PURAFIX®
Depth filter plates

EN Data sheet

QUALI FILTRES
SIEBEC Group

Filtration plates dedicated to the pharmaceutical industry and applications requiring high purity.

A product of the brand FILTROX

Description

Depth filter plates are used for solid-liquid separation. They represent a well-established and recognized technology in the field of microfiltration.

Filter plates are primarily composed of finely fibrillated cellulose, forming a three-dimensional mesh through which the liquid flows. Depending on the plate grade, mineral-based additives (such as kieselguhr or perlite) are incorporated into the cellulose matrix to achieve the desired retention characteristics. A thermosetting resin is used as a wet-strength agent. This resin imparts an electrokinetic potential, also known as zeta potential, to the plate, which enables the retention of negatively charged particles or microorganisms, even those with sizes smaller than the pores of the filtration medium, through adsorption.

The different grades of PURAFIX® filter plates cover retention thresholds ranging from coarse filtration to sterilizing filtration. They are available in all standard sizes, both square (200x200 mm to 1200x1200 mm) and round, with or without holes.

The PURAFIX® filter plates have been specifically developed for use in critical applications such as pharmaceutical manufacturing. They are characterized by their exceptionally low ion and pyrogen content.

Components

Bleached and purified cellulose

Natural inorganic filtration aids (diatomaceous earth, perlite)

Cationic wet-strength agent (polyamide < 3%)

Utilisation

Depth filter sheets are used in plate filters such as those in the FILTROX NOVOX® range. The sheets have a rough side and a smooth side (marked with the grade and batch number). They must be installed so that the turbid product enters through the rough side, with the filtrate exiting from the smooth side. The filter should be rinsed in co-current flow at a rate approximately 1.5 times the filtration flow rate for 15 to 20 minutes. The sheets can be sterilized using hot water (85°C) or steam (125°C).

To ensure effective filtration, the fluid flow must be constant and steady, without pressure surges, to prevent phenomena such as particle release or the formation of preferential pathways. Filter sheets are considered clogged when the differential pressure reaches 2.5 bar for clarifying filtration or 1 bar for sterile filtration.

Extractable materials

The PURAFIX® filter plates meet the requirements of the German Food and Consumer Goods Law (Lebensmittel-Bedarfsgegenstände und Futtermittelgesetzbuch – FGB), the recommendation XXXVI/1 from the Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung – BfR), and the evaluation criteria of the FDA (US Food and Drug Administration) CFR 21 § 177.2260. The filter plates are manufactured under controlled conditions to ensure the highest standards of quality and purity (FDA Drug Master File: DMF #16418).

Quality assurance

Quality control complies with 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
- Certificat Kasher
- EU Safety Data Sheets can be downloaded from our website..

Chemical resistance

Substance	Concentration (%)	T = 20°C	T = 80°C
NaOH	1	+++	+++
HCl	5	+++	+
HNO_3	5	+++	+
H_2SO_4	10	+++	+
Acetic acid	-	+++	+++
Citric acid	10	+++	+++
Paracetic acid	0.1	+++	+++
Butanol	80	+++	+++
Ethanol	80	+++	+++

+++ resistant | + limited resistance

Please contact us for data on other chemical substances.

Pyrogen content

Endotoxin release : <0.125EU/ml.

MDCP and DCP in wet-strength agents: compliant with legal regulations..

GMO : absent.

Allergenic substances: absent.

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PURAFIX® CH P range

Code	Nominal retention threshold[2] (µm)	Permeability[3] (l/m²/min)	Basis weight (g/m²)	Ash content (%)	Thickness (mm)	Type of filtration
CH 6P	35 - 15	2800 - 3600	750 - 950	<1	3.2 - 3.4	Rough filtration
CH 9P	30 - 10	1500 - 2100	800 - 1000	<1	3.2 - 3.4	Rough filtration
CH 15FG[1]	20 - 8.0	1200 - 1400	1100 - 1300	42.0 - 46.0	4.0 - 4.2	Rough filtration
CH 21HP	15 - 6.0	690 - 865	1000- 1200	19.5 - 24.5	3.7 - 3.9	Clarifying filtration
CH 31HP	12 - 5.0	280 - 360	1300 - 1500	39.5 - 44.5	4.4 - 4.6	Clarifying filtration
CH 41HP	9.0 - 4.0	240 - 300	1200 - 1400	29.5 - 34.5	3.7 - 3.9	Clarifying filtration
CH 71HP	3.0 - 1.5	170 - 210	1200 - 1400	35.5 - 40.5	3.7 - 3.9	Fine filtration
CH 101HP	1.5 - 0.6	98 - 121	1300 - 1400	39.4 - 44.4	3.7 - 3.9	Germ reduction
CH ST 110P	0.8 - 0.5	68 - 80	1300 - 1500	46.1 - 51.1	3.7 - 3.9	Sterilizing filtration
CH ST 130P	0.6 - 0.4	42 - 52	1350 - 1550	47.5 - 52.5	3.7 - 3.9	Sterilizing filtration
CH ST 140P	0.4 - 0.2	26 - 34	1400 - 1600	47.5 - 52.5	3.7 - 3.9	Sterilizing filtration
CH ST 145ZP[1]	0.3 - 0.1	19 - 29	1500 - 1700	47.5 - 52.5	3.9 - 4.1	Sterilizing filtration
CH ST 150P	0.2 - 0.04	10 - 16	1500 - 1700	47.5 - 52.5	3.9 - 4.1	Sterilizing filtration

[1] Z / FG = highly cationized filter plates
[2] The retention values of the filter plates are relative and provided for reference purposes. The retention characteristics of a depth filter are influenced by various parameters (e.g., flow rate, pressure, product viscosity, pH, etc.).
[3] Permeability is a laboratory-measured value used to characterize a plate; it does not correspond to the filtration flow rate.

Load reduction values (LRV)

Code	Pathogen	Charge	LRV
CH 101HP	Reduction of pathogen levels in the filtrate		
CH ST 110P	Serratia marcescens	1.0 x 10^7 / cm^2	>5
CH ST 130P	Serratia marcescens	1.0 x 10^8 / cm^2	>7
CH ST 140P	Serratia marcescens	1.0 x 10^9 / cm^2	>8
CH ST 145ZP	Serratia marcescens	1.0 x 10^9 / cm^2	>8
CH ST 150P	Brevundimonas diminuta	1.0 x 10^9 / cm^2	>8

Serratia marcescens : ATCC 14756
Brevundimonas diminuta : ATCC 19146

PURAFIX® CH P ion content

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 process description can be found in the validation guide.

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