PURAFIX®

DEPTH FILTER SHEETS

«Low Ion» or «Low Ion and Low Pyrogen»
For pharmaceutical and other high purity applications

Characteristics

PURAFIX® depth filter sheets represent an approved and established filtration technology for solid liquid separation.
The three dimensional medium assures superior retention capacity for solid particles at a high flow rate.
The pore sizes can be fine enough to retain bacteria and thus produce a sterile liquid (logarithmic retention of bacteria up to LRV 8). The dirt holding capacity of a PURAFIX® depth filter sheet can be up to 4 kg per m^2.
In the filtration process, solid particles are slowed down and eventually retained by the tortuous path inside the filter sheet and by electrokinetical interactions («zeta potential»). Through this unique mechanism, a high capacity (long lifetime of filter until plugging) can be achieved.
PURAFIX® and PURAFIX® P are highly pure depth filter media. PURAFIX® has a very low ion release and PURAFIX® P has both, low ion and a low pyrogen release.
All materials are FDA approved.

Applications

The broad variety of available porosities allow for their use in a wide range of applications. Porosity grades are available from coarse over fine to germ reducing and germ removing filtration («sterile filtration»).
Examples of industries:
- API (Active pharmaceutical ingredients)
- Biotech (pharmaceuticals)
- Beverage (spirits)
- Enzymes
- Herbal or other natural extracts
- Pharmaceutical intermediates
- Solvents

Sheet sizes

PURAFIX® sheets are available in various sizes and shapes up to 1215 x 2425 mm: square, rectangular, round, with/without holes, foldover, etc.

Available grades

Standard version	High capacity version*	Retention rate [µm]	
CH 6 (P)		35 – 15	Coarse filtration
CH 9 (P)		30 – 10	
CH 15 (P)		20 – 8.0	
CH 20 (P)	CH 21H (P)	15 – 6.0	Clarifying filtration
CH 30 (P)	CH 31H (P)	12 – 5.0	
CH 40 (P)	CH 41H (P)	9.0 – 4.0	
CH 50 (P)		6.0 – 3.0	
CH 70 (P)	CH 71H (P)	3.0 – 1.5	Fine filtration
CH 100 (P)	CH 101H (P)	1.5 – 0.6	Germ reducing filtration
CH ST 110 (P)		0.8 – 0.5	Sterile filtration
CH ST 130 (P)		0.6 – 0.4	
CH ST 140 (P)		0.4 – 0.2	
CH ST 150 (P)		0.2 – 0.04	

*Provides increased dirt holding capacity for longer lifetime.

Handling

Depth filter sheets are used in a plate and frame filter, such as the FILTROX NOVOX® series. The sheets need to be wetted in place and pre-flushed with 50 L/m^2. A pressure difference between in and outlet assures constant flow.
The sheets are exhausted when the differential pressure exceeds a certain value (1.0 – 2.5 bar, depending on porosity and application).

Sterilization conditions

The sheets can be sterilized with hot water (85°C) or inline steam (125°C).

Logarithmic bacteria retention value (LRV)
LRV of germ reducing or germ removing sheets:

Type	Test germ	Load	LRV
CH 101 H (P)	Germ reducing (reducing the no. of germs in filtrate)		
CH ST 110 (P)	Serratia marcescens	1.0 X 10^7/cm²	>6
CH ST 130 (P)	Serratia marcescens	1.0 X 10^8/cm²	>7
CH ST 140 (P)	Serratia marcescens	1.0 X 10^9/cm²	>8
CH ST 150 (P)	Brevundimonas diminuta	1.0 x 10^9/cm²	>8
Test germs:	Serratia marcescens, ATCC 14756 Brevundimonas diminuta, ATCC 19146		

Pyrogen release (for PURAFIX® «P» series, only)
Due to a special manufacturing process the PURAFIX® P series has a reduced specified endotoxin release < 0.125 EU/ml.

Chemical resistance (filter sheets)

Substance	Concentration [%]	Resistance T = 20° C	T = 80° C
NaOH	1	r	r
	2	r	lr
HCl	5	r	lr
HNO_3	5	r	lr
H_2SO_4	10	r	lr
Acetic Acid	Conc.	r	r
Citric Acid	10	r	r
Peracetic Acid	0.1	r	r
Butanol	80	r	r
Ethanol	80	r	r

r = resistant; lr = limited resistant
For the complete list please refer to our special documentation

FILTROX quality assurance
FILTROX assures the best quality control according to international standards:
– ISO 9001 (Quality management)
– ISO 14001 (Environmental management)
– HACCP
– FDA drug master file: # 16418
External tests of filter sheets were performed and certified according to
– CFR requirements by the NAmSA
FILTROX is using polyamidoamine as a wet strength agent in its filter sheets. The ISEGA Institute for food analysis in Aschaffenburg (Germany) performed a test for extractable MCPD and DCP. The FILTROX filter sheets extracts were below the detection limit of the approved standard method for DCP and MCPD.
All sheets are kosher for passover.

Validation support
For validation support of pharmaceutical applications there is a comprehensive validation guide available, containing all current certificates, analysis results (FDA, CFR, USP...), declarations (GMO, TSE).

EU safety data sheets
EU safety data sheets for all types of PURAFIX® sheets can be downloaded from the FILTROX website.
Hardcopies are available upon request.

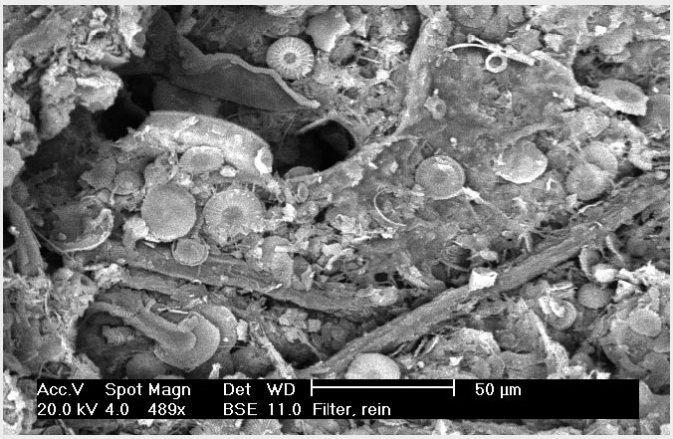
Material
Purified and bleached cellulose, natural inorganic filter aids, polyamidoamine (< 3%).
Free of plastic fibers and formaldehyde. The filter sheets are free of GMO and common allergens.

Disposal
Uncontaminated sheets can be recycled like paper, composted or disposed with the domestic waste.
Contaminated sheets must be disposed according to the contamination.

Storage life and conditions
Sheets should be stored in their original packaging in an odorless, dry and ventilated environment.
We recommend to use the filter sheets within 36 months after purchase.

Options
In applications of enzymes with high cellulase activity«Cellulase Resistant» filter sheets (Pat. pend.) are available.
CH 15 or CH 71H are also available in a version with extra high zeta potential: CH 15S and CH 71S. The additional positive charge leads to a higher adsorption of negatively charged particles, such as dye molecules.
For intermediates or pre filtration with lower demands on ion or pyrogen release we recommend FIBRAFIX®, our food approved standard grade of filter sheets.
Please contact your local FILTROX dealer.

Diatomaceous earth
Sheets with an ash content > 1 contain diatomaceous earth (DE / «Kieselguhr») or perlite as an inorganic filter aid.
FILTROX uses only natural kieselguhr with a cristobalite content < 1 % (detection limit).



REM picture of a depth filter sheet: round/disc-structures are DE particles, long structures represent cellulosic fibers

Your FILTROX dealer:

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