

Your First Choice Virus Filter That You Can Absolutely Rely On

Key features for virus removal filters in continuous downstream processing

1. Adaptable to fluctuating product streams
2. Robust viral clearance over extended process times (days)



Challenges in Continuous Downstream Processing

Challenges

Dynamic product streams

Long-duration virus filtration

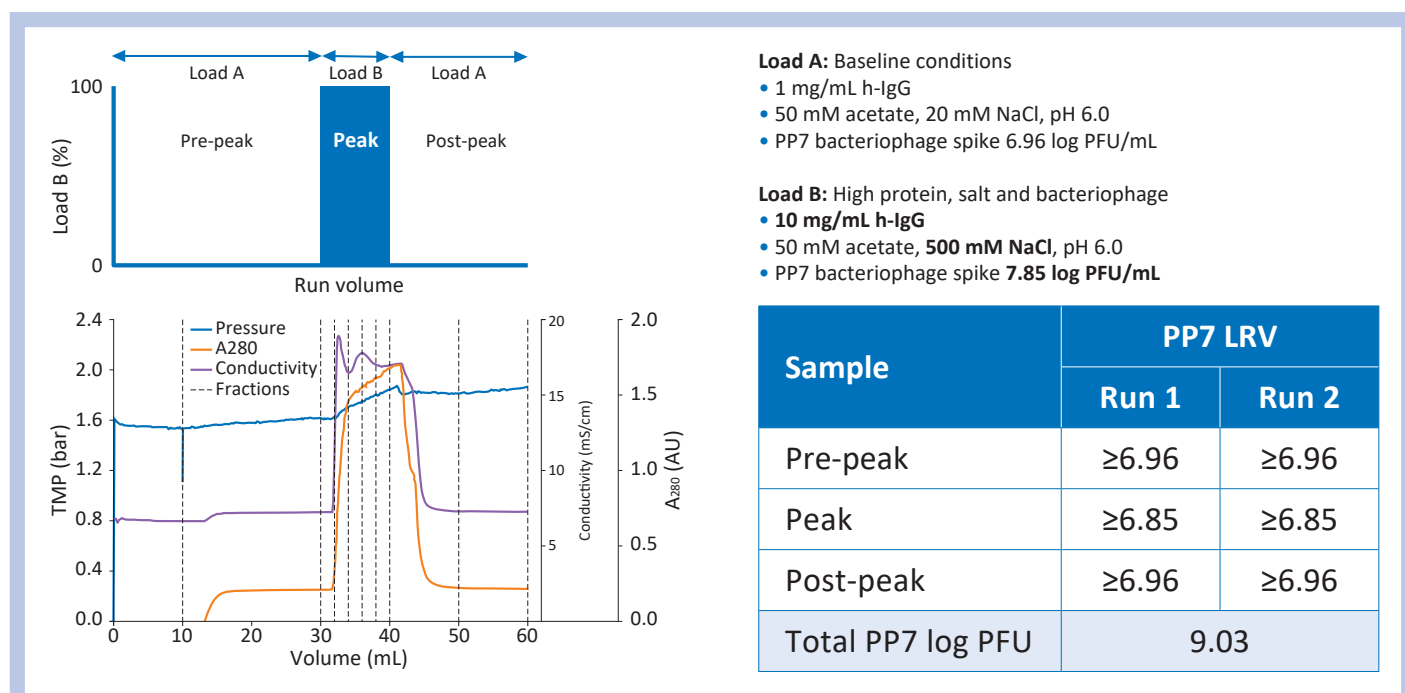
Essential requirements

Adaptable to fluctuations in filtration conditions

Robust viral clearance over extended process times (days)

1. Planova™ BioEX is adaptable to fluctuations in filtration conditions

► Achieved PP7 LRV ≥ 6.85 with a mock elution peak of high protein, salt and bacteriophage



Collaboration paper is available here:

<https://doi.org/10.1002/btpr.2962>



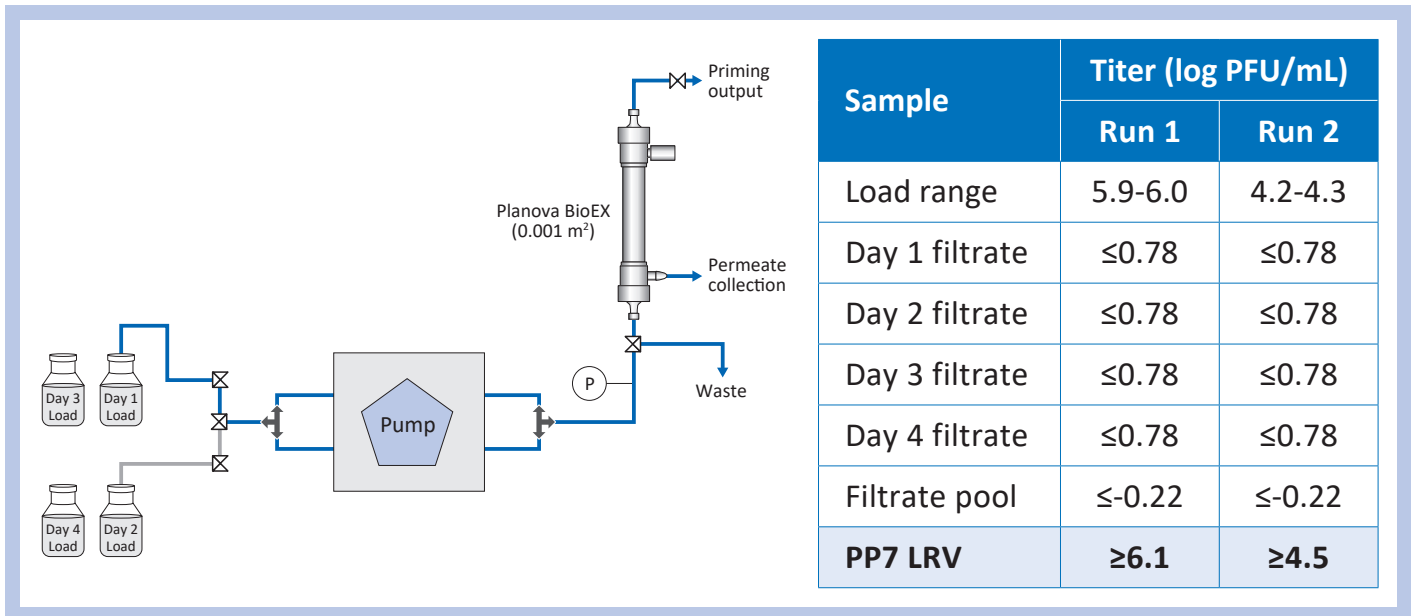
Scott Lute (US FDA CDER/OPQ/OBP/DBRR II), Julie Kozaili (Asahi Kasei Bioprocess America) *et al.* *Biotechnology Progress*, 2020 (adapted)

Filtration conditions:

- Filter surface area: 0.001 m²
- Constant flow rate: 1.0 mL/min (60 L/(h·m²))
- Pressure: <2 bar (29 psi)

2. Planova™ BioEX has robust viral clearance capability for continuous processing

- ▶ Examined feasibility of extended processing with a target 4 day filtration
- ▶ Achieved long-duration virus filtration while maintaining PP7 LRV ≥ 4.5



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Filtration conditions:

- Filter surface area: 0.001 m²
- Constant flow rate: 1.2 mL/min (72 L/(h·m²))
- Starting pressure: around 2 bar (29 psi)
- 0.025 g/L h-IgG
- 50 mM acetate, 20 mM NaCl, pH 6.0
- Daily fresh feed solution with PP7 spike
- Throughput: 5200 – 6900 L/m²

Planova™ BioEX Technical Support and Training Service

Technical Support for Your Process

- ✓ Responsive technical support and trainings from virus filtration experts
- ✓ Hands-on training with Planova Operators Course
- ✓ Full support across all phases from process development to manufacturing
- ✓ Technical consulting for continuous downstream processing



From Asahi Kasei Bioprocess

We appreciate your interest in our products.

This Planova BioEX Spotlight examines the requirements for achieving robust viral clearance during continuous filtration. Planova BioEX filters are adaptable to fluctuating conditions and can be incorporated into continuous processes with varying durations and conditions. With careful consideration of virus spike levels and filtration parameters, it is possible to design appropriate scale-down models for viral clearance validation studies. Optimal performance of these filters remains highly protein- and buffer-specific.

Please request additional information or technical support from an account manager, or visit our website. You can rely on our technical support on virus filtration process development, optimization and filter operation any time you need assistance.

