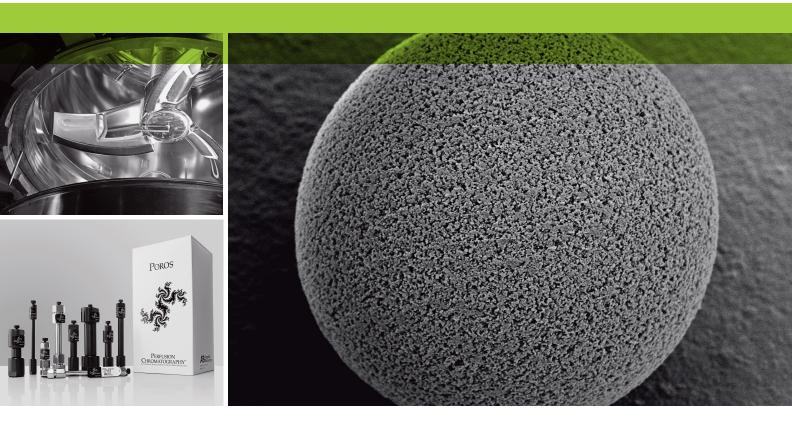


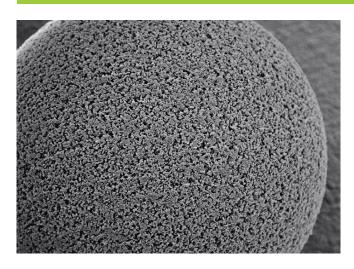
POROS[®] Perfusion Chromatography[®] Media

Accelerate your process to a new speed



High performance on a large scale

Applied Biosystems POROS[®] Perfusion Chromatography[®] products are today's best-performing chromatographic media for process-scale bioseparations. These rigid, robust particles enable high-resolution separations with 2–3x the throughput of conventional fast-flow gels. They are easier to handle and pack and offer outstanding cleanability.





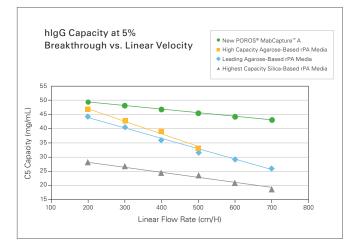
To maintain the highest standards of quality and consistency, POROS® 50 micron Perfusion Chromatography® products are manufactured under rigorous quality systems in Applied Biosystems' 30,000 sq ft state-of-the-art chemical manufacturing facility. POROS® media is available in a range of selectivities designed especially for today's recombinant protein and other biological purification challenges. A broad range of pre-packed POROS® columns for both process analysis and lab-scale purifications are also available and incorporated into biotherapeutic research, process development, and quality control environments. The number of customers using POROS[®] media for the production of FDA-approved biotherapeutic products is growing.

Applied Biosystems is a global technology leader in the pharmaceutical and biotechnology industries and has been a driving force in life science research since 1981. POROS[®] media was introduced in 1990 and has been manufactured at a large scale since 1995.

High capacity, speed, and resolution enable improved process productivity

Perfusion enables performance

At the heart of POROS[®] Perfusion Chromatography[®] media is the novel porous structure of the particles. In contrast with conventional chromatography media particles, which are characterized by small diffusive pores, POROS[®] particles are characterized by the addition of large "throughpores". These large throughpores allow a small percentage of convective flow through the particles, quickly carrying biomolecules to the smaller diffusive pores on the surface. Reducing the distance over which diffusion to the particle-binding surface occurs also reduces the time required for sample molecules to interact with the binding sites. Consequently, diffusion is no longer limiting, and flow rates can be dramatically increased—without compromising capacity or resolution.



High dynamic binding capacity

Figure 1. POROS[®] media provide high dynamic binding capacities and excellent capture efficiencies at high linear velocities. That translates into smaller column volume, reduced buffer consumption, and decreased process time—which add up to higher process throughput.

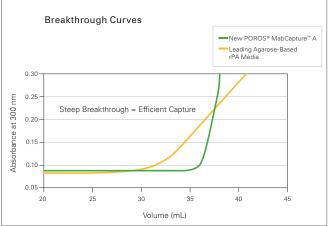
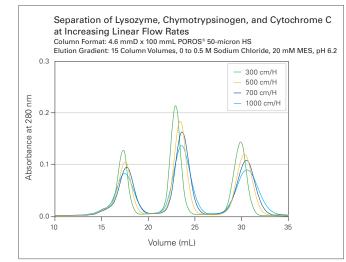
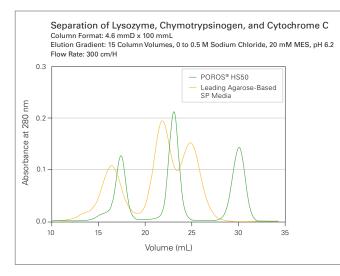


Figure 2. Effective capture efficiency of the POROS[®] media is demonstrated by the sharp protein breakthrough curve at 5% and 10% breakthrough. Soft gel sorbents tend to show protein breakthrough much earlier in the load.



Speed without sacrifice



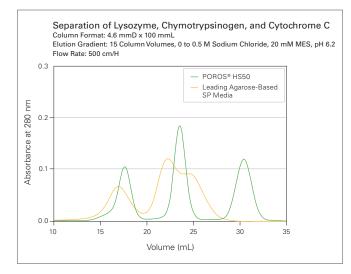


High resolution

The 50 micron particle size of POROS[®] media offers an excellent balance of resolution and operating backpressure. As with capacity, the resolution is minimally affected by increases in linear velocity, allowing the separation steps to be carried out at higher speeds than with most soft gel sorbents.

Robust chemical stability

POROS[®] particles are rigid polymeric beads that are coated with a proprietary hydrophilic polymer onto which the various functional groups (ion exchange, affinity, etc.) are covalently attached. The result is a highly robust, chemically stable product that is ideally suited for large-scale biopharmaceutical applications.



Figures 3–5. Resolving power of POROS[®] 50 micron HS versus conventional soft gel media.







Figure 6. Rigorous cleaning does not impact product recovery and provides excellent re-use performance.



Intraparticle convection unlocks the performance required for today's chromatographic separations.

The stability of POROS[®] 50 micron polymeric beads and surface chemistries allows for aggressive cleaning and sanitization with all of the common agents used in biopharmaceutical processes, including strong acids, bases, chaotropic salts, and organic solvents.

Easy packing and handling

The rigid structure of POROS® particles resists shrinking and swelling due to changing mobile phase conditions. Columns can be packed quickly and easily without specific ionic or pH conditions or settling steps that are required for most chromatography products. With POROS® media, there is no need to add 15–25% more media to a column to make up for bed compression, as is the case with most conventional soft gel media.

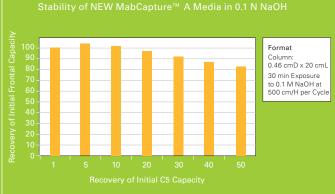


Figure 7. Even after cleaning for multiple cycles with 0.1 N NaOH, MabCapture™ A media shows maintenance of binding capacity for human immunoglobulin G.



Figure 8. Backpressures associated with columns of typical length packed with POROS[®] 50 micron media under standard conditions. Higher flow rates can be achieved while staying under the 3 bar limit of most process skid and column systems.

Quality you can count on-from start to finish



State-of-the-Art

In 2003, we moved into our newly constructed and validated state-of-the-art media manufacturing facility in Bedford, Massachusetts. The 30,000 sq ft plant is dedicated to the production of POROS® Perfusion Chromatography® media. All of Applied Biosystems, including the Bedford facility, is ISO 9001-2000 certified and our manufacturing plant is audited regularly by POROS® customers.



Complete Control

Unlike manufacturers who purchase their base sorbent and then add the chemistry, Applied Biosystems produces POROS® media from start to finish. This gives us complete traceability and control over the entire process. Also, because we control the entire manufacturing process, our customers are protected from supply shortages and disruptions.



Ready-to-Use

The base material is polymerized, coated, and chemically modified in a closed system. POROS® media are then polished, sized, and exchanged into shipping solvent prior to packaging. The finished product is free of fines and does not require pre-treatment (or de-fining) prior to use.

HIGH-PERFORMANCE PRODUCTS FOR PROCESS APPLICATIONS

POROS[®] MabCapture[™] A: Increase throughput without increasing the size of your process column. The highest performance Protein A affinity media for large-scale purification of monoclonal antibodies from cell culture, POROS[®] MabCapture[™] A offers unmatched capacity vs. flow rate performance with the physical and chemical stability of a rigid polymeric support.

POROS® 50 micron HS: A strong cation exchange media based on a sulfopropyl functionality, POROS® 50 micron HS is designed for the purification of more basic proteins and biomolecules. It is especially well-suited for the separation of process impurities and aggregates and is an excellent choice for both capture and polishing applications.

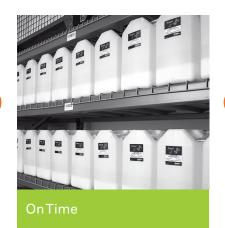
POROS[®] 50 micron HQ: A strong anion exchange media, POROS[®] 50 micron HQ uses a unique quaternized polyethyleneimine functional group to separate molecules with selectivity unlike any other commercially available strong anion exchange products.

POROS[®] 50 micron PI: A weak anion exchange media, POROS[®] 50 micron PI utilizes the same polyethyleneimine functional group as POROS[®] 50 micron HQ, but with a unique selectivity that allows elution via pH change or increasing ionic strength. The large pore structure of this 50 micron product makes it ideal for purification of large biomolecules, such as plasmids and viral particles.



Consistent

Quality and release testing is performed at all stages of the POROS® manufacturing process to ensure a final product that consistently meets all release specifications. The battery of tests performed on every batch of POROS® media includes: frontal capacity, protein separations, FTIR, process fines, ionic capacity, bioburden, endotoxin, and leaching.



Batch sizes of our 50 micron products are between 100–260 L with the capability of pooling approved batches to generate a single batch of 400 L. Products are available in 50 mL, 250 mL, 1 L, 5 L, and 10 L volumes and are typically in stock for immediate delivery. Although significant safety stocks are maintained, lead times for large, made-to-order quantities are generally 6–12 weeks. Source of the second se

Quality and Support

Quality control and assurance are critical aspects of our product support. All 50 micron POROS® products are backed by full regulatory support information and Drug Master Files. POROS® media is used in the manufacture of numerous FDA-approved biotherapeutics and many products in various stages of clinical production.

POROS[®] 50 micron D: Another weak anion exchanger based on a polyhydroxylated polymer functionalized with dimethyl amino alkyl groups, POROS[®] 50 micron D is similar to DEAE. If DEAE is a standard step in your process, then POROS[®] D is a great way to take your resolution and throughput to the next level.

POROS® 50 micron Heparin: A popular affinity ligand media for the purification of serum growth factors, coagulation factors, and lipoproteins, POROS® 50 micron Heparin can be operated at much higher flow rates than conventional soft gel supports.

POROS[®] 50 micron MC: A metal affinity ligand based on a imidodiacetate group, POROS[®] 50 micron MC uses metal chelate chromatography to purify histidine-rich proteins and histidine-tagged proteins from complex feed streams. With POROS[®] 50 micron MC, you can easily scale up metal chelate chromatography from laboratory scale to highthroughput processing.

POROS[®] 50 micron R1 and R2 Reverse Phase: These products offer fast, high-resolution separation of proteins at process scale. The large pore structure and lower phase ratio of these two products allows recovery of intact proteins or large biomolecules such as plasmids or viral vectors to provide high-resolution, reversed-phase separations without loss of material and with rapid linear velocities.

Established expertise. Ongoing commitment. Continued innovation.

When you purchase POROS[®] Perfusion Chromatography® media from Applied Biosystems, you're assured of the highest quality, in the quantities you need, when and where you need it. You're also assured of professional service and support from one of the most respected companies in the industry. POROS[®] products are backed by one of the world's most extensive service and support networks.

At Applied Biosystems, we recognize that the most important part of our commitment to process chromatography is our commitment to you, our customer. We take great pride in offering each and every POROS® customer personalized support from knowledgable professionals who are trained and dedicated to make sure your media and separation needs are met. We are committed to continued innovation, striving to provide improved, cutting-edge tools to the biotherapeutic research, development, and manufacturing markets.

To learn more about POROS[®] Perfusion Chromatography[®] media, please visit www.appliedbiosystems.com.

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Headquarters

850 Lincoln Centre Drive | Foster City, CA 94404 USA Phone 650.638.5800 | Toll Free 800.345.5224 www.appliedbiosystems.com

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