cobetter®
filtration

Viruclear RC Series

Virus Filter Designed For Complex Process Fluids

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Silicone Cassette Format

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 ease of validation, it has been widely used to ensure biological products' virus safety.

The Viruclear RC series has a nominal pore size of 20 nm. Based on a size exclusion mechanism, it can effectively remove a variety of viral particles, including parvoviruses.

Rigid Plastic Cassette Format

Cobetter's new Viruclear RC series virus removal filters, made from regenerated cellulose, are specifically designed for difficult-to-filter protein solution.The natural excellent hydrophilicity of regenerated cellulose makes it have lower adsorption, higher protein recovery rate, and better filterability in complex liquids containing hydrophobic proteins, aggregates and other impurities.

The Viruclear RC series will serve as another solution to address the underperforming projects of the Viruclear VF plus series. It is particularly suitable for biological products from human plasma, providing customers with a more comprehensive virus filtration solution.

The Viruclear RC series can be provided in the form of silicone cassette containing preservation solution, and rigid plastic cassette with pure water package. The rigid plastic cassette is shipped with sterile package. Customers may choose according to their own applications.

Product Features

- RC membrane has natural excellent hydrophilic properties providing virus removal membrane with low adsorption and high yield
- Asymmetric membrane structure and pre-filtration layer on the upper surface give the membrane excellent anti-fouling performance
- The narrow pore size distribution of the selective layer gives the membrane good separation performance
- Robust virus removal capabilities
- Chemically stable
- Ease of installation, filtration and integrity test

Typical Application

- Coagulation factors
- Immunoglobulin
- Biochemical extract
- Fusion protein
- Antibodies

Viruclear RC

Regenerated Cellulose Virus Removal Filter

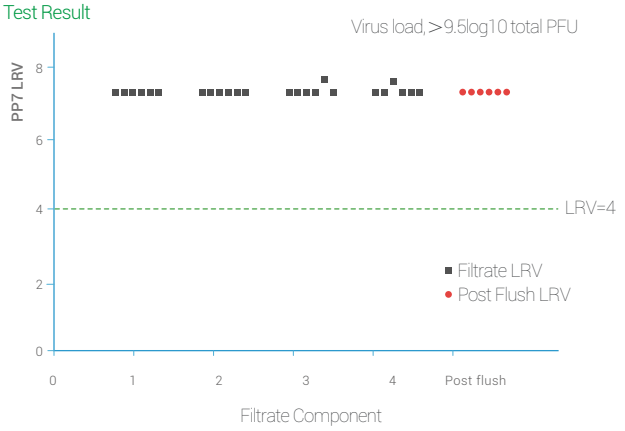
Robust Removal of Virus

Test Condition

The test temperature was 21°C, and 6 parallel experiments were set up to conduct PP7 phage retention tests to evaluate the virus clearance ability.

Filter	Viruclear RC
Model Virus	PP7, spiking load＞10^7 PFU/mL
Sampling Points	50L/m^2, 100L/m^2, 150L/m^2, 200L/m^2
Pressure Release Duration	30min
Post-use Buffer Flush	20L/m^2

Test Result



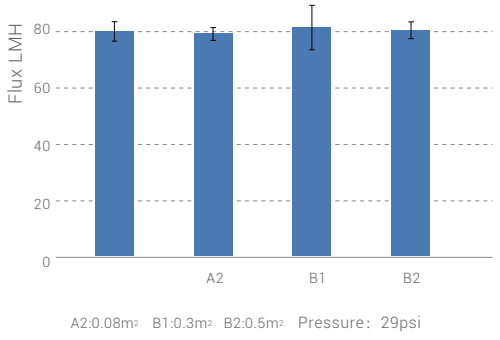
The protein solution was 0.1 g/L IVIG pre-filtered by 0.22um prefilter.

Model virus selection: Pseudomonas aeruginosa PP7 phage is specified in the PDA TR41 regulation as a model virus for parvovirus.

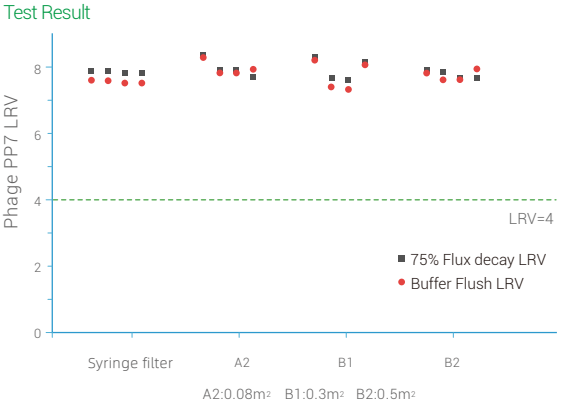
Viruclear RC has a robust virus removal capability. Even under the worst-case scenario of multiple pressure interruptions during filtration, Viruclear RC maintains robust virus retention.

Linear Scalability

The RC filter series demonstrates consistent water flux across different scales with robust virus clearance capability, exhibiting excellent linear scalability.



Test Result



Viruclear RC H

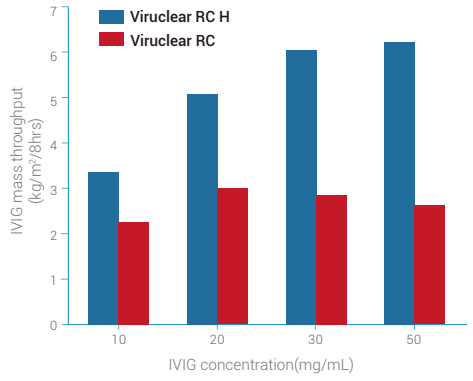
RC Material Virus Removal Filter Suitable for High-Concentration Feed Solutions

Featuring a robust regenerated cellulose (RC) membrane, the newly launched RC H series provides improved structural stability, maintaining consistent pore size and flow channels during constant pressure filtration.The RC H filter enables higher process fluxes with high-concentration protein solutions and offers increased protein mass capacity for complex feed streams, all while providing robust virus removal.This filter finds particular application in the virus clearance step for blood products, such as high-concentration Intravenous Immunoglobulin (IVIG).

Higher Mass Capacity

The filtration performance of the RC and RC H filters was compared under constant pressure conditions (30 psi) at room temperature. Parallel experiments were conducted to filter IVIG solutions of different concentrations . Then compare protein mass throughput after 8 hours of filtration. This result thus serves to highlight the performance differential between the two filters in high-concentration liquid applications.

Test result



Viruclear RC, Viruclear RC H 8-hour mass loading diagram of filtration of IVIG materials with different concentrations

Robust Virus Retention Capability

Test Condition

PPV rentention test of IVIG from multiple customers

Filter	Viruclear RC H Syringe Filter
Model virus	PPV, 10^7 total PFU or 4% volume ratio
Protein solution	3 batches of 5% IVIG solution from 4 customers
Constant pressure	2.0~2.5bar

Test Result

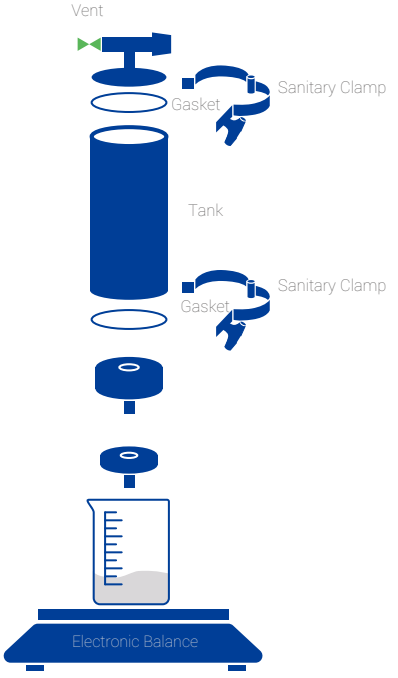
· No PPV was detected in all tests

Virus Removal Filtration Process Development Services

Our technical engineers will work with customers to optimize the process parameters of the virus removal filtration process to obtain stable, efficient and economical filtration operations.

Virus Removal Filterability Experimental Device

Schematic Diagram of Virus Removal Filter Assembly



Product Specifications

	Product Specifications	Filtration Area	Proceeding Amount
Viruclear RC Series Virus Removal Filter	Syringe filter	2.5cm²	Process development and virus removal verification
	Pilot scale	0.015 / 0.08 / 0.3 / 0.5m²	⩽100L
	Production scale	1.5m²	＞100L

Filter Structural Materials

	Scale	Membrane Material	Cassette Format	Component(Shell)	Filtration Area	Accessories Material
Viruclear™ RC Series	DS	RC	Syringe	PP	2.5cm²	Silicone
	Pilot Scale	RC	Silicone cassette Rigid Plastic cassette	Silicone Epoxy-resin	0.015/0.08/ 0.3/0.5m²	PP
	Production Scale	RC	Silicone cassette Rigid Plastic cassette	Silicone Epoxy-resin	1.5m²	PP
Corevital™ SMDA Series	DS	PVDF	Syringe	PP	0.72/3.4/4.5cm²	-
	Pilot Scale	PVDF	Single-use capsule filter	PP	180/420/660cm² 0.12/0.16/0.28m²	Silicone rubber
	Production Scale	PVDF	Single-use capsule filter	PP	0.55/1.1/1.65m²	Silicone rubber
Viruclear™ PNY Series	DS	Nylon	Syringe	PP	3.4cm²	-
	Pilot Scale	Nylon	Single-use capsule filter	PP	0.025/0.12/0.3m²	Silicone
	Production Scale	Nylon	Single-use capsule filter	PP	0.6/1.2/1.8m²	Silicone
Viruclear™ PCE Series	DS	PES	Syringe	PVDF	2.8cm²	PP
	Pilot Scale	PES	Plastic-housing cassette	PVDF	0.017/0.07/0.22m²	PP
	Production Scale	PES	Plastic-housing cassette	PVDF	0.5/1.5m²	PP
Viruclear™ PDT Series	DS	Cellulose, DE, Nylon	Syringe	PP	4.5cm²	-
	Pilot Scale	Cellulose, DE, Nylon	Single-use capsule Filter Single-use capsule Filter(M02)	PP PP/GF	0.027/0.15/0.4m² 0.027/0.054m²	Silicone / PP
	Production Scale	Cellulose, DE, Nylon	Single-use capsule Filter Single-use capsule Filter(M02)	PP PP/GF	0.92/1.1m² 0.11/0.55/1.1m²	Silicone / PP
Viruclear™ PDS Series	DS	Silica, composite fiber, Nylon	Syringe	GF reinforced PP	4.5cm²	Silicone rubber
	Pilot Scale	Silica, composite fiber, Nylon	Single-use capsule Filter	GF reinforced PP	0.027/0.054m²	Silicone rubber
	Production Scale	Silica, composite fiber, Nylon	Single-use capsule Filter(M02)	GF reinforced PP	0.11/0.55/1.1m²	Silicone rubber

Ordering Information

Corevital™ SMDA Prefilter

Bricap™ SFU Syringe filter

☐☐☐	☐☐	SMDA	☐	☐	P
Syringe Filter Scale	Connection type	Filter Membrane Configuration	Sterilization method	Package	Industry Code
U13 0.72cm²	CP Luer lock Female Luer	SMDA SMDA 0.2/0.1μm	G Gamma Compatible	1 1 pc/pk	P Biopharmaceutical
U22 3.4cm²	Luer lock Male Luer				
U33 4.5cm²					

Bricap™ C Series Capsule Filter

☐	☐☐☐	☐	SMDA	☐	☐	☐	P
Shell Type	Syringe Filter Scale	Inlet/outlet type	Filter Membrane Configuration	Sterilization method	Package	Product type	Industry Code
Blank Normal	C01 180cm²	T 19mm(3/4")sanitary flange	SMDA SMDA 0.2/0.1μm	A Autoclavable only	1 1 pc/pk	Blank Standard	P Biopharmaceutical
K Transparent	C02 420cm²	K 14mm(9/16")sanitary flange		G Gamma Compatible		Q	
	C03 660cm²	F 31mm(11/4")sanitary flange		S Sterile capsule filter			
				C Sterile breathing bag sterile packaging			

Bricap™ L Series Capsule Filter

☐	☐☐☐	☐	SMDA	☐	☐	☐	P
Shell Type	Syringe Filter Scale	Inlet/outlet type	Filter Membrane Configuration	Sterilization method	Package	Product type	Industry Code
Blank Normal	L02 0.12m²	S 38mm(11/2")sanitary flange	SMDA SMDA 0.2/0.1μm	A Autoclavable only	1 1 pc/pk	Blank Standard	P Biopharmaceutical
K Transparent	L03 0.16m²	T 19mm(3/4")sanitary flange		G Gamma Compatible		Q	
	L05 0.28m²	K 14mm(9/16")sanitary flange		S Sterile capsule filter			
	L10 0.55m²			C Sterile breathing bag sterile packaging			
	L20 1.1m²						
	L30 1.65m²						

Ordering Information

Viruclear™ PNY Prefilter Syringe Filter

V P	N Y	□□	□□	P
Application	Membrane Material	Component code	Number of filters per package	Industry Code
VP	NY Nylon	DS Syringe filter Filtration area 3.4cm²	N9 For syringe filters only, one package contains 9 filters N1 Single package	P Biopharmaceutical

Capsule Filter

V P	N Y	□□□	□□□	□□	P
Application	Membrane Material	Component code	Component code	Number of filters per package	Industry Code
VP	NY Nylon	C02 250cm² L02 0.12m² L05 0.3m²	TT 3/4 inch, TC connection	N1 Single package	P Biopharmaceutical

V P	N Y	□□□	□□□	□□	P
Application	Membrane Material	Component code	Component code	Number of filters per package	Industry Code
VP	NY Nylon	L10 0.6m² L20 1.2m² L30 1.8m²	SS 1.5 inch, TC connection	N1 Single package	P Biopharmaceutical

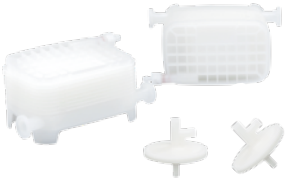
Ordering Information

Viruclear™ PCE Prefilter Syringe Filter

V P	C E	□□	□□	P
Application	Membrane Material	Scale	Package	Industry Code
VP	CE Cationic modified PES membrane	DC 2.8cm²	N9 9 pcs/pk N1 1 pc/pk	P Biopharmaceutical

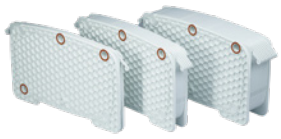
Plastic-housing Cassette

V P	C E	□□	□□□	□□	P
Application	Membrane Material	Scale	Filtration Area	Package	Industry Code
VP	CE Cationic modified PES membrane	LA Lab(0.017m² & 0.007m²) FL Flow(0.22m² & 0.5m² & 1.5m²)	002 0.017m² 008 0.007m² 026 0.22m² 050 0.5m² 150 1.5m²	N1 1 pc/pk	P Biopharmaceutical



Viruclear™ PDS Prefilter (Synthetic Depth Filter)

V P	D S	□□	□□	P
Application	Membrane Material	Membrane cassette scale (Effective filtration area)	Package	Industry Code
VP	DS Synthetic depth media	DS 4.5cm² 27 M02 0.027m² 54 M02 0.054m² M1 M02 0.11m² M5 M02 0.55m² MX M02 1.1m²	N9 9 pcs/pk(only for syringe filter) N1 1 pc/pk	P Biopharmaceutical



Ordering Information

Viruclear™ PDT Pre-filter(Depth filter)

V P

Application

VP

D T

Membrane Material

DT Depth Filter

Membrane Cassette Code

DS Syringe Filter
Filtration area 4.5cm²

Package

N9 9 pcs/pk(only for syringe filter)
N1 1 pc/pk

P

Industry Code

P Biopharmaceutical

Viruclear™ PDT Virus Removal Pre-filter(Depth filter)

V P

Application

VP

D T

Membrane Material

DT Depth Filter

Membrane Cassette Code

L4 L08TT
Filtration area 0.027m²

SA CSCD
Filtration area 0.15m²

SC CSCE
Filtration area 0.4m²

27 M02
Filtration area 0.027m²

54 M02
Filtration area 0.054m²

Package

N9 9 pcs/pk(only for syringe filter)
N1 1 pc/pk

P

Industry Code

P Biopharmaceutical

Viruclear™ PDT Virus Removal Pre-filter(Depth filter)

V P

Application

VP

D T

Membrane Material

DT Depth Filter

Membrane Cassette Code

SB CSCB
Filtration area 0.92m²

SM CSCM
Filtration area 1.1m²

M1 M02
Filtration area 0.11m²

M5 M02
Filtration area 0.55m²

MX M02
Filtration area 1.1m²

Package

N1 1 pc/pk

P

Industry Code

P Biopharmaceutical

Ordering Information

Viruclear™ RC Syringe Filter

V F	R C	□□	□□	P
Application	Membrane Material	Membrane Cassette Code	Package	Industry Code
VF Virus filtration	RC Regenerated cellulose	DS Syringe Filter Filtration area 2.5cm²	N9 9 pcs/pk(only for syringe filter) N1 1 pc/pk	P Biopharmaceutical

Viruclear™ RC Silicone Cassette

V F	R C	□	□□	□□	P
Application	Membrane Material	Disposable Deflector	Membrane Cassette Code	Package	Industry Code
VF Virus filtration	RC Regenerated cellulose	D Integrated N Non-integrated	A1 Pilot Component 1 Filtration Area 0.015m² A2 Pilot Component 2 Filtration Area 0.08m² B1 Scale-up component 1 Filtration Area 0.3m² B2 Scale-up component 2 Filtration Area 0.5m² B3 Scale-up component 3 Filtration Area 1.5m²	N1 1 pc/pk	P Biopharmaceutical

Viruclear™ RC H Syringe Filter

V F	H	R C	□□	□□	P
Application		Membrane Material	Membrane Cassette Code	Package	Industry Code
VF Virus filtration		RC Regenerated cellulose	DS Syringe Filter Filtration area 2.5cm²	N9 9 pcs/pk N1 1 pc/pk	P Biopharmaceutical

Ordering Information

Viruclear™ RC H Silicone Cassette

V F	H	R C	☐	☐☐	☐☐	P
Application		Membrane Material	Disposable Deflector	Membrane Cassette Code	Package	Industry Code
VF Virus filtration		RC Regenerated cellulose	D Integrated N Non-integrated	A1 Pilot Component 1 Filtration Area 0.015m² A2 Pilot Component 2 Filtration Area 0.08m² B1 Scale-up component 1 Filtration Area 0.3m² B2 Scale-up component 2 Filtration Area 0.5m² B3 Scale-up component 3 Filtration Area 1.5m²	N1 1 pc/pk	P Biopharmaceutical

Viruclear™ RC H Rigid Plastic Cassette

V	2	R C	☐	☐☐	P
Application	Encapsulant	Membrane Material	Disposable Deflector	Membrane Cassette Code	Industry Code
V Virus filtration	2 Rigid plastic	RC Regenerated Cellulose	D Integrated N Non-integrated	A1 Pilot Component 1 Filtration Area 0.015m² A2 Pilot Component 2 Filtration Area 0.08m² B1 Scale-up component 1 Filtration Area 0.3m² B2 Scale-up component 2 Filtration Area 0.5m² B3 Scale-up component 3 Filtration Area 1.5m²	P Biopharmaceutical

cobetter® filtration

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