

Fluorodyne® II Hydrophilic PVDF Filter Cartridges

Ideal for Large-volume Sterile Filtration



Pall **Fluorodyne** II filter cartridges feature a unique hydrophilic modified polyvinylidene difluoride (PVDF) membrane with ultra-low binding properties, broad chemical and temperature resistance, and higher flows than competitive PVDF or other membrane cartridges. High-area pleated into single open-ended (SOE) AB sanitary style cartridges, **Fluorodyne** II filters are available 0.45 µm rated for stabilization, filtration of viscous fluids and membrane prefiltration, 0.2 µm rated for sterilization, and 0.1 µm rated for sterilization and mycoplasma removal. They are recommended for pharmaceuticals including ophthalmics and other dilute preservative solutions, biologicals including dilute protein solutions, cold and hot WFI, chemicals, aggressive solvents and sanitizing agents.

Features and Benefits

- Higher flows per cartridge for smaller assemblies or reduced change-outs
- DJL provides 0.1 µm retention with 0.2 µm flow
- Lower extractables
- Stable in 90 °C (184 °F) WFI
- High protein recoveries
- Rapid preservative recoveries
- Inherently water wettable
- Compatible with organic solvents, acids and chemicals⁽¹⁾.
- Resin and surfactant-free
- Melt-sealed, non shedding

⁽¹⁾ Except ketones and amides.

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

- Built-in PVDF prefiltration layers
- Repeatedly 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

Quality and Bio-Safety Biological Tests

Integrity

- Every filter tested during manufacture. Test correlated to microbial 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 Sterile Purified Water

Steam Resistance

- Lot samples multi-cycle autoclave challenged

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

Fluorodyne II Hydrophilic PVDF Filter Cartridges

Technical Specifications

Materials of Construction

Membrane	Hydrophilic Polyvinylidenedifluoride (PVDF)
Support, Drainage, 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.

Microbial Removal Ratings⁽²⁾

DBL	0.45 µm microbial-rated (Typical <i>Serratia marcescens</i> Tr > 10 ⁶)
DFL	0.2 µm sterilizing-grade
DJL	0.1 µm mycoplasma-rated, sterilizing-grade (Typical <i>Acholeplasma laidlawii</i> Tr > 10 ⁸)

⁽²⁾ Lot samples of sterilizing-grades retain >10⁷ cfu/cm² of *Brevundimonas diminuta* per mod. ASTM F838-83 and FDA guidelines.

Configuration (AB Code 2 and 7)⁽³⁾

Double 226 O-ring adapter
Fin end with bayonet lock

⁽³⁾ Alternate adapter codes available.

Nominal Dimensions

Lengths	5 in. (127 mm), 10 in. (254 mm), 20 in. (508 mm), 30 in. (762 mm)
Diameter	70 mm (2.75 in.)

Nominal Filter Area per 10 in. (254 mm) Element

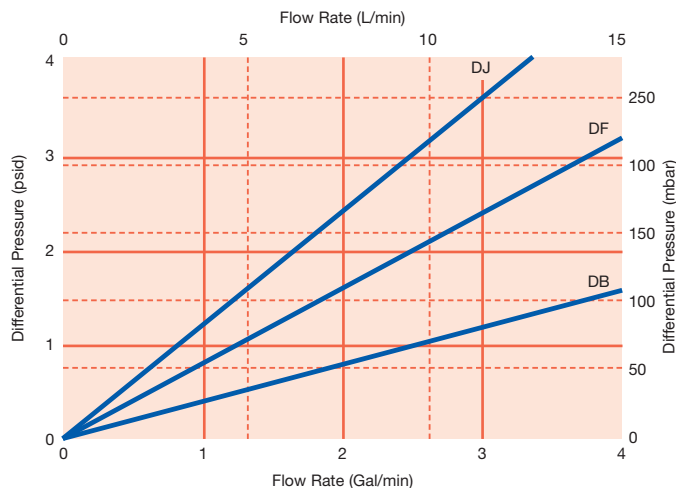
Size Code	DBL	DFL	DJL
Effective Filter Area	0.55 m ² (6 ft ²)	0.51 m ² (5.5 ft ²)	0.51 m ² (5.5 ft ²)

Operating Conditions⁽⁴⁾

Maximum Differential Pressure and Temperature	5.3 bard (77 psid) to 50 °C (122 °F)
	3.4 bard (49 psid) to 90 °C (194 °F)

⁽⁴⁾ Using compatible fluids.

Typical Liquid Flow Rates⁽⁴⁾



⁽⁴⁾ Typical initial clean media ΔP per 10 in. (254 mm) element; water at 20 °C (68 °F); viscosity 1 cP. For assistance in filter assembly sizing and housing selection, contact your local Pall representative.

Aqueous Extractables (NVR)⁽⁶⁾ per 10 in. (254 mm) Element

Typically < 5 mg

⁽⁶⁾ In water at 20 – 25 °C (68 °F – 77 °F) after autoclaving.

Autoclavable or Steamable in situ⁽⁷⁾

Cumulative Steaming Exposure	30 hours (1-hour cycles) at 125 °C (257 °F) 10 hours (1-hour cycles) at 140 °C (284 °F)
Hot Water Sanitization	To 90 °C (194 °F) at 0.5 bard (7 psid)

Forward Flow⁽⁷⁾

DBL	13 mL/min at 1240 mbar (18 psi)
DFL	12 mL/min at 2760 mbar (40 psi)
DJL	29 mL/min at 4475 mbar (65 psi)

⁽⁷⁾ Forward Flow allowable limit per 10 in. (254 mm) cartridge at given test pressure, water wet, air test gas.

Part Numbering and Ordering Information

Code	Nominal Length	Code	Removal Rating	Code	Cartridge Style	Code	Filter Grade	Code	Gasket Option
05	5 in. (127 mm)	DBL	0.45 µm	7	Double 226 O-ring with bayonet lock and fin end	P	Pharmaceutical*	H4	Silicone
1	10 in. (254 mm)	DFL	0.2 µm	2 ⁽⁸⁾	Double 226 O-ring with bayonet lock and flat end	Omit	General Use	Other materials available on request.	
2	20 in. (508 mm)	DJL	0.1 µm			* 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.			
3	30 in. (762 mm)								

⁽⁸⁾ AB05 size only.