ Hose Barb Outlet	212	334	x
3⁄8″ Hose Barb I/O	211	332	x
1″ Hose Barb I/O	x	405	x
Operational Radius	80	80	80

Advanced Microdevices Pvt. Ltd.
20-21, Industrial Area, Ambala Cantt-133 006, INDIA
Tel : +91-171-2699290, 2699471
E-mail : info@mdimembrane.com
Website : www.mdimembrane.com