

Fluorodyne II Pharmaceutical Grade Filters

**0.1µm filtration at
0.2µm filter flow rates**

**0.1µm Rated Sterilising Grade
Filters for Enhanced Sterility
Assurance in the Pharmaceutical
and Biotechnology Industries**

Sterilising grade filters are vital for sterilising liquid products, water and additives during the manufacture of pharmaceuticals, diagnostic products and cosmetics.

In some applications the presence of unusually small micro-organisms, such as mycoplasmas and diminutive bacteria, may require the use of sterilising grade filters with a rating finer than the normal standard of 0.2µm. Pall has developed a 'Fluorodyne' II filter rated at 0.1µm to give enhanced sterility assurance for these applications.

The 'Pall' 0.2 µm rated DFLP grade **Fluorodyne II** filter has proven very successful since its introduction in 1995. The high flow rates and low product adsorption seen with this product has helped to increase process efficiency in many applications. The technology used to produce this filter has been developed further to produce a cartridge with the **removal efficiency of a 0.1µm filter and a flow rate similar to many 0.2µm filters.**

High removal efficiencies and high flow rates

Pall 0.1µm rated DJLP grade **Fluorodyne II** filters are manufactured using two layers of proprietary hydrophilic PVDF membrane. The upstream layer is rated at 0.2µm and the downstream layer rated at 0.1µm. This construction offers many benefits including:-

- Total removal of *Brevundimonas diminuta* (ATCC19146) and correlated to the Forward Flow test at $\geq 10^7/\text{cm}^2$ challenge
- High removal efficiency for diminutive micro-organisms e.g. *Acholeplasma laidlawii* (ATCC28206) typical titre reduction 10^8



- High flow rates - 0.1µm filtration at flow rates comparable to many 0.2µm filters
- Long life due to built-in pre-filtration

Comprehensive validation support

Pall provides comprehensive validation documentation for users of 0.1µm rated **Fluorodyne II** filters, including:

- *Brevundimonas diminuta* challenge to demonstrate compliance with FDA requirements for sterilising grade filters
- *Acholeplasma laidlawii* removal efficiency
- Manufacturing QC testing

Further information can be obtained from Pall Scientific and Technical Report USTR 1650.

Where required our Validation Services Group can also provide in-process validation support to help you meet current regulatory requirements.

Applications

Sterilising filtration where diminutive bacteria may be present.

Applications where higher security than can be provided by a 0.2µm filter is desirable. These may include:

- High purity protein products
- Tissue culture media and sera
- Diagnostic products
- Solutions containing preservatives
- Water systems

Materials of Construction

Membrane	Double layer hydrophilic PVDF
Support and Drainage Layers	Polypropylene
Core Cage and closed Endcap	Polypropylene
Adaptor	Polypropylene with an encapsulated stainless steel reinforcing ring
O-rings	Silicone elastomer

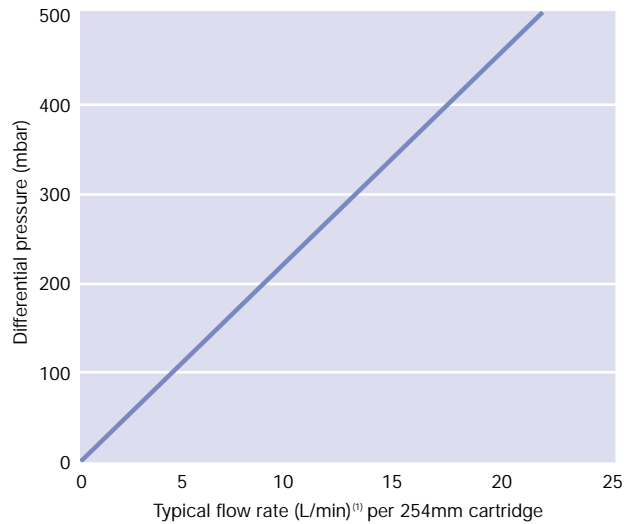
Steam Sterilisation

Max steaming temperature	140°C
Max cumulative exposure	5 hours at up to 140°C 30 hours at up to 125°C

Removal Efficiencies

<i>Brevundimonas (Pseudomonas) diminuta</i> (ATCC19146)	Sterile at challenge levels $\geq 10^7/\text{cm}^2$
<i>Acholeplasma laidlawii</i> (ATCC28206)	Typically TR = 10^8

Liquid Flow vs. Differential Pressure



⁽¹⁾ Differential pressures are for liquids with a viscosity of 1cP. Differential pressures for other viscosities can be conservatively estimated by multiplying the indicated differential pressure by the viscosity in cP.

Maximum Differential Pressure

In forward direction up to 50°C up to 80°C	5.3 bard 3.4 bard
In reverse direction	0.3 bard
During steaming in forward direction	0.3 bard

Extractables⁽²⁾

Extractables in deionised water at 20°C	Typically <5mg per 254m filter
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⁽²⁾ Test details available in Pall Validation Guide USTR1650

Ordering Information

Pall Part number: AB

D J L 7 P H4

Code	Nominal length
1	254mm
2	508mm
3	762mm
4	1016mm

Code 7 adaptor
Double O-ring with bayonet lock and locating fin

Pharmaceutical Grade

Silicone O-rings



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