Technical Data Sheet

PURADISC®

MODULES WITH PURAFIX® DEPTH FILTER SHEETS

Description

Lenticular modules containing high-purity PURAFIX® CH depth filter sheets manufactured under tightly controlled conditions.

- Low levels of extractable endotoxins and ions
- Regulatory support

Module Versions

Standard: Standard lenticular module
HT: High-temperature resistance module

Components

Filter Sheet: Purified and bleached cellulose from sustainable sources, natural filter aids, wet strength agent

Modules: Standard: Polypropylene
HT: Polyamide

Gaskets: MVQ silicone sealing gasket (optionally EPDM, FKM, NBR)

Extractable Endotoxins

< 0.125 EU/mL after rinsing with 50 L/m² WFI.

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

Dimensions

	12" M		12"		16"	
Adapter type(1)	DOE	DOR	DOE	DOR	DOE	DOR
Height [mm]	132	178	272	330	272	330
Filtration area [m²]	0.6	0.7	1.8		3.6	
Number of lenses	5	6	16		16	
Weight dry/wet(2) [kg]	2.0 / 3.5		4.4 / 8.5		8.6 / 17	
Diameter [mm]	290		290		400	

(1) DOE: Double Open End (flat adapter), DOR: Double O-Ring (plug-in adapter), (2) indicative values

Product Range

PURAFIX® grade	Retention rate [µm]	Water value(3) [L/m²×min]	Ash content [%]	Filtration type
CH 06	15.0 – 35.0	2800.0 – 3600.0	<1.0	Coarse
CH 09	10.0 – 30.0	1500.0 – 2100.0	<1.0	Coarse
CH 15	8.0 – 20.0	960.0 – 1240.0	19.5 – 24.0	Coarse
CH 21	6.0 – 15.0	690.0 – 865.0	19.5 – 24.5	Fine
CH 31	5.0 – 12.0	280.0 – 360.0	39.5 – 44.5	Fine
CH 41	4.0 – 9.0	240.0 – 300.0	29.5 – 34.5	Fine
CH 50(4)	3.0 – 6.0	200.0 – 240.0	35.0 – 40.0	Fine
CH 71	1.5 – 3.0	170.0 – 210.0	35.5 – 40.5	Fine
CH 101	0.6 – 1.5	98.0 – 121.0	39.4 – 44.4	Fine
CH 110	0.5 – 0.8	69.0 – 81.0	46.1 – 51.1	Sterile
CH 130	0.4 – 0.6	43.0 – 52.0	47.5 – 52.5	Sterile
CH 140	0.2 – 0.4	26.0 – 35.0	47.5 – 52.5	Sterile
CH 150(4)	0.04 – 0.2	10.0 – 16.0	47.5 – 52.5	Sterile

(3) Δp = 100 kPa, the indicated water value does not correspond to the effective flow rate
(4) for standard module only

Bacterial Retention

PURAFIX® grade	Bacterial species	Number of cells	LRV
CH 110	Serratia marcescens	$1.0 \times 10^6/cm^2$	>5.0
CH 130	Serratia marcescens	$1.0 \times 10^8/cm^2$	>7.0
CH 140	Serratia marcescens	$1.0 \times 10^9/cm^2$	>8.0
CH 150	Brevundimonas diminuta	$1.0 \times 10^9/cm^2$	> 8.0

Operating Conditions

Parameter	Recommendation
Maximal differential pressure	2.4 bar
Maximal differential pressure for sterile filtering sheets	1.2 – 1.5 bar
Rinsing volume	50.0 L/m^2
Maximum temperature (continuous)	82 °C (110 °C HT)
Maximum temperature (short-term)	90 °C (140 °C HT)
Minimum temperature	-5 °C
Sterilization	Hot water or chemically

Chemical Stability

				Gasket material			
Substance	[%]	Media	PP	MVQ	EPDM	FKM	NBR
NaOH	1.0	r	r	r	r	lr	r
HCl	5.0	r	lr	lr	lr	r	lr
HNO_3	5.0	r	r	nr	lr	r	nr
H_2SO_4	10.0	r	r	nr	lr	r	nr
Citric acid	10.0	r	r	r	r	r	r
Acetic acid	20.0	r	lr	nr	lr	r	nr
Peracetic ac	0.1	r	r	r	lr	lr	lr
Acetone	conc	r	lr	lr	r	nr	nr
Ethanol	80.0	r	r	lr	r	r	nr
SO_2	0.1	r	r	r	r	r	nr

r = resistant, lr = limited resistance, nr = not resistant, at 50°C. 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 certification

Packaging and Storage

Filter modules are hygienically packed in plastic bags and placed in cardboard boxes. They must be stored in their original packaging in a dry, odorless, and well-ventilated area. The modules 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 modules 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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