

PLANOVA

15N, 20N & 35N Virus Removal Filters

VIRUS REMOVAL FOR BIOTHERAPEUTIC PRODUCTS







Traditional PLANOVA Qualities

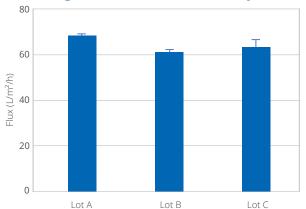
Planova filters demonstrate excellent filterability for a wide range of products, from plasma-derived medicinal products to monoclonal antibodies, thanks to its regenerated cellulose hollow fiber. Planova filters also show robust virus removal capability under various solution and operating conditions.

The unique hollow fiber membrane structure enables Planova filters to demonstrate reliable reproducibility and scalability.

High Lot-to-Lot Consistency

» Planova shows consistent flux and virus removal across different lots.

Average flux for Planova 20N by lot



Feed solution: 1g/L BSA solution, 20 mM phosphate, 50 mM NaCl, pH 7

Filtration pressure: 98 kPa

Filter used: 0.001 m² Planova 20N three in a lot

PPV removal for Planova 20N by lot

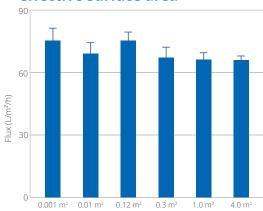
		PPV LRV
Lot A	Filter 1	>6.19
	Filter 2	>6.19
	Filter 3	>5.69
	Filter 1	>6.02
Lot B	Filter 2	>6.19
	Filter 3	>6.19
Lot C	Filter 1	>6.19
	Filter 2	>6.19
	Filter 3	>6.02

Feed solution : 5% D-MEM solution Feed volume : 55 L/m² Filtration pressure : 98 kPa Filter used : 0.001 m² Planova 20N

Excellent Scalability

- » Speedy scale-up and technical transfer from process development to manufacturing
- » Consistent water flux for small-scale and large-scale filters

Average flux for Planova 20N by effective surface area



Note: Water flux was measured at 19.6 kPa and converted to 98 kPa by calculation



Ready to Use

- » Shipped sterilized, available immediately after opening
- » No pre-wetting process required (Supplied as filled with purified water)



Materials & Operation Ranges

		4.0 m ²	1.0 m ²	0.3 m ²	0.12 m ²	0.01 m ²	0.001 m ²
	Hollow fiber membrane		Cuprammonium regenerated cellulose				
	Housing and headers	Polycarbonate					
	Sealant	Polyurethane					
Component	Other components Other components Polysulfone Polypropylen		bonate ulfone	Silicone SUS304*			
Supplied As		Filled with purified water**					
Sterilization Method		Autoclaving					
Operating Pressure (TMP)		≤98 kPa					
Operating pH		3-9					

^{*:} For 0.1, 0.3 m² pinband

^{**:} Purified water in 4.0 m² filters contains NaCl (<0.1%).

¹ Planova 35N filters can be used as effective prefilters prior to final virus filtration with 15N or 20N.

² Planova 75N filters are prefilters designed to remove impurities or aggregated proteins prior to final virus filtration and are not virus removal filters.

³ Planova 75N filters are only available in membrane surface areas of 1.0, 0.3, 0.01 and 0.001 m².

Product lineup & Catalog numbers



	Effective Surface Area (m²)	Catalog No.
	4.0	15N4-000
	1.0	15F1-000
Planova 15N	0.3	15NZ-300
	0.12	15NZ-120
	0.01	15NZ-010
	0.001	15NZ-001

	Effective Surface Area (m²)	Catalog No.
	4.0	20N4-000
	1.0	20F1-000
Planova 20N	0.3	20NZ-300
	0.12	20NZ-120
	0.01	20NZ-010
	0.001	20NZ-001

	Effective Surface Area (m²)	Catalog No.
	4.0	35N4-000
	1.0	35F1-000
Planova 35N	0.3	35NZ-300
	0.12	35NZ-120
	0.01	35NZ-010
	0.001	35NZ-001

	Effective Surface Area (m²)	Catalog No.
	1.0	75F1-000
Planova 75N (Prefilter)	0.3	75NZ-300
	0.01	75NZ-010
	0.001	75NZ-001

Asahi Integrity Test Kits for Gold Particle Test

Asahi Integrity Test Kits	Volume (ml)	Catalog No.
AGP-HA15	880	AGP-HA15M
	110	AGP-HA15S
AGP-HA20	880	AGP-HA20M
	110	AGP-HA20S
AGP-HA35	880	AGP-HA35M
AGP-HASS	110	AGP-HA35S

Step 1	Step 2	Step 3
Pre-Use Integrity Test (Leakage Test)	Filtration	Post-Use Integrity Test (Leakage Test and GPT*)

^{*} The Asahi Gold Particle Test Kit is used for Gold Particle Test as a post-use integrity test for the Planova N Series.



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