Pall Corporation

Contact Us: www.pall.com/contact

Ultipor® VF Grade DV50 Virus Removal Filter Cartridges

Description

Ultipor® VF Grade DV50 Virus Removal filter cartridges feature innovative hydrophilic PVDF microporous membranes to remove significant levels of viruses from biological solutions, while enabling > 95% transmission of proteins up to 300 kD or larger. Using patented Ultipleat® crescent-shaped pleated elements, the filters to incorporate 1.6 m² (17.5 ft²) of filter area per 10 in. (254 mm) element in standard single open-ended (SOE) AB sanitary style cartridges. Ultipor VF cartridges achieve practical flows and pressure drops while effectively removing nanometer-size viral contaminants with high protein yields. An optional sub-0.1 µm rated prefilter (Grade DVD) and Fluorodyne® II filters enhance throughputs and employ the same PVDF membrane material for ease of validation. Typical applications include purification of biopharmaceuticals, tissue and plasma derivatives, protein additives, culture media, diagnostic reagents, buffers and diluents.

Features and Benefits

- Sanitary direct flow cartridges
- 6 log Titer Reduction (T_R) for 50 nm viruses (DV50 grade)
- Robust size exclusion mechanism
- PVDF microporous membranes
- Narrow pore-size distribution
- Inherently water wettable
- Low binding for high protein yields
- Very low extractables
- Steamable in situ
- 100% integrity-tested
- Individually serialized
- Manufactured for use in conformance with cGMP
- ISO 9000 Certified Quality System
- Pharmaceutical P optimized
- Certificate of Test provided
- Validation Guide available
- Discs and mini-cartridges (SBF Junior Style) available

Quality and Bio-Safety Biological Tests

Integrity

- Every DV50 grade 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 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

Products in this datasheet may be covered by one or more patents including :
EP 0 667 800
EP 0 982 061
EP 1 380 331
US 5,543,047
US 5,690,765
US 5,725,784
US 6,113,784
US 7,083,564
US 7,318,800
US 5,736,051

Specifications

Materials of Construction

Membrane	Hydrophilic modified polyvinylidenefluoride (PVDF)
Support and Drainage	Polyester
Core, Cage and End Caps	Polypropylene
Code 7 Adapter	Polypropylene with encapsulated stainless steel reinforcing ring for steaming in situ
O-rings	Silicone[1]

[1] Other polymers available

Removal Ratings

DVD	Sub-0.1 µm prefilter
DV50	T_R 10^6 for 50 nm viruses[2]

[2] Lot samples retain log 10^6 T_R of 53 nm spherical non-enveloped bacteriophage

Configuration (AB Code 7)

Double 226 O-ring adapters, 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.)

Nominal Filter Area[3]

DVD	0.9 m² (9.5 ft²)
UDV50	1.63 m² (17.5 ft²)

[3] Per 10 in. (254 mm) element

Typical Flow Rate

Clear water flow is 1 L/min @ 2 bard (29 psid)

Operating Conditions*

Maximum Differential Pressure during Integrity Testing	6.0 bard (90 psid)
Maximum Differential Pressure for Continuous Service	3 bard (43.5 psid)
Recommended Operating ΔP	1-2 bard (15 – 29 psid)

* Laboratory tests confirm viral T_R is in independent of pressure differential to 3.1 bard (45 psid)

Autoclave and Steaming in situ**

Maximum Temperature	125 °C (257 °F)

** Laboratory tests confirm multi-cycle resistance. Filters should be qualified in actual use. Contact Pall for recommended procedures

Aqueous Extractables (NVR) per 10 in. (254 mm) Element***

< 25 mg after autoclaving (water wet)
< 5 mg after installation integrity testing (30% IPA/water wet), water flush and autoclaving

*** In water at 20 – 25 °C (68 – 77 °F) after autoclaving

Ordering Information

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	Removal Rating
DVD	Sub-0.1 µm prefilter
UDV50	10^9 for 50 nm viruses

Code	Filter Grade
P	Pharmaceutical*

* 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.

Contact Information

Corporate Headquarters: Pall Corporation, 25 Harbor Park Drive, Port Washington, New York, USA 11050, Web: www.pall.com, Tel: 1-516-484-5400, Contact: www.pall.com/contact

Revision Date: 08/25/2010