AsahiKASEI BIOPROCESS | BioOptimal™

PROCESS INTENSIFICATION USING BioOptimal™ MICROFILTERS IN PERFUSION CELL CULTURE

High Product Sieving • Reduced Fouling • Excellent Scalability

Actual product will have a GHS label

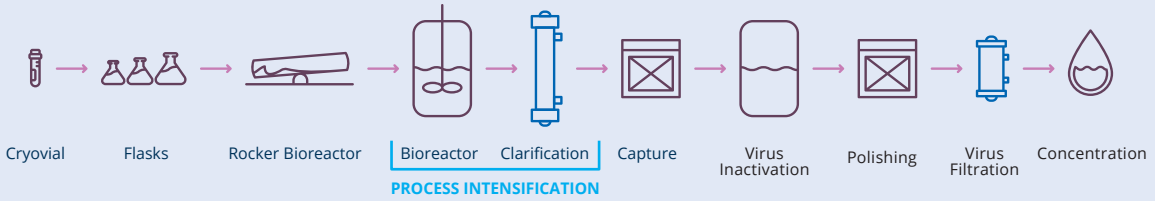
BioOptimal™ MICROFILTERS

BioOptimal microfilters are a family of advanced microfiltration assemblies engineered for cell clarification in intensified recombinant protein and monoclonal antibody (mAb) production. Utilizing Asahi Kasei's hollow fiber membranes of various pore sizes and materials, BioOptimal microfilters deliver high sieving efficiency, minimize cell damage and facilitate scaling up intensified cell culture processes.

BioOptimal microfilters are ideal for N perfusion in intensified upstream processing strategies, including Tangential Flow Filtration (TFF), reverse Tangential Flow Filtration (rTFF), and Alternating Tangential Flow Filtration (ATF) clarification modes. Additionally, BioOptimal microfilters are compatible with other common upstream culture strategies in use today, including N-1 perfusion, fed-batch and traditional batch processes.

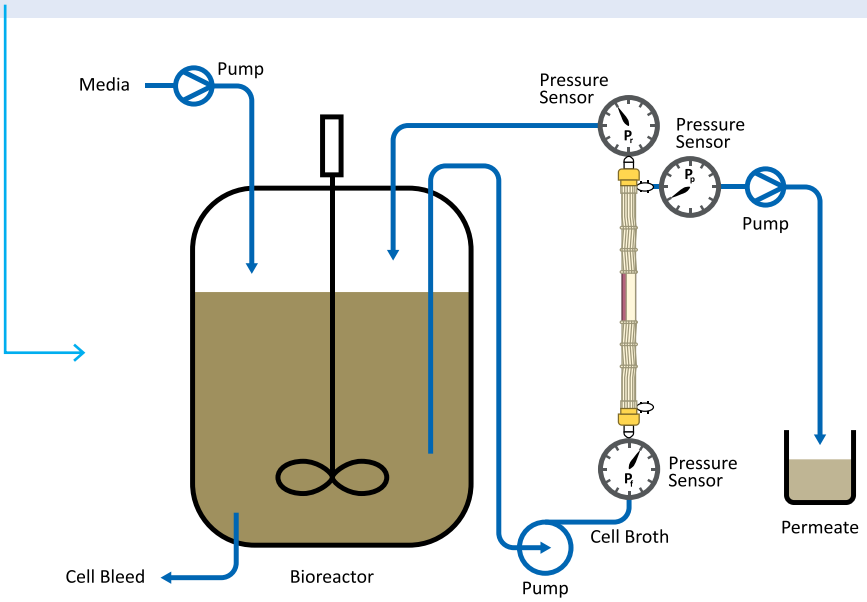
FEATURE	=	BENEFIT
High product sieving during N-perfusion	=	High yields
Low transmembrane pressure (TMP) and shear rate	=	Fewer filter change-outs
Excellent scalability	=	Trusted from development to GMP manufacturing

THE ANTIBODY PRODUCTION PROCESS



PERFUSION UNIT OPERATION

Figure 1
Perfusion unit operation within the antibody production process



PRODUCT LINEUP

BioOptimal™ UMP

FOR N PERFUSION

Optimized for TFF and rTFF in N perfusion, delivering high sieving and long, stable filtration in high density cell cultures.

BioOptimal™ MF-SL

FOR N PERFUSION

Flexibly designed for TFF, rTFF and ATF in perfusion culture, offering both high sieving and long, stable filtration.

BioOptimal™ UJP

FOR N-1 PERFUSION

Ideal for N-1 perfusion applications, providing long and stable filtration even under high flux conditions.

Actual product will have a GHS label

FILTER	UMP	MF-SL	UJP
Hollow fiber material	Polyvinylidene fluoride (PVDF)	Polysulfone (PS)	PVDF
Nominal pore size (μm)	0.2	0.4	0.65
Inner diameter (mm)	1.4	1.4	1.1
Effective surface area (m^2)	8.8, 3.8, 1.9, 0.77, 0.34, 0.19, 0.09, 0.02	8, 1, 0.19, 0.005	3.7, 1.8, 0.76, 0.32, 0.19, 0.1, 0.02
Max operating pressure	300 kPa, 43.5 psi	200 kPa, 29.0 psi	300 kPa, 43.5 psi
Cleaning/Sterilization procedures	CIP, SIP (125°C)	CIP, SIP (123°C)	CIP, SIP (125°C)

N PERFUSION WITH BioOptimal UMP MICROFILTERS

BioOptimal UMP is a high-performance hollow fiber microfilter specifically designed for TFF and rTFF in perfusion culture processes. Engineered for process intensification, it offers exceptional antibody permeability (product sieving), enabling both cost reduction and increased product yield. Its robust design ensures long-term operational stability, mitigating common harvest issues such as membrane fouling.

MONOCLONAL ANTIBODY N PERFUSION CASE STUDY

BioOptimal UMP | Product Sieving

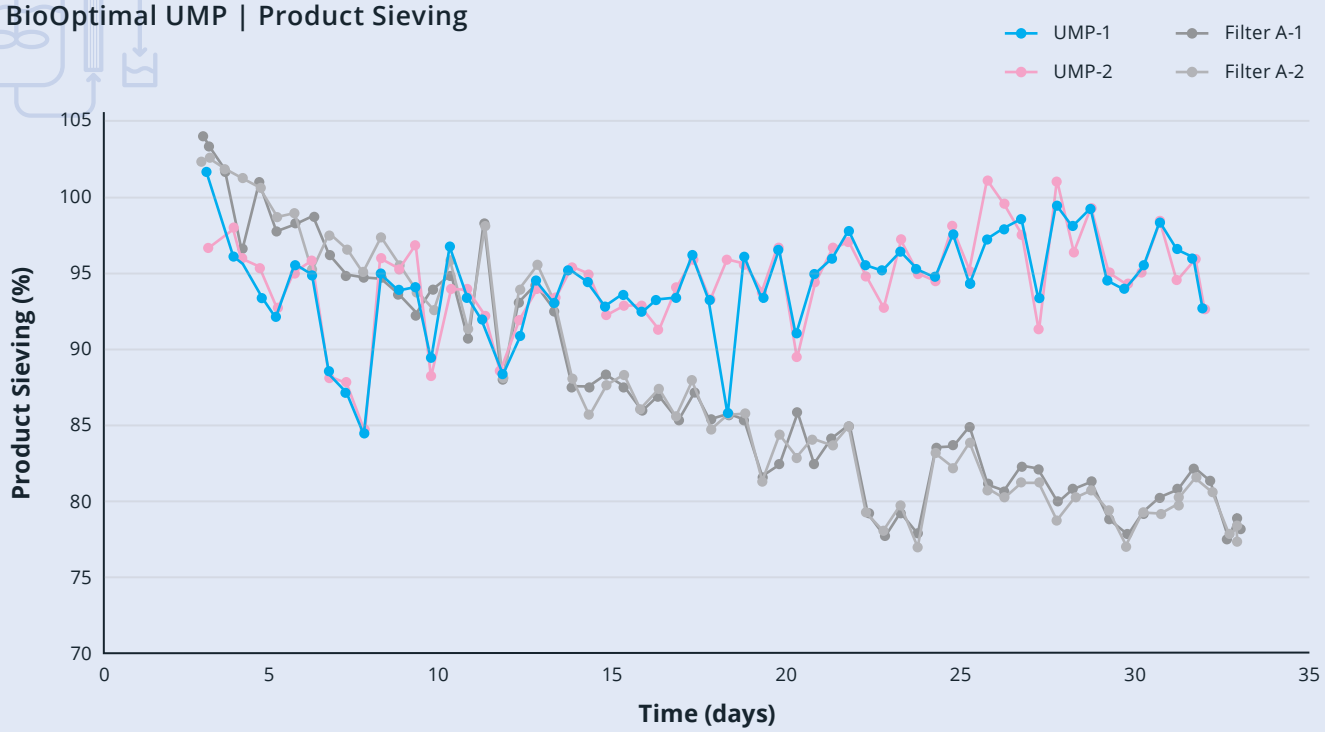


Figure 2 Product sieving during N perfusion in TFF mode on BioOptimal UMP

BioOptimal UMP maintained >90% product sieving during 32 days of perfusion culture

CONDITIONS

Cell type: CHO cells producing mAb

Target cell density: ~150 x 10^6 cells/mL

Permeate flux: 0.3 – 2.6 LMH

Shear rate: 500 s^{-1}

Operation mode: TFF

Internal data

Actual product will have a GHS label

MONOCLONAL ANTIBODY N PERFUSION CASE STUDY: CUSTOMER DATA[1]

BioOptimal UMP | Product Sieving at Various Shear Rates & Permeate Fluxes

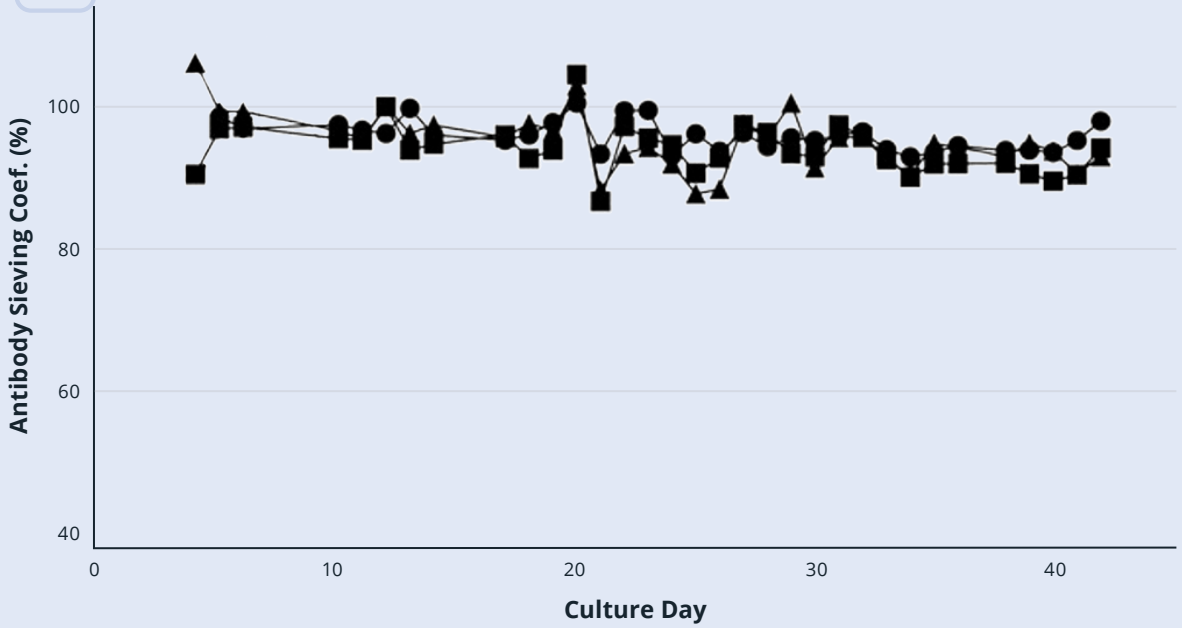


Figure 3 Antibody sieving coefficient during N perfusion at various shear rate and permeate flux settings. Figure adapted to show only BioOptimal UMP data [1]

Run	Shear rate	Permeate flux
—●—	1250 s^{-1}	1 LMH
—■—	2000 s^{-1}	1 LMH
—▲—	2000 s^{-1}	2 LMH

UMP shows antibody sieving coefficient >85% throughout 40 days, independent of the crossflow shear rates and permeate fluxes studied

CONDITIONS

Cell type: CHO cells producing mAb

Medium exchange rate: 0.75 VVD

Target cell density: 65 – 85 x 10^6 cells/mL

Operation mode: TFF

[1] BioOptimal UMP is shown as Asahi Kasei Microza 0.2 µm UMP in the original paper. Pinto NDS, Brower M. Wide-surface pore microfiltration membrane drastically improves sieving decay in TFF-based perfusion cell culture and streamline chromatography integration for continuous bioprocessing. *Biotechnology and Bioengineering.* 2020; 117: 3336–3344. https://doi.org/10.1002/bit.27504

N PERFUSION WITH BioOptimal MF-SL MICROFILTERS

BioOptimal MF-SL is our original hollow fiber microfilter that also achieves high product sieving in N perfusion cultures, enabling improved manufacturing efficiency by way of process intensification. A versatile microfilter, BioOptimal MF-SL demonstrates excellent performance in TFF, rTFF and ATF applications, thereby supporting most intensification methods today. Additionally, BioOptimal MF-SL is well-suited for traditional fed-batch and batch cultures, making it a platformable microfilter option.

MONOCLONAL ANTIBODY N PERFUSION INTERNAL CASE STUDY: TFF MODE

BioOptimal MF-SL | Product Sieving

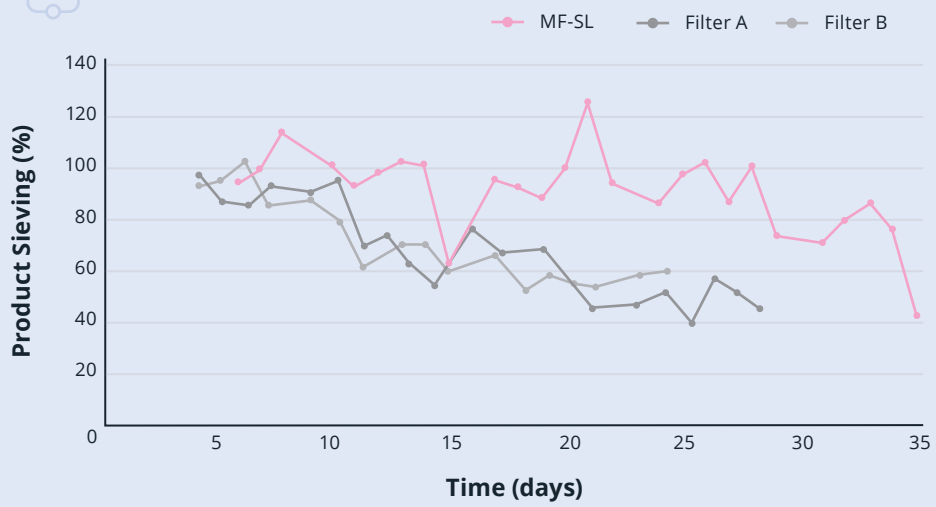


Figure 4 Product sieving during N perfusion in TFF mode on BioOptimal MF-SL

CONDITIONS

Cell type: CHO cells producing mAb

Medium exchange rate: 0.75 – 2.5 VVD

Target cell density: 60 – 90 × 10^6 cells/mL

Permeate flux: 0.2 – 0.8 LMH

Shear rate: 1500 s^{-1}

Operation mode: TFF

Internal data

BioOptimal MF-SL maintained product sieving above 80% for >27 days of perfusion culture in TFF mode

MONOCLONAL ANTIBODY N PERFUSION INTERNAL CASE STUDY: ATF MODE

BioOptimal MF-SL | Product Sieving

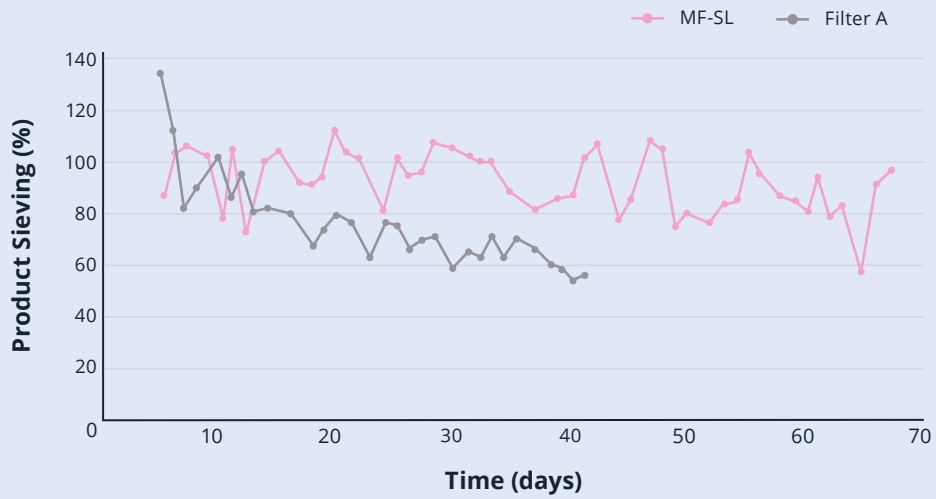


Figure 5 Product sieving during N perfusion in ATF mode on BioOptimal MF-SL

CONDITIONS

Cell type: CHO cells producing mAb

Medium exchange rate: 0.75 – 2.5 VVD

Target cell density: 50 – 70 × 10^6 cells/mL

Permeate flux: 0.2 – 0.8 LMH

Shear rate: 1500 s^{-1}

Operation mode: ATF

Internal data

BioOptimal MF-SL maintained product sieving above 80% for >60 days of perfusion culture in ATF mode

PRODUCT LINEUP & CATALOG NUMBERS

BioOptimal™ UMP

Effective surface area (m^2)	Catalog number
8.8	UMP5247R
3.8	UMP3247R
1.9	UMP3147R
0.77	UMP2147R
0.34	UMP1147M
0.19	UMP1147R
0.09	UMP1047R
0.02	UMP0047R

BioOptimal™ MF-SL

Effective surface area (m^2)	Catalog number
8	MFSL8000
1	MFSL1000
0.19	MFSL0190
0.005	MFSL0005

BioOptimal™ UJP

Effective surface area (m^2)	Catalog number
3.7	UJP3247R
1.8	UJP3147R
0.76	UJP2147R
0.32	UJP1147M
0.19	UJP1147R
0.1	UJP1047R
0.02	UJP0047R

Actual product will have a GHS label

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