cobetter®
filtration

Viruclear RC Series

Virus Removal Filter
Suitable for Complex Products

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▲ Viruclear RC Silicone Cassettes (Suspended Screen)

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 validation, it has been widely used and can greatly improve the viral safety of biological products. The interception pore size of the Viruclear RC series is nominally 20nm, which is based on a size exclusion mechanism and can effectively remove various virus including parvovirus (the smallest virus currently known in nature).

In order to deal with products that are difficult to filter, Cobetter has launched a new series of virus removal filter made of Regenerated Cellulose,The natural and excellent hydrophilicity of regenerated cellulose materials enables lower adsorption, higher protein recovery and better filtration performance in complex products containing hydrophobic proteins, polymers and many impurities. The Viruclear RC series will be used as another solution to deal with the poor performance of the Viruclear VF Plus series. It is especially suitable for virus removal filtration in the extraction and preparation of biological products from human plasma, providing customers with a more comprehensive solution.

Features

· Unique surface hydrophilic improvement of PES membrane , which gives high mass capacity and high yield of virus retentive membrane
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· Composite supported membrane structure effectively improves the strength of the filter membrane
· Narrow pore size distribution gives the membrane good separation performance
· Robust virus removal capabilities
· Chemically stable
· Easy to install, use and test

Typical Applications

· Blood clotting factor
· Immunoglobulin
· Biochemical extracts
· Fusion protein
· Antibody fragments

Viruclear RC Series

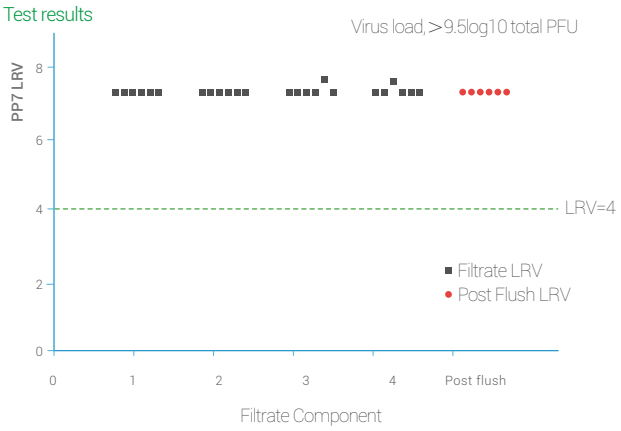
Regenerated Cellulose Material Virus Removal Filter

Robust Removal of Virus

Test Condition

The test temperature is 21°C, set up six groups of parallel experiments for PP7 phage retention test to evaluate the parvovirus clearance ability.

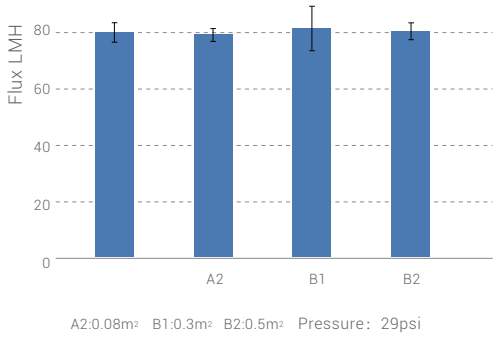
Filter	Viruclear RC
Model virus	PP7, added amount>10^7 PFU/mL
Load capacity up to	50L/m^2, 100L/m^2, 150L/m^2, 200L/m^2
Pressure interruption	30min
Post flush	20L/m^2

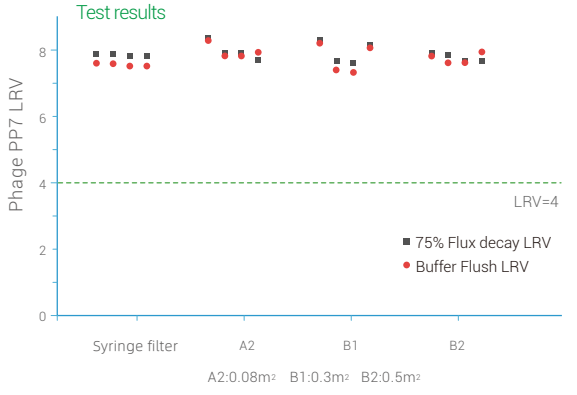


The standard solution selected for the test is 0.1g/L 0.22μm pre-filtered IVIG solution. Model virus selection: Pseudomonas aeruginosa PP7 phage is designated as a parvovirus model virus in the PDA TR41 rules. Viruclear RC products provide powerful virus removal capabilities and can handle the harshest conditions in the production process - multiple pressure interruptions. Viruclear RC maintains strong virus retention after multiple interruptions.

Linear Scalability

There is almost no significant difference in the water flux of Viruclear RC of different specifications (25℃, 29psi), and it maintains robust virus removal capabilities and has good linear amplification.





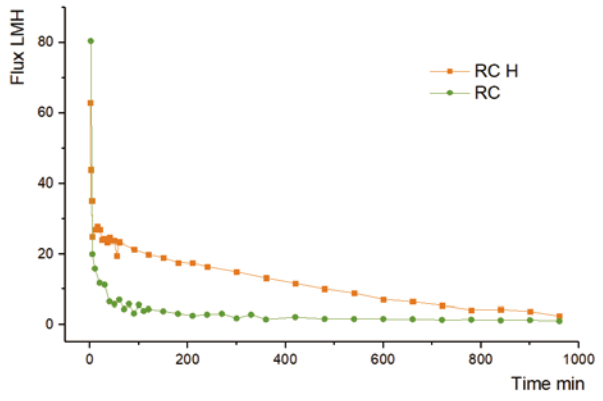
Viruclear RC H Series

RC material Virus Removal Filter Suitable for High Concentration Products

Viruclear RC H is a newly launched virus removal filter based on RC composite membrane. It further improves membrane strength and structural stability. It can maintain good pore size and flow channel structure, and can maintain high process flux when filtering high concentration protein solution, further improving the filtration ability for complex products and high concentration products while maintaining high efficiency virus removal ability. It is especially suitable for virus filtration of high concentration IVIG solution etc. in blood products industry.

Higher Process Throughput

A comparison of the filtration process flux of the Viruclear RC and Viruclear RC H filters, performed at room temperature and 30 psi under constant pressure filtration conditions, with the same 50 g/L intravenous gammaglobulin (IVIG), illustrates the difference in performance between the two filters when filtrating high concentration proteins.



Comparison of flux decay trends over time for Viruclear RC and Viruclear RC H in series with Viruclear PNY for filtration of the same solution.

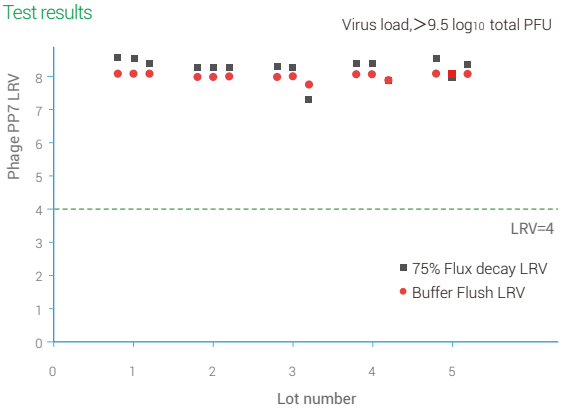
Robust Removal of Virus

Test Condition

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

Filter	Viruclear RC H Syringe Filter
Model virus	PP7, added amount＞107 PFU/mL
Feed solution	0.1 g/LIVIG, Loading volume: 400L/m2, Buffer flush volume: 20L/m2
Constant pressure	30 psi

Test results

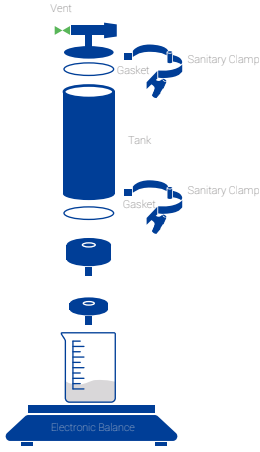


Virus Removal Filtration Process Development Service

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.

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Adopt Viruclear PDT depth prefilter.

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Increase the effective filtration area of PNY or PDT.

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Dilute, and reduce protein concentration.

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Optimize pH and conductivity of solution, and add stabilizer.

Product Specification

	Specification	Effective Filtration Area	Processing Capacity
Viruclear RC Virus Removal Filter Series	Syringe filter	2.5cm²	Process development and virus removal validation
	Pilot scale	0.015 / 0.08 / 0.3 / 0.5m²	⩽100L
	Production scale	1.50m²	＞100L

Product Specification

	Specification	Membrane	Format	Shell	Effective Filtration Area	Assessries material
Virus Removal Filter	DS	RC	Syringe filter	PP	2.5cm²	Silicone
	Pilot scale	RC	Silicone cassette	Silicone	0.015/0.08/ 0.3/0.5m²	PP
	Production scale	RC	Silicone cassette	Silicone	1.50m²	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
	Production scale	Nylon	Single-use Plastic-housing Cassette	PP	0.60/1.20/1.80m²	Silicone
PDT Depth Prefilter	DS series	Cellulose, Diatomite, Nylon	Syringe filter	PP	4.5cm²	PP
	Pilot scale	Cellulose, Diatomite, Nylon	Single-use Plastic-housing Cassette	PP	0.027/0.15/0.4m²	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	PP PP

Ordering Information

Viruclear PDT Virus Removal Prefilter (Depth Filter)

V P	D T	□□	□□	P
Application	Material of Membrane	Type	Quantity/Package	Market
VP Viruclear PDF	**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 PDF	**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 PDF	**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** mNylon, Modified nylon membrane	**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** mNylon, Modified nylon membrane	**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** mNylon, Modified nylon membrane	**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 RC Removal Syringe Filter with PP Shell (DS)

V F	R C	□□	□□	P
Application	Material of Membrane	Type	Quantity/Package	Market
VF Virus filtration	RC	**DS** Syringe filter (2.5cm²)	**N9** Only for syringe filter, 9pcs / pk (3 batchs, 3 pcs per batch) **N1** 1pcs / pk	**P** Biopharmaceutical

Viruclear RC Silicone Cassette (Suspended Screen)

V F	R C	□	□□	□□	P
Application	Material of Membrane	Single-use Deflector	Type	Quantity/Package	Market
VF Virus filtration	RC	**D** Integration **N** Non-integrated	**A1** Pilot module 1 Filtration Area 0.015m² **A2** Pilot module 2 Filtration Area 0.08m² **B1** Production module 1 Filtration Area 0.3m² **B2** Production module 2 Filtration Area 0.5m² **B3** Production module 3 Filtration Area 1.5m²	**N1** 1pcs / pk	**P** Biopharmaceutical

Viruclear RC H Removal Syringe Filter with PP Shell (DS)

V F	H	R C	□□	□□	P
VF Virus filtration		Material of Membrane RC	Type **DS** Syringe filter (2.5cm²)	Quantity/Package **N9** 9 pcs / pk **N1** 1pcs / pk	Market **P** Biopharmaceutical

Viruclear RC H Silicone Cassette (Suspended Screen)

V F	H	R C	□□	□□	P
Application		Material of Membrane	Type	Quantity/Package	Market
VF Virus filtration		RC	**A1** Pilot module 1 Filtration Area 0.015m² **A2** Pilot module 2 Filtration Area 0.08m² **B1** Production module 1 Filtration Area 0.3m² **B2** Production module 2 Filtration Area 0.5m² **B3** Production module 3 Filtration Area 1.5m²	**N1** 1pcs / pk	**P** Biopharmaceutical

Please contact us for more information

Hangzhou Cobetter Filtration Equipment Co.,Ltd.

Sales Add 13-18 F, Building 1, Zicheng International Innovation Center, No.39 Jincheng Road, Xiaoshan District, Hangzhou 311215, China

Factory Cobetter Park, Heshang New Material Industrial Park, Xiaoshan District, Hangzhou 311265, China

Tel +86 400-070-4266
Fax +86-571-87704256
www.cobetterfiltration.com