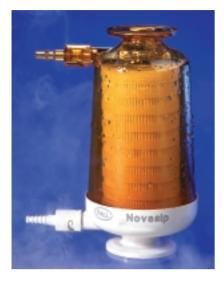
Novasip[™] DV20 and DV50 Virus Removal Filter Capsules Steam-In-Place Capsules for Virus Filtration





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

- ≥ 3 Log Titer Reduction (LTR) for 20 nm viruses
- ≥ 6 log LTR for ≥ 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
- * For Gamma-irradiated products and maximum allowable dosage, please contact Pall.

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.

Novasip DV20 and DV50 Virus Removal Filter Capsules Technical Specifications

Materials of Construction

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

⁽¹⁾ Other polymers available.

Nominal Dimensions

	CLM05DV20	C3DV50
Length	84 mm (3.3 in.)	157 mm (6.18 in.)
Diameter	123 mm (4.8 in.)	123 mm (4.8 in.)
Nominal Filter Area	0.07 m ² (0.75 ft ²)	0.4 m² (4 ft²)

Inlet and Outlet

Virus Removal

DV20	$T_{\text{R}} \geq 10^{\text{s}}$ for 25 nm PP7 bacteriophage $T_{\text{R}} \geq 10^{\text{s}}$ for 53 nm PR772 bacteriophage
DV50	$T_{\text{R}} \geq 10^{\text{\tiny 6}}$ for 50 nm PR772 bacteriophage

Operating Conditions

Recommended Operating Pressure	1 – 2 bard (15 – 29 psid)
Maximum Differential ⁽¹⁾ Pressure	3 bard (43.5 psid).

⁽¹⁾ 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 ⁽²⁾ .

⁽²⁾ 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	1	
Part Number	Media	Type Rating
CLM05DV20P1G	Hydrophilic PVDF	For viruses ≥ 20 nm
CL3DV50P1G	Hydrophilic PVDF	For viruses ≥ 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.