

# Novasip™ DV20 and DV50 Virus Removal Filter Capsules

## Steam-In-Place Capsules for Virus Filtration



**Novasip** Ultipor VF capsule filters are disposable, Junior Style steamable assemblies designed to remove parvoviruses and other viruses from protein solutions.

The **Novasip** DV20 grade capsule filter utilizes an **Ultipor** VF-grade DV20 grade pleated membrane cartridge to remove parvoviruses and other viruses as small as 20 nm from protein solutions up to 5 – 10 liters.

The **Novasip** DV50 grade capsule filter incorporates an **Ultipor** VF DV50 grade **Ultipleat** membrane cartridge for removal of viruses 40 – 50 nm and larger.

**Novasip Ultipor** VF capsule filters are supplied non-sterile and can also be Gamma-irradiated.\*

### Features and Benefits

- $\geq 3$  Log Titer Reduction (LTR) for 20 nm viruses
- $\geq 6$  log LTR for  $\geq 50$  nm viruses
- Robust size exclusion mechanism
- Narrow pore-size distribution
- Low binding for high protein yields
- Inherently water wettable
- Very low extractables
- Autoclavable or steamable in situ
- Gamma-irradiatable
- 100% integrity-tested
- Individually serialized
- Manufactured for use in conformance with cGMP
- Pharmaceutical P optimized with certificate of test provided
- Clear housing for easy venting
- New design sanitary valves:
  - ◆ Non-removable for safety
  - ◆ Non-threaded for cleanliness

### Quality and Bio-Safety Biological Tests

#### Integrity

- Every filter integrity tested during manufacture. Test correlated to viral (phage) retention

#### Biological Tests

- Meets USP Biological Reactivity Test, in vivo, for Class VI-121 °C Plastics

#### Effluent Quality Tests\*

- Meets Cleanliness per USP Particulates in Injectables
- Non-Fiber-Releasing
- Non-Pyrogenic per USP Bacterial Endotoxins ( $< 0.25$  EU/mL)
- Meets Total Organic Carbon and Water Conductivity per USP Purified Water, pH per USP Sterile Purified Water

#### Autoclave Resistance

- Lot samples multi-cycle autoclave challenged

\* Per lot samples soak or rinse-up flush aliquots.

\* For Gamma-irradiated products and maximum allowable dosage, please contact Pall.

# Novasip DV20 and DV50 Virus Removal Filter Capsules

## Technical Specifications

### Materials of Construction

<b>Filter Medium</b>	Hydrophilic polyvinylidenedifluoride (PVDF)
<b>Support and Drainage</b>	Polyester
<b>Core, Cage and Endcaps</b>	Polypropylene
<b>Housing Shell</b>	Polyetherimide
<b>O-rings<sup>(1)</sup></b>	Silicone

<sup>(1)</sup> Other polymers available.

### Nominal Dimensions

	CLM05DV20	C3DV50
<b>Length</b>	84 mm (3.3 in.)	157 mm (6.18 in.)
<b>Diameter</b>	123 mm (4.8 in.)	123 mm (4.8 in.)
<b>Nominal Filter Area</b>	0.07 m <sup>2</sup> (0.75 ft <sup>2</sup> )	0.4 m <sup>2</sup> (4 ft <sup>2</sup> )

### Inlet and Outlet

26 – 38 mm (1 – 1½ in.) sanitary flange

### Virus Removal

<b>DV20</b>	$T_R \geq 10^5$ for 25 nm PP7 bacteriophage $T_R \geq 10^6$ for 53 nm PR772 bacteriophage
<b>DV50</b>	$T_R \geq 10^6$ for 50 nm PR772 bacteriophage

### Operating Conditions

<b>Recommended Operating Pressure</b>	1 – 2 bard (15 – 29 psid)
<b>Maximum Differential<sup>(1)</sup> Pressure</b>	3 bard (43.5 psid).

<sup>(1)</sup> **Note:** Maximum assembly pressure is 6.0 bard (90 psid) for short-term integrity testing.

### Aqueous Extractables (NVR)

< 5 mg/capsule (Deionized water at 20 °C [68 °F])

### Flow/Pressure (Water, 25 °C [77 °F])

3.2 mL/min at 5860 mbar (85 psi) for CLM05DV20P1G

0.3 L/min @ 2 bar (29 psi) for CL3DV50P1G

### Sterilization

Autoclavable and Steamable in situ for 3 x 1-hour cycles at up to 125 °C (257 °F) (non-irradiated product only). Gamma-irradiatable<sup>(2)</sup>.

<sup>(2)</sup> Contact Pall for recommended procedures.

### Effluent Quality Tests (P Tests)

Meets Cleanliness per USP Particulates in Injectables.

Non-Fiber-Releasing

Non-Pyrogenic per USP Bacterial Endotoxins (< 0.25 EU/mL)

Meets Total Organic Carbon and Conductivity per USP Purified Water, pH per USP Sterile Purified waters.

### Ordering Information

Part Number	Media	Type Rating
<b>CLM05DV20P1G</b>	Hydrophilic PVDF	For viruses $\geq 20$ nm
<b>CL3DV50P1G</b>	Hydrophilic PVDF	For viruses $\geq 50$ nm

**Note:** For suggested qualification protocols, test/validation discs, sizing and sterilizing recommendations, multi-element forward flow values or other information, please contact Pall or your local Pall representative.