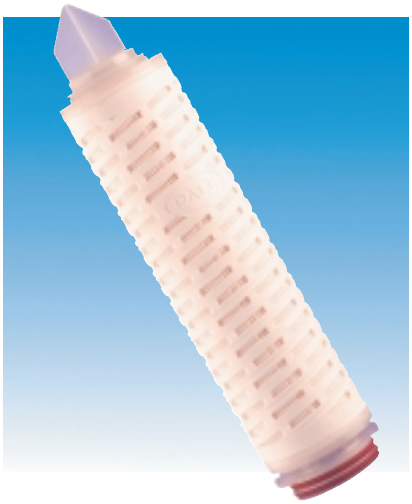
Ultipor® VF Grade DV20 Virus Removal Filter Cartridges

Removal of Viruses as small as 20 nm



Pall **Ultipor** VF grade DV20 filter cartridges are integrity-testable, direct flow filters for size exclusion removal of viruses as small as 20 nm from biological solutions. The innovative DV20 hydrophilic PVDF microporous membrane also enables > 95% transmission of proteins up to 160 kiloDaltons. Using a standard single open-ended (SOE) AB sanitary style cartridge design, **Ultipor** VF DV20 filters achieve practical flows and pressure drops in process-scale purification of BioPharmaceuticals, tissue and plasma derivatives and protein additives. Where required, suitable prefilters employing the same PVDF membrane material are available, simplifying process optimization and filtration system validation.

Features and Benefits

- Sanitary direct flow cartridges
- Robust size exclusion mechanism
- ≥ 3 log T_R for > 20 nm viruses
- ≥ 6 log T_R for > 50 nm viruses
- Low binding for high protein yields
- High transmission of albumin and IgG
- Very low extractables
- Autoclavable and Steamable in situ (SIP)
- 100% integrity-tested (correlated to virus retention)
- Manufactured for use in conformance with cGMP
- Pharmaceutical P optimized with Certificate of Test provided
- Validation Guide available

Claims based on challenges with bacteriophage (bacterial viruses) PP7 (25 nm) and PR772 (53 nm) in 1% Bovine Serum Albumin in phosphate-buffered saline at pH 7.4, 20 °C (68 °F).

***Note:** These filters are also available in **Kleenpak** Nova capsule format.*

Quality and Bio-Safety Biological Tests

Integrity

- Every DV20 grade filter integrity tested during manufacture. Test correlated to viral (phage) removal

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 Conductivity per USP Purified Water; pH per Sterile Purified Water

Autoclave Resistance

- Lot samples multi-cycle autoclave challenged

** Per lot sample or rinse-flush aliquots.*

Forward Flow Integrity Test

- Diffusional flow integrity test, carried out by standard upstream or downstream methods
- Correlated to 3 log T_R for 25 nm PP7 phage and ≥ 6 log T_R for 53 nm PR772 phage
- **Test Wetting Fluid:** 30% IPA (20% EtOH values also available)
- Water or buffer-wet values for installation confirmation can also be provided
- **Test Pressure:** 85 psi (air test gas) Contact Pall for cartridge values and correlation data
- Validation Guide available

Ultipor VF Grade DV20 Virus Removal Filter Cartridges

Technical Specifications

Materials of Construction

Membrane	Hydrophilic modified polyvinylidenedifluoride (PVDF)
Support and Drainage	Polyester
Core, Cage and End Caps	Polypropylene
Code 7 Adapter	Polypropylene with encapsulated stainless steel reinforcing ring
O-rings	Silicone

Configuration (AB Code 7)

Double 226 O-ring adapter

Fin end with bayonet lock.

Nominal Dimensions

Lengths	10 in. (254 mm), 20 in. (508 mm), 30 in. (762 mm), 40 in. (1016 mm)
Diameter	70 mm (2.75 in.)

Operating Conditions

Recommended Operating ΔP	1 – 2 bard (15 – 29 psid)
Maximum Differential Pressures	6.0 bard (90 psid) during integrity testing 3.1 bard (45 psid) for continuous service

Nominal Filter Area

1.0 m^2 (10.8 ft^2) per 10 in. (254 mm) element

Aqueous Extractables (NVR)

< 5 mg per 10 in. (254 mm) element in deionized water at 20 °C (68 °F), process-ready (after integrity testing in 30% IPA/water, water flush and autoclaving).

Autoclave and Steaming in situ[1]

Maximum Temperature	125 °C (257 °F)

[1] Contact Pall for recommended procedures to qualify filters under actual conditions of use.

Typical Liquid Flow Rate[2]

15 L/h/10 in. (254 mm) module at 30 psid for 1% Bovine Serum Albumin in phosphate-buffered saline at pH 7.4, 20 °C (68 °F)

[2] Claims based on challenges with bacteriophage (bacterial viruses) PP7 (25 nm) and PR772 (53 nm) in 1% Bovine Serum Albumin in phosphate-buffered saline at pH 7.4, 20 °C (68 °F).

Removal Ratings

3 Log T_R for viruses > 20 nm

6 Log T_R for viruses > 50 nm

Part Numbering and Ordering Information

Part Number	Nominal Length
AB1DV207PH4	10 in. (254 mm)
AB2DV207PH4	20 in. (508 mm)
AB3DV207PH4	30 in. (762 mm)
AB4DV207PH4	40 in. (1016 mm)

Ordering Information for Recommended Prefilters

AB □ □ **7** □ □ □

Code	Nominal Length
1	10 in. (254 mm)
2	20 in. (508 mm)
3	30 in. (762 mm)
4	40 in. (1016 mm)

Code	Rating	Filter Type
DV20	≥ 3 log T_R for viruses > 20 nm	**Ultipor** VF
UDV50	≥ 6 log T_R for viruses > 50 nm	**Ultipor** VF
DVD	Sub 0.1 µm virus prefilter	**Ultipor** VF
DJL	0.1 µm (+ 0.2 µm prefilter layer)	**Fluorodyne** II
DFL	0.2 µm (double-layer)	**Fluorodyne** II
DBL	0.45 µm (+ 0.65 µm prefilter layer)	**Fluorodyne** II

Code	Filter Grade
P	Pharmaceutical*
Omit	General Use

* Pall pharmaceutical-grade filters are designed for use in conformance with CGMP in Manufacturing, Processing, Packing or Holding of Drugs (21CFR210) and CGMP for finished Pharmaceuticals (21CFR211.72) including batch release certificate and full traceability.

Code	Gasket Option
H4	Silicone

Other materials available on request.