Technical Data Sheet

PURAFIX® ET-R

DEPTH FILTER FOR ENDOTOXIN REDUCTION

Description

High purity depth filter solution manufactured under tightly controlled conditions for endotoxin reduction earlier in the process.

- Easy handling
- Scalable solutions
- Fits into existing equipment
- Overall costs reduction



Components

Purified and bleached cellulose from sustainable sources, natural filter aids, wet strength agent, and synthetic fibers (ET-R1 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	ET-R1 and ET-R4 <0.06 EU/mL(1) ET-R2 <0.125 EU/mL(1)
Beta-glucans	ET-R1 and ET-R4 <100 pg/mL(1) ET-R2 N/A
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 [%]
ET-R1	0.1 – 0.4	26.0 – 35.0	3.8 – 4.1	50.2 – 55.2
ET-R2	1.5 – 3.0	170.0 – 210.0	3.7 – 3.9	35.5 – 40.5
ET-R4	1.0 – 2.0	115.0 – 133.0	3.5 – 3.7	36.3 – 41.3

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

Operating Conditions

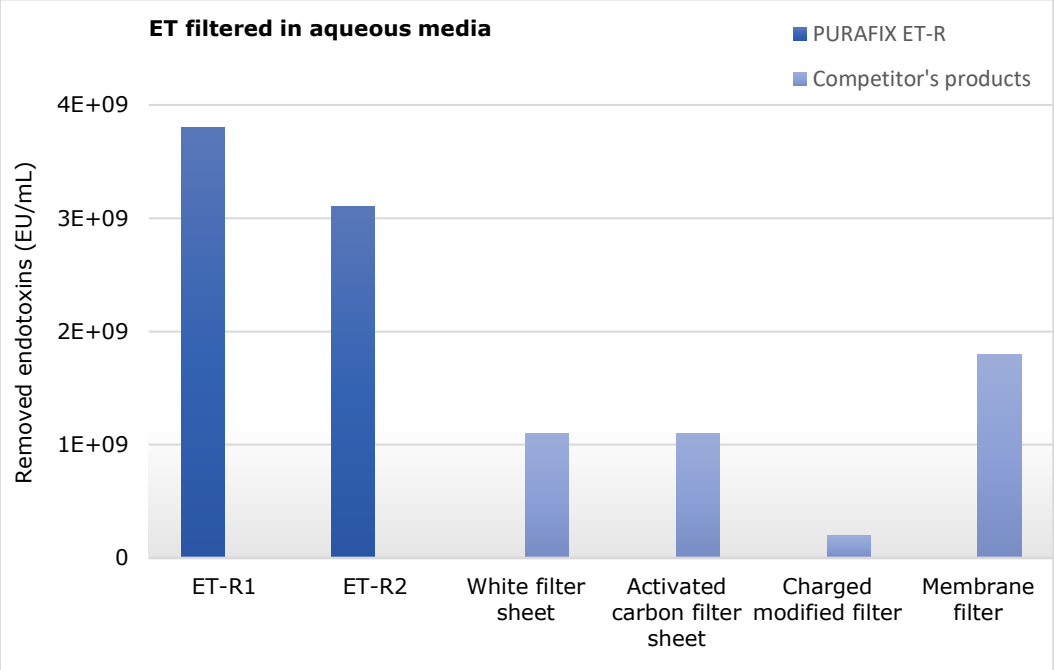
Parameter	Recommendation
Maximum differential pressure	2.5 bar
Change out differential pressure	1.2 - 1.5 bar
Rinsing volume	50.0 L/m²
Sterilization	Water 85.0 °C / Steam 125.0 °C

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

Chart



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 is recommended.

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.

Related Products

Series	Description
PURAFIX® CH ZP	High purity sheets with a positive zeta-potential
PURAFIX® PF P	High purity sheets for plasma fractionation
FILTRODISC™	Lenticular depth filter modules
NOVOX®	Plate & frame filter sheet systems
LABTROX	Equipment for laboratory trials

Remarks

All information is based on current knowledge and does not claim to be complete. No liabilities can be derived from this information. The user is advised to perform an incoming goods control. FILTROX reserves the right to make changes in the course of technical improvements.

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