Technical Data Sheet

PURAFIX® PF

DEPTH FILTER SHEET FOR PLASMA FRACTIONATION

Description

High-purity depth filter sheets manufactured under tightly controlled conditions designed for plasma fractionation.

- Low beta-glucans and endotoxins
- Low ions
- Scalable solutions
- Fits into existing equipment

Components

Purified and bleached cellulose from sustainable sources, natural filter aids, wet strength agents, synthetic fibers (except PF 80), and cationization agents (PF 80 and PF 120 only).

Formats

All standard sizes and tailored formats are available.

Extractable Ions

Ca	Mg	Pb	Zn	Cd	Cu	Ni	Co	Fe	Al
<1.0	<0.5	<0.06	<0.01	<0.005	<0.01	<0.02	<0.025	<0.05	<0.05

mg/L after rinsing with 50 L/m² WFI

Extractable

Substance	Description
Endotoxins	<0.06 EU/mL(1)
Beta-glucans	<100.0 pg/mL(1)
Heavy metals	<50.0 ppm (according to recommendation XXXVI/1, BfR)
MCPD / DCP from wet strength agent	In accordance with legal regulations
GMO	Absent
Allergic substances	Absent

(1) after rinsing with 50 L/m² WFI

Product Range

Grade	Retention rate [µm]	Water value(2) [L/m²×min]	Thickness [mm]	Ash content [%]	Filtration type
PF 09	10.0 – 30.0	1500.0 – 2100.0	3.2 – 3.4	<1.0	Coarse
PF 50	1.5 – 4.0	173.0 – 225.0	3.3 – 3.6	23.0 – 28.0	Fine
PF 80	0.8 – 2.0	115.0 – 133.0	3.5 – 3.7	36.3 – 41.3	Fine
PF 120	0.4 – 0.7	61.0 – 77.0	3.5 – 4.0	39.0 – 44.0	Sterile
PF 140	0.1 – 0.4	26.0- 35.0	3.8 – 4.1	50.2 – 55.2	Sterile

(2) Δp = 100 kPa, the indicated water value does not correspond to the effective flow rate

Bacterial Retention

Grade	Bacterial species	Number of cells	LRV
PF 120	Serratia marcescens	$1.0 \times 10^7/cm^2$	>6
PF 140	Serratia marcescens	$1.0 \times 10^9/cm^2$	>8

Operating Conditions

Parameter	Recommendation
Maximum differential pressure	2.5 bar
Maximum differential pressure for sterile filtering sheets	1.2 – 1.5 bar
Rinsing volume	50 L/m²
Sterilization	Water 85 °C / Steam 125 °C

Chemical Stability

		°C				°C				°C	
Substance	**[%]**	**20**	**80**	**Substance**	**[%]**	**20**	**80**	**Substance**	**[%]**	**20**	**80**
NaOH	1.0	r	r	HCl	5.0	r	lr	SO_2	0.1	r	n/a
NaOH	2.0	r	lr	HNO_3	5.0	r	lr	Acetone	conc	r	r
Peracetic ac.	0.1	r	lr	H_2SO_4	10.0	r	lr	Ethanol	80.0	r	r
Acetic acid	20.0	r	r	Citric acid	10.0	r	r	Butanol	80.0	r	r

r = resistant, lr = limited resistance. This table is for guidance purposes only

Quality Assurance

Certified to:
- ISO 9001 (quality management)
- ISO 14001 (environmental management)
- ISO 22000 (food safety)
- Kosher standard

Compliant to:
- Recommendation XXXVI/1 of the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR)
- FDA (US Food and Drug Administration) 21 CFR 177.2260 e-k
- EU-Directive 10/2011
- USP Class VI

Packaging and Storage

Filter sheets are hygienically shrink-wrapped and packaged in cardboard boxes. They must be stored in their original packaging in a dry, odorless, and well-ventilated area. The sheets should be used within 36 months from the date of manufacture.

Disposal

The respective official regulations for disposal must be followed depending on the filtered product. Uncontaminated sheets can be disposed of as non-hazardous waste.

Remarks

The validity of the information cannot be guaranteed for every application. All information is based on current knowledge and does not claim to be complete. No liabilities can be derived from this information. FILTROX reserves the right to make changes in the course of technical improvements.

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