

Pellicon® XL 50 Cassette

Easy-to-use, high performance, linearly scalable tangential flow filtration cassette for process development work at volumes from 50 to 1000 mL

Concentrate, desalt, and exchange buffers with the Pellicon® XL 50 cassette for your small volume process needs (typical starting volumes: 50 to 1000 mL).

The Pellicon® XL 50 cassette offers our superior ultrafiltration and microfiltration membranes in a wide range of molecular weight cutoffs and pore sizes to achieve truly linear scalability to our Pellicon® family of capsules and cassettes. Whether you choose our Biomax® membrane for its high flux and wide pH compatibility, the Ultracel® membrane for its low protein binding and easy cleaning, or the Durapore® microfiltration membrane for its ultra-low protein binding and excellent retention performance, you can be assured of reliable and consistent performance. Whichever membrane you choose, we have a Pellicon® product family to cover your needs.

For linear scalability to exist within a family of TFF devices, the channel geometry must be carefully designed and controlled. The feed and permeate flow channels in every Pellicon® XL 50 cassette are designed to provide comparable pressure drop, flow velocity and concentration profile to the larger Pellicon® capsules and cassettes, offering true linear scalability.

Easy to Use

- Self-contained no holder required
- Industry standard luer connections



Speed to Market

- True linear scalability to Pellicon® Capsules and Pellicon® cassettes (see protein performance scalability data)
- One device for screening, process development, scalability studies, and small volume processing

Applications

- Concentration, desalting and buffer exchange of proteins, insulin, polysaccharides, liposome, viruses, plasmids, colloids cell suspensions, and mammalian cells
- · Harvest, washing or clarification of cell cultures, lysates, and fermentation broths
- Sample preparation
- · Membrane selection studies
- Preparation of material for clinical trials
- Small-volume processing



Protein Performance Scalability

Small-scale devices that are shown to provide predictable and reliable results that are calculable to the performance of their equivalent larger devices enables the use of smaller volumes of often-times expensive process streams to effectively, efficiently, and economically develop a process that will predictively indicate ever-increasing larger-scale needs.

Pellicon® XL 50 cassette was evaluated for scalability to Pellicon® Capsule and Pellicon® 3 cassette and data is presented in **figure 2** and **figure 3**. This study demonstrates the scalability using Bovine Gamma Globulin (BgG) and Bovine Serum Albumin (BSA) BgG as model protein streams. The protein challenge consisted of transmembrane pressure (TMP) excursions at 10 g/L of BgG and 20 g/L of BSA protein concentrations to evaluate protein flux performance and compared with average and +/- 20% range of the same for Pellicon® Capsule and Pellicon® 3 cassettes. The results demonstrate excellent scalability with consistent flux data across Pellicon® XL 50 cassette made at different process settings.

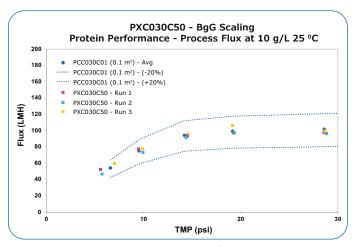


Figure 2: Performance Scalability of Pellicon® XL 50 cassette to Pellicon® Capsule using Bovine Gamma Globulin (BgG)

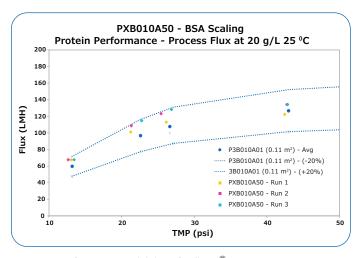


Figure 3: Performance Scalability of Pellicon $^{\otimes}$ XL 50 cassette to Pellicon $^{\otimes}$ 3 cassette using Bovine Serum Albumin (BSA)

Consistent High Product Recovery and High Flux

High-quality Ultrafiltration (UF) Membranes

Ultracel® membranes are the membranes of choice for high-recovery purification. These void-free membranes combine ultra-low protein binding and low fouling with solvent resistance and superb mechanical strength. Casting the regenerated cellulose membrane onto a microporous polyethylene substrate creates a uniform, robust structure, with high integrity and greater resistance to back pressure.

Biomax® membranes are well suited for applications requiring high flux, low to moderate protein binding, and harsh chemical cleaning and/or sanitization. Made of polyethersulfone (PES), these void-free membranes are caustic and chlorine resistant.

Both the Ultracel® and Biomax® membranes deliver faster processing speeds with higher yields resulting in shorter processing times and more compact processing systems.

The Premier Microporous (MF) Membrane

The long established Durapore® hydrophilic PVDF microfiltration membrane offers an exceptional combination of high-flux, low-protein binding, and high product recoveries.

Low Working Volume

The Pellicon® XL 50 cassette's low upstream holdup (1.0 mL) and working volumes (as low as 15 mL) permit high concentration factors to be reached and maximize recovery of small sample volumes.

Superior Filter Quality

Pellicon® XL 50 cassettes are 100% integrity tested in manufacturing to ensure consistent and reliable performance. The integrity test procedure and specifications are supplied in the Certificate of Quality so users can confirm integrity.

Specifications

Pellicon® XL 50 Cassette

Materials of Construction		
Membranes	Polyethersulfone (Biomax®)	
	Composite regenerated cellulose (Ultracel®)	
	Hydrophilic polyvinylidene fluoride (Durapore®)	
Screens	Polypropylene	
Exterior Housing	Polypropylene	
Fittings/connectors	Polypropylene	
Luer Caps	Polypropylene	
Specifications		
Fittings	Female Luer	
Filtration Area	50 cm ² (0.05 ft ²)	
Device Width	3.0 cm (1.2 in.)	
Device Length	18.8 cm (7.4 in.)	
Upstream Holdup Volume (typical)	1.0 mL	
Maximum Operating Pressure	5.6 bar (80 psig)	
Optimum Tangential Flow Rate for Polarized Solutions	4 – 8 L/m²/min	
Membrane pH Compatibility	Biomax® membranes: 1 - 14	
	Ultracel® membranes: 2 – 12 (continuous)	
	Ultracel® membranes: 2 – 13 (cleaning)	
	Durapore® membranes: 1.5 – 9 (continuous)1 – 11 (cleaning)	
Biocompatibility/Toxicity	All wetted parts have been tested and meet the requirements of USP <88>, Class VI Biological Test for Plastics.	
Extractables	Gravimetric extractables level \leq 7.5 mg/device after RO water flush. USP oxidizables test negative after RO water flush.	
Prefiltration Requirements	Prefiltration of sample using 100 µm nominal pore size filter is recommended.	

Membrane Selection Guide

Biomax® membranes - polyethersulfone

- Suitable for storage in alkaline and acidic solutions
- pH range 1 14
- Hydrophilic and low protein binding
- Void-free for higher yield and reliability

Ultracel® membranes – composite regenerated cellulose

- The most hydrophilic and lowest protein binding
- Stable, reproducible flux and resistance to fouling by proteins, lipids and antifoams
- Easiest UF membranes to clean

Durapore® membranes (Pellicon® 2 cassettes only)

- Hydrophilic and ultra-low protein binding
- High flux
- Excellent retention performance
- · High mechanical and chemical resistance

A Choice of Feed Channel Screens

For optimal performance in a range of applications Pellicon® XL 50 cassettes incorporate two types of feed-channel screens:

Type A screen is optimized to operate Biomax® 5, 8, 10, 30 and 50 kDa membranes with maximum flux with low-viscosity solutions.

Type C screen is optimized to operate Ultracel® 5, 10, 30, 100, 300, 1000 kDa membranes and Biomax® 100, 300, 500, 1000 kDa membranes with maximum flux with more concentrated protein solutions. The type C screen is also available with Durapore® 0.1, 0.2, 0.45 and 0.65 μm membranes for harvesting cell cultures and clarification of protein and viral cultures.

Ordering Guide and Information:

Membrane	NMWCO kDa or microns	Approximate molecular weight range of solutes retained >99%, kDa	Cat No.
Polyethersulfone			
Filters with A Screen			
Biomax®-5	5	5 – 12 (growth factors, hormones)	PXB005A50
Biomax®-8	8	25 – 50 (growth factors, hormones)	PXB008A50
Biomax®-10	10	50 – 100 (growth factors, hormones)	PXB010A50
Biomax®-30	30	100 – 140 (enzymes)	PXB030A50
Biomax®-50	50	140 - 300 (IgGs)	PXB050A50
Filters with C Screen			
Biomax®-100	100	300 – 500 (small viruses and antigens)	PXB100C50
Biomax®-300	300	>500 (IgMs, large viruses)	PXB300C50
Biomax®-500	500	>.03 µm (colloids, particulates)	PXB500C50
Biomax®-1000	1,000	>.03 µm (colloids, particulates)	PXB01MC50
Composite Regenerated Cellulose			
Filters with C Screen			
Ultracel®-5	5	8 -18 (proinsulin, hematopoetic factors)	PXC005C50
Ultracel®-10	10	18 – 60 (hemoglobin, enzymes)	PXC010C50
Ultracel®-30	30	60 – 200 (monoclonal IgGs)	PXC030C50
Ultracel®-100	100	200 - 500 (small viruses and antigens)	PXC100C50
Ultracel®-300	300	>500 (large viruses, lgMs)	PXC300C50
Ultracel®-1000	1,000	>.03 µm (colloids, particulates)	PXC01MC50
Hydrophilic PVDF			
Filters with C Screen			
Durapore®	0.10 μm	clarify cell lysates and protein solutions, clarify viral cultures	PXVVPPC50
Durapore®	0.22 μm	harvest and wash colloidal suspensions, bacterial cells, clarify protein solutions and viral cultures	PXGVPPC50
Durapore®	0.45 μm	harvest and wash colloidal suspensions, cell and viral cultures, clarify protein solutions and viral cultures	PXHVMPC50
Durapore®	0.65 µm	harvest cell cultures or colloidal suspensions	PXDVPPC50

Each Pellicon® XL 50 cassette is packaged one per box and includes Operating Instructions, an Accessory Kit, and Certificate of Quality.

Accessories	
Pellicon® XL 50 Cassette Accessory Kit	
4 Luer barb fittings, 4 tubing clamps, 1 retentate clamp, Dow Corning® Pharma Advanced Pump Tubing, 1.2 m (4 ft)	XXPXLFTKT
Pellicon® XL 50 cassette stand	XXPXLSTND

Pellicon® Ultrafiltration Family

Pellicon® Capsules

Our single-use Pellicon® Capsules provide high flux and linear scalability in a plug 'n play format for optimum process flexibility and productivity. It is holderless, pre-sterilized and ready-to-use in minutes, enabling fast and safe changeover. The feed channel screen is designed for superior mass transfer and recoveries are optimal with proven ultra-low binding Ultracel® membrane. Its automated manufacturing process provides performance consistency and linear scalability within the Pellicon® Capsules and Cassettes families.

For more information, refer to the Pellicon® Capsules datasheet DS1285EN.



Pellicon® 3 Cassettes

Pellicon® 3 cassettes are advanced, highperformance cassettes that are ideal for today's higher titer therapeutic antibodies, as well as for the more demanding filtration processes that require higher operating pressures, temperatures, concentrations and caustic cleaning regimes.

The robust design and automated manufacturing process of our industry leading Pellicon® 3 cassettes ensure exceptional consistency and enhanced linear scalability across all cassette sizes for each screen type from the bench to full-scale manufacturing.

For more information, refer to Pellicon® 3 data sheets DS1209EN (Ultracel® membrane) and DS1324EN (Biomax® membrane).



Pellicon® 2 Cassettes

For processing volumes from 100 mL to 1000 L, we offer Pellicon® 2 cassettes These high performance TFF filters are used for biopharmaceutical process development, scale-up/scale-down, concentration, purification and cell harvesting applications. The same ultrafiltration and microfiltration membranes incorporated in Pellicon® XL 50 cassettes are found in the Pellicon® 2 cassettes and can easily and reliably scale up for use in pilot or manufacturing plants.

For more information and specifications, refer to Pellicon® 2 data sheet DS1210EN.

TFF Systems

Cogent® Lab Systems

Pellicon® XL 50 cassette is designed to be operated with a state-of-the-art Cogent® Lab 150 system. When developing a TFF step at small scale, using a model that is representative of large-scale performance is essential. It not only allows for the successful transfer from laboratory scale to larger volumes, but also maintains consistent process parameters.

Our family of Cogent® Lab systems use similar design, sensing technologies, and accessories as our manufacturing-scale equipment. With a homogeneous design and flow range from 20 to 6000 mL/min, our Cogent® Lab systems have been specifically created to simplify process development. These systems offer linear performance and a uniform and intuitive software experience, reducing training requirements and ensuring smooth scale-up and scale-down.

For more information and specifications, refer to Cogent® Lab Systems data sheet DS8631EN.



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