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
- $\geq 3 \log_{10}$ TR for > 20 nm viruses
- $\geq 6 \log_{10}$ TR 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

Bacterial Endotoxins

- 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 $3 \log_{10}$ TR for 25 nm PP7 phage and $\geq 6 \log_{10}$ TR 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

<table>
<thead>
<tr>
<th>Membrane</th>
<th>Hydrophilic modified polyvinylidenedifluoride (PVDF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support and Drainage</td>
<td>Polyester</td>
</tr>
<tr>
<td>Core, Cage and End Caps</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Code 7 Adapter</td>
<td>Polypropylene with encapsulated stainless steel reinforcing ring</td>
</tr>
<tr>
<td>O-rings</td>
<td>Silicone</td>
</tr>
</tbody>
</table>

Configuration (AB Code 7)

Double 226 O-ring adapter
Fin end with bayonet lock.

Nominal Dimensions

<table>
<thead>
<tr>
<th>Lengths</th>
<th>10 in. (254 mm), 20 in. (508 mm), 30 in. (762 mm), 40 in. (1016 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter</td>
<td>70 mm (2.75 in.)</td>
</tr>
</tbody>
</table>

Operating Conditions

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

Nominal Filter Area

1.0 m² (10.8 ft²) 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

Maximum Temperature | 125 °C (257 °F) |
(1) Contact Pall for recommended procedures to qualify filters under actual conditions of use.

Typical Liquid Flow Rate

15 L/hr/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) P27 (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 Tₜ for viruses > 20 nm
6 Log Tₜ for viruses > 50 nm

Part Numbering and Ordering Information

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Nominal Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>AB1DV207PH4</td>
<td>10 in. (254 mm)</td>
</tr>
<tr>
<td>AB2DV207PH4</td>
<td>20 in. (508 mm)</td>
</tr>
<tr>
<td>AB3DV207PH4</td>
<td>30 in. (762 mm)</td>
</tr>
<tr>
<td>AB4DV207PH4</td>
<td>40 in. (1016 mm)</td>
</tr>
</tbody>
</table>

Ordering Information for Recommended Prefilters

<table>
<thead>
<tr>
<th>Code</th>
<th>Nominal Length</th>
<th>Code</th>
<th>Rating</th>
<th>Filter Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 in. (254 mm)</td>
<td>DV20</td>
<td>≥ 3 log Tₜ for viruses &gt; 20 nm</td>
<td>Ultipor VF</td>
</tr>
<tr>
<td>2</td>
<td>20 in. (508 mm)</td>
<td>UDV50</td>
<td>≥ 6 log Tₜ for viruses &gt; 50 nm</td>
<td>Ultipor VF</td>
</tr>
<tr>
<td>3</td>
<td>30 in. (762 mm)</td>
<td>DVD</td>
<td>Sub 0.1 μm virus prefilter</td>
<td>Ultipor VF</td>
</tr>
<tr>
<td>4</td>
<td>40 in. (1016 mm)</td>
<td>DJL</td>
<td>0.1 μm (&gt; 0.2 μm prefilter layer)</td>
<td>Fluorodyne II</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DFL</td>
<td>0.2 μm (double-layer)</td>
<td>Fluorodyne II</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DBL</td>
<td>0.45 μm (&gt; 0.65 μm prefilter layer)</td>
<td>Fluorodyne II</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Filter Grade</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Pharmaceutical*</td>
<td>Silicone</td>
</tr>
</tbody>
</table>

* 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.

Other materials available on request.