# 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/m$^2$. Furthermore, any available filter sheet grade is available as lenticular module (FILTRODISC™, see brochures for DISCSTAR™ and FILTRODISC™ 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 wettened 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/m² 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 | *Serratia marcescens* | $1.0 \times 10^7/cm^2$ | >5 |
| CH ST 130P | *Serratia marcescens* | $1.0 \times 10^8/cm^2$ | >7 |
| CH ST 140P | *Serratia marcescens* | $1.0 \times 10^7/cm^2$ | >8 |
| CH ST 145ZP | *Serratia marcescens* | $1.0 \times 10^7/cm^2$ | >8 |
| CH ST 150P | *Brevundimonas diminuta* | $1.0 \times 10^7/cm^2$ | >8 |
| Test germs | *Serratia marcescens:* ATCC 14756<br>*Brevundimonas diminuta:* 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 |
| $H_2SO_4$ | 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 = 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.

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