cobetter®
filtration

Viruclear VF Series
Virus Removal Filter

Viruclear VF Series
plastic housing cassette

Viruclear VF

New Generation Reliable & Effective Virus Removal Filter

Viruclear VF Series
silicone cassette

Virus filtration is a robust virus clearance method in the production process of common biopharmaceutical products. Due to its simple and gentle operation, clear mechanism, and easy verification, it has been widely used in the downstream purification process of blood products such as coagulation factors, immunoglobulins, and recombinant proteins and antibody biological products expressed in animal cells to ensure virus safety.

The most widely used virus filtration product is the 20nm pore size parvovirus removal filter in the current market. Size exclusion is the main mechanism of virus removal. The target products with molecular sizes smaller than the pore size of the membrane can pass through the membrane, and the virus with sizes larger than the membrane pore size can be intercepted.

Based on its physical interception characteristics, whether the diameter of 80-120 nm mouse leukaemia virus is a retrovirus or the diameter of about 20 nm of parvovirus, can be reliable and efficient interception. Virus clearance meet regulatory requirements that log reduction values (LRV)≥4 log.

Cobetter Viruclear VF series virus removal filters features an asymmetric polyethersulfone (PES) membrane, greatly improve the fouling space, and provides strong interception and removal fouling for protein aggregates and potential viruses. The part near the water surface consists of a precision retention layer with about 20 nm and the pore size distribution is uniform, which can achieve robust retention of parvovirus and robust retention maintained during process interruption/depressurization. Cobetter Viruclear VF series virus removal filters also provide good scalability, while integrity testing using an easy-to-operate diffusion flow method.

Features

· Unique surface hydrophilic improvement of PES membrane , which gives high mass capacity and high yield of virus retentive membrane
· Asymmetric membrane structure, high porosity, and high flux
· Robust removal of parvovirus
· ≥ 4.0 log removal of model virus
· Robust retention maintained during process interruption
· Chemically stable
· Easy to install, use and test

Viruclear VF Plus

Performance-optimized PES Virus Removal Filter

Optimizing the membrane preparation process based on the first generation Viruclear VF, Cobetter has launched the optimized composite PES membrane virus removal filter Viruclear VF Plus.

The strength of the optimized membrane structure is better guaranteed, the protein filtration capacity is effectively increased, and it has better adaptability to relatively complex products . Viruclear VF Plus, as the PES membrane virus retentive product line promoted by Cobetter, is mainly aimed at the purification of biological agents such as recombinant proteins expressed in animal cells, monoclonal antibodies, ADCs, higher purity/stability bispecific antibodies, etc.

Better Product Adaptability

The effectiveness of virus removal filtration of protein solution is closely related to the properties of protein solution. Product such as high concentration, low purity, strongly hydrophobic, stabiliser etc, often pose a greater challenge to virus filtration. The table below provides an example of the filtration performance of a typical customer's monoclonal antibody using the Viruclear VF/VF Plus/and foreign competitive filters, with the VF Plus providing a significant improvement in filtration performance for this particular product.

Test number	Prefilter	Virus removal filter	End load	Filter result			
				Water flux	Initial flux	End flux	Flow decay
1	CBT Viruclear PDT	CBT Viruclear VF	89 L/m^2	600LMH	283LMH	47LMH	83%
2	CBT Viruclear PDT	CBT Viruclear VF	107 L/m^2	557LMH	361LMH	75LMH	71%
3	CBT Viruclear PDT	Competitor's syringe filter	1056 L/m^2	484LMH	464LMH	134LMH	71%
4	CBT Viruclear PDT	CBT Viruclear VF Plus	1220 L/m^2	646LMH	646LMH	78LMH	83%

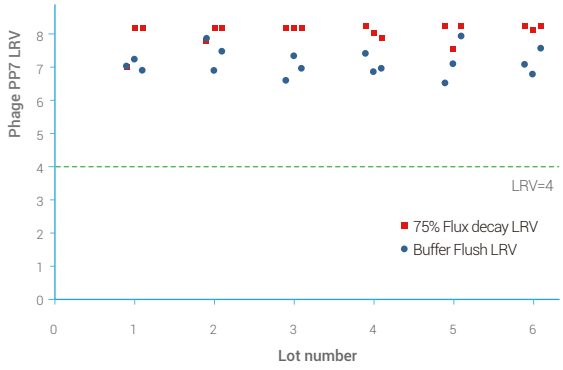
Robust Removal of Virus

Test Condition

Multiple batches of syringe filters are used for PP7 phage challenge experiments at room temperature, 30 psi.

Filter	Viruclear VF Plus WD Syringe Filter
Model virus	PP7, added amount＞10^7 PFU/mL
Feed solution	0.1 g/LIVIG, Loading volume: 600L/m^2, Buffer flush volume: 30L/m^2
Constant pressure	30 psi
Flux decay	to 25% of initial flux;

Test results



The standard solution chosen for testing is 0.1g/L of 0.22um prefiltered IVIG solution. Model Virus Selection: Pseudomonas aeruginosa bacteriophage PP7, which is specified in the regulation PDA TR41 as a model virus for parvovirus.

The virus removal robustness of the Viruclear VF Plus product is further enhanced to ensure stable virus retention above the regulatory level. Viruclear VF Plus also ensures robust virus retention under the worst case during process interruption.

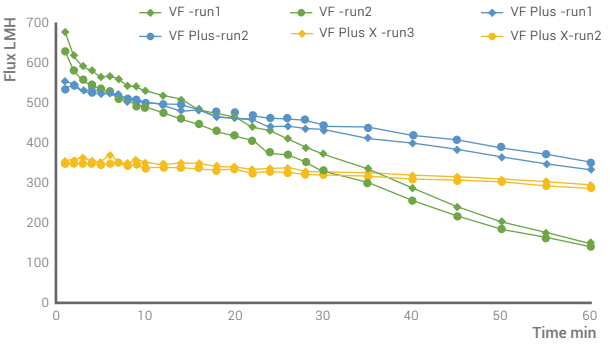
Viruclear VF Plus X

Enhanced Capacity PES Virus Removal Filter

Viruclear VF Plus X as a newly launched virus removal filter based on PES membrane ,has further improved structural fouling capacity. It has better adaptability to complex products and higher mass or volume capacity at the expense of a certain water flux, especially suitable for biological products with high protein aggregates content and poor stability, such as bevacizumab, unstable bispecific antibodies and fusion proteins. Viruclear VF Plus X is a supplement and alternative to Viruclear VF Plus in the fields of recombinant protein and antibody applications, and can take care of both filtration applications for some biological enzymes and low concentration blood products.

Stronger Anti-blocking Ability

Compare the filtration performance of Viruclear VF, Viruclear VF Plus and Viruclear VF Plus X at room temperature and 30psi constant pressure. Parallel experiments filter 0.4g/L IVIG solution, and the comparison of flow decay can reflect the difference of filtration performance of several filters.



Viruclear VF, Viruclear VF Plus and Viruclear VF Plus X
Comparison of Flux decay with time when filtering the same solution

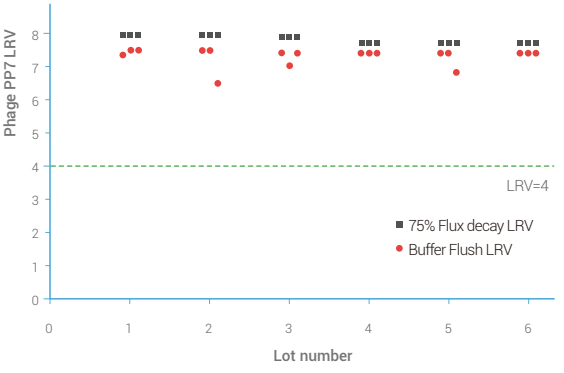
Robust Removal of Virus

Test Condition

Multiple batches of syringe filters are used for
PP7 phage challenge experiments at room temperature, 30 psi.

Filter	Viruclear VF Plus WD Syringe Filter
Model virus	PP7, added amount > 10^7 PFU/mL
Feed solution	0.1 g/LIVIG, Loading volume: 600L/m^2, Buffer flush volume: 30L/m^2
Constant pressure	30 psi
Flux decay	to 25% of initial flux;

Test results



Typical Applications

Monoclonal Antibody

Bispecific Antibody

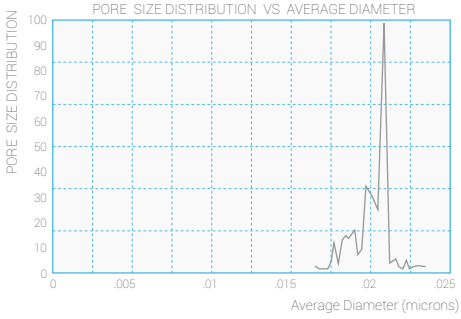
Fc-fusion proteins

Nanobody

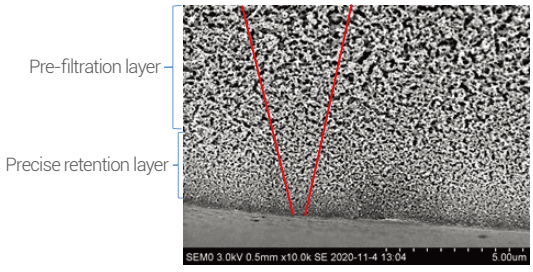
Recombinant Covid vaccine

Small-molecule recombinant proteins (< 180 kD), etc.

Pore Size Distribution of Virus Retentive Membrane



Viruclear VF Plus membrane pore size distribution



SEM image of virus removal filter membrane

Specification

	Specification	Effective Filtration Area	Application
Virus Removal Filter	WD series	2.8cm²	For process development and virus clearance validation research
	Membrane	4.1cm²	For process development and virus clearance validation research
	Pilot scale	0.017/0.07/0.22m²	≤200L
	Production scale	0.50/1.50m²	>200L
PNY-Nylon Prefilter	DS series	3.4cm²	For process development and virus clearance validation research
	Pilot scale	0.025/0.12/0.30m²	≤200L
	Production scale	0.60/1.20/1.8m²	>200L
PDT-Depth Prefilter	DS series	4.5cm²	For process development and virus clearance validation research
	Pilot scale	0.027/0.15/0.4m²	≤200L
	Production scale	0.11/0.55/0.92/1.1m²	>200L

Material of Products

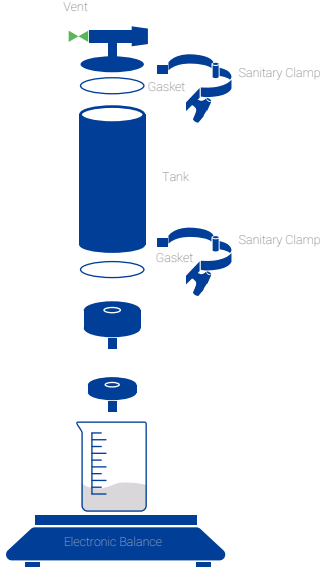
	Specification	Membrane	Format	Shell	Effective Filtration Area	Assessries material
Virus Removal Filter	WD series	PES	Syringe filter	PVDF	2.8cm²	-
	Pilot scale	PES	Single-use Plastic-housing Cassette Silicone cassette	PVDF Silicone	0.017/0.07/0.22m² 0.018/0.08/0.26m²	Silicone, PP PP
	Production scale	PES	Single-use Plastic-housing Cassette Silicone cassette	PVDF Silicone	0.50/1.50m² 0.50/1.50m²	Silicone, PP PP
PNY Nylon Prefilter	DS series	Nylon	Syringe filter	PP	3.4cm²	Silicone,
	Pilot scale	Nylon	Single-use Plastic-housing Cassette	PP	0.025/0.12/0.30m²	Silicone, PP
	Production scale	Nylon	Single-use Plastic-housing Cassette	PP	0.60/1.20/1.80m²	Silicone, PP
PDT Depth Prefilter	DS series	Cellulose, diatomite, Nylon	Syringe filter	PP	4.5cm²	Silicone,
	Pilot scale	Cellulose, diatomite, Nylon	Single-use Plastic-housing Cassette	PP	0.027/0.15/0.4m²	Silicone, PP
	Production scale	Cellulose, diatomite, Nylon	Single-use Plastic-housing Cassette Single-use Plastic-housing Cassette (M02)	PP PP, GF	0.92/1.1m² 0.11/0.55/1.1m²	Silicone, PP

Virus Removal Filtration Process Development Service

Our technical engineers will work with customers to optimize the process parameters during the process development of virus removal filtration to obtain to obtain a robust, efficient and economical filtration operation.

Virus Removal Filterability Testing Device

Virus Removal Assembly Sketch Map



Optimization Strategy of Virus Removal Filtration Process

Replace the traditional microporous prefilter with the adsorption-type nylon membrane filter PNY.

↓

Adopt Viruclear PDT depth prefilter.

↓

Increase the effective filtration area of PNY or PDT.

↓

Dilute, and reduce protein concentration.

↓

Optimize pH and conductivity of solution, and add stabilizer.

Ordering Information

Viruclear PDT Virus Removal Prefilter (Depth Filter)

V P	D T	□□	□□	P
Application	Material of Membrane	Type	Quantity/Package	Market
VP Viruclear PDT	**DT** Depth filter	**DS** Syringe filter (4.5cm^2)	**N9** Only for syringe filter, 9pcs / pk **N1** 1pcs / pk	**P** Biopharmaceutical

Viruclear PDT Virus Removal Prefilter (Depth Filter)

V P	D T	□□	□□	P
Application	Material of Membrane	Type	Quantity/Package	Market
VP Viruclear PDT	**DT** Depth filter	**L4** L08TT(0.027m^2) **SA** CSCD(0.15m^2) **SC** CSCE(0.4m^2)	**N1** 1pcs / pk	**P** Biopharmaceutical

Viruclear PDT Virus Removal Prefilter (Depth Filter)

V P	D T	□□	□□	P
Application	Material of Membrane	Type	Quantity/Package	Market
VP Viruclear PDT	**DT** Depth filter	**SB** CSCB(0.92m^2) **SM** CSCM(1.1m^2) **M1** M02 Cassette(0.11m^2) **M5** M02 Cassette(0.55m^2) **MX** M02 Cassette(1.1m^2)	**N1** 1pcs / pk	**P** Biopharmaceutical

Ordering Information

Viruclear PNY Virus Removal Prefilter (Nylon Filter)

V P	N Y	□□	□□	P
Application	Material of Membrane	Type	Quantity/Package	Market
VP Viruclear PNY	NY Nylon	DS Syringe filter (3.4cm^2)	N9 Only for syringe filter, 9pcs / pk N1 1pcs / pk	P Biopharmaceutical

Viruclear PNY Virus Removal Prefilter (Nylon Filter)

V P	N Y	□□□	□□	□□	P
Application	Material of Membrane	Type	Type	Quantity/Package	Market
VP Viruclear PNY	NY Nylon	C02 250cm^2 L02 0.12m^2 L05 0.30m^2	TT 3/4" TC	N1 1pcs / pk	P Biopharmaceutical

Viruclear PNY Virus Removal Prefilter (Nylon Filter)

V P	N Y	□□□	□□	□□	P
Application	Material of Membrane	Type	Type	Quantity/Package	Market
VP Viruclear PNY	NY Nylon	L10 0.60m^2 L20 1.20m^2 L30 1.80m^2	SS 1 1/2" TC	N1 1pcs / pk	P Biopharmaceutical

Ordering Information

Viruclear VF Plus Virus Removal Syringe Filters with PVDF Shell (WD)

V F	P	E S	□□	□□	P
Application		Material of Membrane	Type	Quantity/Package	Market
VF Virus filtration	**P** PLUS	**ES** mPES, hydrophilic modified PES membrane	**DC** Syringe filter (2.8cm^2)	**N9** Only for syringe filter, 9pcs / pk (3 batchs, 3 pcs per batch)	**P** Biopharmaceutical
				N1 1pcs / pk	

Viruclear VF Plus Removal Plastic-housing Cassette

V F	P	E	S	□□	□□□	□□	P
Application		Material of Membrane	Configuration Code	Type	Filtration Area	Quantity/Package	Market
VF Virus filtration	**P** PLUS	**E** PES	**S** Standard	**LA** Lab (0.017m^2 & 0.07m^2)	**002** 0.017m^2	**N1** 1pcs / pk	**P** Biopharmaceutical
				FL Flow (0.22m^2 0.50m^2 & 1.50m^2)	**008** 0.07m^2		
					026 0.22m^2		
					050 0.50m^2		
					150 1.50m^2		

Ordering Information

Viruclear VF Plus Virus Removal Sillicon Cassette (Suspended Screen)

V F	P	M P	□□	□□	P
Application		Material of Membrane	Type	Quantity/Package	Market
VF Virus filtration	**P** PLUS	**MP** mPES, hydrophilic modified PES membrane	**A1** Pilot module 1 Filtration Area 0.018m^2 **A2** Pilot module 2 Filtration Area 0.08m^2 **B1** Production module 1 Filtration Area 0.26m^2 **B2** Production module 2 Filtration Area 0.5m^2 **B3** Production module 3 Filtration Area 1.5m^2	**N1** 1pcs / pk	**P** Biopharmaceutical

Viruclear VF Plus X Virus Removal Syringe Filter with PVDF Shell (WD Syringe Filter)

V F	X	E S	□□	□□	P
Application		Material of Membrane	Type	Quantity/Package	Market
VF Virus filtration	**X** PLUS X	**ES** mPES, hydrophilic modified PES membrane	**DC** Syringe filter (2.8cm^2)	**N9** Only for syringe filter, 9pcs / pk (3 batchs, 3 pcs per batch) **N1** 1pcs / pk	**P** Biopharmaceutical

Ordering Information

Viruclear VF Plus X Virus Removal Plastic-housing Cassette

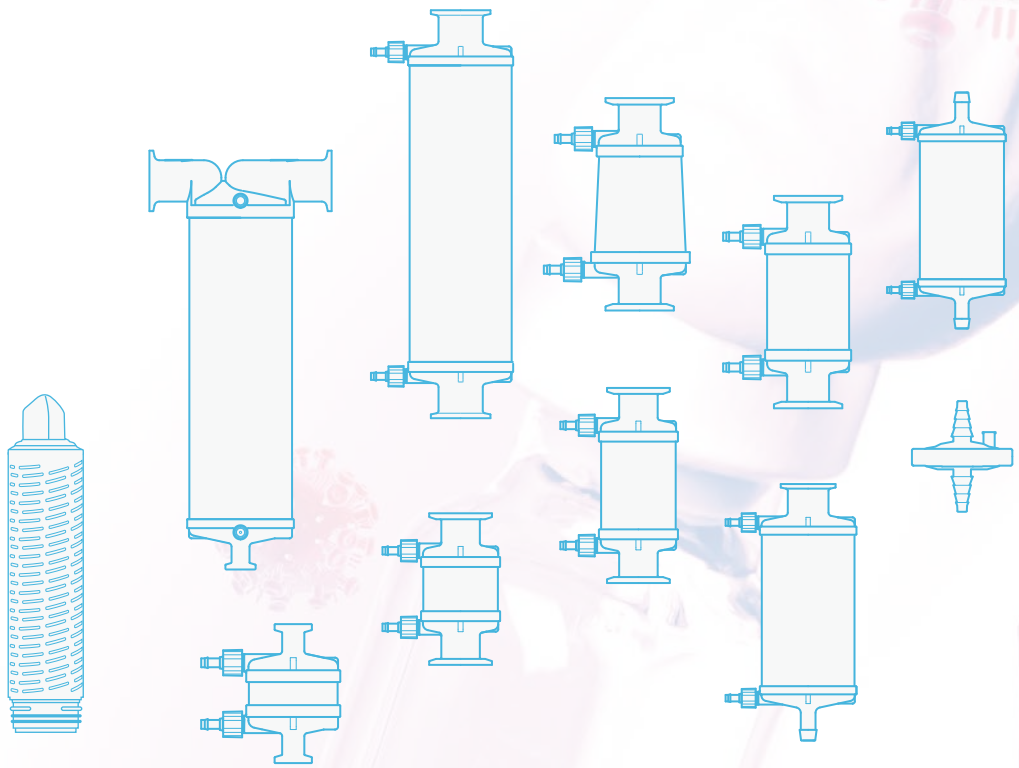
V F	X	E	S	□□	□□□	□□	P
Application		Material of Membrane	Configuration Code	Type	Filtration Area	Quantity/Package	Market
VF Virus filtration	**X** PLUS X	**E** PES	**S** Standard	**LA** Lab ($0.017m^2$ & $0.07m^2$) **FL** Flow ($0.22m^2$ $0.50m^2$ & $1.50m^2$)	**002** 0.017m **008** 0.07m **026** 0.22m **050** 0.50m **150** 1.50m	**N1** 1pcs / pk	**P** Biopharmaceutical

Viruclear VF Plus X Virus Removal Sillicon Cassette (Suspended Screen)

V F	X	M P	□□	□□	P
Application		Material of Membrane	Type	Quantity/Package	Market
VF Virus filtration	**X** PLUS X	**MP** mPES, hydrophilic modified PES membrane	**A1** Pilot module 1 Filtration Area $0.018m^2$ **A2** Pilot module 2 Filtration Area $0.08m^2$ **B1** Production module 1 Filtration Area $0.26m^2$ **B2** Production module 2 Filtration Area $0.5m^2$ **B3** Production module 3 Filtration Area $1.5m^2$	**N1** 1pcs / pk	**P** Biopharmaceutical

Our Mission

Through Excellent Products & Sustainable Innovative Solutions,
We Help Customers Solve Process Problems & Increase Yield.



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