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Vented Disc Filter Capsules

ENGINEERING YOUR SUCCESS.

Supporting filtration trials, providing confidence when scaling up

Product Description & Intended Use

Parker vented disc filter capsules are intended to provide a convenient, encapsulated device format for use in bench-top filtration trials to establish and validate filter capacity and other relevant key performance parameters during the research and development stages of drug production.

The disc capsule design shares materials of construction with the larger filter cartridge and capsule formats, namely the demicap and large-scale MURUS capsules available for the PROPOR SG / HC / BR / MR and PROCLEAR PP / PP+ families of biopharmaceutical filtration products.

Pairing these products with SciLog FilterTec laboratory systems and SciLog sensing technology allows small-scale simulation of filtration processes to be performed, collecting large volumes of real-time data to provide a high degree of confidence when transitioning to pilot-scale and subsequently on to full-scale GMP manufacturing filtration processes.

Product Selection / Scale-up factors

Filter sizing should be supported by empirical data generated via filtration trials and interpreted in relation to the final process objectives. However, initial filter selection is primarily driven by the level of retention required.

For applications where sterile filtrate is required, PROPOR SG should be the primary option. If sterile filtration of a difficult-to-filter solution is needed, then PROPOR HC can be employed.

Bioburden reduction for intermediary filtration steps or in applications where true sterility is not required can be provided by PROPOR BR.

Mycoplasma retention in applications such as mammalian cell growth media filtration is provided by PROPOR MR.

Due to the retention mechanisms involved, depth filter performance is liable to vary significantly in relation to process parameters and solution characteristics. Therefore, it is recommended that where possible, assessment of depth filter performance is conducted based on data generated under simulated conditions, using experimental data to demonstrate the level of retention / protection provided for the application.

Scaleable single-use filtration solutions

Scaleable single-use filtration solutions

Effective Filtration Area (EFA) *	Liquid vented discs		E Size		B Size		A Size		K Size		10" Size	
	cm^2	in^2	m^2	ft^2	m^2	ft^2	m^2	ft^2	m^2	ft^2	m^2	ft^2
PROCLEAR PP **	14.50	2.25	0.07	0.75	0.14	1.50	0.28	3.01	0.37	3.98	0.79	8.50
PROCLEAR PP +	14.50	2.25							0.25	2.69	0.50	5.40
PROPOR BR	14.50	2.25	0.05	0.53	0.10	1.07	0.20	2.15	0.26	2.79	0.55	5.92
PROPOR SG	14.50	2.25	0.05	0.53	0.10	1.07	0.20	2.15	0.26	2.79	0.55	5.92
PROPOR HC	14.50	2.25	0.05	0.53	0.10	1.07	0.20	2.15	0.26	2.79	0.55	5.92
PROPOR MR	14.50	2.25	0.05	0.53	0.10	1.03	0.19	2.09	0.24	2.58	0.50	5.38

* Correct at time of publication
** Maximum area. For surface area for a specific rating, please contact your local Parker representative.


DEMICAP PROPOR MR
DEMICAP TETPOR LIQUID
DEMICAP PROPOR LR
FLOW
MURUS PROPOR SG
FLOW
MURUS PROPOR MR
FLOW
MURUS PROPOR SG
FLOW
MURUS PROPOR SG

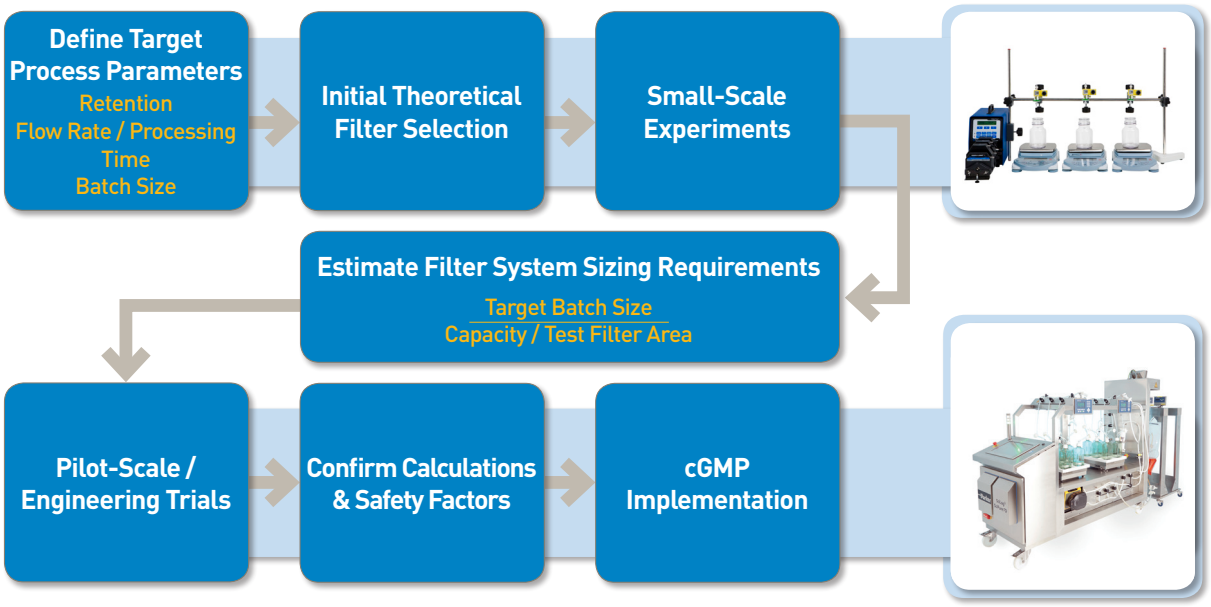
Confidence when scaling up

By using a structured, analytical approach under simulated process conditions at the process development stage, it is possible to accurately predict filter performance at cGMP level.

Results gleaned during initial experiments to determine the most appropriate bioprocessing conditions can be scaled up to cGMP production – so long as a robust experimental design is initally adopted.

Take, for example, a case study for determining the correct sizing for a filter used in a critical sterilization step of a high potency drug product.

Figure 1: The process for successful scale-up



Methodology

The process for successful scale-up (Figure 1) begins with the manufacturer identifying a target product and the process parameters which a bioprocess must work within to the ensure quality of the final product.

Small-scale experiments using a theoretical selection of filters will allow the manufacturer to estimate filter system sizes, which can then be tested in pilot-scale and engineering trials. Because the capacity is directly proportional to the filter area, data from the smaller scale experiments can be scaled up to dermine the required system size for the target process.

Experimental variability can also be introduced through differing filter formats, drug products batches or process equipment at a pilot-scale or during full engineering trials to confirm the initial findings.

To ensure scale-up predictability, sizing should be performed using a scale model of the target process. Ideally, processing time should remain constant, and the flow rate should be adjusted as a function of test batch volume.

The SciLog® FilterTec system measures differential pressure across a filter during testing, allowing real-time assessment of filter blocking characteristics and further optimization through the use of prefiltration stages. Constant flow testing is performed until the differential pressure across the filter reaches a defined, predetermined end point.

Scale-up testing

For this case study, to match the requirements of large-scale manufacturing, sterilization filtration of a high-potency drug was required. The process was defined by the maximum batch size of 25 L of bulk product and an upstream pressure limit of 2 barg (29 psig).

Mid-batch filter blockage or damage to the single-use manifold resulting from overpressure was not acceptable because of the hazardous nature of the drug product.

Small-scale disc testing was performed on a Parker PROPOR HC vented disc filter capsule using a target flow rate of 10 mL/min. A 20 per cent factor of safety was applied to the upstream pressure limit resulting in a maximum allowable pressure of 1.6 barg (23.2 psig). The PROPOR HC vented disc filter capsule achieved an actual flow rate of 8.5 mL/min and a throughput of 92.4 mL before the disc was considered blocked (Figure 2). Scaled-up relative to effective filtration area, this is the equivalent to 35 L of bulk product through a 10 inch (250 mm) filter capsule, which is capable of processing a 25 L batch while incorporating a 40 per cent safety factor in capacity.

Confirmation of this analysis through the use of a pilot-scale trial provides further assurance that the results are repeatable on a larger scale and that the batch could be processed without the risk of filter blockage.

A structured analytic approach creates confidence when scaling up. Furthermore, the use of automation during this process allows increased accuracy through the removal or potential operator variability.

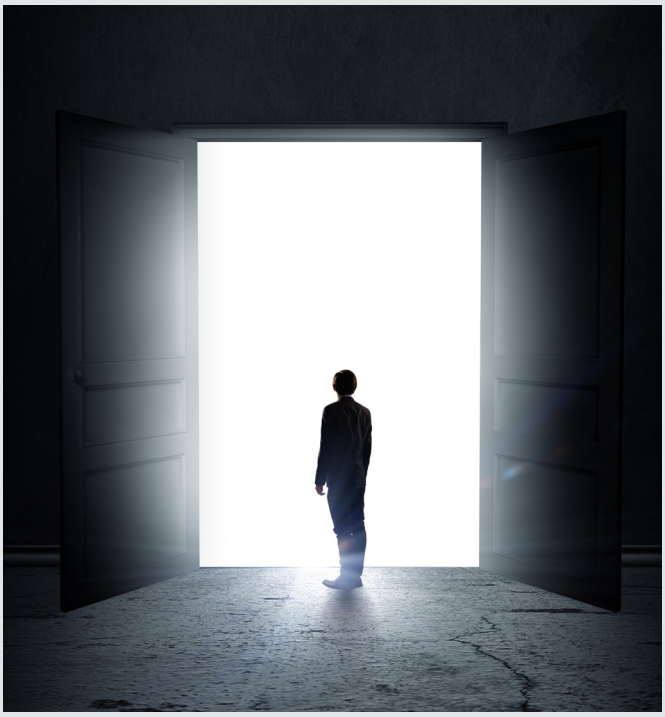
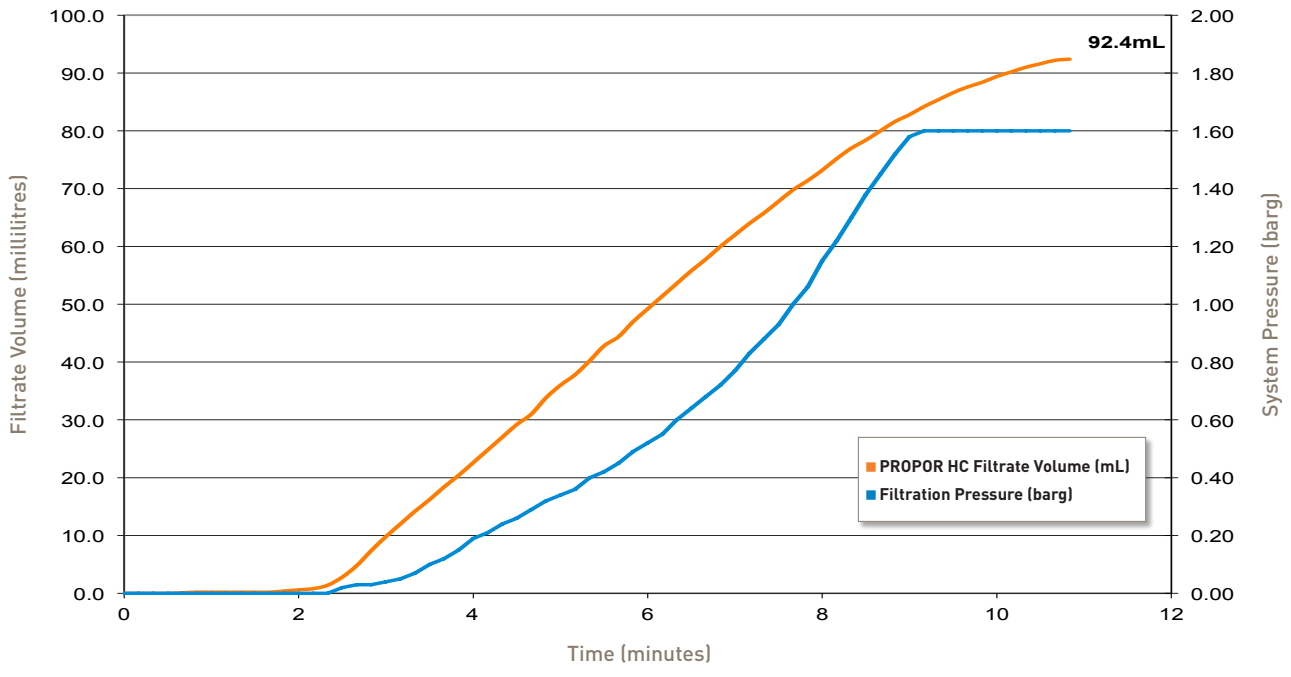
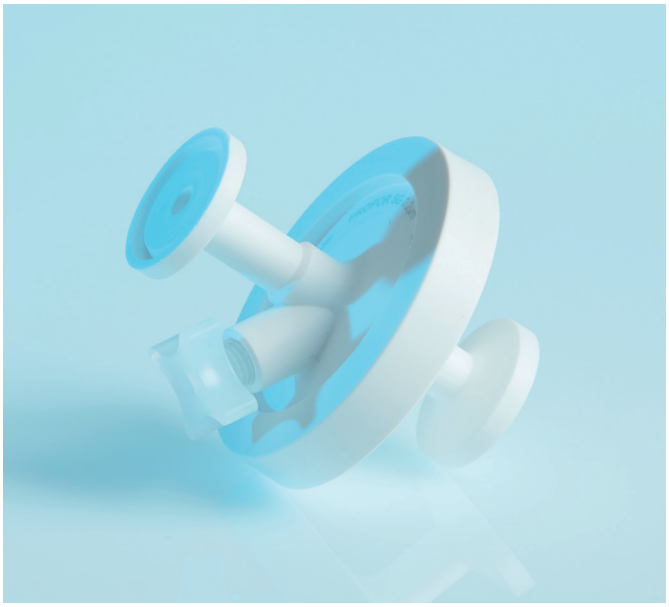


Figure 2: *Filtration volume versus pressure versus time*



Materials of construction

	Polypropylene housing	Nylon valve & silicone o-ring	PES membrane	Polypropylene depth media	Polyester depth media	Polyester support	Polypropylene support
PROPOR SG	•	•	•			•	
PROPOR HC	•	•	•			•	
PROPOR BR	•	•	•			•	
PROPOR MR	•	•	•			•	
PROCLEAR PP	•	•		•	•		•
PROCLEAR PP+	•	•		•	•		•



Maximum operating conditions

- 2 barg @ 60oC
- 5 barg @ ambient (intermittently for bubble point testing)

Autoclave & gamma sterilization resistance

- Gamma stable up to 50 kGy
- One autoclave cycle up to 130 oC (note liquid vented discs are not suited to in-line sterilization)

Compliance & biocompatibility

All materials of construction used in Parker vented disc filter capsules are compliant with FDA Code of Federal Regulations Title 21, Part 177 and meet biosafety requirements specified in USP <87> and USP <88>.

Shelf life

- PROPOR liquid vented discs 3 years.
- PROCLEAR liquid vented discs 5 years
- Post gamma irradiation all products 1 year

Integrity testing

The minimum bubble point specification for each product type is listed below:

- PROPOR BR: 2480 mbar
  (tested in air, wetted with water @ 20°C
- PROPOR HC 3380 mbar
  tested in air, wetted with water @ 20°C
- PROPOR MR 2360 mbar
  tested in air, wetted with 60:40 IPA / Water @ 20°C
- PROPOR SG 0.2 micron: 3380 mbar
  0.45 micron: 2480 mbar
  tested in air, wetted with water @ 20°C

Parts should be fully wetted prior to testing, flushed with purified water (or 60:40 IPA / water) and vented to ensure that all air is removed from the filter housing.

Once fully vented, parts should be flushed for a minimum of 30 seconds at a differential pressure of 500mbar to ensure complete wetting.

Parker recommends using an automated integrity test unit such as PORECHECK IV to perform bubble point testing. The appropriate connections and PPE should be employed during integrity testing to ensure that the procedure can be performed safely when the system is under pressure.

Vented disc capsule ordering information

PROPOR SG*

ZVSG50 — 020 TT — PN3

Code	Format	Code	Rating	Code	Fitting	Code	Pack
ZVSG50	50mm Ø Encapsulated Disc	020 045	0.2 µm 0.45 µm	TT	½" TCF	PN3	Pack of 3, non-sterile

PROPOR HC*

ZVHC50 — 620 TT — PN3

Code	Format	Code	Rating	Code	Fitting	Code	Pack
ZVHC50	50mm Ø Encapsulated Disc	620	0.2 µm	TT	½" TCF	PN3	Pack of 3, non-sterile

PROPOR BR*

ZVBR50 — 020 TT — PN3

Code	Format	Code	Rating	Code	Fitting	Code	Pack
ZVBR50	50mm Ø Encapsulated Disc	020	0.2 µm	TT	½" TCF	PN3	Pack of 3, non-sterile

PROPOR MR*

ZVMR50 — 610 TT — PN3

Code	Format	Code	Rating	Code	Fitting	Code	Pack
ZVMR50	50mm Ø Encapsulated Disc	610	0.1 µm	TT	½" TCF	PN3	Pack of 3, non-sterile

PROCLEAR PP*

ZVPP50 – [ ] TT – PN3

Code	Format
ZVPP50	50mm Ø Encapsulated Disc

Code	Rating
96	0.6 µm
01	1.0 µm
02	2.0 µm
03	3.0 µm
05	5.0 µm
07	7.0 µm
10	10. 0µm
15	15. 0µm

Code	Fitting
TT	½" TCF

Code	Pack
PN3	Pack of 3, non-sterile

PROCLEAR PP+*

ZVPL50 – [ ] TT – PN3

Code	Format
ZVPL50	50mm Ø Encapsulated Disc

Code	Rating
95	0.5 µm
96	0.6 µm
01	1.0 µm

Code	Fitting
TT	½" TCF

Code	Pack
PN3	Pack of 3, non-sterile

*Vented disc format not intended for use in GMP production environment.

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