



Seitz® P-series Depth Filter Sheets



Optimized for Low Extractables, Endotoxins and Beta Glucans

Seitz depth filter media meet the highest pharmaceutical standards for:

- ▶ Quality
- ▶ Lot-to-lot consistency
- ▶ Manufacturing control
- ▶ Low extractable content
- ▶ Low endotoxin content
- ▶ Low beta glucans content

Benefits

- ▶ P-grade sheets are steam sterilizable to 125 °C for 30 minutes.
- ▶ All P-grade depth filter sheets meet the specifications for the biological tests listed in the current version of the USP Class VI at 121 °C.
- ▶ P-grade sheets are fully lot traceable.
- ▶ Supporting Validation Guide available upon request. Please reference USTR 2366.

Seitz P-series depth filter sheets were specifically developed for the strict requirements in the biotech and pharmaceutical industries. Manufactured with stringent in-process control methods assures consistent filtration quality, a high purity of filter medium, and alignment with the requirements of the pharmaceutical industry.

The P-series depth filter sheets are available in eleven different grades. Due to specific manufacturing methods, the distinguishing feature of the P-series sheets is their high purity resulting in a very low release of extractables as well as an extremely low endotoxin content (< 0.06 EU/mL prior to rinsing with 50 L/m² of WFI). As part of Pall's standard flushing recommendations, further reduction of extractable and endotoxin levels can be achieved (as documented in Pall Validation Guide reference USTR 2366).

Scalability and Convenience

The P-series depth filter media is also available in a wide range of capsule and module formats and sizes, enabling the choice of the most convenient and efficient filter for the specific process requirements.

The range in filter sizes provides effective scalability, for processing volumes from <1 L to over 20,000 L, while the single-use capsule formats offer increased processing efficiencies and reduced operator exposure to potentially hazardous fluids.

For more details on these capsule and module formats, please contact Pall or visit www.pall.com.

Scalability – Effective Filter Area

Filter Design and Size	Effective Filter Area
Supracap™ 60 Capsules (< 1 to 3 L)	
Capsule	26 cm ² (0.028 ft ²)
Supracap 100 Capsules (3 to 100+ L)	
5 in. capsule	0.05 m ² (0.54 ft ²)
10 in. capsule	0.1 m ² (1.08 ft ²)
20 in. capsule	0.2 m ² (2.15 ft ²)
30 in. capsule	0.3 m ² (3.23 ft ²)
Supracap 200 Capsules (50 to 2,000+ L)	
Capsule with 9 cells	1.0 m ² (10.8 ft ²)
Capsule with 16 cells	1.8 m ² (19.4 ft ²)
Supradisc™ I Modules (50 to 20,000+ L)	
Size code 203	0.3 m ² (3.3 ft ²)
Size code 205	0.5 m ² (5.5 ft ²)
Size code 209	1.0 m ² (10.8 ft ²)
Size code 216	1.8 m ² (19.4 ft ²)
Size code 409	2.1 m ² (22.6 ft ²)
Size code 416	3.7 m ² (40.0 ft ²)
Size code 421	5.0 m ² (54.0 ft ²)
Supradisc II Modules (50 to 20,000+ L)	
Size code 232	1.8 m ² (19.4 ft ²)
Size code 440	5.0 m ² (54.0 ft ²)
Stax™ Capsules (50 to 20,000+ L)	
Small	0.5 m ² (5.5 ft ²)
Medium	1.0 m ² (10.8 ft ²)
Large	2.0 m ² (21.5 ft ²)

Available Product Range and Typical Applications

- ▶ **EKXP up to SUPRA 80 P** grades are ultra fine particle and microorganism-reducing filter sheets for depth filtration in the biotechnology and pharmaceutical industries. Typical applications include clarification of fermenter broth, TFF permeate, cell cultures, protection of chromatography columns and TFF membrane processes, protection of sterile filter membranes, filtration of therapeutical proteins, vaccines, diagnostics and blood products, filtration of nutrients and DNA and virus removal.
- ▶ **K 100 P up to K 250 P** are depth filter sheets for fine filtration in the pharmaceutical and biotechnological industries. Typical applications include filtration of fermenter broth, TFF permeate, therapeutical proteins, vaccines, diagnostics and blood products, filtration of nutrients, separation of adsorbents, and filter aids.
- ▶ **K 700 P and K 900 P** are depth filter sheets for coarse filtration in the biotechnological industries. Typical applications include filtration of fermenter broth, cell culture, therapeutical proteins, vaccines, diagnostics and blood products.

Top: Seitz filter sheets
 Middle: Supracap 60 and Supracap 100 capsules
 Bottom: Supradisc modules
 Left: Stax capsules



Materials of Construction

The filter matrix specifically developed for the P-series depth filter media provides particle retention rates down to 0.05 μm and enables optimal pre-filtration of biological products as well as protection of downstream process steps.

Comprised of cellulose fibers, filter aids (diatomaceous earth and perlite) and resins, the P-series depth filter media takes advantage of two dynamic mechanisms for the removal of contaminants, electrokinetic charge and size exclusion.

Cellulose is used to construct the initial filter matrix to which filter aids and other additives are impregnated into and improve contaminant removal and loading capabilities of the filter sheets.

Filter aids such as diatomaceous earth and perlite are immobilized within the cellulose matrix in various concentrations to provide specific contaminant removal, screening and permeabilities to each grade in the P-series family of depth filter sheets.

Resins are utilized as binders for the filter matrix to improve the filter sheets' overall wet tensile strength. Due to their electrokinetic adsorption properties, resins are also used to increase the retention of small particles, those smaller than the actual porosity of the filter medium, host cell proteins, endotoxins, DNA, and viruses.

The filter sheets meet the specifications set forth in the US Code of Federal Regulations Title 21, parts 177.2260 e, f, g, h, i, j, k, l, the materials for all plastic components are listed in US Code of Federal Regulations Title 21, part 177.1520. The Quality Management System of Pall has been certified according to DIN EN ISO 9001 by TÜV Cert (Certification Office TÜV Rheinland, Sicherheit und Umweltschutz GmbH).

Technical Service

For best possible results and maximum reliability it is recommended a test run under actual process conditions be performed. Depth filtration requires detailed knowledge of the product and the filtration sequence. In this area, Pall specialists can provide valuable assistance; they are able to perform filtration tests at the production or R & D site or in our Scientific and Laboratory Services (SLS) laboratories. Pall offers hands-on assistance and places its extensive technical resources at the disposal of its customers in the form of worldwide technical advice, including cost reduction programs, process review and problem solving.

Figure 1

Typical Permeability ($\text{L}/\text{m}^2/\text{min}$) @ 1 bar

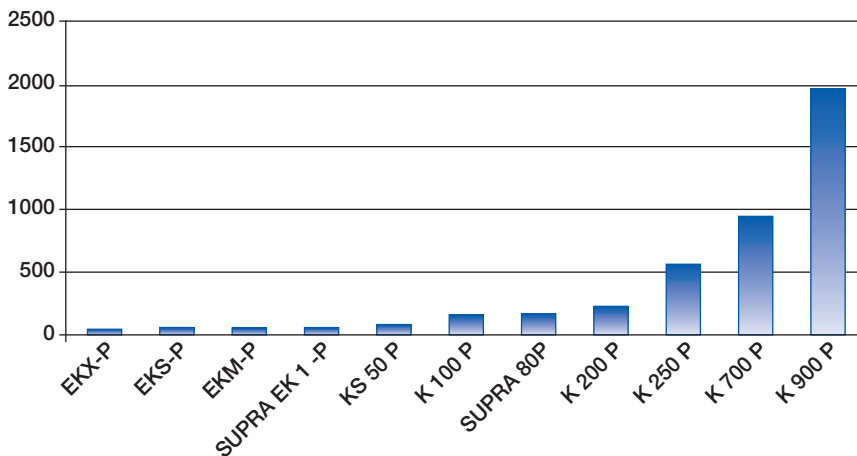
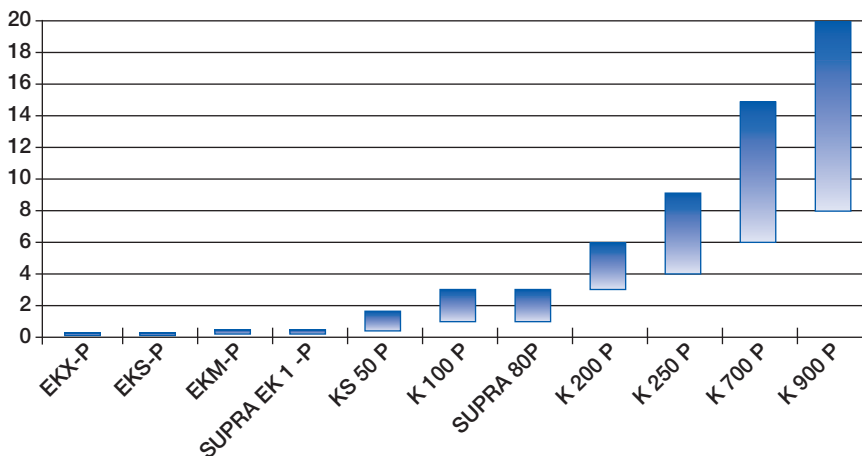


Figure 2

Retention Rating in μm



Filter Media Specifications

Code	Depth Filter Type	Retention Rating in μm	Typical Ash Content in %	Endotoxin Level in EU/mL (Before Rinsing)
PEKX	EKX-P	0.05 – 0.2	62	< 0.06 EU/mL
PEKS	EKS-P	0.1 – 0.3	58	< 0.06 EU/mL
PEKM	EKM-P	0.2 – 0.5	51	< 0.06 EU/mL
PEK1	SUPRA EK 1 P	0.2 – 0.5	47	< 0.06 EU/mL
P050	KS 50 P	0.4 – 0.8	46	< 0.06 EU/mL
P100	K 100 P	1.0 – 3.0	46	< 0.06 EU/mL
P080	SUPRA 80 P	1.0 – 3.0	49	< 0.06 EU/mL
P200	K 200 P	3.0 – 6.0	46	< 0.06 EU/mL
P250	K 250 P	4.0 – 9.0	46	< 0.06 EU/mL
P700	K 700 P	6.0 – 15.0	46	< 0.06 EU/mL
P900	K 900 P	8.0 – 20.0	46	< 0.06 EU/mL

For regulatory and validation information, please refer to the following documents Pall publication USTR 2366 (Pall P-series Depth Filter Media) and USTR 2404 (Pall Supradisc HP Depth Filter Media).

Furthermore the following documents are available:

- ▶ Technical Data Sheet
- ▶ Certificate of Analysis available on request
- ▶ EU Safety Data Sheet

Important Note:- Use of this product in a manner other than in accordance with Pall's current recommendations may lead to injury or loss. Pall cannot accept liability for such injury or loss. Because of developments in technology, these data and/or procedures are subject to continual review and update. Please contact Pall for additional information.



Seitz P-series depth filter sheets are available in a wide range of shapes and sizes.



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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

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