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Pellicon® Capsules with Ultracel® Membrane

Innovative single-use tangential flow filtration (TFF) devices for streamlined bioprocessing.

Pellicon® Capsules with Ultracel® membrane are the ideal TFF devices for the filtration of solutions that require single-use capabilities, including enhanced ease-of-use, process flexibility, rapid product turnaround, and reduced operator exposure.

The Pellicon® Capsule is the first of its kind—a true single-use TFF device. Self-contained, it employs a holderless and torqueless design, allowing operators to easily install, use, and remove Pellicon® Capsules. Supplied gamma sterilized with preservative-free reverse osmosis water, the new single-use Pellicon® Capsule comes ready to use in minutes. Its design and automated manufacturing process provides unbeatable performance consistency and enhanced linear scalability within the Pellicon® Capsule family as well as within Pellicon® cassettes.

Benefits

- Plug 'n play, holderless design
- Gamma sterilized with preservative-free RO water
- True single-use capsule for fast and flexible product changeover
- Optimum recovery with proven Ultracel® composite, solvent-resistant membrane
- Superior mass transfer and flux with optimum feed channel screen
- Pellicon® TFF proven performance and linear scalability

Applications

- Monoclonal antibodies
- Antibody drug conjugates
- Recombinant and non-recombinant proteins

Plug 'n Play, Holderless Design

The simplified, innovative, self-contained design of the Pellicon® Capsule significantly reduces installation efforts by eliminating the need for a holder or torqueing. The easy installation and connectivity of the Pellicon® Capsule minimizes the time, labor, and expense associated with assembling and disassembling TFF devices.

Gamma Sterilized and Preservative-free

For added convenience, Pellicon® Capsules are supplied gamma sterilized. This feature eliminates the need for membrane sanitization before product contact. Pellicon® Capsules are also supplied with preservative-free reverse osmosis water, significantly reducing pre-use flushing requirements.

Fast Product Changeover

The holderless, self-contained design of the Pellicon® Capsule is ideal to easily and safely remove the entire single-use TFF flow path immediately after product recovery. This enhances product changeover efficiency and saves time, labor, fluids, and footprint in the manufacturing plant due to no cleaning validation requirements, ultimately increasing plant productivity and process flexibility with reduced cross-contamination risks.

Optimum Product Recovery and High Yields

Ultracel® composite membranes offer low fouling and low protein binding capabilities for excellent product retention, recovery, and high yields. Ultracel® membranes are constructed of regenerated cellulose cast on a microporous substrate for defect-free membranes with superior robustness compared to conventional products. The composite technology offers a mechanically robust design able to withstand extreme operating conditions.

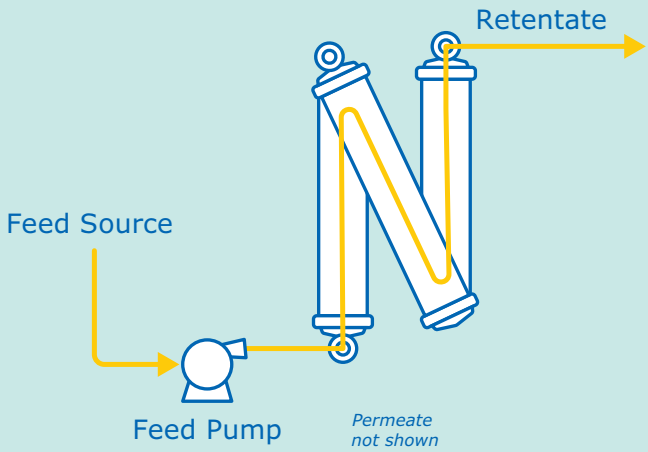
Superior Flux with Optimum Feed Channel Design

The new Pellicon® Capsules with Ultracel® membrane contain the C feed channel screen. The C screen is the ideal feed channel turbulence promoter for optimal flux performance for the concentration of therapeutic antibodies and other applications that require high mass transfer.

Pellicon® Capsules for Single-Pass TFF

As part of the BioContinuum™ Ultrafiltration Platform, Pellicon® single-pass TFF is a powerful purification tool that runs at constant operating conditions to concentrate product pools without recirculation, allowing for higher final concentrations and improved product recovery compared to traditional batch processes. It can easily run connected with other steps to reduce in-process volumes and intensify operations in the purification of therapeutic proteins.

Pellicon® Capsules are ideally suited for single-pass TFF. The single-pass flow path is configured by simply connecting the capsules in series, typically using the “N” configuration where capsules are connected directly from port to port, retentate to feed.



Applications

- In-process volume reduction
- In-line dilution/de-salting
- Intensified capture or polishing
- Final formulation/concentration

A Look into Pellicon® Capsules for ADCs

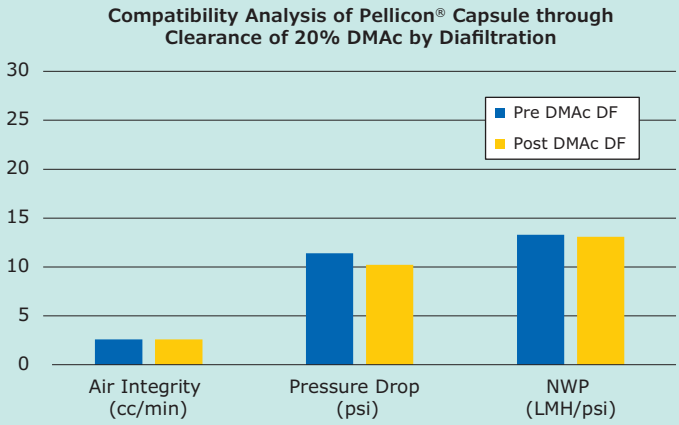
Pellicon® Capsules are ideal for use in antibody drug conjugates (ADCs) manufacturing processes. Special considerations are required for the TFF step after conjugation of the antibody with the cytotoxic agent due to increased toxicity and occasional presence of organic solvents.

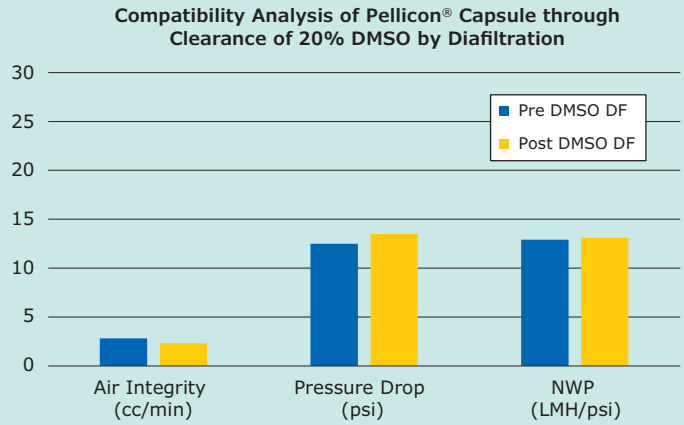
Operator Safety

Closed mode UF/DF is enabled when Pellicon® Capsules are paired with specifically designed Mobius® FlexReady Solution with Smart Flexware® Assemblies, mitigating risks of operator exposure during processing. The capsules' self-contained design, which eliminates the need of a compression holder, further facilitate operators to easily and safely remove the filters without hardware disconnection.

Excellent Solvent Compatibility

Pellicon® Capsules are manufactured using the most modern polymers and plastics. This enables excellent solvent compatibility with DMSO and DMAc, the most commonly used solvents in ADC processing.





Solvent resistance of Pellicon® Capsules with Ultracel® membrane to 20% DMAc and 20% DMSO.

Reliable Performance and Linear Scalability

All Pellicon® Capsules are manufactured with the same materials of construction and utilize the same flow channel length and height, turbulence promoter, and flow direction, ensuring consistent performance at every scale. Furthermore, Pellicon® Capsules provide the same high performance as Pellicon® cassettes and are linearly scalable, making it easy to transition from and to cassettes.

Manufacturing Consistency and Reproducibility

Our controlled, automated manufacturing process provides the highest level of capsule performance consistency. The high level of process control ensures consistent, reproducible performance in terms of scale up and scale down, from run to run, and campaign to campaign, ensuring process consistency. All Pellicon® Capsules are manufactured in accordance with an ISO 9001 Quality Management System.

Quality Assurance

All Pellicon® Capsules are manufactured using the same equipment, process, and quality assurance. Each Pellicon® Capsule lot is 100% integrity tested during manufacturing to ensure that every filter is integral, robust, and within specification. Additionally, Pellicon® Capsules are subjected to a complete array of quality control release tests. Each capsule is identified with a unique serial number and shipped with an individual Certificate of Quality.

Services and Support

The Emprove® Program provides dossiers with comprehensive product-specific test data, quality statements and regulatory information in a readily available format to simplify your compliance needs during different stages of development and manufacturing. To accelerate and simplify your path to market, BioReliance® Validation Services can help you select, test and validate the filters, assemblies and systems you need and assist with meeting your process and regulatory requirements.

Specifications

Materials of Construction

Pellicon® Capsule Filter

Membrane: Composite Regenerated Cellulose (Ultracel®)
Screens: Polypropylene, Polyester
Internal Seals: EPDM, Thermoplastic Elastomer
Housing/Core/Port-Caps: PPO/PS Blend
Potting Material: BPA-free epoxy, Polyurethane

Assembly Components

Connectors, AseptiQuik® G/L: Polycarbonate
Sanitary Gaskets/Tubing: Silicone
Clamps: Glass-reinforced Nylon
Hose Fittings/Clamp Tamper-evident Covers: Polypropylene
Hose Clamps: Stainless Steel

Accessory Components

Base for 1.5 m² Device: PPO/PS Blend and Cold-rolled Steel with Powder Coat
Base for 3 & 4.5 m² Manifolds: Cold-rolled Steel with Powder Coat
Manifolds Center Unification Bracket: Polycarbonate

Pellicon® Capsule Stand

Base: Stainless Steel
Clips: Carbon Fiber Reinforced Nylon

Sterility

This product is sterilized by gamma irradiation. The sterilization has been validated according ISO 11137.

Storage Conditions

Temperature: 15–30 °C
Storage Solution: Reverse osmosis water

Operating Conditions

Recommended Feed Flow Rate: 4–8 L/min per m²
pH Range: 2-13
Maximum Forward TMP: 50 psi (3.5 bar) at 4-30 °C

Maximum Inlet Pressure

Filter Only: 80 psi (5.5 bar) at 4–30 °C
Filter with Connectors or 1 m² Manifold: 75 psi (5.1 bar) at 4–30 °C
3 & 4.5 m² Manifolds: 60 psi (4.1 bar) at 4-30 °C

Manufacturing Release Criteria

100% Integrity Tested
Each unit must pass our integrity test based on air flow through the fully wetted membrane of the filter, and a housing leak integrity test.

Flow Rate and Pressure Drop
Each unit must pass our pressure drop test with water at 25 °C and average cross flow rate of 6 L/min per m².

Regulatory Information

Component Material Toxicity
All parts in fluid paths were tested and meet the criteria of the USP <88> Biological Reactivity Tests for Class VI Plastics.

Particulates/Non-Fiber Releasing
The product meets the requirements for a non-fiber releasing filter as defined in 21 CFR 210.3 (b)(6) after a water flush of 20 L/m² and confirmed using USP <788> test method and specification.

Bacterial Endotoxins (non-toxic)
A sample aqueous extract contains <0.25 EU/mL per USP <85> as determined by the Limulus Amebocyte Lysate (LAL) test.

ISO 9001 Quality Standard
This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality System Standard.

Connection, Nominal Dimensions and Hold-up Volume

Area	Connection	Length, in. (cm)	Diameter, in. (cm)	Wet Weight, lbs. (kg)	Feed Channel mL	Permeate Channel mL
Pellicon® Capsule Devices						
0.1 m^2	3/4 in. Sanitary Flange	13.9 (35.3)	1.5 (3.8)	0.9 (0.4)	26	62
	AseptiQuik® G Connectors	16.2 (41.1)	1.5 (3.8)	0.9 (0.4)	38	68
0.5 m^2	3/4 in. Sanitary Flange	13.9 (35.3)	2.3 (5.7)	1.7 (0.8)	107	143
	AseptiQuik® G Connectors	16.2 (41.1)	2.3 (5.7)	1.7 (0.8)	119	149
1.5 m^2	AseptiQuik® G Connectors	17.2 (43.7)	4.1 (10.3)	6.6 (3.0)	455	719

Area	Assembly Type	Connection	Height, in. (cm)	Length, in. (cm)	Width, in. (cm)	Tubing ID, in.	Wet Weight lbs. (kg)	Feed Channel mL	Permeate Channel mL
Pellicon® Capsule Manifolds									
1 m^2	G	AseptiQuik® G Connectors	7.7 (19.6)	15.9 (40.5)	13.5 (34.4)	3/8	11 (5)	254	306
3 m^2	G	AseptiQuik® G Connectors	15.9 (40.4)	17.4 (44.2)	17.9 (45.4)	3/4	22 (10)	1108	1537
	L	AseptiQuik® L Connectors	16.5 (42.0)	18.5 (46.9)	19.0 (48.2)	3/4		1128	1547
	E	AseptiQuik® L Connectors	18.1 (45.9)	18.5 (46.9)	19.0 (48.2)	1		1288	1627
4.5 m^2	G	AseptiQuik® G Connectors	21.5 (54.6)	17.4 (44.2)	17.9 (45.4)	3/4	31 (14)	1665	2307
	L	AseptiQuik® L Connectors	22.1 (56.2)	18.5 (46.9)	19.0 (48.2)	3/4		1683	2316
	E	AseptiQuik® L Connectors	23.7 (60.2)	18.5 (46.9)	19.0 (48.2)	1		1857	2403

Accessory	Height, in. (cm)	Width, in. (cm)	Depth ID, in. (cm)
Pellicon® Capsule Stand			
Stand for sizes 0.1, 0.5 or 1 m^2	10.5 (26.7)	4.5 (11.4)	7.0 (17.8)

Ordering Information

Description	Feed, Retentate & Permeate Port Fittings	Cat. No.
Pellicon® Capsule Devices		
0.1 m^2 Ultracel® 30 kDa, C Screen	3/4 in. Sanitary Flange	**PCC030C01**
	AseptiQuik® G Connector	**PCC030C01C**
0.5 m^2 Ultracel® 30 kDa, C Screen	3/4 in. Sanitary Flange	**PCC030C05**
	AseptiQuik® G Connector	**PCC030C05C**
1.5 m^2 Ultracel® 30 kDa, C Screen	AseptiQuik® G Connector	**PCC030C15C**
Pellicon® Capsule Manifolds		
1 m^2 Ultracel® 30 kDa, C Screen	AseptiQuik® G Connector	**PCC030C10G**
3 m^2 Ultracel® 30 kDa, C Screen	AseptiQuik® G Connector	**PCC030C30G**
	AseptiQuik® L Connector	**PCC030C30L**
	AseptiQuik® L Connector	**PCC030C30E**
4.5 m^2 Ultracel® 30 kDa, C Screen	AseptiQuik® G Connector	**PCC030C45G**
	AseptiQuik® L Connector	**PCC030C45L**
	AseptiQuik® L Connector	**PCC030C45E**
Pellicon® Capsule Stand		
Specially designed optional accessory, conveniently supports up to two 0.1 m^2 capsules in parallel or three in series on one side and one 0.5 m^2 capsule or one 1 m^2 manifold on the other side.		**PCX001**

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