

ClariPro GK-γ Hydrophilic PES Membrane Small Capsule Filters

ClariPro GK-γ hydrophilic PES membrane capsule filters are ready to use, gamma sterilizable disposable filtration devices. These are specially designed filters incorporating a microglass fiber upstream layer and a downstream PES membrane final layer and are used as pre-filters in biopharmaceutical process development as well as manufacturing process for difficult to filter solutions.

The microglass fiber layer offers high dirt holding capacity and efficient retention of colloidal particles to give clear downstream in case of difficult to filter turbid solutions. The downstream PES membrane offers absolute retention, and low protein binding along with high flow rates.



Quality Assurance

These filter devices are manufactured in class 10,000 clean rooms under ISO 9001 certified quality management systems and are deeply validated to meet compendia and regulatory requirements.

Applications

- Precipitate removal post viral inactivation
- Pre-filtration of serum solutions
- Clarification of cell harvest supernatants
- Polishing of turbid solutions

Specifications

Construction

Pore Size	0.1µm, 0.2µm, 0.5µm			
Membrane	Hydrophilic PES			
Pre-filter	Microglassfiber			
Support Layers	Polyester			
Body and Core	Polypropylene			

Integrity Testing/Retention

Bacterial Retention	0.1µm: LRV> 6 for <i>B.diminuta</i> ATCC 19146 per cm ² of filter area 0.2µm: LRV> 5 for <i>B.diminuta</i> ATCC 19146 per cm ² of filter area			
---------------------	--	--	--	--

Size

Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	150 cm ²	500 cm ²	1000 cm ²	1500 cm ²

Vent and Drain	1/4" Hose Barb with Silicone 'O' ring for 2", 5" and 8" capsule filters			
----------------	---	--	--	--

Operational

Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	60 psi (4 Kg/cm ²) @ 30 °C			

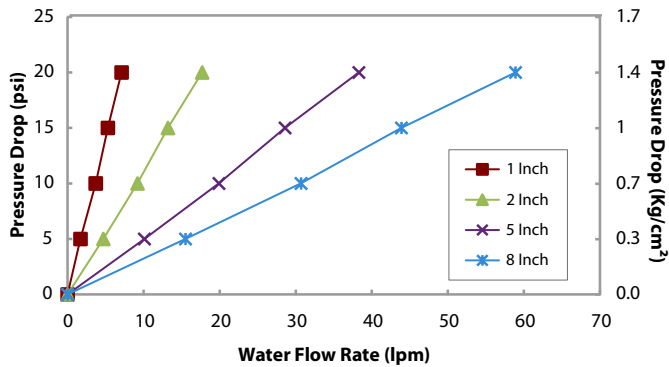
Sterilization By Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters should not be autoclaved or in-line steam sterilized.			
------------------------------------	--	--	--	--

Assurance

Toxicity	Passes Biological reactivity Test, <i>In Vivo</i> , as per USP <88> for Class VI plastics			
Fiber Release	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release			
Particle Release	The filtrate complies with USP <788> test for particulate matter in injections			
Extractables with WFI	Passes NVR test as per USP <661>			
Oxidizable Substances	Passes test as per USP <1231>			

Water Flow Rates

ClariPro GK- γ 0.5 μ m



Ordering Information

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
ClariPro GK- γ	DGKX	1"	51	0.1 μ m	36	1/4" SHB	A	Yes	R		Non Sterile	1	1	01
		2"	52	0.2 μ m	01	1/2" Hose Barb	D	No****	X		Gamma Sterile	3		
		5"	53	0.5 μ m	04	1 1/2" Sanitary Flange	E							
		8"	57			3/4" Sanitary Flange	S							
						Quick Connector	J							
						Single Step 1/2" Hose Barb*	Q							
						Female Luer Lock	U							
						Male Luer Slip**	W							
						3/16" Hose Barb***	N							
						3/8" Hose Barb*	I							

Example:

DGKX	57	04	DD	R	X	1	01
------	----	----	----	---	---	---	----

Example for Non Sterile: DGKX5704EERX101

Example for gamma Sterile: DGKX5704EEXX301

* Single step 1/2" hose barb and 3/8" hose barb end connections are not available in 1" capsule filters

** Male luer slip is available only in 1" capsule filter as outlet

***3/16" hose barb end connection is available in:

- 1" and 2" capsule filters as inlet and outlet

- 5" as outlet only

****Gamma sterilized capsule filters cannot be gamma irradiated again

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