

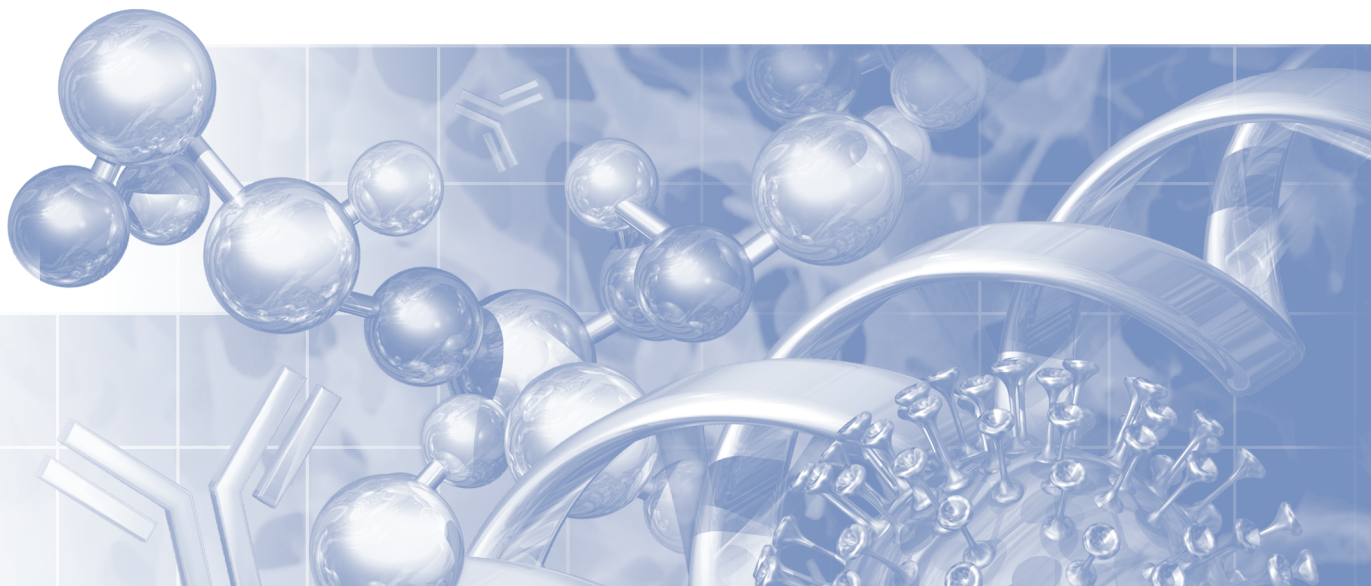


Life Sciences

Application Note

USTR 2612

Scalability of Ultipor® VF DV20 and UDV20 Virus Removal Filter Cartridges



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1. Introduction

Ultipor VF UDV20 virus removal filter cartridges are direct flow filters which provide an efficient and economical method for removing the smallest viruses from biological solutions.

Testing of virus membranes such as Ultipor VF DV20 is typically carried out at small scale due to the cost of viral validation and the limited availability of test material during process development. Using small disc formats to scale to advanced fanpleat and laid-over pleat designs means that there is at least a 900-fold difference in the effective filtration areas as well as a change from flat sheet disc to pleated membrane cartridge format. Measurements made over several manufacturing lots support that the clean water flux has linear scalability (Table 1). The tests outlined in this document further demonstrate that process fluid flux behavior is also independent of scale and format of Ultipor VF DV20 membrane (see Table 2).

Table 1
Summary of Water Flux Scalability Data

Filter Format	Part Number	Nominal Filtration Area	Typical Water Flux at 2.1 bar (30 psi) and 20 °C (L.m⁻².h⁻¹)	Mean Water Flux Scaling Factor from Flat Sheet Membrane
Minidisc Capsule	10MCFDV20	0.00096 m ²	21.7	N/A
47mm Disc in FTK200 Holder	FTKDV20047	0.0011 m ²	21.7	N/A
Novasip™ Capsule	CLM05DV20P1G	0.07 m ²	22.0	1.02
10 in. Fanpleat	AB1DV207PH4	1 m ²	21.6	1.00
10 in. Laid-over Pleat	AB1UDV207PH4	2 m ²	21.2	0.98

Minor differences in typical water flux are likely due to sampling variation and are not considered significant.

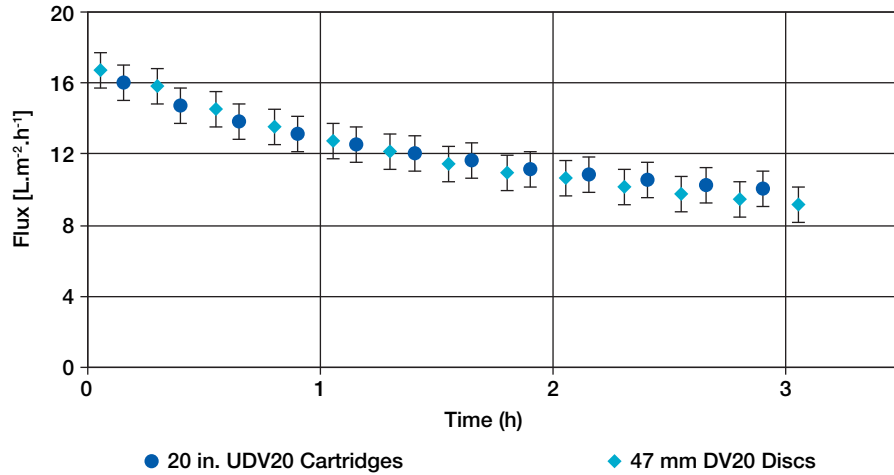
2. Methods

To test scalability of protein filterability data generated using 47 mm discs in FTK200 holders, a high-fouling lot of human gamma globulin powder (hlgG, Lot G225203, Seracare Life Sciences, MA) was specifically selected in order to generate sufficient fouling to provide a flux decay response. 2 g.L⁻¹ of the powder was dissolved in a pH 7.4 buffer containing 10 mM sodium phosphate and 140 mM sodium chloride before being pre-filtered using 0.1 µm Fluorodyne® II Grade DJL filters.

Duplicate 47 mm discs and 20 in. laid-over pleat construction Ultipor VF UDV20 membrane cartridges were tested in parallel with hlgG using a 500 L stainless steel pressure vessel. The discs and cartridges were made from different membrane lots with similar clean water fluxes. The test was then repeated on the following day using the same lot of hlgG prepared in the same way. For further details and advice on effective operation of Ultipor VF DV20 or UDV20 virus removal filter cartridges, see Pall publication USTR 2512¹ or contact your local Pall representative. The pressures upstream of all filters and downstream of the 20 in. cartridges were monitored throughout the 2.1 bar (30 psi) constant pressure test. Fluid temperatures were also monitored at one disc inlet and one cartridge inlet.

Figure 1

Flux vs Time for 47 mm Discs (n = 4) and 20 in. Laid-over Pleat Cartridges (n = 4) Tested in Parallel at 2.1 bar (30 psi) Constant Pressure and 22 °C. Data represents the Mean ± 1 Standard Deviation



3. Scalability

The graph in Figure 1 shows comparable flux profiles for discs and laid-over pleat construction cartridges. This demonstrates comparable filterability performance for discs and cartridges despite an increase of over 3000-fold in filtration area and a change to a high performance pleated format. The corresponding process flux scaling factor is close to unity as shown in Table 2 alongside fanpleat Ultipor VF DV20 membrane cartridge data previously generated with similar tests using bovine IgG. The scaling factor is the average flux achieved for a cartridge in 3 hours relative to the 47 mm disc average flux.

Ultipor VF DV20 and laid-over pleat UDV20 cartridges successfully pack high areas of membrane into cartridge format while maintaining membrane flux and throughput performance at this high membrane packing density.

Table 2

Summary of Ultipor VF DV20 IgG Filterability Scalability Data

Cartridge Format	Nominal Filtration Area	Number of Cartridges Tested	Number of 47 mm Disc Controls	Mean Scaling Factor of Average Flux from 47 mm Discs
20 in. Laid-over Pleat UDV20 (AB2UDV207PH4)	2 x 2 m ²	4	4	1.02
10 in. Fanpleat DV20 (AB1DV207PH4)	1 m ²	1	3	0.95

4. System Sizing

Several complex factors in addition to scalability are considered in system sizing. Your local Pall representative will work with our system sizing experts to ensure our systems deliver your processing requirements.

5. References

1. USTR 2512: Preparation, Use, and Integrity Testing of Pall Ultipor® VF DV20 Filter Cartridges and Capsules.



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