

PLANOVA™ S20N

Next Generation Superior Cellulose Membrane



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Planova virus removal filters were launched in 1989 and with the addition of Planova S20N, we can further meet new challenges the industry brings.

Providing seamless scalability along with high quality and reliable performance, Planova S20N is the optimal filter for removing viruses in biologicals, from antibody-based therapeutics to plasma-derived products.



Key Features of Planova S20N



Robust Virus Removal Capability

Contributes to the safety and high quality of biologics manufacturing through high virus removability for various viruses and process designs



Processing More, Faster

With a superior regenerated cellulose membrane that can withstand higher filtration pressure, Planova S20N delivers cost-effective performance with higher processing volumes and reduced processing times



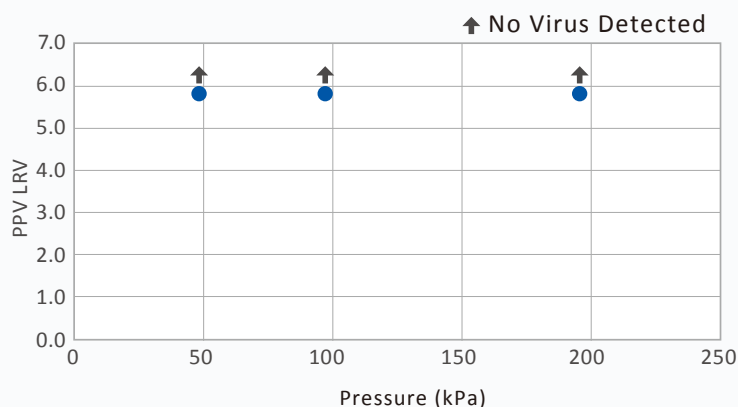
Improved Operational Efficiency

Improved operational efficiency during manufacturing by simplifying the post-use integrity test

Robust Virus Removal Capability

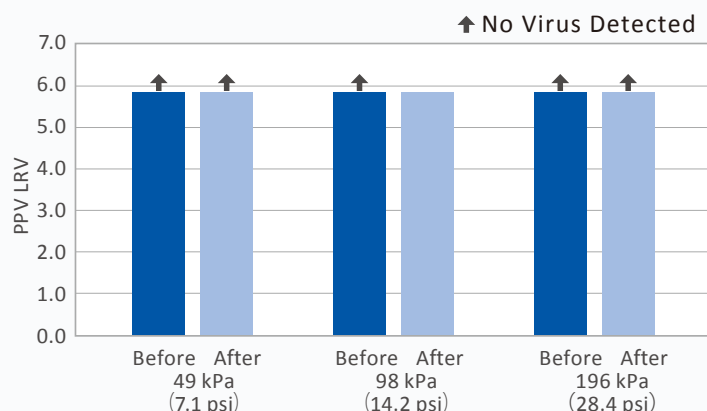
Planova S20N shows high virus LRV with various viruses and process designs

High Virus LRV Regardless of Filtration Pressure



PPV LRV results for 300 L/m² Planova S20N processes with 10 mg/mL h-IgG ranging from 49 kPa (7.1 psi) to 196 kPa (28.4 psi).

Effective Virus Removal After Process Pause



PPV LRV results for 300 L/m² pre-pause pool and total pool, including a 3-h pause followed by 30 L/m² of 10 mg/mL h-IgG solution ranging from 49 kPa (7.1 psi) to 196 kPa (28.4 psi).

Virus Safety Demonstrated for Various Viruses

Virus	Size (nm)	Total pool LRV after 30-min process pause
MVM	18 - 24	≥5.3
PPV	18 - 24	≥5.8
EMCV	25 - 30	≥5.9
BVDV	50 - 70	≥5.9
HIV	80 - 120	≥4.1
PRV	120 - 200	≥5.4

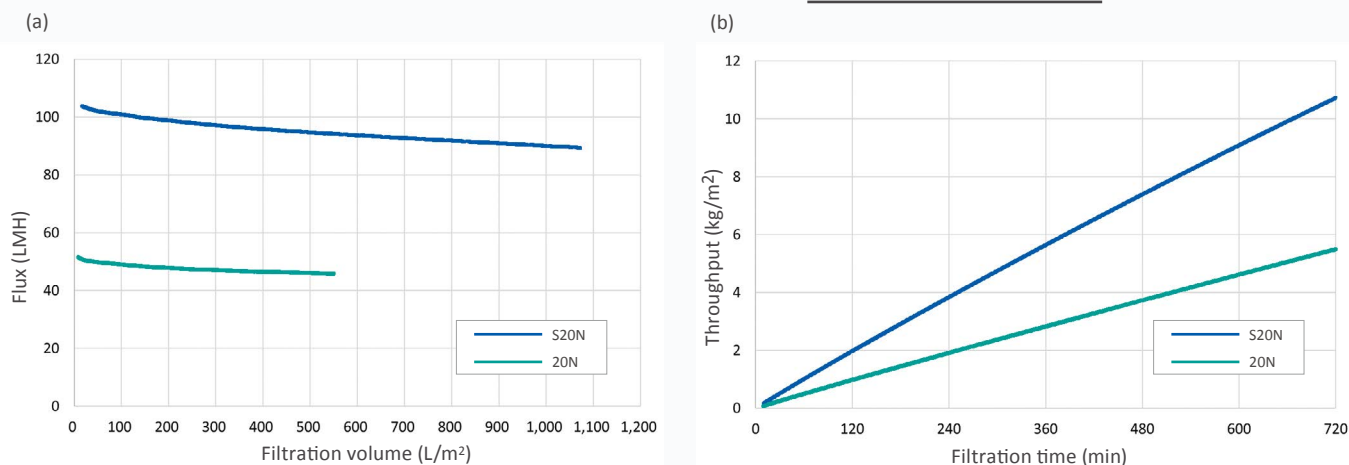
Virus LRV results for the total pool of 165 L/m², including a 30-min pause followed by 15 L/m² for Planova S20N processes with 1 mg/mL h-IgG in 100 mM NaCl at 196 kPa (28.4 psi).

Processing More, Faster

Superior Regenerated Cellulose Withstands Higher Pressure

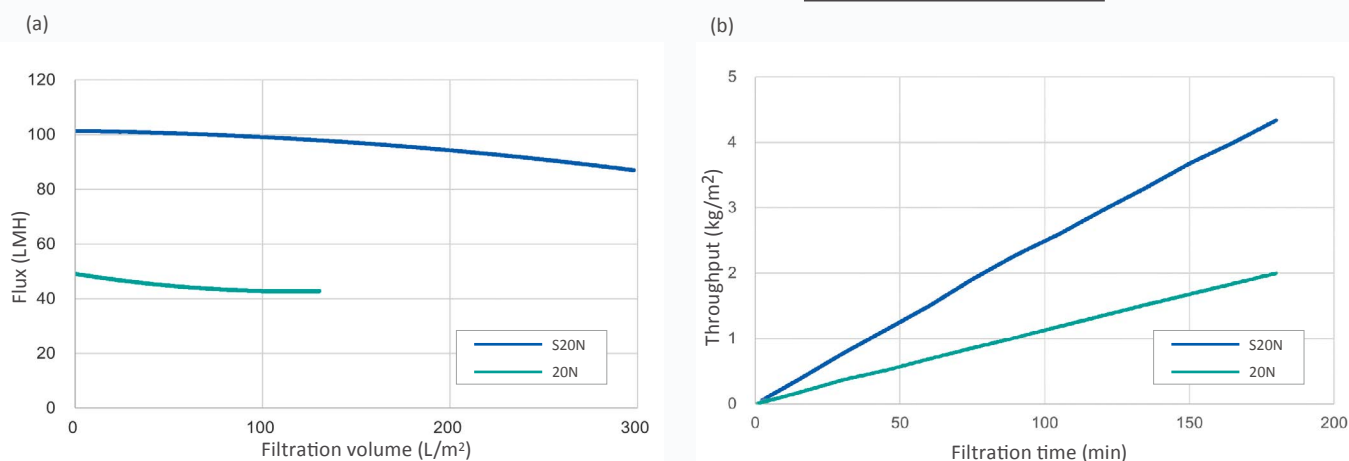
The superior regenerated cellulose membrane of Planova S20N withstands higher filtration pressure and resists clogging to deliver stable filterability with higher flux and throughput.

Higher Flux and Higher Throughput for Plasma Proteins (IgG)



Comparison of filtration performance (a) flux and (b) protein throughput of Planova S20N and Planova 20N filters for 10 mg/mL h-IgG, pH 4-5, 10.6 mS/cm. Filtration pressure was 196 kPa (28.4 psi) for Planova S20N and 98 kPa (14.2 psi) for Planova 20N.

Higher Flux and Higher Throughput for Monoclonal Antibody



Comparison of filtration performance (a) flux and (b) protein throughput of Planova S20N and Planova 20N filters for 15 mg/mL IgG4 monoclonal antibody, pH 5.5, acetic acid buffer 100mM with 200mM NaCl. Filtration pressure was 196 kPa (28.4 psi) for Planova S20N and 98 kPa (14.2 psi) for Planova 20N.

Improved Operational Efficiency

- » Just like other Planova filters, Planova S20N arrives at your site “ready to use” – no pre-wetting or sterilization is required prior to use in filtration
- » The post-use integrity test is simplified to only a leakage test – no GPT* required
- » Planova S20N will contribute to operational efficiency during process scale-up and manufacturing

*GPT (Gold Particle Test) is a pore size distribution test conducted on post-use Planova 15N, 20N and 35N filters.

Sequence of Planova S20N Operation

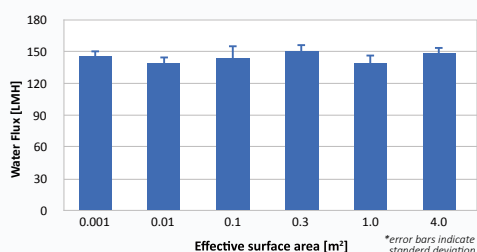


Excellent Scalability and High Lot-to-Lot Consistency

Planova S20N shows

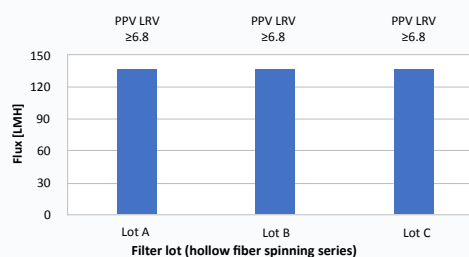
- » Consistent water flux across filter sizes
- » Stable flux and virus removal across different lots

Predictable Process Development



Water flux results are shown for Planova S20N at 196 kPa (28.4 psi).

Safe and Stable Manufacturing with Worry-Free Operation



PPV LRV and flux across three spinning series are shown for a total pool of 150 L/m² of 1 mg/mL h-IgG in 100 mM NaCl at 196 kPa (28.4 psi).

Specifications & Operating Parameters

Specifications & Operating Parameters			Effective Surface Area (m ²)					
			4.0	1.0	0.3	0.1	0.01	0.001
Component	Hollow fiber membrane		Cuprammonium regenerated cellulose					
	Housing and headers		Polycarbonate					
	Sealant		Polyurethane					
	O-rings		Silicone					
	Nozzle plugs		Silicone				- ^a	
	Nozzle caps		-				Silicone	
	Ferrule caps		Polycarbonate				-	
	Luer lock plugs		-				Polypropylene	
	Balloon cap holders		Polycarbonate				-	
	Gaskets ^b		Silicone				-	
	Balloon caps		Silicone				-	
	Nozzle stoppers		-	Silicone			-	
	Clamp bands		Poly-sulfone	-				
	Threaded clamps	Clamp bolts	-	Polypropylene			-	
		Clamp nuts	-	Polypropylene			-	
Lock nuts		Polycarbonate	-					
Supplied as			Filled with purified water ^c					
Sterilization method			Autoclaving					
Packaging format			Packed individually in sterilized bags					
Operating pressure (TMP)			≤216 kPa (31.3 psi)					
Operating pH			3-9					
Biological safety			Conformance with USP standards for class VI plastics					

^a Not applicable

^b Gaskets are used for connecting quick clamps to nozzles of Planova S20N filters with effective surface areas of 4.0, 1.0, 0.3 and 0.1 m²

^c Purified water in 4.0 m² Planova S20N filters contains < 0.1% NaCl

Product Lineup & Catalog Numbers

Planova S20N	Effective Surface Area (m ²)	Catalog No.
	4.0	S20-LF40
	1.0	S20-LF10
	0.3	S20-3000
	0.1	S20-1000
	0.01	S20-0100
	0.001	S20-0010

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