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Kleenpak™ Nova Capsules with Supor® EKV Membrane

Description

Pall filters with Supor grade EKV membrane are 0.2um rated filters, validated for the retention of B.diminuta (ATCC 19146) when challenged with a concentration 10^7 cfu per cm² membrane. Featuring dual polyethersulfone (PES) membrane layers, they achieve high flow rates for extended filter life and low filtration costs. The low protein and preservative binding properties of Supor allows for maximum transmission of active ingredients. With broad liquid compatibility, the filters are suitable for the sterile filtration of a wide range of low fouling fluids including buffers, biological fluids, tissue culture media and ophthalmic products amongst others.

Pall's range of Kleenpak Nova capsules are designed for use in medium to large scale production environments ($\sim 100 \text{ L}$ to 1000 s L), often selected by the end user following scaling studies using smaller Kleenpak capsule formats. With the 'AB-style' cartridge format at its core, this capsule filter style can be supplied with the most comprehensive range of filter media.



Key Features and Benefits

- ▶ Encapsulated format for higher flexibility, minimized cleaning and low installation costs
- Hydrophilic polyethersulfone membrane for low adsorption and wide chemical compatibility
- > Patented laid-over pleat technology resulting in high-area for excellent capacity and high flow rates
- Built-in, asymmetric prefilter layer for high capacity and low filtration costs

Quality Standards

- Manufactured for use in conformance with cGMP
- ▶ All individual filters integrity tested during manufacture test correlated to microbial retention
- ▶ ISO 9000 Certified Quality System
- ▶ Meets USP Biological Reactivity Test, in vivo, for Class VI-121 °C Plastics
- Certificate of Test provided includes:
 - Fabrication Integrity
 - Bacterial Retention
 - Materials of Construction
 - Effluent quality for cleanliness, TOC and Water Conductivity, pH and Pyrogens

Specifications

Materials of Construction

Filter Membrane	Hydrophilic PES		
Support/Drainage	Polypropylene		
Core/End Caps	Polypropylene		
Cage	Polypropylene with TiO ₂ (white colored)		
O-rings	Silicone elastomer		
Sealing Technology	Thermal bonding without adhesives		
Housing Bowl	Polypropylene		
Housing Head*	Polypropylene		

^{*}Formulated with TiO2 whitener which does not contribute to organic extractables

Operating Parameters⁽¹⁾

Maximum Temperature	40 °C	
Maximum Operating Pressure	3 bar (44 psi) at 40 °C	
Maximum Differential Pressure	3 bar (44 psi) at 40 °C	

(1) In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

Sterilization⁽²⁾

Autoclave	1 x 60 minutes at 125 °C
Gamma irradiation	Maximum of 50 kGy

^{(2) •} Pre-sterilized Kleenpak Nova capsules must not be re-sterilized

Typical Extractables in Water at 20 °C

< 25 mg after 4 hours extraction (per 254 mm module)

Nominal Dimensions

In Line	NP5	NP6	NP7	NP8
Maximum Diameter including valves	154 mm (6.1 in.)	154 mm (6.1 in.)	154 mm (6.1 in.)	154 mm (6.1 in.)
Length with hose barb inlet/outlet	275 mm (10.8 in.)	397 mm (15.6 in.)	644 mm (25.4 in.)	895 mm (35.2 in.)
Length with sanitary inlet/outlet	213 mm (8.4 in.)	335 mm (13.2 in.)	584 mm (23.0 in.)	834 mm (32.8 in.)
T Style	NP5	NT6	NT7	NT8
Maximum Diameter including valves	N/A	240 mm (9.5 in.)	240 mm (9.5 in.)	240 mm (9.5 in.)
Length	N/A	349 mm (13.7 in.)	598 mm (23.5 in.)	848 mm (33.4 in.)

Nominal Effective Filter Area (EFA)

0.6 m² per 254 mm cartridge (6.5 ft² per 10 in subassembly used in NP/ NT 6 to 8 size Kleenpak Nova filter)

0.26 m² (2.8 ft²) per 125 mm (5 in.) cartridge

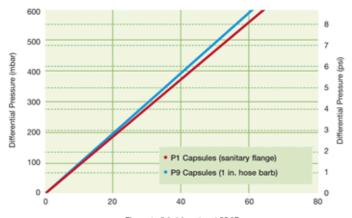
Typical Flow Characteristics

In Line

Kleenpak Nova capsules must not be sterilized in-situ by passing steam under pressure
 Water wet Supor EKV capsules prior to steaming to retain full water wettability for integrity testing

^{*}Tested on elements without pre-flushing

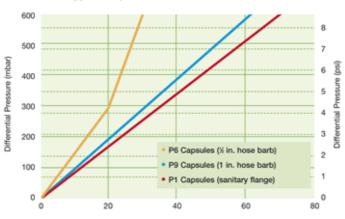
Kleenpak Nova (NP) Typical Liquid Flow vs. Differential Pressure



Flow rate (L/min), water at 20 °C For liquids other than water, multiply differential pressure by fluid viscosity (cP).

T Style

Kleenpak Nova (NT) Typical Liquid Flow vs. Differential Pressure

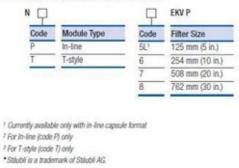


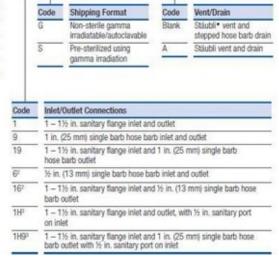
Flow rate (L/min), water at 20 °C
For liquids other than water, multiply differential pressure by fluid viscosity (cP)

Ordering Information

Ordering Information

Part Number: (example: NP5LEKVP1G)





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