

Planova™ BioEX Spotlight Vol.3

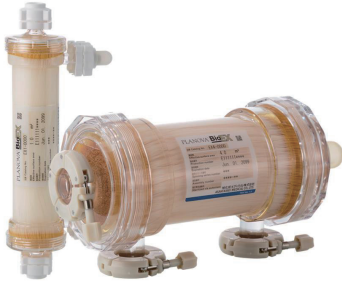
Your First Choice Virus Filter That You Can Absolutely Rely On

Pre-Clinical

Phase I

Phase III

Commercial
Manufacturing

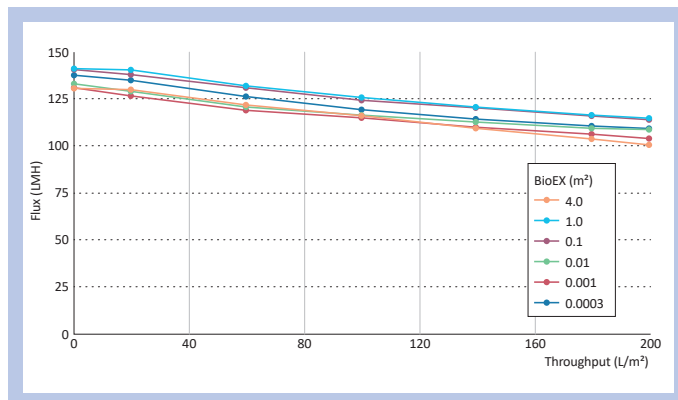


Key Features for virus removal filters at manufacturing scale

1. Excellent Scalability
2. High Lot-to-Lot Consistency
3. Ease of Operation

1. Planova™ BioEX shows consistent flux and high recovery across all filter sizes

► Easy to achieve technical transfer to manufacturing from early process development phases



Daniel Strauss, Asahi Kasei Bioprocess America, *Planova Workshop*, Philadelphia, 2016 (adapted)

Filtration conditions

Feed solution: 1 g/L BSA, 20 mM phosphate, 50 mM NaCl, pH 7
Feed volume: 200 L/m², Spiking condition: ~6 log₁₀ PFU/mL PP7
Pressure: 343 kPa (49.7 psi)

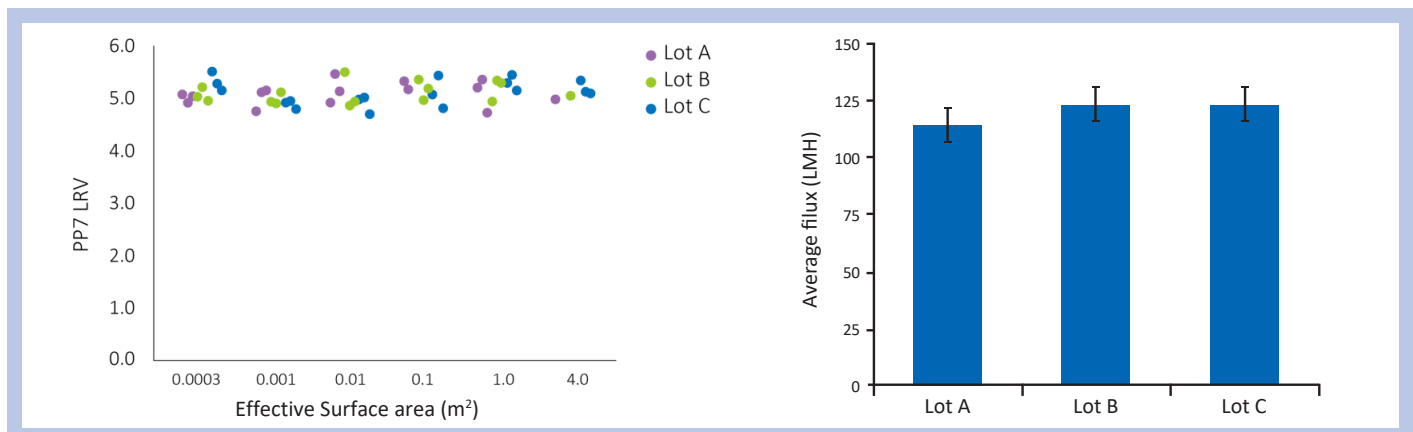
Run	Filter surface area (m ²)	Pressure (bar)	Flux (LMH)	Recovery
Run 1	0.001	3	83	98%
Run 2	0.001	2.5	72	99%
Run 3	0.1	2.5	73	99%
12,000 L scale	4.0	2.0	72	100%

Franz Nothelfer, Boehringer Ingelheim, *Planova Workshop*, Athens, 2015 (adapted)

2. Planova™ BioEX shows consistent performance across lots

► Lot-to-Lot consistency reduces trouble during operations

► Worry-free operation contributes to safe and stable manufacturing for your molecules



Daniel Strauss, Asahi Kasei Bioprocess America, *Planova Workshop*, Philadelphia, 2016 (adapted)

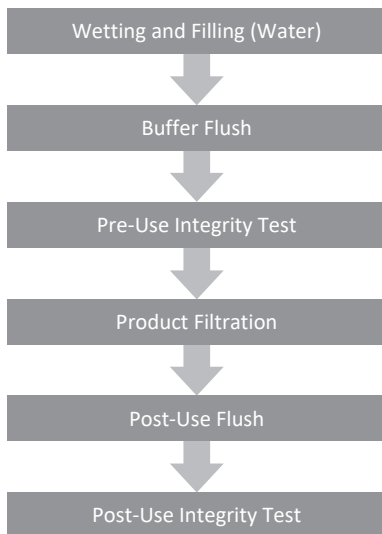
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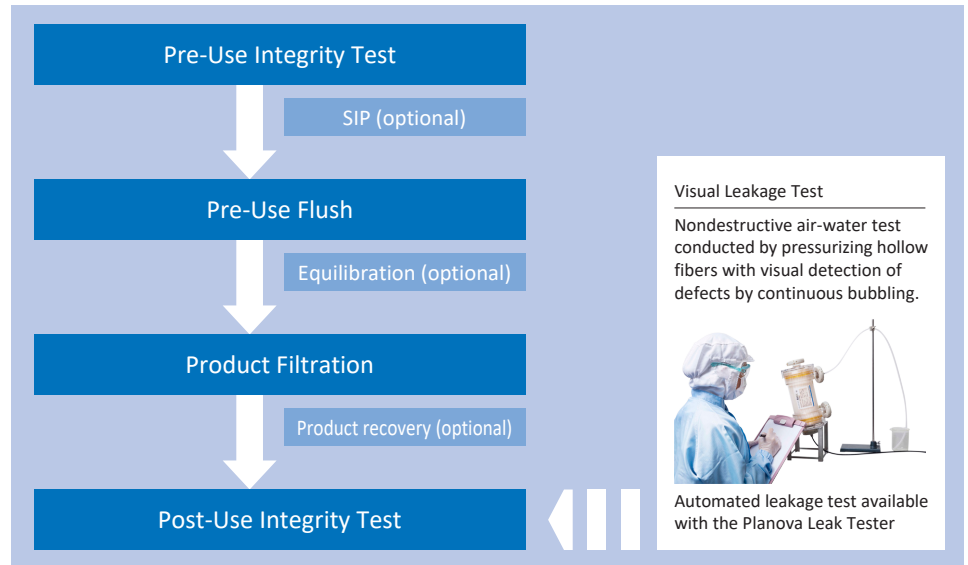
3. Planova™ BioEX comes ready to use and is easy to use

- ▶ Planova BioEX filters are provided in a wetted and sterilized state
- ▶ Virus filtration and integrity test can be completed within one manufacturing shift

A Typical Operation Scheme for Dry-type Flat-Sheet Membrane Device



Planova BioEX Operation Scheme



Planova™ BioEX Specifications and Technical Support

Specifications

Membrane format	Hollow fiber
Membrane material	Hydrophilic modified PVDF
Housing material	Polycarbonate
Effective surface area (m ²)	4.0, 1.0, 0.1, 0.01, 0.001, 0.0003
Maximum operating pressure	343 kPa (49.7 psi)
SIP tolerant	YES (≥0.1 m ²)
Sterilization	Autoclaved (121 °C) prior to shipment
Integrity test	Leakage test

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



From Asahi Kasei Bioprocess

We appreciate your interest in our products.

This Planova BioEX Spotlight highlights key considerations for manufacturing professionals working at commercial scale and shows why Planova BioEX is your filter of choice to ensure virus safety of biopharmaceutical products. So far, we have introduced the features of Planova BioEX with an overview of the most recent data in Vol. 1 and key considerations for professionals working in early phases in Vol. 2. In our next installments, we will introduce more detailed data of Planova BioEX filtrations under various conditions.

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.

