Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

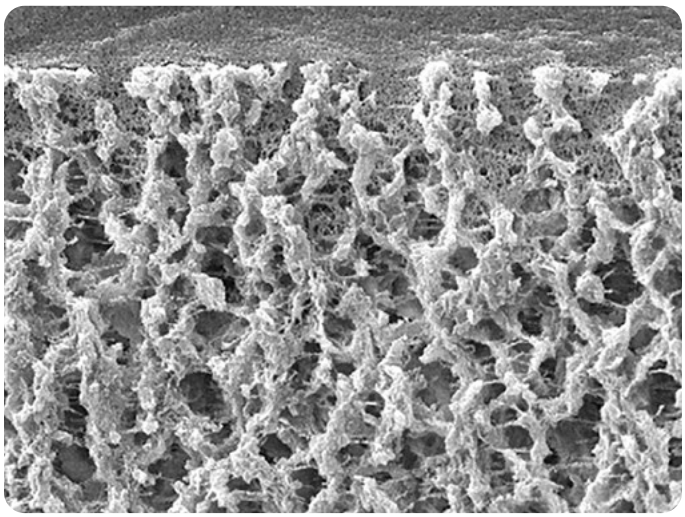
Ultracel® Membranes

The membrane of choice for ultra-low protein binding and robust performance during concentration and diafiltration of therapeutics

Ultracel® void-free composite membranes combine ultra-low protein binding, low fouling and organic solvent resistance with 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 reverse pressure.

Advantages of Choosing Ultracel® Membranes

- Void-free cellulose layer results in excellent retention and improved integrity
- Composite structure gives the membrane improved back pressure resistance
- Regenerated cellulose membrane provides ultra-low protein binding and low fouling during use
- Ultracel® membranes are available in a wide range of molecular weight cut-offs to meet all of your application needs



Ultracel® composite regenerated cellulose with void-free structure.

MilliporeSigma

Improved Integrity

The void-free structure of Ultracel® membranes gives them virtually undetectable downstream air flow compared to conventional UF membranes (Figure 1).

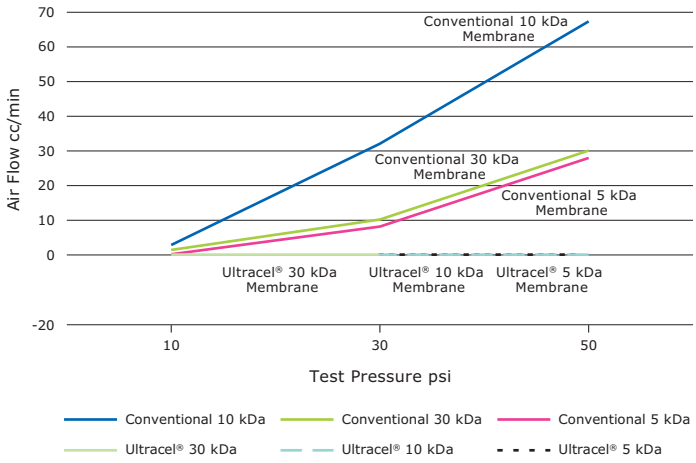


Figure 1.

Air flow integrity testing of Ultracel® membranes versus conventional UF membranes.

Low Protein Binding

Ultracel® membrane, a naturally hydrophilic regenerated cellulose membrane, exhibits the lowest non-specific protein binding of any UF membrane. As a result, the low protein-binding Ultracel® membrane exhibits low fouling characteristics, and is easily cleaned.

Polyethersulfone and cellulose acetate used in conventional UF membranes bind proteins at much higher levels than regenerated cellulose (Figure 3).

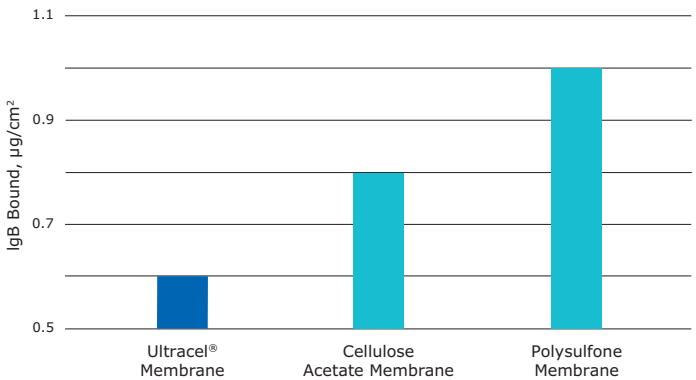


Figure 3.

Protein binding of Ultracel® membrane versus conventional UF membrane.

Improved Reverse Pressure Resistance

Ultracel® membrane has great resistance to reverse pressure pulses (reverse pressure) compared to conventional UF membranes (Figure 2).

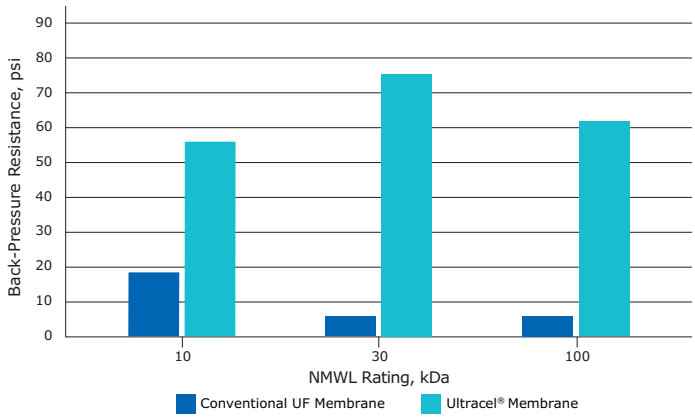


Figure 2.

Reverse pressure resistance of Ultracel® membrane versus conventional UF membrane.

Consistent Process Performance

Even when used with high concentrations of protein, Ultracel® membrane maintains its flux through multiple cleaning cycles, demonstrating low fouling nature (Figure 4).

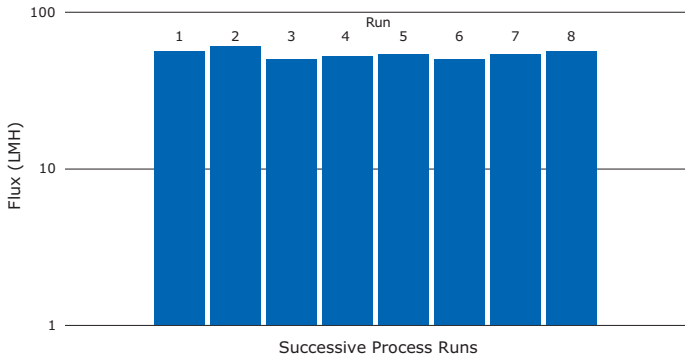


Figure 4.

Low fouling characteristics of Ultracel® membranes in human serum albumin.

Improved Cleanability

A simple caustic cleaning regimen restores normalized water permeability (NWP) to near initial levels following sequential process runs (Figure 5).

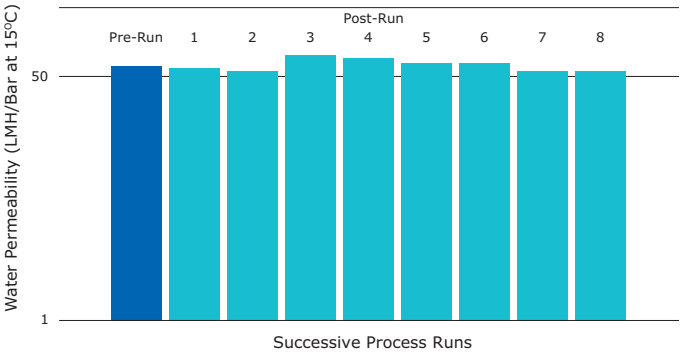


Figure 5.

Consistent return of water permeability after cleaning.

Ultracel® Membrane Mixed Dextran Test

The need for more rejection information and for better membrane manufacturing consistency and control led us to develop the Mixed Dextran Rejection Test for UF membranes.

A large number of marker solutes has been used in the past to characterize the retention properties of ultrafiltration (UF) membranes. Traditionally, solutions of single proteins were used and a ranking system of Nominal Molecular Weight Limits (NMWL) was adopted by the UF user community. For each membrane, the NMWL value gives an estimate of the molar mass of the smallest protein that is retained at an arbitrarily selected minimum level (usually 90%). This system of ranking has proved to be very useful and is still used to classify UF membranes. The NMWL method, however, offers very limited information about the properties of UF membranes (approximate rejection value for only one solute size) and therefore, is no longer sufficient for the sophisticated user of state-of-the-art separation processes.

Although protein processing represents the most common type of application for UF membranes, using proteins as markers has many disadvantages, such as availability in sufficient purity, diversity of protein shape, structure and physical properties, and high cost. To satisfy the need for testing a wide variety of UF membranes, one has to select proteins of vastly different sizes. An undesirable consequence of this selection is the potential variation of other properties, such as isoelectric point (resulting in different charge at a given pH), the nature and proportion of hydrophobic and hydrophilic groups on the surface of the molecule (resulting in different adsorption properties), solubility, and size-to-molecular-weight relationship. All these differences can significantly affect the measured rejection values and therefore make the interpretation more difficult.

Our rejection profile test uses dextrans as test markers. This allows an evaluation of the rejection properties of a UF membrane for a range of solute sizes spanning from solutes that are completely passed through the membrane to solutes that are completely retained, so that one test generates a complete rejection curve (Figure 6).

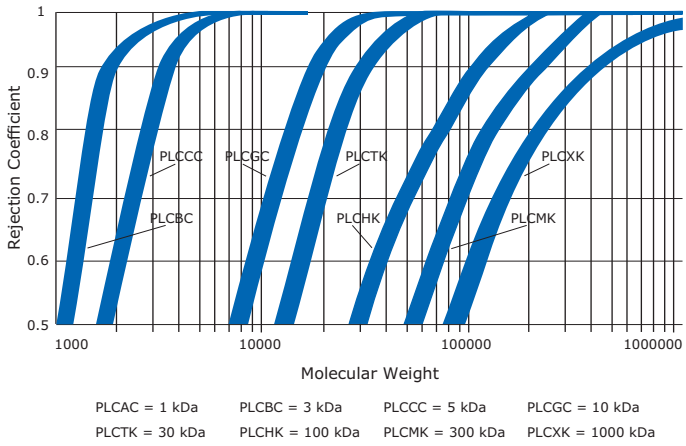


Figure 6.

UF membrane dextran retention profile.

Note: the dextran curves shown are only illustrations.

Low adsorption of dextrans to many UF membranes joins with optimized and controlled boundary conditions in the rejection profile test to assure that the measured rejection profile reflects as closely as possible the steric rejection properties of UF membranes, and therefore offers useful information about the membrane pore size distribution. To take advantage of these characteristics of the rejection profile test, we adopted this test as a standard quality control method for monitoring and controlling the reproducibility of UF membranes. Rejection profile bands were specified for each membrane type. The measured rejection profile of each membrane lot has to fall within these bands. The result has been a significant improvement in lot-to-lot reproducibility of the rejection performance of our UF membranes.

Ultracel® Membrane Specifications*

Materials of Construction	Composite regenerated cellulose pH compatibility: 2—13 (up to 13.7 for cleaning of 10 kDa and 30 kDa cassettes*) *Reference AN1175EN00 Reverse Pressure: ≥ 30 psi
Relative Protein Binding	Ultra low for use with dilute protein solutions (less than 0.1 mg/mL)

Ultracel® Membrane Applications

NMWL† (kDa)	Typical Application
3	Small recombinant proteins, insulin, peptides, oligonucleotides
5	Small recombinant proteins, insulin, peptides, oligonucleotides
10	Hemoglobin, enzymes, pegylated small molecules, antibody fragments, albumin
30	Antibodies, recombinant proteins, plasmids, viral vectors (small capsid)
100	Small viruses, viral antigens, plasmids, mRNA, viral vectors (small & large capsid), liposome, polysaccharides
300	Large viruses, IgMs, plasmids, viral vectors (large capsid), liposome, polysaccharides
1000	Large viruses, cells, colloids, particulates

†Nominal Molecular Weight Limit

Device Formats

Ultracel® membranes are found in Pellicon® 3 Cassettes, Pellicon® 2 Cassettes, Pellicon® XL 50 Cassettes, and Pellicon® Capsules. Refer to the individual Pellicon® Cassette and Capsule data sheets to learn which NMWL are available.

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MilliporeSigma
400 Summit Drive
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