



PURAFIX®

DEPTH FILTER SHEETS

For pharmaceutical and other highly pure applications

Depth filter sheets are used to remove particles from liquids. This means that liquids can be clear-, fine- or sterilization-filtered. For depth filtration filter media of a thickness of 2.5–4.5 mm are required. The particles are retained using two filtration principles: 1. surface filtration and 2. depth filtration. The liquid flows through a three-dimensional, asymmetrical fiber network in the depth filter. The solid components are retained using mechanical and electrokinetic effects. This significantly increases the absorption capacity. The purpose of a filtration process is to produce either a liquid (filtrate) or solids (retentate). Depth filtration focuses mainly on the production of liquid filtrate.

Formats are available from 6 cm round to 2.425 m x 1.215 m square. Practically every format in between is possible, which means they can be installed in any commercially available sheet filter. Depth filter sheets have a particle absorption capacity of up to 4 kg/m². Furthermore, any available filter sheet grade is available as lenticular module (FILTRDISC™, see brochures for DISCSTAR™ and FILTRDISC™ modules).

PURAFIX® depth filter sheets have been specifically developed for the use in critical applications such as the processing of biopharmaceutical products. They are characterized by their extremely low levels of ions and pyrogens.

Material

Filter sheets:

- Cleaned and bleached cellulose
- Natural filter aid (kieselgur, perlite)
- Cationic wet strength agent

Handling

Depth filter sheets are used in sheet filters such as those in the FILTROX NOVOX® range. The sheets (except with NOVOX® OD or NOVOX® CP) must be wetted when fitted into the filter and should be pre-rinsed with 50 l/m² of clean water/buffer for industrial applications and for use in the drinks industry. A pressure difference between the inlet and outlet is required to allow flow. The filters are exhausted when the differential pressure exceeds a given value (1–2.5 bar, depending on porosity and application). With certain applications it is possible for the filter sheets to be regenerated. Please refer to the special instructions for this purpose.

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

Retention rates

Sheet type		Retention rate [µm]	Water value* [l/m ² min] Δp= 1 bar	Filtration type
Standard	High performance (increased particle absorption capacity)			
CH 6P		35–15	2800–3600	Coarse filtration
CH 9P		30–10	1500–2100	Coarse filtration
CH 15P		20–8.0	960–1240	Coarse filtration
CH 20P		15–6.0	560–700	Clear filtration
	CH 21HP	15–6.0	690–865	Clear filtration
CH 30P		12–5.0	350–400	Clear filtration
	CH 31HP	12–5.0	280–360	Clear filtration
CH 40P		9.0–4.0	240–280	Clear filtration
	CH 41HP	9.0–4.0	240–300	Clear filtration
CH 50P		6.0–3.0	200–240	Clear filtration
CH 70P		3.0–1.5	160–200	Fine filtration
	CH 71HP	3.0–1.5	170–210	Fine filtration
CH 100P		1.5–0.6	115–145	Germ reducing filtration
	CH 101HP	1.5–0.6	98–121	Germ reducing filtration
CH ST 110P		0.8–0.5	68–80	Sterile filtration (germ removing filtration)
CH ST 130P		0.6–0.4	42–52	Sterile filtration (germ removing filtration)
CH ST 140P		0.4–0.2	26–34	Sterile filtration (germ removing filtration)
CH ST 145ZP**		0.3–0.1	19–29	Sterile filtration (germ removing filtration)
CH ST 150P		0.2–0.04	10–16	Sterile filtration (germ removing filtration)

* does not correspond to the effective flow rate

** ZP = highly charged sheets

Bacterial log reduction value (LRV)

Type	Test pathogen	Load	LRV
CH 100P	Reduction of pathogen quantity in filtrate		
CH ST 110P	<i>Serratia marcescens</i>	1.0 x 10 ⁷ /cm ²	>5
CH ST 130P	<i>Serratia marcescens</i>	1.0 x 10 ⁸ /cm ²	>7
CH ST 140P	<i>Serratia marcescens</i>	1.0 x 10 ⁷ /cm ²	>8
CH ST 145ZP	<i>Serratia marcescens</i>	1.0 x 10 ⁷ /cm ²	>8
CH ST 150P	<i>Brevundimonas diminuta</i>	1.0 x 10 ⁷ /cm ²	>8
Test germs	<i>Serratia marcescens</i> : ATCC 14756 <i>Brevundimonas diminuta</i> : ATCC 19146		

Chemical resistance

Substance	Concentration [%]	Resistance T = 20°C	Resistance T = 80°C
NaOH	1	r	r
	2	r	lr
HCl	5	r	lr
HNO ₃	5	r	lr
H ₂ SO 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 = limitation in resistance

Please contact FILTROX directly for other chemicals.

Extractable materials

FILTROX filter sheets fulfill the requirements of the German Food, Consumer Goods and Feedstuffs Code (Lebensmittel-Bedarfsgegenstände und Futtermittelgesetzbuch – LFGB) Recommendation XXXVI/1 of the Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung – BfR), and the test criteria of the FDA (US Food

and Drug Administration) CFR 21 Section 177.2260. The filter sheets are manufactured under controlled conditions, to guarantee the highest expectations in terms of quality and cleanliness (FDA Drug Master file: DMF #16418).

PURAFIX® CH P ion values

Ion	ppm	Ion	ppm
Ca	<1	Cu	<0.01
Mg	<0.5	Ni	<0.02
Pb	<0.06	Co	<0.025
Zn	<0.01	Fe	<0.05
Cd	<0.005	Al	<0.05

The description of the methods can be found in the filter sheet validation guide.

Pyrogen values

Endotoxin release: <0.125 EU/ml
MCPD and DCP in the wet strength agent: in accordance with legal regulations
GMO: absent
Allergenic substances: absent

The description of the method can be found in the filter sheet validation guide.

Packaging

FILTROX filter sheets of all standard sizes are hygienically shrink-wrapped and packaged in boxes. Special packaging (non-standard sizes or unboxed) is available on request.

Storage period and conditions

The sheets must be stored in their original packaging in an odorless, dry and well vented area. We recommend using the sheets within 36 months of the date of manufacture.

Disposal

Untainted sheets can be disposed of with normal household waste. Used sheets must be disposed of in accordance with the type of contamination.

Quality assurance

Quality checks meet international standards:

- ISO 9001:2008 (quality management)
- ISO 14001:2004 (environmental management)
- ISO 22000 (food safety)
- FDA Drug Master file: DMF #16418
- FDA 21 CFR compliance
- Kosher certificate
- EU safety data sheets can be downloaded from the website.