

Planova™ BioEX Spotlight Vol.2

Your First Choice Virus Filter That You Can Absolutely Rely On

Pre-Clinical

Phase I

Phase III

Commercial Manufacturing

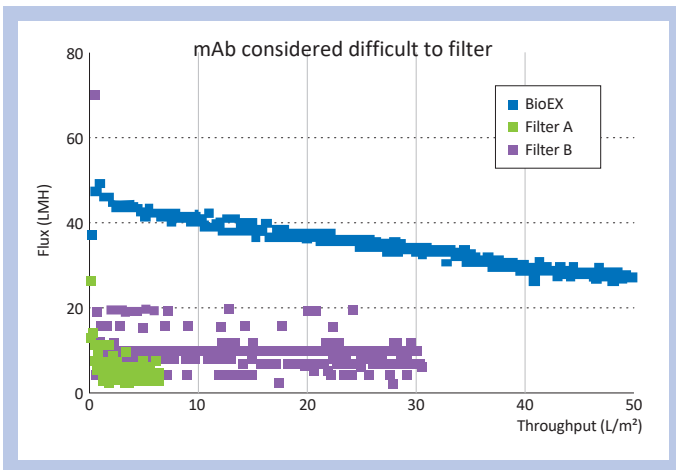
Key Features for virus removal filters in early phases

1. High Capacity and Compatibility
2. Robust Virus Removal
3. Consistent Flux With Minimal Decay

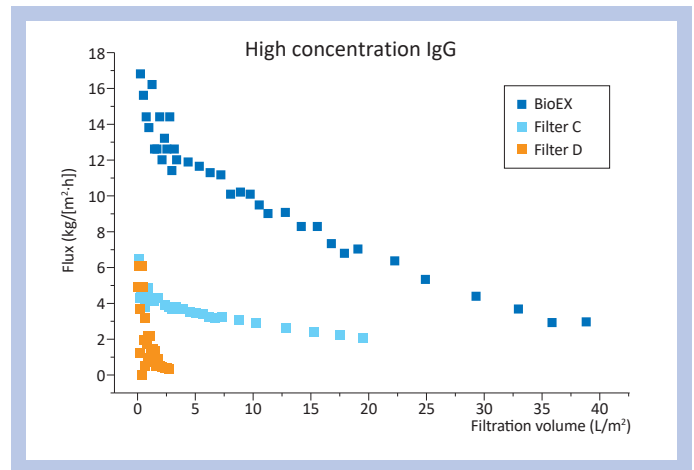


1. Planova™ BioEX affords excellent filterability with various products and conditions

► Minimize time and resource requirements in the virus filtration step



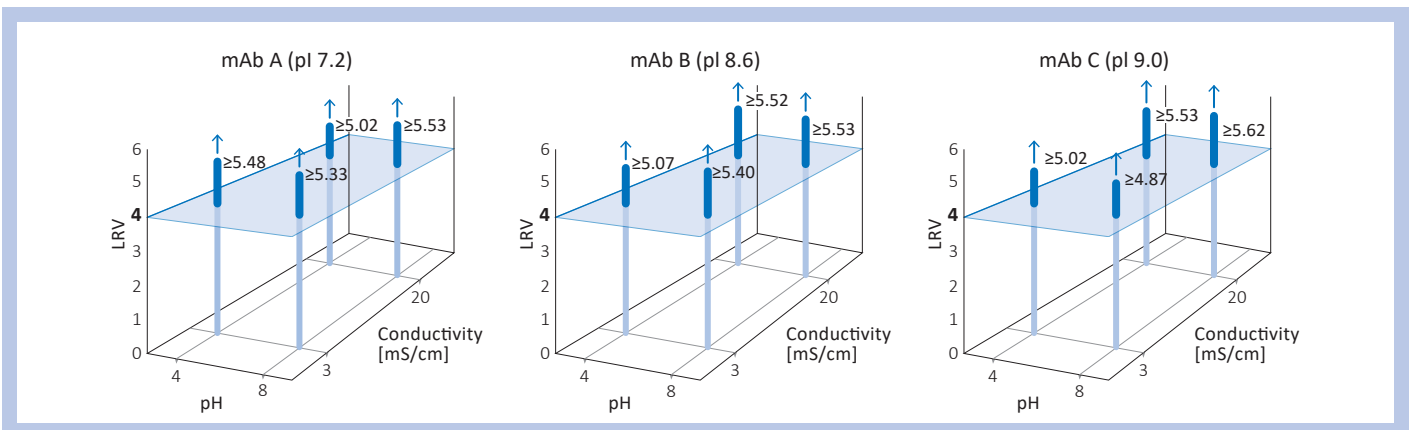
Eva Gefroh, Amgen, *American Chemical Society*, 2010 (adapted)
Feed solution: 20 g/L



Innocent Bekard, CSL Behring, *Planova Workshop*, Cambridge, 2012 (adapted)
Feed solution: 60 g/L

2. Planova™ BioEX has robust virus removal capability for confidence in virus safety

► Achieve LRV > 4 under various conditions, allowing speedy process development for your product



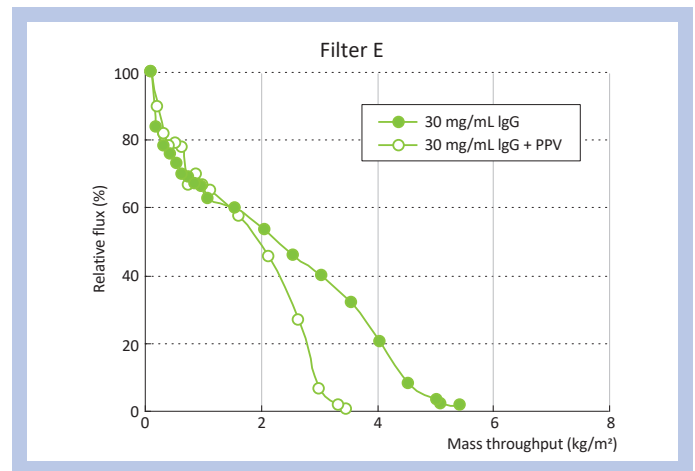
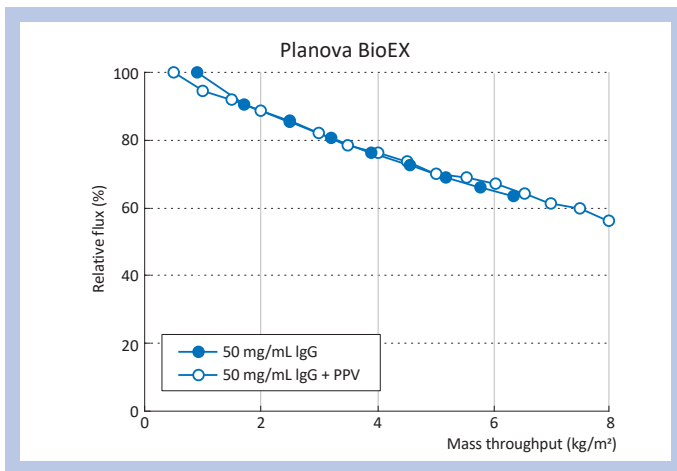
Joshua Goldstein, Janssen, *Planova Workshop*, Washington, 2014 (adapted)

Filtration condition

Feed solution: 5 g/L Feed volume: 50 L/m²

3. Planova™ BioEX shows consistent flux with minimal decay

- ▶ Seamlessly complete the viral clearance study owing to minimal impact of the virus spike
- ▶ Avoid oversizing your process based on consistent performance without and with virus spike



Tomoko Hongo-Hirasaki, Asahi Kasei Medical, *Planova Workshop*, Philadelphia, 2016 (adapted)

Filtration condition

Feed solution: Various concentrations of IgG (mg/mL), 100 mM NaCl, pH 4.5
 Spiking: 0.5 vol% with serum-free PPV
 Pressure: 3.0 bar

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

- ✓ Technical consultation on virus filtration process development, scale-up, optimization and filter operation
- ✓ Viral clearance study service prior to GLP virus validation
- ✓ Planova Operators Course for personnel training and development



From Asahi Kasei Bioprocess

We appreciate your interest in our products.

This Planova BioEX Spotlight highlights key considerations for process development professionals working in early phases. 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.

In Vol. 3 of the Planova BioEX Spotlight, we will introduce key considerations for virus removal processing at Phase III and show why Planova BioEX is your filter of choice to ensure virus safety of biopharmaceutical products.

