PALL®

Laboratory

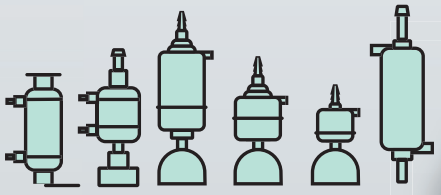
High-performance filtration for media, reagent manufacturing, protein purification, and cell culture. Pall Laboratory offers a complete portfolio of filtration solutions ranging from research grade syringe filters to pharmaceutical GMP manufacturing. Pall is your partner for all your filtration needs.

AcroPak™ Capsule Filters

*Filtration. Separation. Solution.*SM

A Filter for Every Step in Your Process

From drug discovery and basic research to process development and production, Pall Corporation is the single source for all your filtration needs.



Buffer, Media, and Reagent Manufacturing

Primary Applications

- Sterile filtration of media, buffers, or reagents
- Pre-filtration and clarification

AcroPak Advantages

- Increased throughput improves productivity
- High filtration capacity for longer production runs
- Wider range of solution compatibility

Protein Purification

Primary Applications

- Purification of proteins from CHO and HEK cells
- Cell debris and bioburden removal

AcroPak Advantages

- Fast filtration & throughput
- Great cell-and debris-holding capacity
- High recovery of proteins (low protein binding)
- Single-capsule filtration for entire batch

Cell Culture and Bioburden Filtration

Primary Applications

- Sterilization of cell cultures
- Upstream and downstream filtration
- Bioburden removal

AcroPak Advantages

- Fast, efficient sterile filtration of cell culture additives
- Protect cell culture quality
- Multiple pore size options for bioburden removal

Scale up Filtration for Easier Validation, Tech Transfer, and Faster Time-to-Market

Pall Laboratory offers products that use the same membranes and materials that scale up from syringe filters to GMP manufacturing-scale filters. This means scientists can research, develop, and validate their processes with lab-scale filters and then, as volumes increase or processes move to manufacturing scale, the same filters are available in larger sizes with pharmaceutical certificates. This advantage ensures identical filtration performance, chemical and biological compatibilities, and efficiencies as a process scales up in size — shortening redevelopment and accelerating time to market.

UpScale ScaleUp

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Buffer, Reagent, and Media Manufacturing

Sterility is critical in buffer/reagent manufacturing and media preparation to ensure the purity and integrity of the final product. Leachables and extractables must be minimized to prevent contamination.

Filter efficiency: filtration must be performed quickly and have high volume capacity so that no matter the solution, turbidity, or volume only one capsule filter is required. This eliminates waste and process variability from changing capsule filters mid-run.

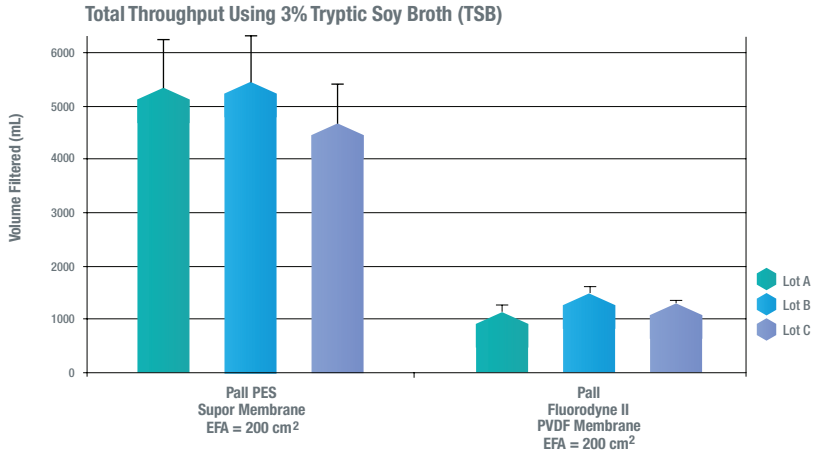
Membrane compatibility: buffers and reagents have different chemical contents with varying pH levels. The capsule's construction, material, and internal membrane must be compatible with a wide range of solutions to eliminate time-consuming change outs for each new application or batch lot.

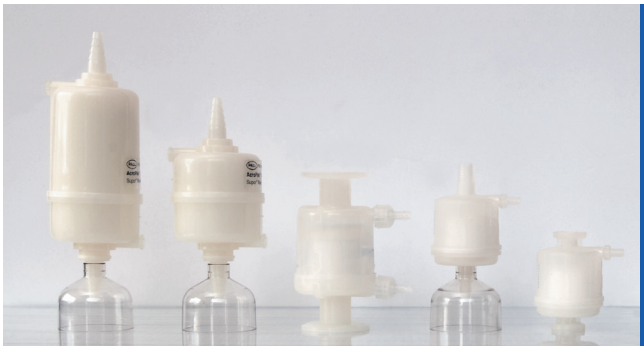
Low-binding: A filter should be inert and not bind endogenous components, such as proteins. Media frequently contains serum or large proteins that must be efficiently filtered. This is particularly critical when low quantities of protein are added to the media.

Filter Performance Varies Widely Among Manufacturers

AcroPak capsule filters are designed for high performance across all buffer, reagent, and media manufacturing applications.

- Consistent pore sizes ensure solution sterility
- Great throughput sterilizes solutions faster, improving productivity
- High-performance membranes allow longer production runs without change outs
- Low-binding filtration minimizes capture of proteins from solutions





Why AcroPak capsules?

With 70 years of membrane development expertise, Pall's proprietary filtration technology achieves outstanding performance for high throughput, superior capacity, and great membrane compatibility. Consistent pore size ensures sterility. Plus, our products feature low leachables and extractables and low protein binding.

PALL® Laboratory

Protein Purification

Filter efficiency: filtration must be performed quickly and have high volume capacity so that no matter the solution, turbidity, or volume; only one capsule filter is required. This eliminates protein recovery loss and process variability from changing capsule filters mid-run.

AcroPak capsule filters maintain their effectiveness with high-density cell cultures

The ability to filter an entire cell culture broth through a single capsule, no matter the turbidity level, is important to avoid the risk of product loss that results from filter change outs and process delays.

Filtering a wide range of cell culture densities and viabilities through one capsule is essential to ensure a standardized, efficient purification process.

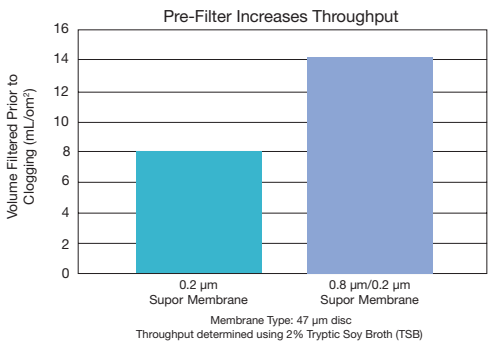
Low protein binding membrane is critical to ensure high protein recovery.

Pall Laboratory's AcroPak capsules with dual-layer membranes allow quick, efficient filtering of a wide range of cell densities and viabilities. These products have built-in pre-filters that remove cell debris and bioburden first, ensuring the final filtration layer will not clog prematurely.

AcroPak capsules withstand the challenges of variable, high cell density protein purification.

- Built-in pre-filters enable low viability, high-turbidity solution filtration through one capsule
- High recovery of proteins from CHO and HEK cells (lowest protein binding)
- Fast flow and throughput improve lab productivity
- **Optional Supracap™ depth filter capsule can be added inline to eliminate the need for upstream centrifugation**

Researchers want more proteins, which come from higher cell densities. But this can lead to lower viability that can prematurely clog the filter and stop the entire process. Pall Laboratory Acropak capsules are designed to handle highly turbid cell cultures.



Cell Culture Sterile Filtration and Bioburden Reduction

Sterility is the primary objective for cell culture filtration. The media (serum, PBS, water, etc.) that comes into contact with the broth must be sterile to avoid contaminating the cell solution. A 0.2 µm sterile filter can eliminate biological contamination, environmental contamination, or foreign matter due to contaminated upstream products or improper user handling. AcroPak capsule's high performance filtration is ideal to ensure your cell culture sterility.

- Cell culture sterility is assured by filtering media and additives, eliminating the risk of contamination
- Culture quality is protected
- Filter sizes available from syringe to capsules for in-hood or bench-top processing

Bioburden Reduction

AcroPak capsule filters are also available with larger membrane pore sizes to provide fast, efficient, bioburden reduction for upstream filtration processes.

Mycoplasma Reduction

AcroPak capsules are available with 0.1 µm membrane for mycoplasma retention.

AcroPak Capsule Quality*

AcroPak filters come with rigorous quality claims and are tested to ensure they meet high performance standards:

- 100% integrity tested (where noted)
- Endotoxin level: <0.25 EU/mL using Limulus Amebocyte Lysate test
- Bacterial retention: 0.2 µm lot samples retain 10^7 cfu/cm^2 of *B. diminuta* per modified ASTM F838
- Mycoplasma reduction: 0.1 µm lot samples retain 10^7 cfu/cm^2 *A. Laidlawii per modified ASTM F838*
- Biological safety: passes United States Pharmacopeia (USP) biological reactivity test in vivo <88>
- Sterilization (where noted): by gamma irradiation

*Refer to product data sheets for specific tests and claims on individual products.

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AcroPak Products

Filtration Membranes

Pall Laboratory filters incorporate high-performance, proprietary membrane technology.

- **Supor PES (Polyethersulfone):**
  With high flow and capacity, broad fluid compatibility, low protein adsorption, active ingredients, and stabilizers, Pall PES membranes are best suited for filtration of preparative fluids such as buffers, media, and bioprocess intermediates.

- **Supor EKV Asymmetric PES:**
  PES filters with asymmetric membrane layers have the same benefits of Supor PES (above), but with additional debris holding. This makes them ideal for high turbidity, high bioburden solutions.

- **Fluorodyne II PVDF (hydrophilic polyvinylidene fluoride)**
  Low extractables, low product and excipient adsorption, simple validation for the sterilization of a wide range of formulations make PVDF membranes ideal for final filtration

Pre-Filtration Capsules

Whether solutions include high solid loads, particles, or whole cells (millions/mL), Pall Laboratory offers a complete line of pre-filter capsules that allow efficient filtration of the most difficult and dirty solutions:

- **Supracap depth filters:**
  0.4 to 30 µm, Seitz® depth media

- **Mini-Profile capsules:**
  0.5 to 5 µm, polypropylene

Capsule pore size and EFA* sizes

- **AcroPak with Supor**
  - 0.8/0.2, 0.8/0.45, 0.2/0.2 and 0.1/0.1 µm
  - 20, 200, 500, 1000 and 1500 EFA

- **AcroPak with Supor EKV**

UpScale ScaleUp

  - Asymmetric 0.65/0.2 µm
  - 20, 200, 400, 800 and 1500 EFA

- **AcroPak with Fluorodyne II**

UpScale ScaleUp

  - 0.1 and 0.2 µm
  - 20, 200, 400 and 800 EFA

*EFA- effective filtration area

For example, AcroPak capsules with Supor membrane have a 0.8 µm pre-filter and 0.2 µm sterile membrane, and the AcroPak capsules with Supor EKV has an asymmetric 0.65 µm pre-filter with a 0.2 µm sterile membrane.

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Filtration. Separation. Solution.SM

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