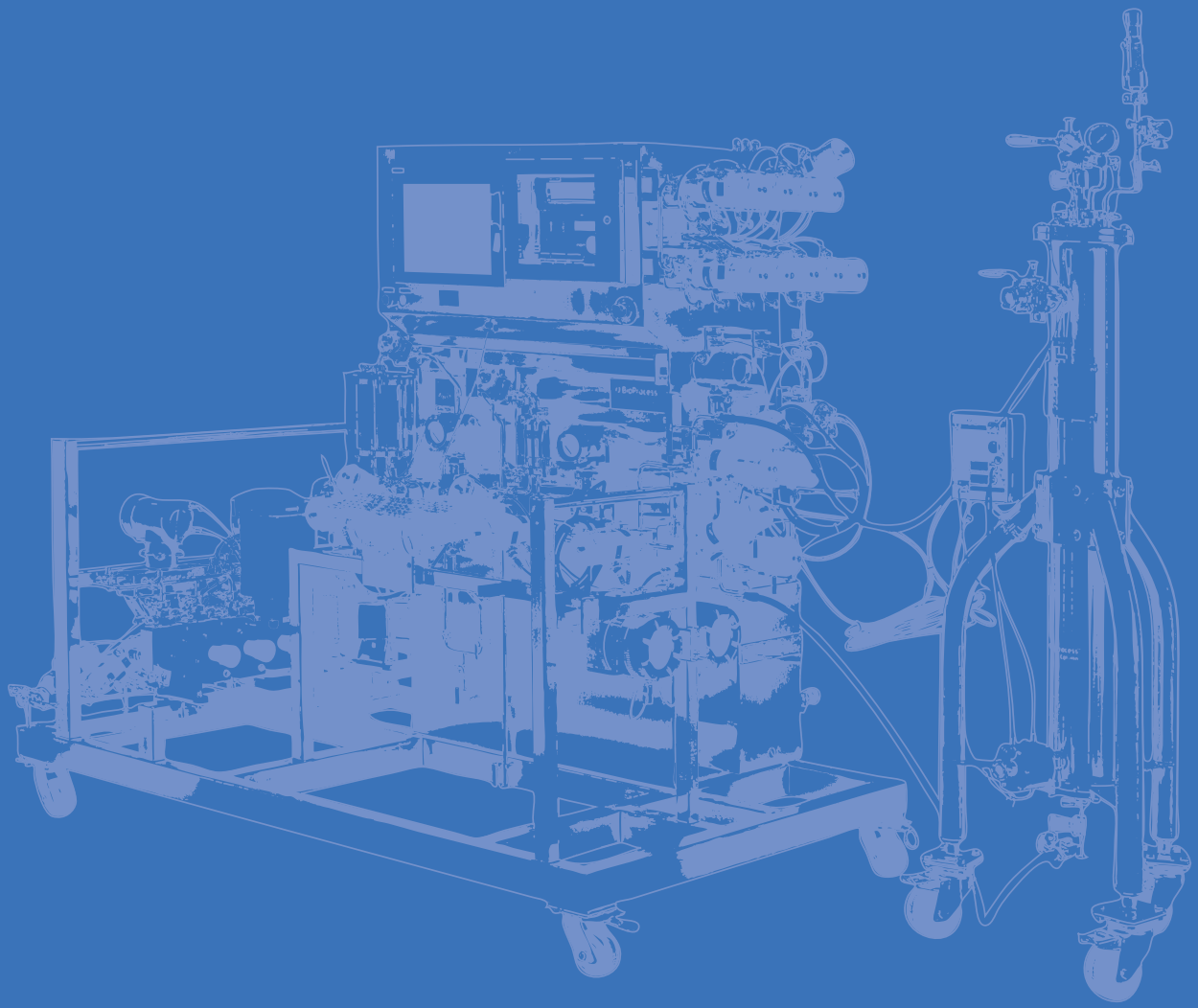
GE Healthcare

BioProcess

Product Guide 2007



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Transforming ideas into innovative drug candidates, optimizing processes, and manufacturing biotech drugs all require multidisciplinary teams. Their challenges are to take candidates and methods quickly and reliably from explorative discovery environments, through testing and clinical trials, and into highly regulated biopharmaceutical production environments. In today's competitive market, the pressure is on improving efficiency and productivity, as well as ensuring process robustness and economy. GE Healthcare continues to develop products and services to support your needs from imagination to biopharmaceutical.

Contents

Fast development and efficient production

Taking biopharmaceuticals from research to market involves transfer from the lab bench, through first-in-human trials, to widespread use by patients. Great care is needed to ensure high quality, while not jeopardizing efficacy or process economy. Meanwhile, the clock is running - production schemes need to be finalized as quickly as possible to ensure maximal returns. To help you meet these challenges, GE Healthcare has developed a range of products, platforms technologies, and services designed to assist you with efficient and robust production.

Reducing time to clinic

Optimizing your production processes offers competitive advantages and is essential to both drug discovery and production. However, discovery labs and pilot plants impose very different challenges on these production processes. The challenges are to take methods from an explorative discovery environment, manage them through testing and clinical trials, and then optimize them to meet the stringent demands of a highly regulated production environment. All the time the pressure is on to secure drug safety and ensure processing robustness and economy. Our aim is to help teams plan, experiment and optimize, manage regulatory requirements, and make smoother transitions into clinical trials and manufacture. This helps bring drug candidates to market in a faster, simpler, more reliable and cost-effective manner.

Meeting today's productivity needs

The initial choice of bioprocessing steps has the greatest impact on how efficiently you manage the fermentation, capture, purification and polishing stages. We offer a broad range of products and platform technologies to address specific process development and manufacturing challenges by offering optimum cell growth media, chromatography media selectivities, sample loadings, membrane cut-offs, and flow rates. Our tools and solutions allow us to provide an integrated approach to processing combining microcarriers, chromatography and filtration techniques.

An example of how GE Healthcare supports more effective and efficient processes are the recently introduced Capto and MabSelect media. These media are designed to meet the high-volume-throughput productivity requirements for high-titer feedstreams and offer high binding capacity for capture of target

molecule. Our latest medium, Capto adhere, offers selective removal of contaminants such as DNA, host cell proteins, leached protein A, aggregates, and viruses. Together with MabSelect SuRe, Capto adhere enables the design of a two-step Mab purification process. Our hardware platforms include lab- and pilot-scale chromatography and filtration systems. Controlled by UNICORN software, these systems allow for true integration of steps with rapid method transfer, and scale-up/scale-down, enabling process developers to get results quickly and simply.

We aspire to be a trusted, knowledgeable supplier and offer an array of specialized services and support for process development, validation, security of supply, and compliance. Our Fast Trak team provides education courses, process development assistance, and validation services. In addition, we offer customized safety stock for media, membranes, and spare parts, as well as service agreements to ensure trouble-free operation. To secure GMP compliance, RSFs (Regulatory Support Files) are available for all BioProcess media, and similar documentation is available for process hardware.

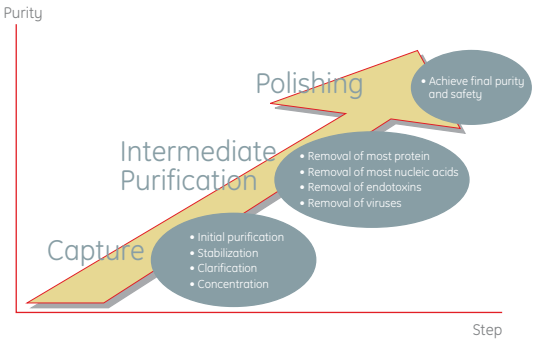
Secure supply

Over the past decades GE Healthcare has supported the rapid growth in biopharmaceutical production - we currently deliver approximately 500 000 laboratory and pilot-scale columns per year, and over the years we have supplied more than 4 250 000 liters/kgs of chromatographic media, more than 12 000 process-scale columns, 2000 BioProcess systems, 200 000 membrane devices, and 1000 filtration skids. We have recently increased our production capacity and services to match demands. We believe security-of-supply is about quality as well as timely delivery of the right quantity, thus we have validated production processes and manufacture according to ISO 9001. Over the past five years we have invested over US$100 million in business continuity systems, processes, training, and equipment. We have worked with a combination of market-leading safety and business continuity consulting firms. Customers and regulatory authorities also closely scrutinize our production routines through on-site audits, on average once a week – an important catalyst in our continuous improvement program. These audits embrace our risk management strategies, R&D capabilities, management, financial strength, and production facility standards as well as distribution and service networks.

We endeavor to be your best supplier. Our greatest motivation is your success.

Integrated downstream purification

We believe that integrated chromatography and filtration platforms can best achieve recovery of the desired product at the required purity, with safety and reliability, with the additional benefit of faster process development. Platform strategies are also the key to driving low-cost production because they help identify significant efficiencies in the production process.



In process development, consideration is given to which stage in the process – Capture, Intermediate Polishing, or Polishing – a particular separation problem should be solved. These steps have to be integrated to create a reliable, economical, and safe process.

Capture

Goals	Techniques	Characteristics	Product ranges
• Initial purification of the target molecule from either crude or clarified feed. Clarification, concentration, stabilization and significant purification from soluble contaminants. The feedstock may contain destructive proteases.	• Filtration • Batch processing • Ion exchange chromatography • Affinity chromatography • Hydrophobic interaction chromatography	• High throughput and capacity to allow rapid processing of crude and/or very viscous feedstock.	• Capto • MabSelect • Sepharose Big Beads • Sepharose Fast Flow/XL • Sephadex ion exchangers • CDM • UNICORN • ProCell, MaxCell • Kvick cassettes • UniFlux • ÄKTAdesign systems • MacroCap • ULTA

Intermediate purification

• Purification steps performed on clarified feed which result in removal of most of the significant impurities including host cell proteins, DNA, viruses and endotoxins.	• Ion exchange chromatography • Hydrophobic interaction • Affinity chromatography • Gel filtration	• Selectivity and capacity are needed at this stage. • Media longevity and ease of handling can be decisive factors.	• Capto • Sepharose Fast Flow/XL • Sepharose High Performance • SOURCE 30 • Sephadex ion exchangers • Sephacryl High Resolution • Sephadex G-25 • UNICORN • ProCell • ÄKTAdesign systems • PlasmidSelect Xtra • ULTA

Polishing

• Final removal of trace contaminants and impurities leaving an active, safe product in a form suitable for formulation or packaging. Contaminants at this stage are often "conformers" of the target molecule, trace amounts of impurities or suspected leakage products.	• Gel filtration • Reversed phase chromatography • Hydrophobic interaction chromatography • Ion exchange chromatography	• Very high resolution combined with high recovery and low leakage.	• Superdex prep grade • Sephacryl High Resolution • Sepharose High Performance • SOURCE • Sephadex G-types • UNICORN • UniFlux • Kvick cassettes • ÄKTAdesign systems

This table defines the terminology we have chosen for the progressive filtration and chromatographic stages in a purification process. Each of these stages has its own specific problems and goals. GE Healthcare has designed products for every stage.

Our aim is to help you plan and perform purification, and make smoother transitions into clinical trials and manufacture. GE Healthcare continues to develop products and services to help bring your drug candidates to market faster.

Product highlights

MabSelect media
Capto media
Chromatography media toolbox
PlasmidSelect Xtra
Butyl Sepharose High Performance
Security of supply
ÄKTAprocess system
ÄKTAcrossflow system
Normal flow filtration
CBS DeltaV standard control solution
Fast Trak e-SYS1 online training
Online support
System and column support
BioProcess Tour
Cell preparation and processing

MabSelect media

The clinical success of monoclonal antibodies is one of the most exciting achievements in our industry, resulting in annual production requirements of several tons – joining insulin and plasma proteins in sheer scale of bulk production. To meet this demand, cell culture capacity is increasing with reactors of 12 000 to 15 000 liters and larger coming on-line. Expression levels, currently in the 0.1 to 1.0 g/l range, are expected to increase several-fold. In downstream processing, efforts are directed at improving process economics by decreasing the number and cost of unit operations. Current trends in antibody production indicate an increased use of MabSelect and Protein A chromatography media for product capture.

MabSelect is a modern range of chromatography media for purification of monoclonal antibodies at large production scale. All MabSelect media feature:

- A base matrix of high-flow agarose.
- High chemical stability: compatible with all aqueous buffers commonly used in Protein A chromatography.
- Regulatory Support File availability.
- Simple scale-up to production-sized columns.
- Large-scale quantities available on request.

Like all our BioProcess media, MabSelect media meet every requirement for process design and scale-up. Prepacked columns and bulk quantities are available. For large-scale packing, we recommend Chromaflow, BioProcess, or BPG columns.

The MabSelect family consists of:

MabSelect

For high purity and throughput at production scale

- Prioritized volume throughput.
- Optimized matrix and ligand coupling.
- The antibody purification standard.
- Available in 1-ml and 5-ml HiTrap columns for convenient start-up.

MabSelect SuRe

Withstands rigorous and cost-effective CIP protocols, (e.g., 0.1 to 0.5 M NaOH)

- Alkali-stabilized rProtein A ligand.
- Generic and economic CIP/ sanitization.
- Product safety and process robustness.
- Low-leakage media.
- Available in 1-ml and 5-ml HiTrap columns for convenient start-up.

MabSelect Xtra

For capturing high-titer antibody feedstocks and reducing processing costs

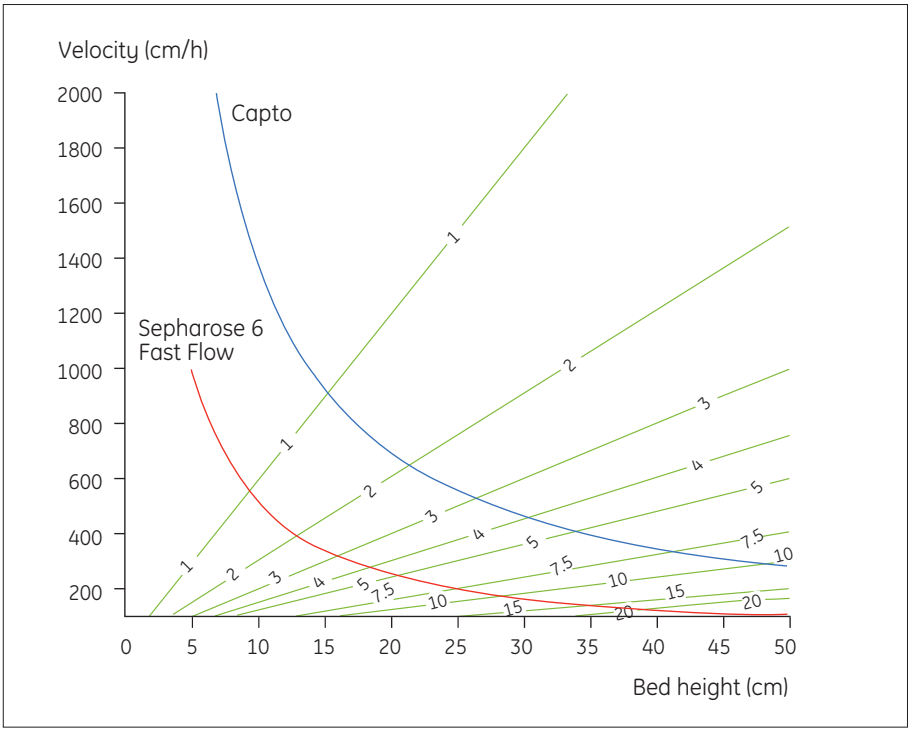
- Outstanding dynamic binding capacity.
- Improved process economics and reduced raw material costs.
- High-purity capture due to minimal non-specific binding.
- Available in 1-ml and 5-ml HiTrap columns for convenient start-up.

For further information, see page 39.

Capto media

Capto is a new BioProcess media product line specifically designed to meet the growing need in the biopharmaceutical market to process large feed volumes in a fast, efficient, and cost-effective way. The base matrix is a highly rigid agarose that allows for a broader working range of flow velocities, bed heights, and sample viscosities at large scale. High flow velocities increase volume throughput and reduce process time. Longer bed heights eliminate the need for large equipment and keep footprints small. High-flow processing of viscous samples means less dilution and shorter cycle times. In addition, the chemical stability of agarose assures long media lifetime even if harsh cleaning-in-place procedures are applied.

Capto media combine high capacity with high flow rates and low back pressures. To assure the suitability of Capto products for large-scale operations, pressure/flow properties are studied and defined at large scale (1 m inner diameter) where there is no wall support present.



Capto media offer a wide range of operating conditions. This figure shows the predicted working range (the area under and to the left of the curved lines) for Capto (blue) and Sepharose 6 Fast Flow (red) in combinations of bed heights and flow velocities in a 1-m diameter column. The green lines show residence time in the column in minutes.

New

Capto adhere is a strong multimodal anion exchanger for intermediate purification and polishing of monoclonal antibodies after capture on Protein A media (i.e., the MabSelect range) by packed bed chromatography.

Capto adhere selectively removes key contaminants such as leached Protein A, aggregates, host cell proteins, nucleic acids, and viruses.

The following Capto products are available:

Capto Q and S

- Capto Q, a strong anion exchanger for capture and intermediate purification.
- Capto S, a strong cation exchanger for capture and intermediate purification.
- Available in 1-ml and 5-ml HiTrap columns for convenient start-up.

Capto MMC

- Capto MMC, a multimodal weak cation exchanger that enables binding of proteins at the conductivity of most standard feed materials.
- Available in 1-ml and 5-ml HiTrap columns for convenient start-up.

Capto adhere

- Capto adhere, a strong multimodal anion exchanger for post-Protein A purification of monoclonal antibodies.
- Available in 1-ml and 5-ml HiTrap columns for convenient start-up.

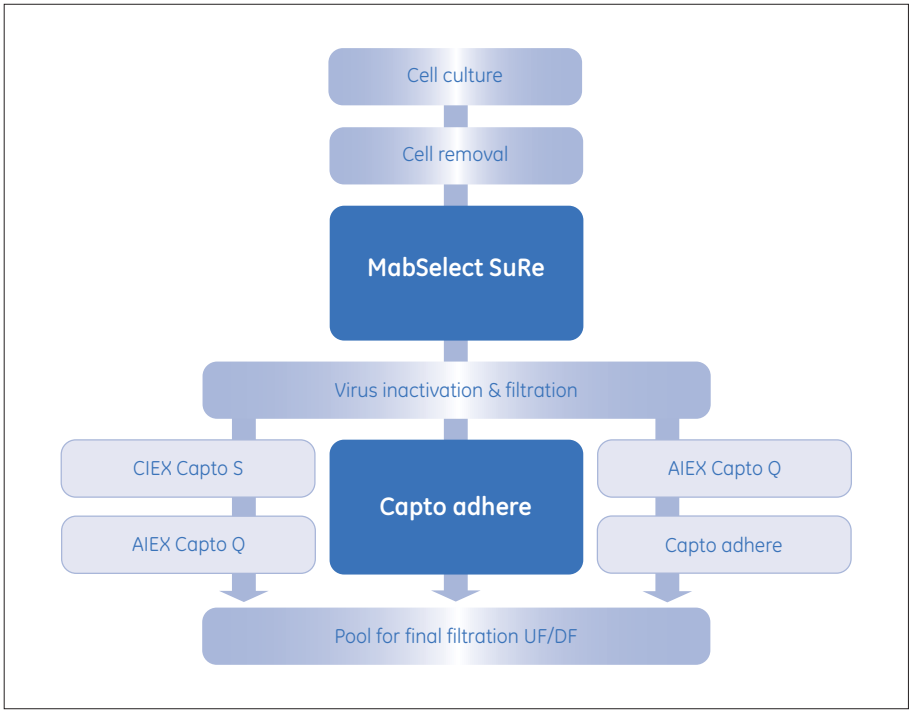
For further information, see page 36.

Chromatography media toolbox for MAb purification platforms

Large-scale purification of MAbs normally consists of three chromatographic steps:

1. Initial capture using Protein A affinity chromatography to give a product of high purity, typically 99%.
2. Initial polishing involving either cationic or anionic exchange chromatography.
3. Final polishing with cationic or anionic exchange chromatography.

The GE Healthcare chromatography media toolbox for MAb purification simplifies this process.



The GE Healthcare chromatography media toolbox.

MabSelect SuRe, characterized by alkaline stability, enhanced protease resistance, and a generic elution profile, is used for the initial Protein A capture step.

The new medium of choice for polishing is Capto adhere. Capto adhere is a strong, multimodal anion exchanger that offers a different selectivity relative to traditional ion exchangers. Capto adhere selectively removes leaked Protein A, aggregates, host cell proteins, nucleic acids, and viruses when run in flow-through mode.

With Capto adhere, the two post-Protein A steps can be replaced by a single polishing step, thereby reducing the overall MAb purification process from three steps to two. If needed, Capto adhere can also be used in combination with Capto Q in a three-step process. An alternative intermediate step is cation exchange chromatography using Capto S.

For further information, see page 36.

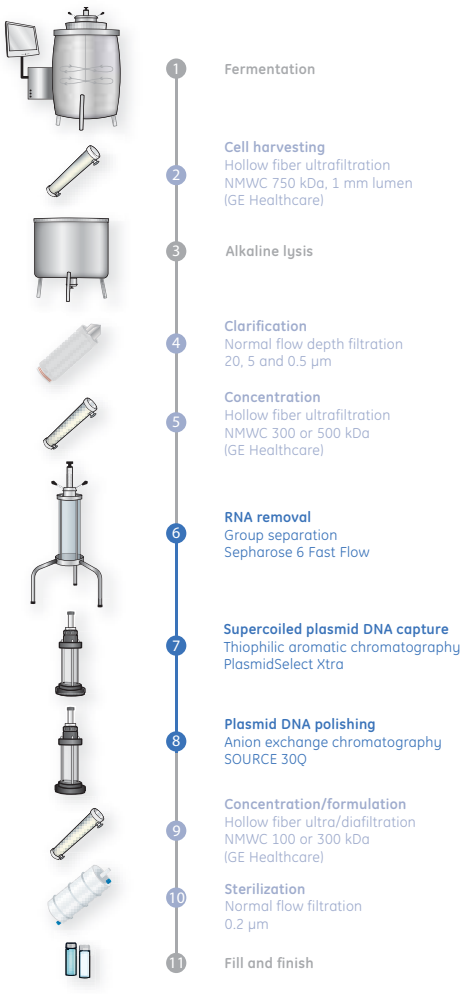
PlasmidSelect Xtra
New

PlasmidSelect Xtra Screening Kit
PlasmidSelect Xtra Starter Kit

The vaccine industry has seen a recent revival as novel development approaches offer hope in the prevention of diseases, protection against pandemics, and defense against terrorist threats. The genuine urgency of many applications demands a standardized approach.

PlasmidSelect Xtra chromatography medium forms the basis of a generic process for purifying supercoiled (sc), covalently-closed circular plasmid DNA suitable for bulk to clinical grade applications.

The process is scalable, robust, and economic and will help meet emerging market needs for DNA vaccine and gene therapy products. Two special kits are also available to rapidly analyze the quantity and quality of plasmid DNA in complex solutions and for convenient process development.



PlasmidSelect Xtra platform:

- Generic process consistent from research to cGMP manufacturing.
- BioProcess Media: Designed, manufactured, and supported for large-scale production.
- Starter kit: Prepacked columns for convenient process development.
- Screening kit: Quick and easy analysis with an ÄKTAdesign system.

For further information, see page 45.

Butyl Sepharose High Performance
New

The GE Healthcare range of media for hydrophobic interaction chromatography is to be expanded by the introduction of the BioProcess medium Butyl Sepharose High Performance.

The medium will now be available as a 1-ml prepacked HiTrap column as well as in the HiTrap HIC Selection Kit, which will now comprise seven different HIC media for ligand screening and small-scale method development. It will also be joined by 1 and 5-liter packs.

For further information, see page 43.

Security of supply

Securing the supply of chromatography media is essential to successful biopharmaceutical development and manufacture. As protein-based drugs and/or vaccines progress further along their route-to-market, manufacturers need to be confident that they can produce enough material, on time, for clinical trials and product launches.

Security of supply means being certain that you will receive the right quantity of media, manufactured to specified quality levels, and delivered at the right time. Given today's competitive marketplace, there really is no room for unnecessary risks.

With an annual media production of 450 000 liters/kilograms, GE Healthcare has the media production capacity to meet your needs.

Safety stock of chromatography media

Media safety stock agreements offer assurance of a smooth, continuous supply of chromatography media. A customized media safety stock agreement guarantees:

- Assured media supply chain efficiency.
- Maintained optimum stock levels of media.
- Minimized downtime and product loss due to an incident occurring during development, campaign production, or regular production.
- Minimized cash layout (transfer cost from balance sheet to profit and loss account).
- Simplified management of consumption fluctuations of production material during therapeutic and clinical trials.
- Help in meeting security and safety demands of regulatory agencies and insurance companies.

GE Healthcare maintains full responsibility for effective media stocking, rotation, and rapid supply during any emergency situations. You choose:

- Stock situation.
- Media products and quantities.
- Maximum shelf life.
- Storage period.
- Commencement date.

For further information, see page 147.

ÄKTAprocess system

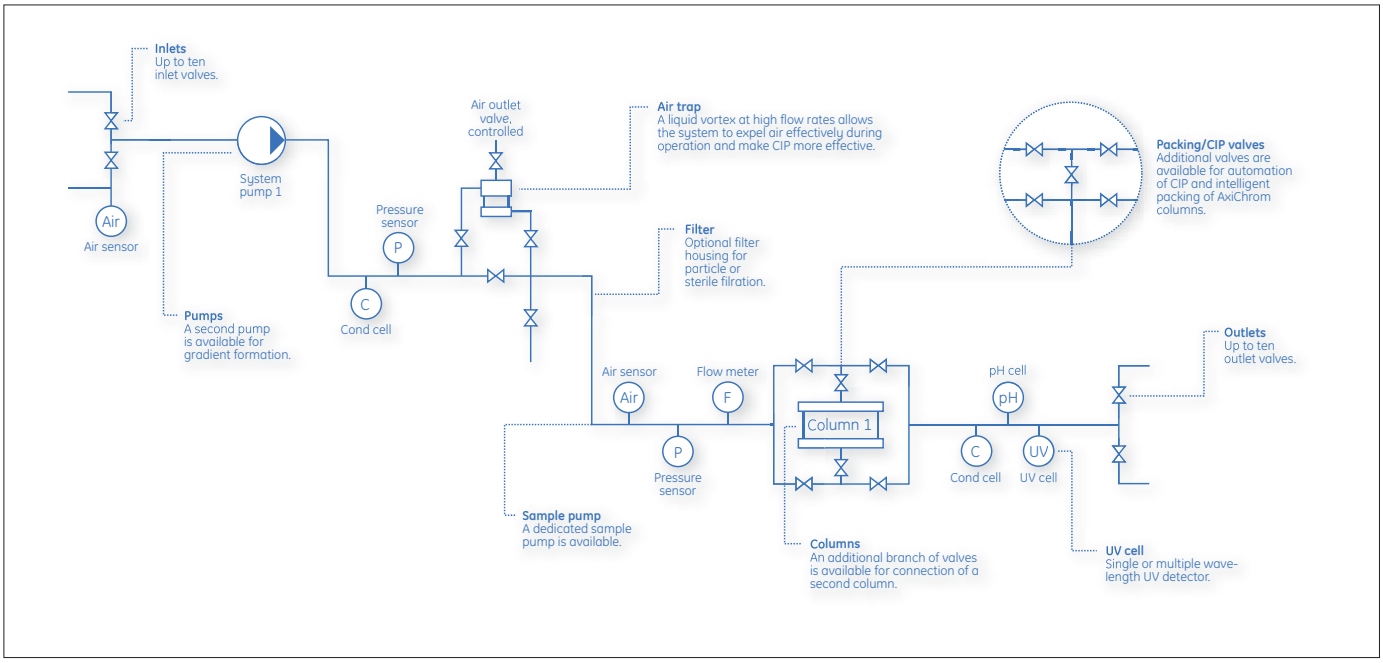
ÄKTAprocess is a new chromatography system platform with thousands of configuration possibilities. To meet specific process demands, the system is customizable with variable construction materials, flow rate ranges, additional valves, pumps, and other instrumentation. The flexibility of the system extends to post-purchase modification, which allows a system to be reassigned to other processes, thereby increasing the versatility and working life of the system. The compact design with a built-in computer allows the system to fit neatly into an existing plant.

Security is an integral part of ÄKTAprocess. The materials used are all USP Class VI and are traceable to their original production batches. The system control unit, CU 960, allows process operation even if communication with the system computer is lost due to physical or operating system faults.

System highlights include:

- Versatile user-configuration with UNICORN control.
- Post-purchase configuration increasing usability and lifespan.
- Full regulatory documentation with USP Class VI materials.
- Now available with one-inch tubing.

For further information, see page 82.



The liquid flow path.

ÄKTAcrossflow system

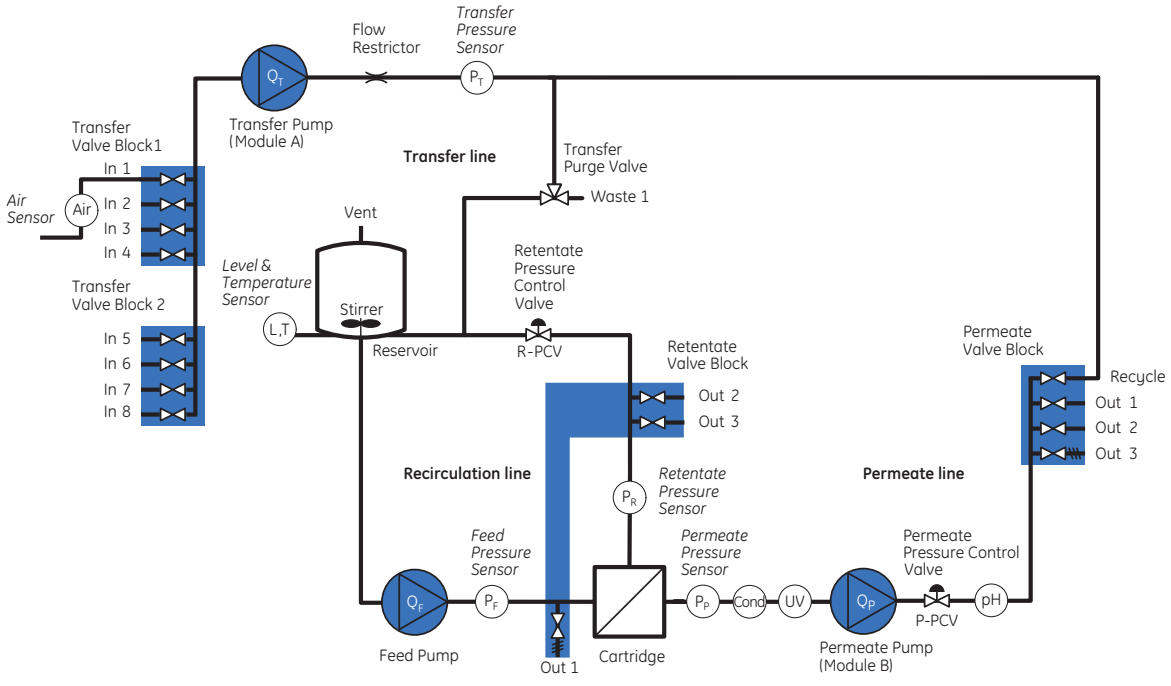
ÄKTAcrossflow is the first fully automated system for cross flow filtration process development and is well-suited for filter screening and process optimization at small-scale. UNICORN software combines intelligent control with ease of use to allow consistent simulation of large-scale conditions and provide data for comprehensive analysis of results.

The system is built with ÄKTAdesign components for reliability, scalability, and flexibility. ÄKTAcrossflow comes complete with UV, pH, and conductivity monitors, as well as air, pressure, and temperature sensors. The valves and fittings are specially developed for hygienic, leak-free operation. Electrically actuated diaphragm valves diminish hold up volumes and prevent dead volumes.

System highlights include:

- Broad application range covering ultrafiltration and microfiltration.
- Flexible operation of hollow fiber cartridges or cross flow cassettes.
- Thorough and efficient process development with full TMP Trans Membrane Protein and flux scouting.

For further information, see page 126.



The ÄKTAcrossflow flowscheme.

Normal flow filtration

New

Normal 'dead-end' flow filtration complements chromatographic separations and is often used when processing and purifying biological fluids.

GE Healthcare introduces the ULTA range of normal flow cartridges that maximize process filtration efficiency from early-phase product development through to full production. Initially available for prefiltering applications, the ULTA range will later be expanded to include sterile filter products.

ULTA Prime CG

ULTA Prime CG filter cartridges and capsules act immediately before chromatography columns and prefilter solutions upstream of the sterilizing grade filter. For general bioburden control, they give 5 logs reduction of bacteria when sterility is not required.

ULTA Prime GF

ULTA Prime GF cartridges utilize a glass microfiber filter medium encased within an upstream polypropylene mesh and a downstream non-woven filter support material. They are dimensionally stable with no media migration.

ULTA Prime PP

With their all-polypropylene construction, ULTA Prime PP cartridges ensure broad chemical compatibility. They are particularly suitable for filtering viscous and aggressive chemicals and solvents. Cartridges do not hydrolyze in aggressive solutions and thus do not contaminate process fluids.

Typical applications

ULTA Prime CG

- Liquid column guard filters for reducing bioburden and prefiltering upstream solutions.

ULTA Prime GF

- Liquid filter cartridges for clarifying, stabilizing, and reducing bioburden in aqueous solutions, media, and biologicals.

ULTA Prime PP

- Liquid filter cartridges for clarifying and prefiltering in biopharmaceutical and ultrapure applications.

For further information, see pages 135–137.

CBS DeltaV Standard Control Solution

Customized Bioprocess Solutions (CBS) created and delivered by GE Healthcare are based on more than 20 years of experience in supplying systems for the commercial production of biopharmaceuticals such as vaccines, insulin, small molecules, peptides, oligonucleotides and monoclonal antibodies. For further information, see page 87.

CBS DeltaV Standard Control Solution

New

DeltaV from Emerson is a powerful DCS solution preferred by many pharmaceutical manufacturers. Its control architecture is now available in a configuration dedicated to protein purification – the CBS DeltaV Standard Control Solution.

This new platform combines the technical capabilities of DeltaV with GE Healthcare's specialist knowledge in large-scale chromatography for downstream processing. It enables efficient protein purification and minimizes time and cost-consuming on-site configuration. In addition, CBS DeltaV Standard Control Solution can be easily adapted by CBS engineers at GE Healthcare to meet specific user needs beyond the standard configuration.

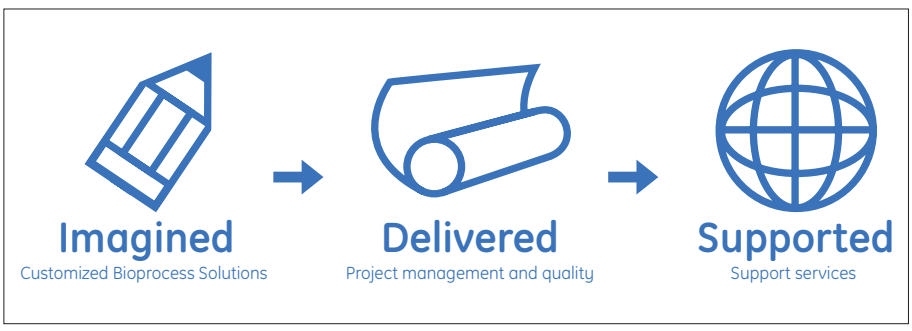
CBS DeltaV Standard Control Solution features include:

- Proven, cost-efficient, and consistent control philosophy across the whole facility.
- Flexible method development plus powerful assessment with UNICORN evaluation module.
- Simplified validation and highly effective evaluation of chromatographic data.

CBS home page

New

CBS now has its own home page that describes its customized solutions to specific end-user production requirements in more detail.



System specification, design and manufacture, as well as installation, validation, and testing are described. The wide range of support services (e.g., service agreements, guaranteed response times, and rapid spare-part delivery) is also outlined.

You can also view a video showing what CBS can do for your business.

For more information visit **www.gehealthcare.com/cbs**

Fast Trak

Fast Trak BioPharma Services provides practical support and advice to those developing biotech products, especially biopharmaceuticals. GE Healthcare experts plus a network of external specialists help you plan, implement, and document downstream purification from start-up to routine production. For further information, see page 140.

Fast Trak courses

Fast Trak Courses help educate and train your personnel in downstream processing. In addition to traditional hands-on courses and laboratory exercises, GE Healthcare now introduces online training.

All course programs undergo continuous improvement. For example, the MAB1 course now includes extensive practical work, and a new UNICORN class for ÄKTAcrossflow has been introduced (SYS3).

e-SYS1
Basic Control of ÄKTAexplorer and ÄKTApurifier using Unicorn

New

The first in our new online series, e-SYS1 provides training for basic control of ÄKTAexplorer and ÄKTApurifier using UNICORN. The course is fully interactive and can be completed at your own pace. Animations, audio instructions, and interactive exercises present system control, basic and advanced programming, and report generation (see **www.gehealthcare.com/ecourses** for more details).

For the latest information about our online and standard courses, visit **www.gehealthcare.com/fasttrak**

New

Fast Trak Center in China

Fast Trak services are available from GE Healthcare Fast Trak Centers in North America, Europe and Asia. Our latest addition strengthens our presence in the rapidly expanding Shanghai region of China.

Fast Trak Center China

GE Healthcare
GE (China) Research and Development Center Co., Ltd

1800 CaiLun Road
Zhangjiang High-tech Park, Pudong
Shanghai 210203 China

Tel: 86 21 50504666-2600
Fax: 86 21 50808591

email: fasttrakasia@ge.com

Online support

Regulatory Support Files

GE Healthcare pioneered the development of Regulatory Support Files to provide customers with detailed information about performance, stability, extractable compounds, and analytical methods for BioProcess media. This information is an invaluable starting point for process development and validation, for preparing Standard Operating Procedures and quality control, and as support for clinical and marketing applications to regulatory agencies. GE Healthcare has over 15 years of experience in providing customers with Regulatory Support Files.

GE Healthcare offers this regulatory support online, including the following features:

- Direct access to Regulatory Support Files.
- Email notification of updates when updates are published.
- Downloadable files in Adobe Acrobat (.pdf) format.
- Online subscription to Regulatory Support Files.
- Sharing subscriptions with colleagues.

As some of the information is proprietary, it is available only after signing a Secrecy agreement.

www.gehealthcare.com/rsf

For further information, see page 145.

Technical support from laboratory to production-scale

Users of GE Healthcare´s columns and systems may need quick and easy access to information regarding their equipment. To meet these needs GE Healthcare has developed an efficient and enhanced support site on the internet.

From its initial focus on standard process-scale columns and systems, the site will expand to cover laboratory-scale equipment as well.

The technical support site gives quick access to detailed information regarding:

- Spare parts for columns, packing stations, and systems.
- Accessories necessary for packing and running columns.
- Columns and systems recommended for your scale and selected medium.
- Column packing.
- A troubleshooting section will guide you to solutions for specific issues.

www.gehealthcare.com/purification_techsupport

For further information, see page 145.

System and column support services

Installation and validation

Dedicated large-scale system and column support services are now available. They range from having GE Healthcare BioProcess service engineers deliver and assemble your system, perform installation tests, and prepare it for operation, to help with certifying the system and its operation with IQ/OQ services. We can also certify upgrades to systems or UNICORN software.

Spare parts

Spare parts are not neglected. To help minimize downtime, we can provide a list of essential parts to keep on site. Holding a guaranteed stock of critical components on your behalf and, for a monthly fee, delivering any designated part according to an agreed time frame, is also part of the service.

Service agreements

Service agreements for BioProcess systems and large-scale columns include comprehensive preventive maintenance scheduled according to requirements, parts support, engineer labor and travel costs, and guaranteed on-site response.

For more information, see page 146.

BioProcess Tour 2007 New

Driving productivity

Our BioProcess Tour 2007 is built around productivity in its broadest sense – increasing output, speeding up development, securing supply, reducing costs, and working more efficiently.

The tour features sessions addressing four focus areas:

- Monoclonal antibodies.
- Process development.
- Manufacturing.
- Vaccines.

Presentations will address scientific and technical issues and overall process aspects, as well as economic and business considerations.

If you work in the biopharma industry and have thought about productivity in any of the terms mentioned above, or if your application or department is related to any of the four focus areas, the BioProcess Tour 2007 is for you.

For more information and to schedule an event, visit **www.gehealthcare.com/bioprocesstour**

Cell preparation and processing

Building on over 30 years experience in the field, GE Healthcare supports cell-based research and therapy by providing quality tools that facilitate the preparation, processing, and storage of blood-derived cells.

Our systems and reagents provide the enabling technologies applied by top medical and research experts in blood cell processing and storage, as well as advanced stem cell research.

Percoll PLUS

New

Percoll PLUS is a sterile density gradient separation medium with low endotoxin levels plus low osmolality, toxicity, and viscosity. It shares the same physical properties and features as Percoll, which is cited in nearly 5000 references. As no antibodies or reagents are needed to bind cells with Percoll PLUS, they always stay in their native, natural state.

Percoll PLUS:

- Particularly useful for clinical research applications where its stability and flexibility help generate reproducible results.
- Well-suited for making finally-formulated sterile density gradient solutions.
- Gradient formulations can be re-sterilized by autoclaving, saving time and money.

For further information, see page 152.

Ficoll-Paque PREMIUM

Ficoll-Paque PREMIUM is a sterile, ready to use density gradient medium used for preparation of human mononuclear cells. This medium is based on Ficoll-Paque PLUS, which has a proven track record as a sterile density medium for the isolation of high yields of mononuclear cells from bone marrow, peripheral blood, and umbilical cord blood.

Ficoll-Paque PREMIUM:

- Manufactured in accordance with GMP and ISO 13485:2003 standards and USP <1043> recommendations for ancillary materials.
- Low levels of endotoxin (< 0.12 EU/ml) secured and tested.

For further information, see page 151.

BioArchive Cryopreservation System

New

BioArchive System is a computer-controlled, liquid nitrogen cryopreservation and storage system that freezes and manages up to 3623 25-ml cord blood samples. By integrating and automating controlled-rate freezing, robotic storage and retrieval, this single instrument ensures precise sample handling and minimizes operator error. BioArchive supports cGMP compliant data acquisition and tracking software.

BioArchive Cryopreservation System:

- Precise, controlled-rate freezing and archiving of cord blood.
- 94% post-thaw cell viability when used with the AXP AutoXpress Platform*.
- Robotic storage and retrieval.

*Data provided by The New York Blood Center.

For further information, see page 153.

AXP AutoXpress Platform

New

AXP AutoXpress Platform is an automated, functionally-closed, sterile system that reduces cord blood volume to a precise 20 ml in less than 40 min, while retaining more than 97% mononucleated cells (MNCs)*. It captures data essential for quality assurance and compliance with current good tissue practices (cGTP). XpressTRAK software tracks and documents each cord blood unit's separation data during and after centrifugation.

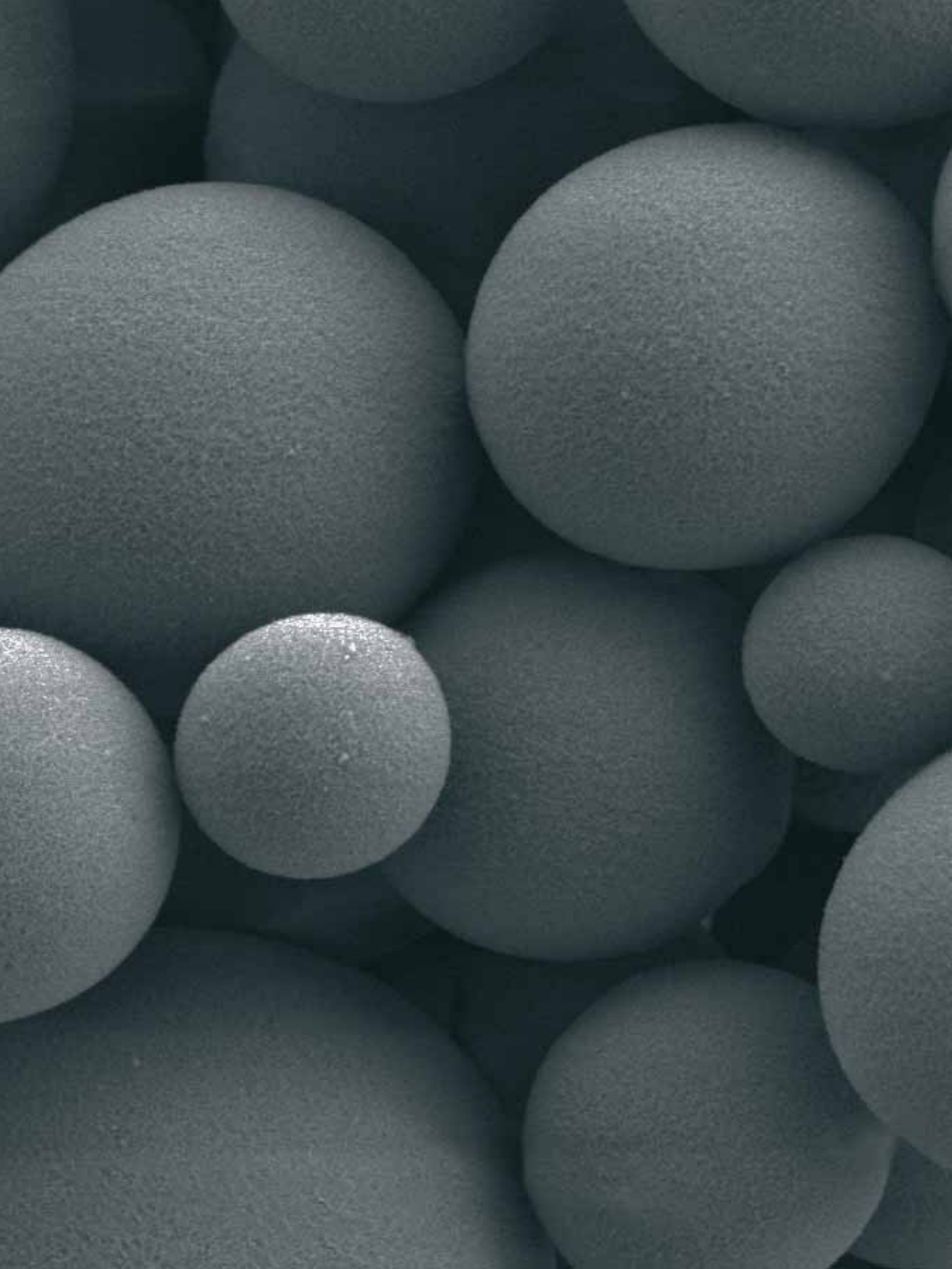
AXP AutoXpress Platform:

- Consistently high recoveries of stem-cell rich MNC cells from cord blood*.
- Simultaneous processing of multiple cord blood units.
- Sterile sample collection through integrated sample pillows.

*Data provided by New York Blood Center (97.9%. sd 4.9%).

For further information, see page 152.

For further information on Cell preparation and processing products, see page 151.
Visit us on the web at **www.gehealthcare.com/cellprep**



Chromatography media

Ion exchange
Affinity
Hydrophobic interaction
Thiophilic aromatic adsorption
Reversed phase
Gel filtration
Custom designed media

Media selection – our strategy

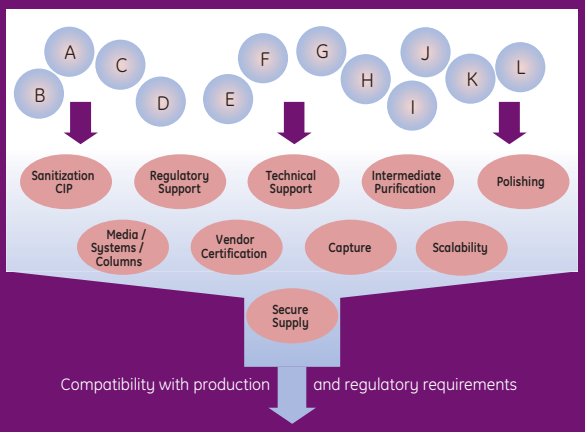
At GE Healthcare we are committed to supplying you with media that pass the rigorous selection requirements demanded for the downstream processing of biopharmaceuticals. Consider three issues:

Performance – The different stages in downstream processing from Capture to Polishing demand media with different characteristics.

Scalability – Is the medium produced at a large enough scale? Can it be packed into large production columns with retained performance?

Security of supply – How is quality assurance? Is the producer geared up to long-term industrial supply issues?

Media selection filter



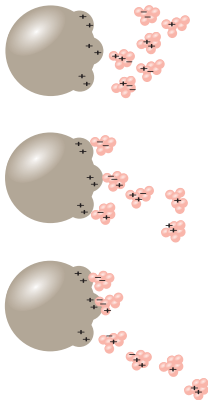
Use only media that pass through this filter.

BioProcess Media – made for bioprocessing

This label designates our media that have been specifically designed to meet the demands of industrial biotechnology:

- **Secure Supply** Large capacity production integrated with clear ordering and delivery routines mean BioProcess Media are available in the right quantity, at the right place, at the right time. Future supplies of BioProcess Media are assured, making them a safe investment for your long-term production.
- **Safety Stock** Our media safety stock agreements offer the right quantity of media, manufactured to specified quality levels, and delivered at the right time. For more information on Safety Stock agreements, see page 20.
- **Validated Manufacture** Produced following validated methods and tested under strict quality control, BioProcess Media fulfill performance specifications. A certificate of analysis is available with each order.
- **Regulatory Support** Regulatory Support Files contain details of performance, stability, extractable compounds and analytical methods available. The essential information in these files is an invaluable starting point for process validation, as well as support for clinical and marketing applications submitted to regulatory authorities.
- **From Capture to Polishing** Specific BioProcess Media have been designed for each chromatographic stage in a process from Capture to Polishing. Using BioProcess Media for every stage results in a systematic approach to method development.
- **High Productivity** High flow rates, high capacity and high recovery contribute to the overall economy of an industrial process.
- **Sanitization/CIP** All BioProcess Media can be cleaned- and sanitized-in-place.
- **Scalability** Packing methods are established for a wide range of scales. You can use the same BioProcess Media for development work, pilot studies, and routine production.

Ion exchange chromatography



Technique description

Separation in ion exchange chromatography (IEX) is based upon the selective, reversible adsorption of charged molecules to an immobilized ion exchange group of opposite charge. An ion exchanger consists of an insoluble porous matrix to which charged groups have been covalently bound.

Anion exchanger groups

ANX: $-CH_2CHOHCH_2NH^+(CH_2CH_3)_2$

DEAE: Diethylaminoethyl $- O-C_2H_4-N^+(C_2H_5)_2-H$

QAE: Quatenary aminoethyl $- O-C_2H_4-N^+(C_2H_5)_2-CH_2CH(OH)CH_3$

Q: Quatenary ammonium $- O-CH_2CHOHCH_2OCH_2CHOHCH_2-N^+(CH_3)_3$

Cation exchanger groups

CM: Carboxymethyl $-O-CH_2COO^-$

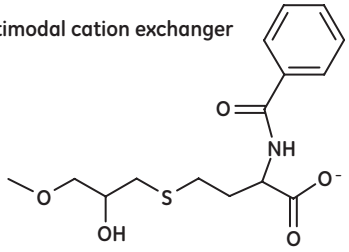
S: Sulphoethyl $-O-CH_2-CH_2-SO_3^-$

SP: Sulphopropyl $-O-CH_2CHOHCH_2OCH_2CH_2CH_2SO_3^-$

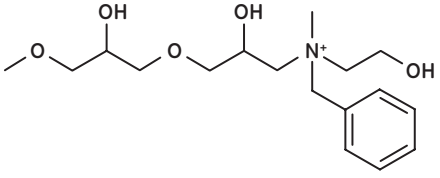
Q, S and SP are strong ion exchange groups that maintain charge capacity over a very wide pH range. The other groups are weak ion exchangers, and their charge capacity varies with pH.

Multimodal ion exchangers

Capto MMC: multimodal cation exchanger



Capto adhere: multimodal anion exchanger



Multimodal ligands constitute a new group of ligands that share the ability to interact with target molecules through multiple types of interactions. In addition to ionic interactions, several other types of interactions are involved such as hydrogen bonding and hydrophobic interaction. The strength of the individual interactions depends on the overall process conditions.

Media containing multimodal ligands possess selectivities that are different from those of "traditional" ligands. GE Healthcare has previously introduced the multimodal medium Capto MMC, which binds proteins at the conductivity of the feed material. This "high salt binding" feature eliminates the need for dilution of feed stocks before loading onto the column.

New Capto adhere, a strong multimodal anion exchanger, is also for packed bed chromatography. The Capto adhere ligand, N-Benzyl-N-methyl ethanol amine, exhibits many functionalities for interacting with target molecules. The most pronounced are ionic interaction, hydrogen bonding and hydrophobic interaction. Capto adhere is designed for post-Protein A purification of monoclonal antibodies.

New and established media

GE Healthcare ion exchangers are well-established in industry. A wide range of base matrices has been developed to address most customer requirements.

Capto is a new product line specifically developed to enable quick and economical handling of large volumes in biopharmaceutical production. The rigidity of Capto media allows for longer bed heights in smaller diameter columns, thereby simplifying column handling as well as reducing investment in large-scale equipment. The Capto line is composed of a strong anion exchanger, Capto Q, a strong cation exchanger, Capto S, a multimodal weak cation exchanger, Capto MMC, and newly-introduced Capto adhere, a strong multimodal anion exchanger. The flexibility offered by Capto media opens new possibilities in large-scale protein purification.

MacroCap SP is a macroporous cation exchanger designed for the purification of PEGylated and other large biomolecules. It allows separation of mono- from oligo- and non-PEGylated proteins with high selectivity, even under high load conditions.

Sepharose Big Beads, Sepharose Fast Flow, Sepharose XL and Sepharose High Performance are other products based on cross-linked agarose. These media are designed for robust, high capacity, high resolution ion exchange chromatography at various stages of process-scale purification. For many years, they have been the industry standard for ion exchange of biomolecules.

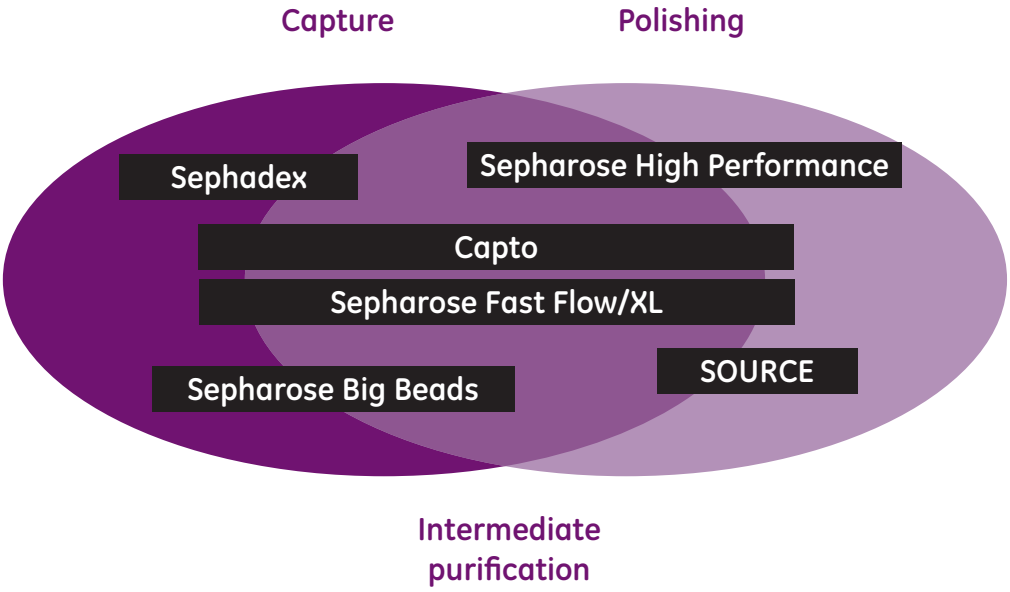
Other key products include Sephadex ion exchangers, based on cross-linked dextran beads and offering high capacities for batch or column mode.

SOURCE media for late-intermediate purification and polishing also belong to a long line of ion exchangers specifically designed to meet the processing needs of the biopharmaceutical manufacturer.

The handbook Ion Exchange Chromatography and Chromatofocusing – Principles and Methods can be obtained through your local GE Healthcare office.

Code No. 11-0004-21.

Selection guide



Getting started

Testing the performance of separation media at the laboratory bench helps you select the best one for process-scale use.

HiTrap columns (1-ml and 5-ml) are a particularly fast, simple, and reproducible way of testing different ion exchange media. They can be operated with a syringe, a peristaltic pump or a chromatography system. A HiTrap IEX Selection Kit contains seven ion exchangers based on Sepharose Fast Flow and Sepharose XL media.

Capto Q, Capto S, Capto MMC, Capto adhere, as well as Q and SP Sepharose High Performance are also available in prepacked HiTrap 1-ml and 5-ml columns.

For method development, HiPrep and HiLoad prepacked column ranges are recommended. They are convenient to use and give reproducible results.

A convenient way of assessing SOURCE 15Q and SOURCE 15S media is to use an ÄKTAdesign system and RESOURCE or 4.6/100 PE (ÄKTAdesign) prepacked columns.

In addition to prepacked columns, many of the media described in this section can be ordered as laboratory-sized packs. (See A–Z of media and chemicals).

Capto

For high productivity capture and intermediate purification

Capto is a new product line to meet large-scale biopharma manufacturers' demands for fast, efficient and cost-effective capture and intermediate purification. It is based on a highly-rigid agarose matrix produced with a manufacturing process that gives significantly improved pressure/flow properties with maintained control over pore structure. The rigid matrix enables high bed heights and purification of viscous samples at high flow rates. Capto Q and Capto S are strong anion and cation exchangers that maximize productivity due to fast mass transfer plus high dynamic binding capacity. Capto MMC is a multimodal weak cation exchanger that is salt tolerant and binds proteins at the conductivity of most standard feed materials. It also has a new selectivity that offers a potential to solve difficult purification problems. Capto adhere is a strong multimodal anion exchanger for intermediate purification and polishing of monoclonal antibodies after capture on Protein A media. In one step, it selectively removes leached Protein A, aggregates, host cell proteins, nucleic acids and viruses from monoclonal antibody feeds over a wide operational window of pH and conductivity. In combination with Protein A media, Capto adhere offers a robust chromatography platform for developing monoclonal antibody manufacturing processes.

- Capto Q
- Capto ViralQ **New**
- Capto S
- Capto MMC
- Capto adhere **New**

MacroCap

For purification of large biomolecules

MacroCap is a new product line designed to purify PEGylated and other large biomolecules. MacroCap SP is a cation exchanger that delivers high product purity and yield at high sample loads. Mono-PEGylated proteins are separable from oligo-PEGylated and native protein in a single run. The MacroCap SP base matrix is hydrophilic and chemically stable, thereby increasing media lifetime.

PEGylation is typically performed after purification of the target protein.

- MacroCap SP

Sephadex

High binding capacities for column or batch techniques

Sephadex ion exchangers are very well established and have been used in industry for many years. Their high binding capacities and reliability make them both simple and economical to use. Due to their excellent stability and ease of packing, Sephadex A-25 and C-25 are popular choices for column techniques. Sephadex A-50 and C-50 are also widely used for batch applications, especially processing crude feedstocks, and in plasma fractionation.

- DEAE Sephadex A-25
- QAE Sephadex A-25
- CM Sephadex C-25
- DEAE Sephadex A-50
- QAE Sephadex A-50
- CM Sephadex C-50

Sepharose Big Beads

For capture steps handling very large volumes of feed or viscous feedstocks

Sepharose Big Beads is the natural choice for the capture step in a process where high throughput and capacity are essential in packed column mode. Typical flow velocities for dilute samples are >1000 cm/h. The large particle size combined with high physical stability ensures rapid processing of viscous samples. These media should be chosen for clarified feedstocks when high throughput is required and resolution is of less importance.

- SP Sepharose Big Beads
- Q Sepharose Big Beads

Sepharose XL

High loading capacities for more productive capture from clarified feedstocks

Q Sepharose XL and SP Sepharose XL have high loading capacities compared with Sepharose Fast Flow ion exchangers. Combined with high throughput, this helps improve the production economy of manufacturing processes. Both adsorbents are based on the well-established Sepharose Fast Flow media.

- Q Sepharose XL
- Q Sepharose XL virus licensed
- SP Sepharose XL

Sepharose Fast Flow

Proven in validated large-scale production of biopharmaceuticals

These media are the first choice for separating crude mixtures early in purification schemes. Here a combination of good resolution and high flow rate is essential. Typical flow velocities for these media are 100 to 400 cm/h.

- DEAE Sepharose Fast Flow
- CM Sepharose Fast Flow
- Q Sepharose Fast Flow
- SP Sepharose Fast Flow
- ANX Sepharose 4 Fast Flow (high sub)

Sepharose High Performance

Where high resolution is essential for intermediate purification and polishing

These media are well-suited for intermediate purification and polishing. Use them when resolution and capacity have priority. Typical flow velocities are 100 cm/h.

- SP Sepharose High Performance
- Q Sepharose High Performance
- CDM CM Sepharose High Performance

SOURCE

For rapid, high-resolution, preparative separations at low or high pressure

SOURCE ion exchangers are monosized, rigid, polystyrene/divinyl benzene matrices for chromatography of proteins, peptides and oligonucleotides. SOURCE 15Q and 15S media are well-suited for complex separations during polishing. SOURCE 30Q and 30S are for intermediate purification and large-scale polishing. Typical flow velocities are up to 1000 cm/h at large-scale, and even higher on the laboratory bench.

- SOURCE 15S
- SOURCE 15Q
- SOURCE 30S
- SOURCE 30Q

HiTrap IEX Selection Kit

This kit allows fast and easy screening of seven different ion exchange ligands based on Sepharose Fast Flow and Sepharose XL, which is excellent for laboratory studies with small sample quantities before scaling up. Contains SP, Q, CM, ANX (high sub) and DEAE Sepharose Fast Flow and Q and SP Sepharose XL in 1-ml HiTrap columns. The kit contains detailed instructions.
Code No. 17-6002-33.

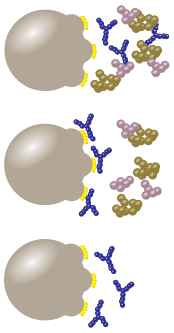
IEX Media Selection Kit

This kit is an excellent tool for use in industrial process development. The kit contains a selection of ion exchangers based on Sepharose to be used in each of the stages in a purification scheme. A comprehensive instruction manual is also included.
For further information, please contact your local GE Healthcare office.

■ = BioProcess Media

CDM = **Custom Designed Media**
produced on receipt of order.

Affinity chromatography



Technique description

The inherent high specificity of ligand: target interactions makes affinity chromatography particularly suitable for the Capture stage of downstream processing. One of the typical advantages of using affinity techniques is that the capacity of the media is usually not affected by the presence of contaminants since they have no affinity for the coupled ligand. The result is reliable product purity, often with purification factors well over 1000, and effective concentration, achieved in a single step. Affinity chromatography may also be suitable for the Intermediate or Polishing stages, to remove small amounts of specific contaminants. In affinity chromatography, the product to be purified adsorbs to an affinity ligand that is coupled to a matrix. The ligand is specific for a single type of protein/peptide molecule, or group of such molecules. The targeted product often binds to the ligand under specific conditions of high or low ionic strength and at a certain pH. After unbound impurities are rinsed away, the product can be eluted by using a step gradient of increasing or decreasing ionic strength and/or by changing the pH, or by a more selective elution technique.

Affinity chromatography

The most widely used affinity chromatography purification step today is the capture of antibodies using the Protein A ligand.

Protein A media

The MabSelect family for the capture of monoclonal antibodies has been developed with industrial needs in mind. The expanded product range focuses on better overall process economy and reduced time for optimization.

Group-specific media

Heparin Sepharose 6 Fast Flow and Blue Sepharose 6 Fast Flow are examples of media with affinity for a group of related molecules.

IMAC media

Immobilized Metal Ion Chromatography (IMAC) is a versatile purification technique for proteins, including histidine-tagged proteins, with an affinity for metal ions. Ni Sepharose 6 Fast Flow is precharged with Ni^{2+} ions and is designed for purification of histidine-tagged proteins, suitable for scale-up and accompanied with a Regulatory Support File. IMAC Separose 6 Fast Flow is the uncharged version (with the possibility to charge the metal ion of your choice), suitable for histidine-tagged proteins as well as other recombinant proteins and native proteins. Chelating Sepharose Fast Flow is the well-established BioProcess IMAC medium and is being used in several approved biopharmaceutical process.

Pre-activated media

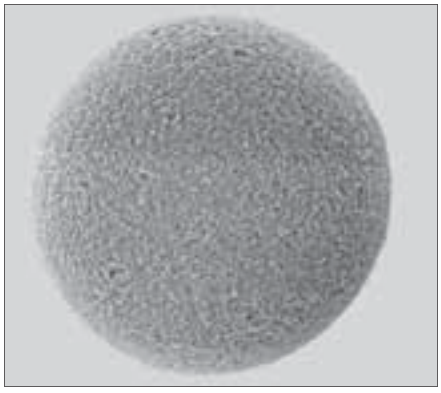
Pre-activated media allow you to couple a ligand appropriate to your application. The choice of medium depends on several factors, for example the groups in the ligand molecule that are suitable for coupling and the chemical stability demands on the resulting affinity medium. CNBr-activated Sepharose 4 Fast Flow and NHS-activated Sepharose 4 Fast Flow are examples of modern pre-activated media suitable for attaching various ligands.

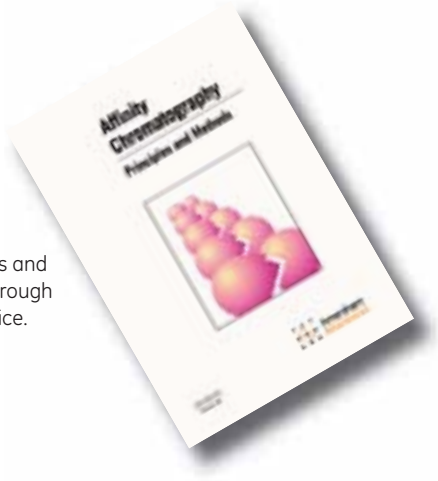
MabSelect media

The commercial success of approved biopharmaceuticals and the growing number of protein-based drug candidates has led to projections of metric tons of monoclonal antibodies (MAbs) being required in a few years. To meet this demand, cell culture capacity is increasing with reactors of 12 000 to 15 000 liters and larger coming on-line. Expression levels, currently in the 0.1 to 1.0 g/l range, are expected to increase several-fold. In downstream processing, efforts are directed at improving process economics by decreasing the number and cost of unit operations. Current trends in antibody production indicate an increased use of Protein A chromatography media for product capture.

Protein A-based chromatography media: the benefits

- High selectivity reduces the number and size of subsequent unit operations through high purities and yields.
- Insensitivity to variations in additives, pH and conductivity facilitates the use of generic protocols.
- Usually validated for both viral clearance and subsequent inactivation.





The handbook Affinity Chromatography – Principles and Methods can be obtained through your local GE Healthcare office.

Code No. 18-1022-29.

MabSelect family overview

MabSelect is the common name for a range of process to production-scale chromatography media for monoclonal antibody purification. All MabSelect media feature:

- A base matrix of high-flow agarose.
- High chemical stability: compatible with allaqueous buffers commonly used in Protein A chromatography.
- Mammalian product-free: no animal-derived components involved in the fermentation or purification of the recombinant Protein A ligand.
- Epoxy as coupling chemistry.
- Recommended storage reagents: 20% ethanol, 2% benzyl alcohol.
- Temperature stability: 4 to 40°C.
- Regulatory Support File.
- Shelf life: 3 years.
- Simple scale-up to production-sized columns.
- Available in HiTrap format for convenient media screening.
- Large-scale quantities available on request.

Like all our BioProcess media, MabSelect meets every requirement for process design and scale-up. Prepacked columns and bulk quantities are available. For large-scale packing, we recommend Chromaflow, BioProcess or BPG columns.

MabSelect

For high purity and throughput at production scale

- Prioritized volume throughput.
- Optimized matrix and ligand coupling.
- The antibody purification standard.

MabSelect SuRe

Withstands rigorous and cost-effective CIP protocols, (e.g., 0.1 to 0.5 M NaOH)

- Alkali-stabilized rProtein A ligand.
- Generic and economic CIP/sanitization.
- Product safety and process robustness.

MabSelect Xtra

For capturing high-titer antibody feedstocks and reducing processing costs

- Outstanding dynamic binding capacity.
- Improved process economics and reduced raw material costs.
- High-purity capture due to minimal non-specific binding.

Product application guide

Getting started

Testing the performance of separation media at the laboratory bench will help you select the best one for process- scale use. All of the media described in this section can be ordered as laboratory-sized packs. Turn to page 160 for the A–Z of media and chemicals.

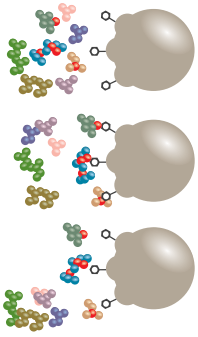
This table is only a brief guide to application areas for our affinity media. For further information on these applications, please contact your local GE Healthcare office.

Target molecules	Affinity media	Applications
-NH_2	■ NHS-activated Sepharose 4 Fast Flow	Ligand immobilization
-NH_2	■ CNBr-activated Sepharose 4 Fast Flow	Ligand immobilization
-NH_2	CDM 6-AKS Sepharose 4 Fast Flow	Ligand immobilization
-NH_2, -OH, -SH	Epoxy activated Sepharose 6B	Ligand immobilization
-COOH, -CHO	CDM Amino Sepharose 6 Fast Flow	Ligand immobilization
Immunoglobulins	■ MabSelect	IgG, some IgM and IgA
	■ MabSelect SuRe	IgG, some IgM and IgA
	■ MabSelct Xtra	IgG, some IgM and IgA
	■ rmp Protein A Sepharose Fast Flow	IgG, some IgM and IgA
	■ rProtein A Sepharose 4 Fast Flow	IgG, some IgM and IgA
	■ nProtein A Sepharose 4 Fast Flow	IgG, some IgM and IgA
	■ Protein G Sepharose 4 Fast Flow	IgG
Histidine-tagged proteins	■ Ni Sepharose 6 Fast Flow	Polyhistidine tagged proteins
	■ IMAC Sepharose 6 Fast Flow	Polyhistidine tagged proteins
GST-tagged proteins	Glutathione Sepharose 4 Fast Flow	Glutathione S-transferase (GST), tagged proteins, other glutathione S-transferases and glutathione-binding proteins
Growth factors	■ Heparin Sepharose 6 Fast Flow	Fibroblast growth factor (FGF) endothelial cell growth factor (ECGF)
	■ Blue Sepharose 6 Fast Flow	
Protein synthesis factors	■ Heparin Sepharose 6 Fast Flow	Initiation factors, elongation factors (EF-1)
Hormones and hormone receptors	Con A Sepharose 4B	Follicle-stimulating
	■ Heparin Sepharose 6 Fast Flow	Oestrogen and androgen receptors
Coagulation proteins	■ Heparin Sepharose 6 Fast Flow	Antithrombin III,
	■ Heparin Sepharose 6 Fast Flow	Factors IX, X, XI, XII, XIIa, prothrombin, thrombin
	■ Chelating Sepharose Fast Flow	Factor IX
Nucleic acids	CDM ECH-Lysine Sepharose 4 Fast Flow	Ribosomal RNA, double stranded DNA
Polysaccharides and glycoproteins	Con A Sepharose 4B	α-D-Glucosyl, α-D-mannosyl
	Lentil Lectin Sepharose 4B	α-D-Glucosyl, α-D-mannosyl
Membrane proteins	Lentil Lectin Sepharose 4B	α-D-Glucosyl, α-D-mannosyl
	Con A Sepharose 4B	α-D-Glucosyl, α-D-mannosyl
Lipoproteins	■ Heparin Sepharose 6 Fast Flow	α-lipoprotein
	Con A Sepharose 4B	low density lipoprotein
Enzymes	■ Heparin Sepharose 6 Fast Flow	Restriction endonucleases, DNA ligase, DNAand RNA polymerases, nucleic acid binding
	■ Blue Sepharose 6 Fast Flow	broad range of nucleotide-requiring enzymes
Protease binding	CDM Benzamidine Sepharose 4 Fast Flow (high sub)	Trypsin, urokinase, prekallikrein, kallikrein
Other	Con A Sepharose 4B	α1-antitrypsin
	■ Blue Sepharose 6 Fast Flow	α2-macroglobulin
	■ Chelating Sepharose Fast Flow	α2-macroglobulin
	CDM Gelatin Sepharose 4 Fast Flow	Fibronectin
	■ Heparin Sepharose 6 Fast Flow	Fibronectin
	ECH-Lysine Sepharose 4 Fast Flow	Plasminogen and plasminogen activator
	■ Blue Sepharose 6 Fast Flow	Albumin
	■ Blue Sepharose 6 Fast Flow	Interferon
	■ Heparin Sepharose 6 Fast Flow	Interferon
	■ Chelating Sepharose Fast Flow	Interferon

■ = BioProcess Media

CDM = **Custom Designed Media** produced on receipt of order.

Hydrophobic interaction chromatography



Technique description

Proteins and peptides differ from one another in their hydrophobic properties and this difference forms the basis of a HIC separation. Salt solutions are used to mediate the binding of sample molecules to a hydrophilic matrix substituted with a hydrophobic ligand.

Widespread application

Hydrophobic interaction chromatography (HIC) has evolved into one of the most powerful methods in preparative biochemistry. Its speed, resolution and capacity rival ion exchange chromatography; its selectivity is complementary to ion exchange and size exclusion chromatography; and its ability to clear endotoxins, nucleic acids, and viruses makes it an indispensable tool for the purification of therapeutic proteins.

Choice of adsorbent

Developing an efficient HIC method involves steps similar to these of other techniques – scouting for potentially suitable adsorbents, optimization and scale-up.

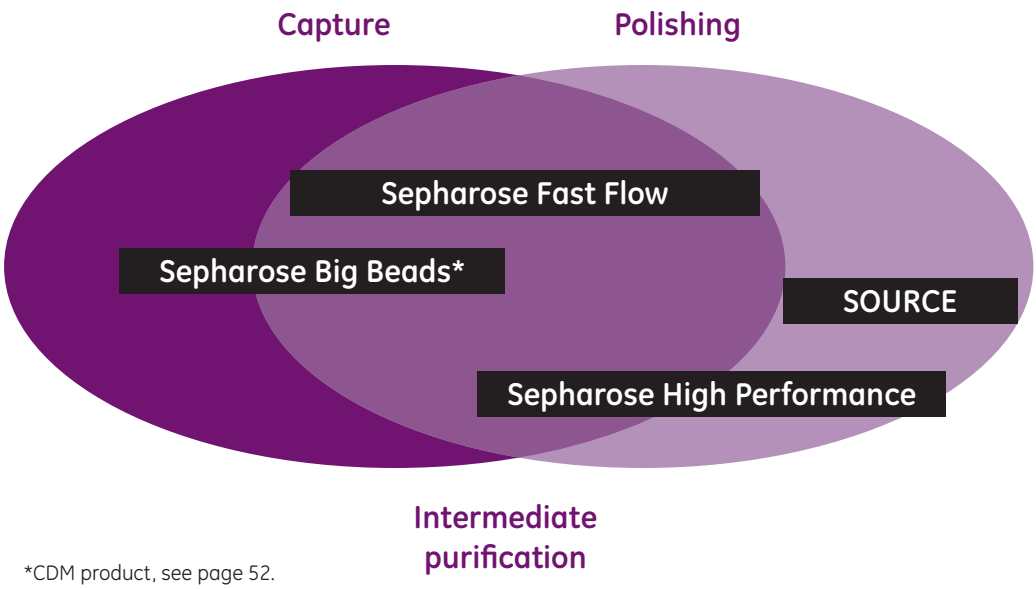
Adsorbents differ in the type of ligand, degree of substitution and base matrix. The correct choice is made after experiments to determine the best selectivity and strength of binding. Choice also depends upon the scale of operation and position in the purification scheme.

Help with experimental design

The theory of HIC, experimental design and process considerations are comprehensively described and discussed in the HIC/RPC handbook. Please contact your local GE Healthcare office to obtain your copy.

Code No. 11-0012-69.

Selection guide



*CDM product, see page 52.

Getting started

Testing the performance of separation media at the laboratory bench will help you select the best one for process- scale use. Note that selectivity cannot always be predicted on the basis of the ligand. To help industrial users compare media, small samples are available on request. Please ask for details.

Many of the media described in this section can be ordered as laboratory-sized packs or as easy-to-use prepacked columns. The small HiTrap columns, operated with a syringe, a peristaltic pump or a chromatography system, allow a particularly fast and simple way of screening key HIC media. They are available as a Selection kit.

HiLoad and HiPrep prepacked columns are convenient and give reproducible results, making them well-suited for method development. The method wizard in UNICORN controlled ÄKTAdesign systems supports the most common scouting procedures, such as automatic media screening.

A tool for screening different HIC media

The HiTrap HIC Selection Kit consists of seven ready to use 1-ml prepacked columns for screening different types of ligands and for method development work at small scale.

- Phenyl Sepharose High Performance
- Phenyl Sepharose 6 Fast Flow (low sub)
- Phenyl Sepharose 6 Fast Flow (high sub)
- Butyl-S Sepharose 6 Fast Flow
- Butyl Sepharose 4 Fast Flow
- Butyl Sepharose High Performance
- Octyl Sepharose 4 Fast Flow
  Code No. 28-4110-07

For testing SOURCE HIC media, we recommend the RESOURCE HIC test kit. It consists of three ready to use 1-ml RESOURCE columns.

- RESOURCE 15PHE
- RESOURCE 15ISO
- RESOURCE 15ETH
  Code No. 17-1187-01

Sepharose Big Beads

Media for capture steps handling very large volumes of clarified feedstock

CDM Phenyl Sepharose Big Beads

The large particle size combined with high physical stability ensures rapid processing of viscous samples.

Sepharose Fast Flow

Media for capture and intermediate purification. Proven in validated large-scale production of biopharmaceuticals

The excellent flow properties and binding capacities of these media make them especially useful for processing large volumes.

The range of Fast Flow HIC media covers different selectivities. The best choice for each application is difficult to predict and therefore several different media need to be tested to find the best selectivity.

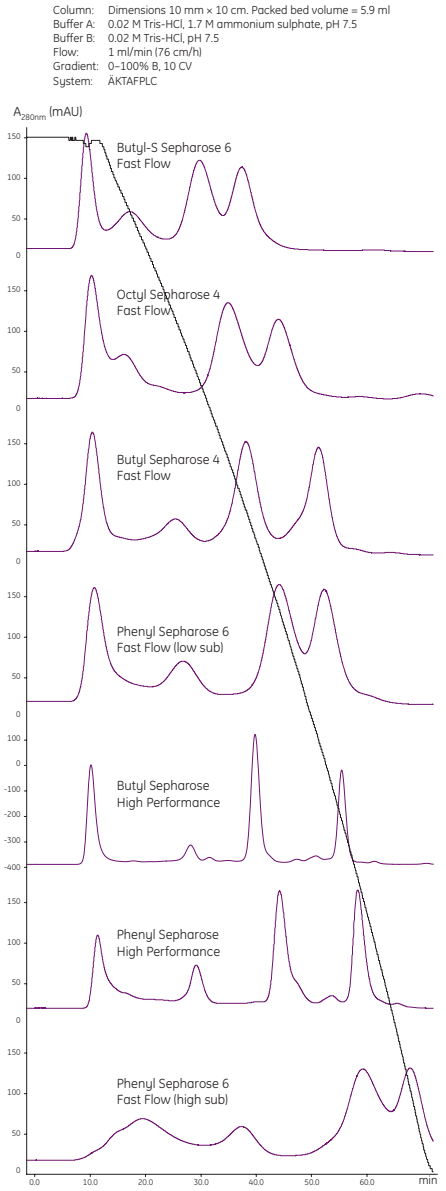
- *Butyl Sepharose 4 Fast Flow*
  The standard aliphatic HIC medium of choice. The ligand gives different selectivity compared with phenyl media.
- *Butyl-S Sepharose 6 Fast Flow*
  A low-hydrohobicity HIC medium for capturing recombinant HBsAg and removing hydrophobic contaminants.
- *Octyl Sepharose 4 Fast Flow*
  Gives different and complementary selectivity compared with phenyl and butyl media.
- *Phenyl Sepharose 6 Fast Flow (high sub)*
  A high capacity HIC medium with a binding capacity for IgG and HSA up to 30 mg/ml at flow velocities of 100 cm/h. Has proven to be a very efficient capture medium.
- *Phenyl Sepharose 6 Fast Flow (low sub)*
  The standard HIC medium of choice with an aromatic ligand.

CDM
- *Butyl Sepharose 6 Fast Flow*
  The butyl ligand on the well-proven Fast Flow matrix.

Sepharose High Performance

Media for intermediate purification and polishing when high resolution is needed

- *Butyl Sepharose High Performance*
  Robust medium for difficult purification problems when high resolution is the main objective. Is also very efficient for polishing monoclonal antibodies.
- *Phenyl Sepharose High Performance*
  Robust medium for difficult purification problems when high resolution is the main objective. Is also very efficient for polishing monoclonal antibodies.



The HIC product portofolio based on Sepharose was screened for selectivity and separation ability for Cytochrome C, RNAse A, Lysozyme and a α-Chymotrypsinogen (eluting in this order). Butyl-S Sepharose 6 Fast Flow is the least hydrophobic medium and Phenyl Sepharose 6 Fast Flow (high sub) the most hydrophobic medium produced by GE Healthcare.

■ = BioProcess Media

CDM = **Custom Designed Media** produced on receipt of order.

SOURCE 15

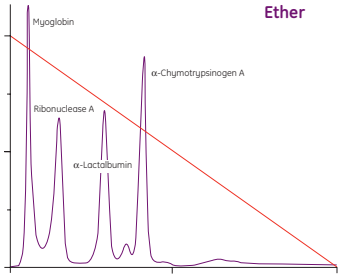
Media for polishing when high resolution is essential

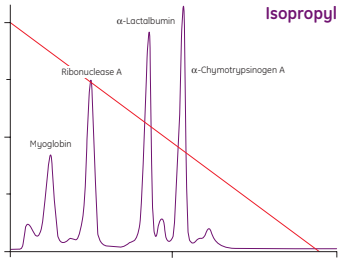
- SOURCE 15ETH
- SOURCE 15ISO
- SOURCE 15PHE

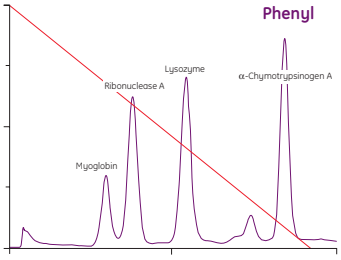
SOURCE 15 HIC media are polymer-based, monosized beads that give excellent resolution. Furthermore, their structure maintains resolution at high loadings and high flow rates. SOURCE 15 HIC media are available with three different ligands (ether, isopropyl and phenyl in increasing order of hydrophobicity), which allows a wide choice when scouting for the optimum one for your application. They are also available prepacked in RESOURCE columns. SOURCE 15PHE is also prepacked in ÄKTAdesign columns.

The HIC portfolio based on SOURCE was screened for selectivity and separation ability. Order of hydrophobicity SOURCE 15ETH <SOURCE 15ISO <SOURCE 15PHE

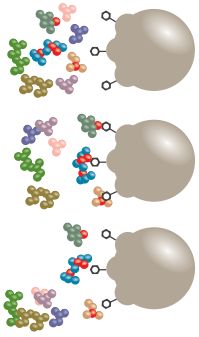
Column: RESOURCE 15ETH
RESOURCE 15ISO
RESOURCE 15PHE
Buffer A: 0.1 M potassium phosphate buffer, 2.0 M ammonium sulfate, pH 7.0
Buffer B: 0.1 M potassium phosphate buffer, pH 7.0
Flow: 1 ml/min
Gradient: 0–100% B, 20 CV







Thiophilic aromatic adsorption



Plasmid purification

PlasmidSelect Xtra, a thiophilic aromatic adsorption chromatography medium, forms the basis of a generic process for purifying supercoiled (sc) covalently closed circular plasmid DNA suitable for bulk to clinical grade applications. The process provides high capacity, delivers high yields, and can be scaled up to fulfill requirements for the economical industrial manufacture of plasmid DNA in highly regulated environments. The same principle can also be used to rapidly analyze the quantity and quality of plasmid DNA in complex solutions. The medium, which uses ionic strength to modulate binding to the matrix, is part of a fully-scalable chromatographic process for purifying supercolied plasmid DNA. This process also employs Sepharose 6 Fast Flow and SOURCE 30Q. The complete purification process comprises both chromatography and filtration steps, such as clarification and ultrafiltration.

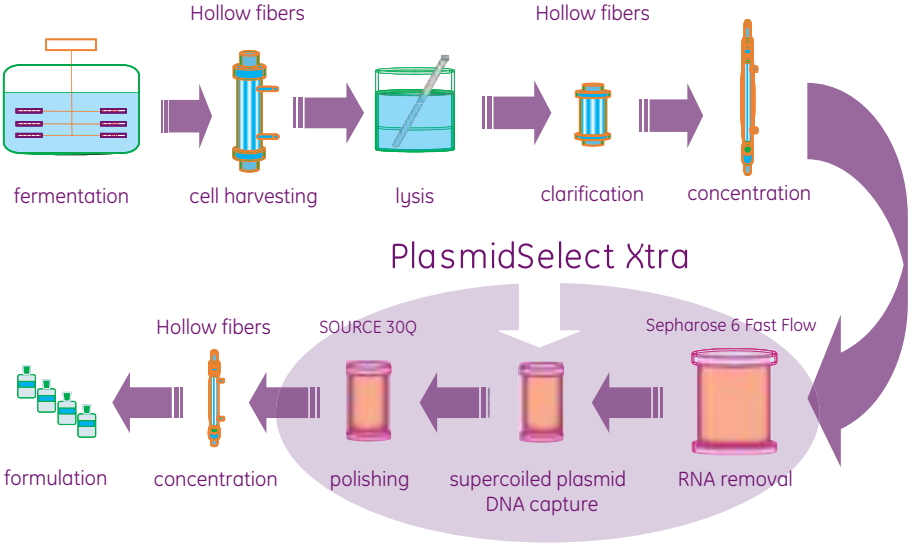
The PlasmidSelect Xtra Starter Kit contains all three media in prepacked columns to to purify at least 5 mg supercoiled plasmid DNA in a single run.

The PlasmidSelect Xtra Screening Kit determines plasmid DNA quantity within 10 minutes and plasmid DNA quality (ratio supercoiled, covalently closed plasmid DNA to open circular) within 30 minutes. It also purifies up to 2 mg plasmid DNA within 1 hour.

PlasmidSelect Xtra platform

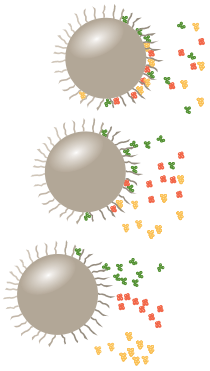
- Generic process for purification of supercoiled plasmid DNA.
- Screening kit: Quick and easy analysis with an ÄKTAdesign system. Code No. 28-4052-69.
- Starter Kit: Prepacked columns for convenient process development. Code No. 28-4052-68.
- Bulk media: Sepharose 6 Fast Flow, PlasmidSelect Xtra, and SOURCE 30Q are BioProcess media available in large quantities for scale-up and manufacture. See A-Z of media and chemicals.

Purification of supercoiled plasmid DNA



The PlasmidSelect Xtra process is for the purification of high-quality supercoiled plasmid DNA and fast analysis of plasmid DNA quantity and quality. PlasmidSelect Xtra Starter Kit contains media in prepacked columns for each of the three chromatography steps. Samples can be withdrawn and analyzed using PlasmidSelect Xtra Screening Kit at any point from fermentation to RNA removal.

Reversed phase chromatography



Technique description

Reversed phase chromatography (RPC) is in theory closely related to hydrophobic interaction chromatography. Both techniques are based on the interaction between hydrophobic patches on the surface of biomolecules and the hydrophobic groups covalently attached to the surface of the matrix. In practice, however, they are different. Media for RPC are typically highly substituted with hydrophobic ligands and the binding of substances to RPC media is usually stronger. Organic solvents are usually required for elution. The technique is mainly applicable for peptides, proteins up to M_r 2.5×10^4 and other low molecular weight biomolecules that are stable in aqueous-organic solvents.

Required for polishing

RPC is a widely-used analytical technique but it is also employed in preparative applications, up to process scale, for more demanding polishing problems, such as separating microheterogeneities from the native molecule of recombinant peptides.

RPC is also a standard technique for purifying synthetic peptides and oligonucleotides. The technique often requires medium to high-pressure columns and systems and explosion-proof equipment for handling high concentrations of flamable volatile organic solvents.

RPC media from GE Healthcare are designed for difficult preparative separations at all scales.

Products

SOURCE 15RPC and SOURCE 30RPC, both BioProcess Media, are designed for fast, high performance preparative separations of biomolecules such as proteins, peptides and oligonucleotides. The media have matrices based on rigid, highly cross-linked, polystyrene/divinyl benzene, with monosized beads of diameters 15 µm and 30 µm respectively. Pore size distribution is controlled and reproducible. Emphasis during development has been on quality, reproducibility and scalability, features that are particularly important for industrial applications.

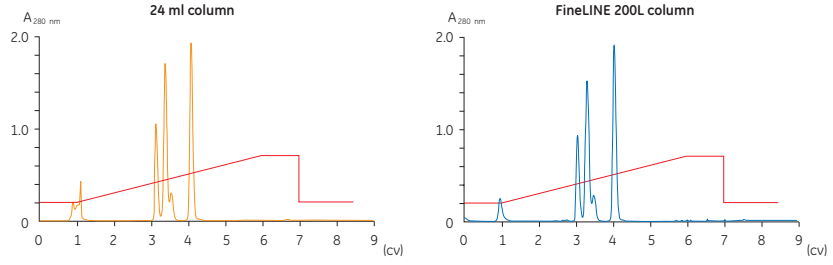
Their wide pH stability (pH 1 to 14) and high capacity make SOURCE RPC media an interesting alternative to silica-based media. The high chemical stability of the matrix offers unmatched flexibility when choosing running and cleaning conditions.

SOURCE 15RPC is intended for polishing where fast, preparative separations with the highest resolution are required. SOURCE 15RPC is also available in prepacked columns – RESOURCE RPC columns and ST 4.6/100 ÄKTAdesign columns – which are well-suited for selectivity screening experiments.

SOURCE 30RPC is well-suited for the polishing stage of industrial processes where high flow velocities and low back-pressures are needed.

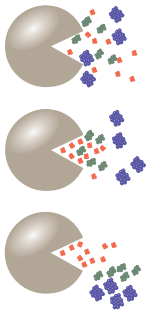
400-fold scale up on SOURCE 30RPC

Column:	SOURCE 30RPC, 10 mm i.d. × 300 mm column (24 ml) 200 mm i.d. × 300 mm column (10 l)
Sample:	Mixture of Angiotensin II, Ribonuclease A and Insulin
Sample load:	0.064 mg/ml media, total load
Solution A:	0.1% TFA/0.05 M NaCl
Solution B:	0.1% TFA/60% n-Propanol
Flow velocity:	150 cm/h
Gradient:	20–70% B, 5 column volumes (cv)



A 400-fold scale up of a model sample mix on SOURCE 30 RPC. Going from a 24-ml laboratory-scale column to a 9.4 liter production-scale column in one step gives what is essentially identical results at both scales.

Gel filtration



Technique description

Gel filtration separates biomolecules according to size. Large molecules elute either in the void volume or early in a chromatographic separation. Smaller molecules, depending on their degree of penetration of the pores of the matrix, elute later. Gel filtration is a simple technique which complements ion exchange, hydrophobic interaction, reversed phase, and affinity.

In process chromatography, gel filtration is used principally for desalting the product, for buffer exchange, or for specific removal of contaminants with molecular weights above or below the desired product's molecular weight. Typically, molecules must differ in size by two-fold to yield a good separation, although other adsorptive effects can augment some separations where molecules are similar in size.

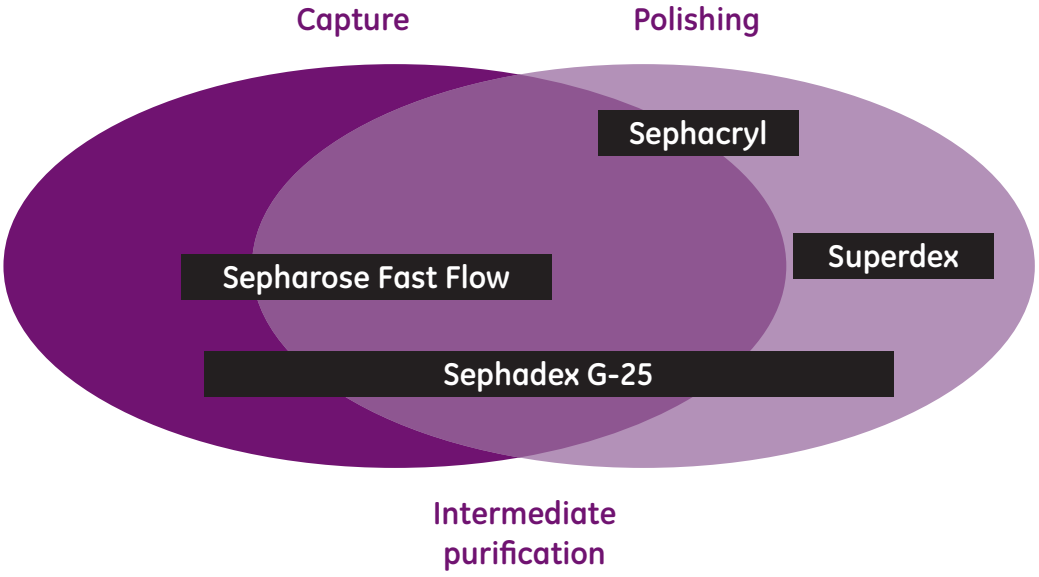
Excellent range

Gel filtration is useful at Polishing or final purification stages where volumes are much lower than at the Capture or Intermediate stages and there is a need to remove dimers or aggregates.
GE Healthcare has an excellent range of gel filtration media ranging from Sephadex G-types and different Sephacryl selectivities, to the Superdex family.

The handbook Gel Filtration – Principles and Methods can be obtained through your local GE Healthcare office or download from our website.

Code No. 18-1022-18.

Selection guide



Important characteristics of media for gel filtration include particle size, pore volume, adsorptive properties and matrix rigidity. Traditionally, media have been manufactured to encompass a broad separation range, but the trend is now towards a focus on a few key separations. These include a renewed interest in separating smaller macromolecules such as peptides and protein fragments, and removing dimers and aggregates. The Sephacryl range of gel filtration products is available in convenient prepacked HiPrep 120-ml and 320-ml columns. The Superdex range of gel filtration media has been specifically designed to solve particular purification problems. The fractionation ranges are narrow and selectivity curves are steep compared with other gel filtration media. Additionally, Superdex media are available in prepacked HiLoad 120-ml and 320-ml columns, which are a convenient way of obtaining reproducible results at lab-scale.

Superdex prep grade

High productivity gel filtration for Polishing

Superdex prep grade is a high resolving gel filtration medium with average particle size of 34 µm. It is a composite of cross-linked agarose and dextran. Superdex 30 prep grade is well-suited for the Polishing and formulation of peptides with molecular weights of less than 1×10^4, Superdex 75 prep grade is designed for the separation of recombinant DNA products, and Superdex 200 prep grade is particularly useful for the separation of monoclonal antibodies from dimers and low molecular weight contaminants (e.g., albumin and transferrin). Typical flow velocity is up to 50 cm/h and back pressure is typically below 3 bar with a 60 cm bed height. All of the Superdex prep grade media are available in prepacked high performance HiLoad 120-ml and 320-ml columns.

- Superdex 30 prep grade
- Superdex 75 prep grade
- Superdex 200 prep grade

Sephacryl High Resolution

Well established high resolution gel filtration for production

Sephacryl High Resolution media give high resolution and are very well established in production process and industrial scale applications. They are a cost effective alternative to Superdex prep grade media. Sephacryl S-100, S-200, and S-300 are available in convenient, prepacked HiPrep 120-ml (16/60) and 320-ml (26/60) columns.

- Sephacryl S-100 High Resolution
- Sephacryl S-200 High Resolution
- Sephacryl S-300 High Resolution
- Sephacryl S-400 High Resolution
- Sephacryl S-500 High Resolution

Sepharose Fast Flow

Industrial scale separations of very large molecules and virus particles

The properties of Sepharose 4 and 6 Fast Flow media make them suitable for industrial scale gel filtration. These media are also well established as matrices for affinity chromatography.

- Sepharose 4 Fast Flow
- Sepharose 6 Fast Flow

Sephadex G-25

Well established for desalting and buffer exchange

Sephadex G-25 media are well established for desalting and buffer exchange in industrial applications. These media have a low exclusion limit and separate macromolecules from salts and buffer substances with a minimum of sample dilution. Prepacked HiPrep 26/10 Desalting columns (53-ml) are available for fast and convenient desalting as well as Hitrap Desalting 1-ml and 5-ml columns.

- Sephadex G-25 Coarse
- Sephadex G-25 Medium
- Sephadex G-25 Fine
- Sephadex G-25 Superfine

Sephadex LH-20

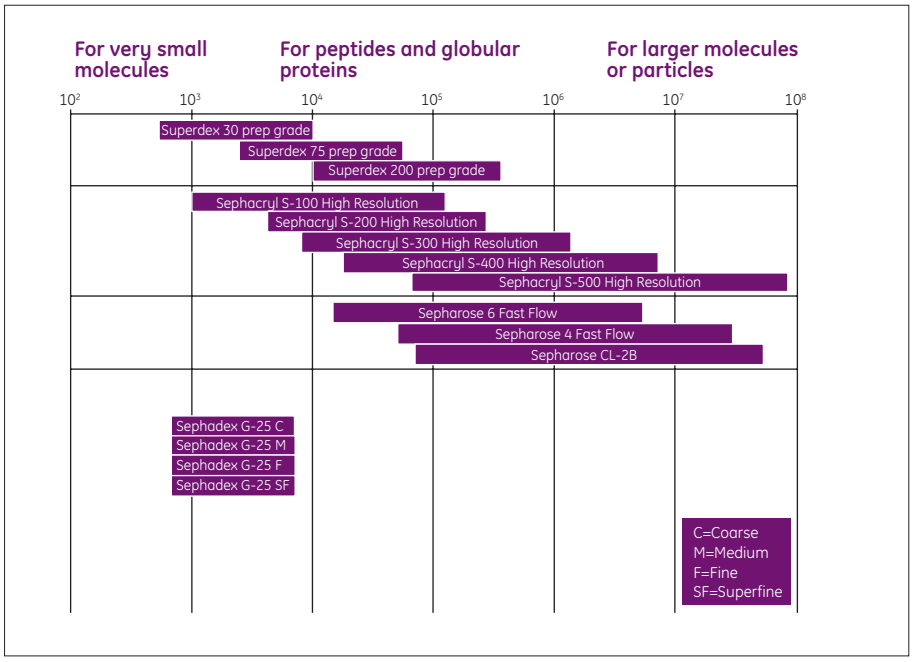
Gel filtration in organic solvents

This medium is for use with organic solvents when separating small molecules, lipids, steroids, fatty acids, hormones, etc.

- Sephadex LH-20

■ = BioProcess Media

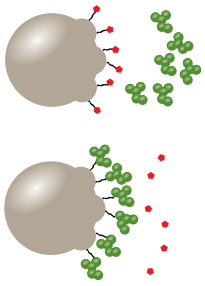
Application guide



Getting started

Testing the performance of separation media at the laboratory bench will help you select the most appropriate for process-scale use. HiLoad and HiPrep prepacked columns are convenient and reproducible and are well-suited for method development.

Custom designed media



GE Healthcare can provide large-scale operators with media designed for specific uses by varying the ligand, coupling chemistry and/or base matrix. Media developed by the Custom Designed Media (CDM) group are fully tested and quality controlled. Although some are made on an exclusive basis for a specific user, others are now generally available on receipt of order. Currently available CDM media are listed opposite.

Note: Many CDM media have become standard products and are classed as BioProcess Media. They are supported accordingly. These media are described elsewhere in this catalog in the relevant technique sections.

Custom designed media projects

A CDM project is run according to ISO 9001 routines and in collaboration with the customer, often under a confidentiality agreement. An experienced team works with you from the initial discussions right through to bulk delivery: establishing your needs, sorting through choices, and producing and testing the finished product to meet your delivery schedules. The final product is often a new combination of our existing base matrices and a ligand. The ligand could be one of our own, be available from an external supplier, extracted from a ligand library or discovered by you. Projects are carried out in three stages – media definition, media assurance and full-scale production and validation.

Media definition

The first stage involves discussions about the construction (matrix, ligands and coupling chemistry) required to obtain the desired product function. Alternatives can be suggested and samples prepared for your evaluation. From this evaluation and further discussions, the medium is defined.

Media assurance

With the product characteristics defined, it is necessary to ensure that we can obtain product consistency in a reproducible and scalable manufacturing process. We confirm with methods of analysis that the agreed product has been produced.
Preliminary specifications are set for the mutually agreed test criteria. Pilot scale volumes can be delivered when needed.

Full-scale production and validation

At this stage, manufacturing is scaled up to a batch-size suitable for future regular production. Test methods are validated and final specifications are set. Finally, the process is validated and transferred to regular production.

Every CDM product is designed to meet the stringent quality standards for commercial industrial use. Each undergoes full quality control, both during development and at full-scale production. Specific studies, such as stability, can be performed and Regulatory Support Files can be provided.
For further information about CDM, please contact your local GE Healthcare office.

Custom products

GE Healthcare offers a large selection of prepacked columns and bulk media encompassing most liquid chromatography techniques. Should you require a special configuration or combination of column and medium not offered in the catalog, just contact your local sales office and ask for Custom Products. See also Process Development on page 91 for details.

Ordering information

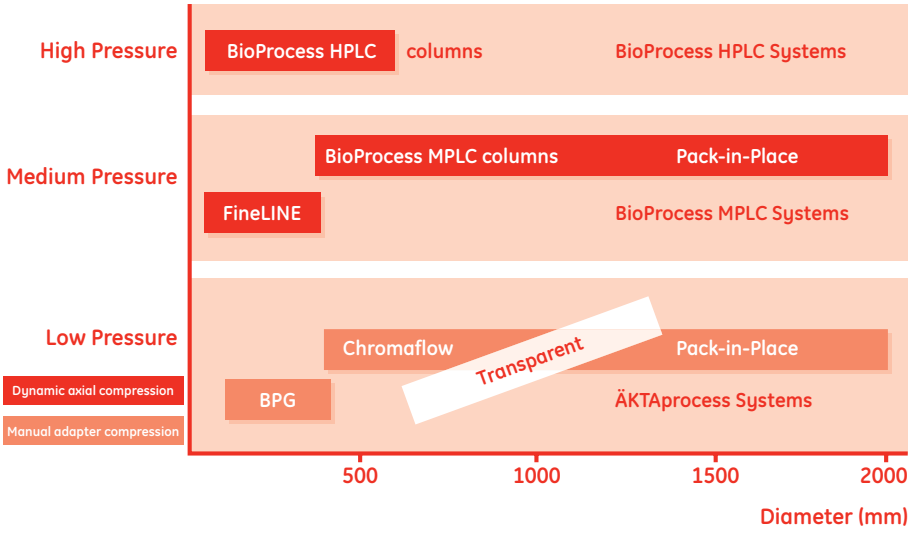
Product	Pack size	Code No.
6-AKS Sepharose 4 Fast Flow	1 l	17-3100-04
Amino Sepharose 6 Fast Flow	1 l	17-3092-09
ANX Sepharose 4 Fast Flow (low sub)	500 ml	17-1286-01
	5 l	17-1286-04
AVB Sepharose HP	75 ml	28-4112-01
	1 l	28-4112-02
Benzamidine Sepharose 4 Fast Flow (high sub)	100 ml	17-5123-01
	500 ml	17-5123-02
	5 l	17-5123-03
Benzamidine Sepharose 4 Fast Flow (low sub)	5 l	28-4108-03
Butyl Sepharose High Performance	1 l	17-5432-03
	5 l	17-5432-04
Butyl Sepharose 6 Fast Flow	1 l	17-5431-03
	5 l	17-5431-04
Chelating Sepharose Big Beads	1 l	17-5272-03
	10 l	17-5272-05
CM Sepharose High Performance	1 l	17-1277-03
	5 l	17-1277-04
	10 l	17-1277-05
ECH-Lysine Sepharose 4 Fast Flow	500 ml	17-0902-02
	5 l	17-0902-04
Gelatin Sepharose 4 Fast Flow	1 l	17-0976-03
	5 l	17-0976-04
IgG Sepharose 6 Fast Flow	200 ml	17-0969-02
	5 l	17-0969-04
Phenyl Sepharose Big Beads	1 l	17-5098-03
	10 l	17-5098-05
Plasminogen Removal Gel	1 l	28-4109-03
Procainamide Sepharose 4 Fast Flow	1 l	28-4111-03
	5 l	28-4111-04

Chromatography columns

INdEX
BPG
Chromaflow
FineLINE
BioProcess MPLC/HPLC

Columns for process chromatography

Selection guide



When a chromatographic step is developed to be an integral part of a manufacturing process, the choice of column is important to assure consistent performance and reliable operation. With over 30 years experience in process chromatography, GE Healthcare can provide you with a wide range of columns that ensures the highest performance from our separation media and meets the demands of modern biopharmaceutical manufacturing. Know-how in packing methodology is available through our User Manuals. Workshops with lectures and hands-on training can be arranged through our Fast Trak services.

Points to consider when selecting your column

- **Dimensions:** To determine the appropriate column diameter at full-scale, calculate the column volume (or medium quantity) required based on your current scale, keeping bed height constant (usually 5 to 20 cm for adsorptive techniques and 50 to 70 cm for gel filtration). If the exact diameter is not available, choose a wider diameter column, the advantage being increased capacity.

- **Specifications:** Particle size, size distribution, flow rates and the solvent used will affect your choice of column. As particle size decreases, operational pressures increase. Two different media with the same nominal particle size, but with different particle size distributions may have significantly different pressure requirements.

  Solvent systems may restrict the choice of column materials, for example plastic or rubber components are unsuitable for use with some organic solvents. High salt buffers may dictate the grade or type of metal component, such as stainless steel 316L.

- **Design features:** Proven hygienic design and high quality materials are necessary if the column is to be used for biopharmaceutical production. A fixed bed column is more hygienic than the respective variable bed height column, but this must be set against the greater flexibility afforded by the variable height.

  For media requiring additional bed compression at the end of the packing procedure, a variable bed height column would be needed. In process development, diagnostics, or reagent manufacturing, some design criteria are less critical, and for example the use of threaded or sanitary connections may not be as important.

  Select only columns with a proven distribution system since performance can be jeopardized with inadequate distribution of sample and buffer. Bed support porosity is dictated by the particle size of the medium used.

- **Regulatory support:** Columns used in biopharmaceutical production or other regulated environments are scrutinized by regulatory authorities. Increasingly, documentation on materials compliance and toxicological data are requested.

  GE Healthcare supports the columns recommended for use in therapeutic manufacturing with hardware product documentation. The information in these files can save you valuable time when submitting clinical and marketing applications to regulatory authorities. In addition, Fast Trak services can support installation and operational qualifications.

- **Technical support online:** The process chromatography technical support portal provides users with a range of information including column and system recommendations, spare parts and accessories for columns and systems, column packing and testing information, and troubleshooting guides. Refer to Regulatory and Technical Support Services.
  www.gehealthcare.com/purification-techsupport

INdEX columns

INdEX are easy-to-use, general purpose, glass columns well-suited for applications such as process development and diagnostics production. These columns are characterized by their simple design and the novel, axial compression packing method that yields a densely packed bed in under 10 minutes.

INdEX range

- Scalable from inner diameters of 70 to 200 mm and bed volumes from 0.1 to 25 liters.
- Pressure rating 3 bar.
- For use with an array of techniques and media, especially Sepharose Fast Flow.
- Proven distribution system.
- Dynamic axial compression yields densely packed, high efficiency beds.
- Materials include electropolished stainless steel, borosilicate glass and polymers.
- Packing devices for longer bed heights.

Overview of INdEX columns

Column	Tube inner diam (mm)	Tube height (cm)	Cross-sectional area (cm^2)	Bed height (cm) min	Bed height (cm) max[1,2]	Bed volume (l) min	Bed volume (l) max[1,2]	Max pressure (bar)[3]
INdEX 70/500	70	50	38	3	32 (41)	0.1	1.2 (1.6)	3
INdEX 70/950	70	95	38	48	61 (79)	1.8	2.3 (3.0)	3
INdEX 100/500	100	50	79	3	32 (41)	0.2	2.5 (3.2)	3
INdEX 100/950	100	95	79	48	61 (79)	3.8	4.8 (6.2)	3
INdEX 140/500	140	50	154	3	32 (41)	0.5	4.9 (6.3)	3
INdEX 140/950	140	95	154	48	61 (79)	7.4	9.4 (12.2)	3
INdEX 200/500	200	50	314	3	32 (41)	0.9	10.0 (12.9)	3
INdEX 200/950	200	95	314	48	61 (79)	15.1	19.2 (24.8)	3

[1] Maximum bed volumes and bed heights are based on a slurry concentration of 75% and a packing compression of 15%.
[2] The figures within brackets are achievable using a packing device.
[3] Use a manometer to monitor the pressure.

What do I need?

Stands and wheels
INdEX 70 and 100 stands have adjustable feet. Castors with brakes are available. INdEX 140 and 200 stands have castors with brakes as standard.

Useful spare parts
Nets: The column is delivered with 23 µm (polypropylene) nets. For media with an average particle diameter <70 µm, change to 10 µm (polyamide) in both adaptors and end-pieces.
Seals: Inspect the seals on a regular basis for signs of wear.

Spare parts to keep on site
All nets, support screens and O-rings. In some cases, a spare tube may be advisable.

Longer bed heights
Packing extensions are available for all diameters. For packing INdEX columns with the packing device for BPG columns, an extra lid kit has to be ordered.

Isolating the column after packing
We recommend using 25-mm blind flanges with clamp and gasket to prevent contamination of the packed bed.

Connecting the column to your system
A clamp and gasket, 6 mm i.d., is required to connect the 25-mm sanitary flanged inlet/outlet to either valves or tubing of the same type. Preflanged tubing in 6 mm i.d. is also available.

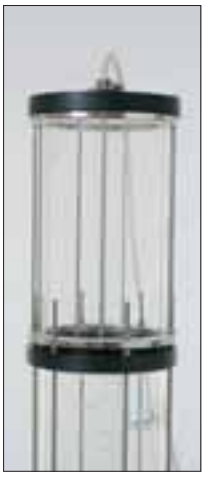
Assembly/disassembly of column
No tools are required as all fittings are finger-tight.

Useful column accessories
Air Traps: INdEX Air Trap Complete includes the air trap, mounting bracket, steel valves, clamps, gaskets and tubings, 25 mm TC.
Top valve: Manually operated valve recommended at the top of the airtrap as an air outlet control.
Manometers: Manometer kits contain a pressure gauge, T-junction, necessary clamps and gaskets for sanitary connections.
Pressure relief valve: Required for the hydraulic packing procedure. It is connected between the pump and hydraulic inlet to ensure flow delivery at a constant pressure throughout the packing procedure.
Safety valve: Precalibrated valve that releases pressure if the calibrated value is exceeded. Recommended if the column may exceed its maximum pressure limit and no other pressure sensor is included in the chromatographic system. T-junction, clamps and gaskets have to be ordered separately.

Ordering information

Column	Code No.
INdEX 70/500	18-1115-06
INdEX 70/950	18-1115-07
INdEX 100/500	18-1104-15
INdEX 100/950	18-1104-16
INdEX 140/500	18-1115-08
INdEX 140/950	18-1115-09
INdEX 200/500	18-1104-17
INdEX 200/950	18-1104-18
Stand	**Code No.**
INdEX 70 stand	18-1103-60
INdEX 100 stand	18-1103-60
INdEX 140 stand	18-1103-61
INdEX 200 stand	18-1103-61

Stands must be ordered separately



Packing extension.

Air trap, top valve, pressure gauge and safety valve.

Accessories for INdEX columns

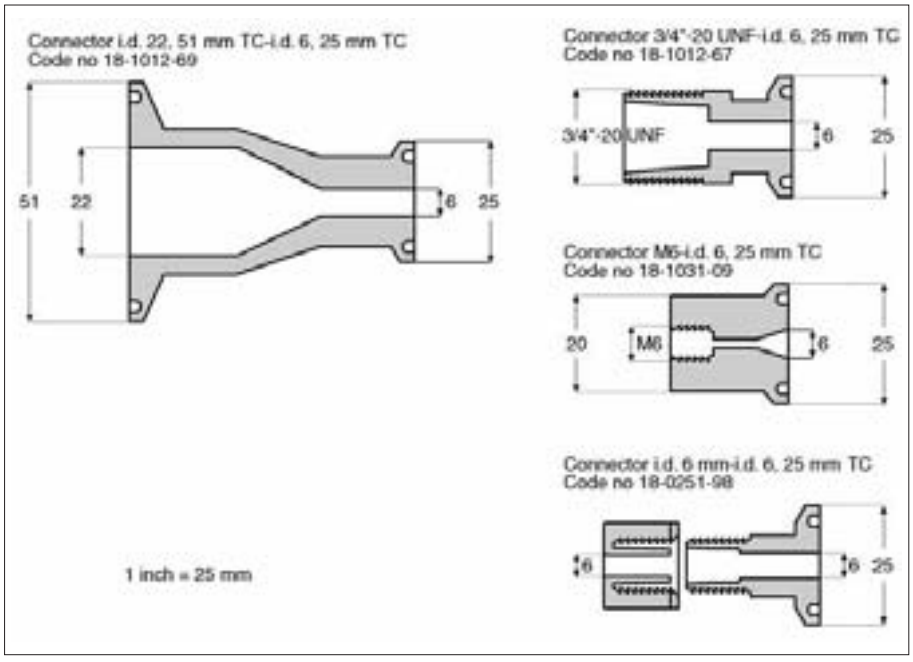
Accessory	INdEX 70	INdEX 100	INdEX 140	INdEX 200	Qty/pack	Material
Air Trap Complete[3]	18-1102-96	18-1102-96	18-1102-97	18-1102-97	1	SS 316/Glass
Top valve[3]	18-1121-44	18-1121-44	18-1121-44	18-1121-44	1	SS 316/EPDM
Valves						
4-port, 2-way[3]	18-5757-01	18-5757-01	18-5757-01	18-5757-01	1	SS 316L/PTFE
4-port, 4-way[3]	18-5758-01	18-5758-01	18-5758-01	18-5758-01	1	SS 316L/PTFE
Valve sealing, washer[6]	18-1128-69	18-1128-69	18-1128-69	18-1128-69	2	PTFE
T-junction[5]	18-1104-29	18-1104-29	18-1104-29	18-1104-29	1	SS 316
Safety valve[4]	18-5738-01	18-5738-01	18-5738-01	18-5738-01	1	SS 316/EPDM
Pressure relief valve[3]	18-1105-36	18-1105-36	18-1105-36	18-1105-36	1	SS 316/FPM
Manometer[4]	18-1119-29	18-1119-29	18-1119-29	18-1119-29	1	SS 316
Manometer kit[4]	18-1119-28	18-1119-28	18-1119-28	18-1119-28	1	–
Castor	18-1001-09	18-1001-09	18-1001-09	18-1001-09	1	–
Adjustable foot	18-1126-93	18-1126-93	18-1126-93	18-1126-93	1	–
Tubing with sanitary fitting						
i.d. 6 mm[3]						
30 cm	18-0005-42	18-0005-42	18-0005-42	18-0005-42	1	PVC
75 cm	18-0005-43	18-0005-43	18-0005-43	18-0005-43	1	PVC
125 cm	18-0005-44	18-0005-44	18-0005-44	18-0005-44	1	PVC
150 cm	18-0005-45	18-0005-45	18-0005-45	18-0005-45	1	PVC
200 cm	18-0005-47	18-0005-47	18-0005-47	18-0005-47	1	PVC
Connectors (see p 61)						
i.d. 6 mm. 25 mm TC						
6 mm threaded	18-0251-98	18-0251-98	18-0251-98	18-0251-98	2	PP
25 mmTC-3/4"-20						
UNF threaded	18-1012-67	18-1012-67	18-1012-67	18-1012-67	2	PP
25 mm TC-M6 threaded	18-1031-09	18-1031-09	–	–	2	PP
25 mm TC-i.d. 22 mm,						
51 mm TC	18-1012-69	18-1012-69	18-1012-69	18-1012-69	2	PP
Clamp 25 mm	18-1001-31	18-1001-31	18-1001-31	18-1001-31	1	SS 304
Clamp 51 mm	44-7134-01	44-7134-01	44-7134-01	44-7134-01	1	SS 304
Gasket 25 mm	18-0019-27	18-0019-27	18-0019-27	18-0019-27	2	EPDM
Gasket 51 mm	18-1012-88	18-1012-88	18-1012-88	18-1012-88	5	EPDM
Blind flange, 25 mm incl. gasket	18-1001-25	18-1001-25	18-1001-25	18-1001-25	1	SS 304/EPDM
Blind flange 51 mm incl. gasket	44-7135-01	44-7135-01	44-7135-01	44-7135-01	1	SS 304/EPDM
Packing device with PP lid[1]	18-1114-35	18-1104-22	18-1114-36	18-1104-23	1	Glass
Lid kit[2] for packing device		18-1108-63	18-1114-37	18-1108-64	1	–

[1] The packing device consists of PP lid, a 380 mm glass tube, flanged, rods, O-rings in EPDM, bed support, adaptor bed support, screws and nuts.
[2] The lid kit consists of PP lid, O-rings in EPDM, bed support, adaptor bed support, screws and nuts. The lid kit can be used together with the packing devices for BPG 100, 140 and 200 columns on INdEX columns of the same size.
[3] 25 mm TC.
[4] 51 mm TC.
[5] 2 × 25 mm, 1 × 51 mm TC.
[6] Fits 2-way and 4-way valves.

Spare parts for INdEX columns

	INdEX 70	INdEX 100 Code No.	INdEX 140 Code No.	INdEX 200 Code No.	Qty/pack Code No.	Material
Column tube 500	18-1114-14	18-1104-49	18-1114-12	18-1104-51	1	Borosilicate glass
Column tube 950	18-1114-15	18-1104-50	18-1114-13	18-1104-52	1	Borosilicate glass
Bed support, adaptor	18-1114-24	18-0251-56	18-1112-99	18-0252-56	2	PP
Bed support 23 µm, adaptor	18-1114-26	18-9251-01	18-1113-01	18-9253-01	2	PP
Bed support 10 µm, adaptor	18-1114-28	18-0251-76	18-1113-03	18-0252-76	2	PA
Bed support, end-piece	18-1114-25	18-0251-55	18-1112-98	18-0252-55	2	PP
Bed support 23 µm, end-piece	18-1114-27	18-9252-01	18-1113-00	18-9254-01	2	PP
Bed support 10 µm, end-piece	18-1114-29	18-0251-77	18-1113-02	18-0252-77	2	PA

Material abbreviations: EPDM=ethylene propylene diene, FPM=fluorocarbon rubber, PA=polyamide, PP=polypropylene, PTFE=polytetrafluoroethene, PVC=polyvinyl chloride, SS=stainless steel.



Literature

Data File	Code No.
INdEX Columns 70-200 series	18-1115-61

BPG columns

BPG columns are glass columns designed for use in the production of biopharmaceuticals or any product made in a regulated or current Good Manufacturing Practice (cGMP) environment. The columns are manufactured with materials carefully selected for their compatibility with the solvents most commonly used in biopharmaceutical manufacture. All polymeric materials are approved according to USP Class VI tests for toxicity.

BPG range

- Scalable from inner diameters of 100 mm to 450 mm and bed volumes from 2 to 131 liters.
- Pressure rating up to 8 bar.
- Proven hygienic design and easy cleaning-in-place.
- For use with a variety of techniques and chromatographic media, especially BioProcess Media (Superdex, Sepharose High Performance and Fast Flow, and Sephacryl).
- Proven distribution system.
- Sanitary TC connections throughout.
- Materials include electropolished stainless steel, calibrated borosilicate glass, EPDM and fluoroplastics – all with high chemical resistance.
- All polymeric materials are approved according to USP Class VI tests for toxicity.
- IQ and OQ documentation packages available.
- Validation support documentation available on request.
- Packing devices available for long bed heights.

Overview of BPG columns

Column	Tube inner diam (mm)	Tube height (mm)	Cross sectional area (cm^2)	Bed height* min (cm)	Bed height* max (cm)	Bed height* with packing device (cm)	Bed vol* min (L)	Bed vol* max (L)	Bed vol* with packing device* (L)	Max pressure (bar)	Total weight (kg)	Overall dimensions d×w×h (cm)
BPG 100/500	100	500	79	0	26	35*	0	2.1	3.8	8	15	48×48×127
BPG 100/750	100	750	79	25	41	66	2.0	3.3	5.3	8	16	48×48×152
BPG 100/950	100	950	79	45	54	83**	3.6	4.3	6.6**	8	17	48×48×172
BPG 140/500	140	500	154	0	26	35*	0	4.0	7.4	6	25	59×59×127
BPG 140/950	140	950	154	45	54	83	6.9	8.3	12.8	6	27	59×59×172
BPG 200/500	200	500	314	0	26	35*	0	8.2	15.1	6	34	59×59×127
BPG 200/750	200	750	314	25	41	66	7.9	12.9	20.7	6	36	59×59×152
BPG 200/950	200	950	314	45	54	83**	14.1	17.0	26.1**	6	39	59×59×172
BPG 300/500	296	500	688	0	26	35*	0	17.9	33.0	4	68	69×69×133
BPG 300/750	296	750	688	25	41	66	17.2	28.2	45.4	4	73	69×69×158
BPG 300/950	296	950	688	45	54	83**	31.0	37.2	57.1**	4	78	69×69×178
BPG 450/500	446	500	1562	3	23	42	4.7	35.9	65.6	2.5	200	80×80×140
BPG 450/750	446	750	1562	22	39	58	34.4	60.9	90.6	2.5	215	80×80×165
BPG 450/1000	446	1000	1562	47	58	83***	73.4	90.6	131.2***	2.5	230	80×80×190

* based on a slurry concentration of 75%, packing compression 15%
** based on a slurry concentration of 80%, packing compression 15%
*** based on a slurry concentration of 85%, packing compression 15%

What do I need?

The column

BPG 100, 140 & 200; stand kit must be ordered separately. BPG 100 has adjustable feet, wheels with brakes are available. BPG 140 & 200 stands have wheels with brakes as standard. BPG 300 & 450; supplied with stainless steel stand with wheels and foot-operated brakes.

Useful spare parts

Nets: The column is delivered with 23 µm (polypropylene) nets.
For media with an average particle diameter <70 µm, change to 10 µm (polyamide) or 12 µm (polypropylene) in both adaptors and endpieces. For Sepharose Big Beads use 54 µm nets.

O-rings: FEP adaptor and sealing O-rings if solvents not compatible with the EPDM O-rings supplied with the column.

Gaskets: Use PTFE gaskets if solvent not compatible with EPDM.

Spare parts to keep on site

All nets, support screens and O-rings. In some cases, a spare tube may be advisable.

Longer bed heights

Packing extensions are available for all diameters.

Isolating the column after packing

We recommend using sanitary stainless steel valves of the appropriate inner diameter to prevent contamination of the packed bed. The 2-way or 4-way valves with a 6 mm i.d. are suitable for BPG 100, 140 and 200 columns. The 10 mm i.d. is suitable for BPG 300 and 450 columns. For storage purposes, the 25-mm blind flange with a clamp and gasket can be used to seal off the column.

Standard accessories: packing extension, tubing, valves, safety valves, air trap, T-junction, pressure relief valve, clamps, gaskets, manometer and top-valve.

Connecting the column to your system

A clamp and gasket, 6 or 10 mm i.d., are required to connect the 25-mm sanitary flanged inlet/outlet to either valves or tubing of the same type. Preflanged tubing in 6 and 10 mm i.d. is available.

Assembly/disassembly of column

A torque wrench with an appropriate sized socket is required and can be ordered separately.

Useful column accessories

Air Traps: BPG Air Trap Complete includes the air trap, mounting bracket, steel valves, clamps and gaskets. For air traps for BPG 100, 140 and 200, tubing is included.

Top valve: Manually operated valve recommended at the top of the airtrap as an air outlet control.

Manometers: Manometer kits contain a pressure gauge, T-junction, and necessary clamps and gaskets for sanitary connections.

Air trap, top valve, manometer and safety valve.

Pressure relief valves: Connected between the pump and column inlet permit flow delivery at a constant pressure throughout the packing procedure.

Safety valve: Precalibrated valve that releases pressure if the calibrated value is exceeded. Recommended if the column may exceed its maixmum pressure limit and no other pressure sensor is included in the chromatographic system. T-junction, clamps and gaskets have to be ordered separately.

Earlier design: For ordering accessories and spare parts to the former design of the BPG 100, 200 and 300 columns, design pressure 3 bar, see Instruction Manual Code No. 18-1030-99.

Suitable systems: BPG columns are designed for use with ÄKTAprocess Systems and have design pressures of 8 bar (BPG 100), 6 bar (BPG 140 and 200), 4 bar (BPG 300) and 2.5 bar (BPG 450). Please contact your local GE Healthcare representative for details.

Ordering information

	Tube height			
Column	500 mm	750 mm	950 mm	Stand
BPG 100	18-1103-01	18-1103-02	18-1103-03	18-1031-10
BPG 140	18-1113-08		18-1113-09	18-1031-20
BPG 200	18-1103-11	18-1103-12	18-1103-13	18-1031-20
BPG 300	18-1103-21	18-1103-22	18-1103-23	included
			1000 mm	
BPG 450	18-1103-71	18-1103-72	18-1103-73	included

Each column includes as standard: 23 µm polypropylene filter bed supports and polypropylene coarse bed supports, 2 clamps, 2 EPDM gaskets, 2 blank caps and O-rings in EPDM.

Column with packing extension.

Accessories for BPG columns

Accessory	BPG 100	BPG 140	BPG 200	BPG 300	BPG 450	Qty/pk	Material
Air Trap Complete[2]	18-1102-96	18-1102-97	18-1102-97	18-1102-98	18-1103-00	1	SS 316/Glass
Top valve[2]	18-1121-44	18-1121-44	18-1121-44	18-1121-44	18-1121-44	1	SS 316L/EPDM
Valves[2]							
4-port, 2-way i.d. 6 mm	18-5757-01	18-5757-01	18-5757-01	–	–	1	SS 316L/PTFE
4-port, 2-way i.d. 10 mm	–	–	–	18-1012-56	18-1012-56	1	SS 316L/PTFE
3-port, 2-way i.d. 15 mm	–	–	–	–	44-5499-90	1	SS 316L/PTFE
4-port, 4-way i.d. 6 mm	18-5758-01	18-5758-01	18-5758-01	–	–	1	SS 316L/PTFE
4-port, 4-way i.d. 10 mm	–	–	–	18-1012-57	18-1012-57	1	SS 316L/PTFE
Valve sealing washer[5]	18-1128-69	18-1128-69	18-1128-69	18-1128-69	18-1128-69	2	PTFE
Pressure relief valve[2] i.d. 6 mm	18-1105-36	18-1105-36	18-1105-36	18-1105-36	–	1	SS 316/FPM
Safety valve[3, 5]	18-1035-80	18-1035-81	18-1035-81	18-1035-82	18-1103-65	1	SS 316/EPDM
T-junction[4]	18-1104-29	18-1104-29	18-1104-29	18-1003-63	18-1003-63	1	SS 316
Manometer kit[3]	18-1031-07	18-1031-07	18-1031-07	18-1031-08	18-1031-08	1	–
Manometer[3]	18-1103-67	18-1103-67	18-1103-67	18-1103-68	18-1103-68	1	SS 316
Castor	18-1001-09	18-1001-09	18-1001-09	18-1001-09	18-1001-09	1	–
Adjustable foot	18-1126-93	18-1126-93	18-1126-93	–	–		–
Manometer 0–10 bar	11-0011-18	11-0011-18	11-0011-18	–	–	1	SS 316
Manometer 0–6 bar	–	–	–	11-0011-19	11-0011-19	1	SS 316
Tubing with sanitary fitting[2]							
30 cm i.d. 6 mm	18-0005-42	18-0005-42	18-0005-42	–	–	1	PVC
30 cm i.d. 10 mm	–	–	–	18-1012-85	18-1012-85	1	PVC
40 cm i.d. 10 mm	–	–	–	18-1012-86	18-1012-86	1	PVC
75 cm i.d. 6 mm	18-0005-43	18-0005-43	18-0005-43	–	–	1	PVC
75 cm i.d. 14 mm	–	–	–	–	18-1027-28	1	PVC
90 cm i.d. 10 mm	–	–	–	18-1012-62	18-1012-62	1	PVC
125 cm i.d. 6 mm	18-0005-44	18-0005-44	18-0005-44	–	–	1	PVC
140 cm i.d. 10 mm	–	–	–	18-1012-63	18-1012-63	1	PVC
150 cm i.d. 6 mm	18-0005-45	18-0005-45	18-0005-45	–	–	1	PVC
170 cm i.d. 10 mm	–	–	–	18-1012-64	18-1012-64	1	PVC
180 cm i.d. 14 mm	–	–	–	–	18-1027-29	1	PVC
200 cm i.d. 6 mm	18-0005-47	18-0005-47	18-0005-47	–	–	1	PVC
200 cm i.d. 10 mm	–	–	–	18-1012-87	18-1012-87	1	PVC
Connectors (see p 78–79)							
i.d. 6, 25 mm TC- 6 mm threaded	18-0251-98	18-0251-98	18-0251-98	–	–	2	PP
i.d. 6, 25 mm TC- 3/4"-20 UNF threaded	18-1012-67	18-1012-67	18-1012-67	–	–	2	PP
i.d. 6, 25 mm TC- M6 threaded	18-1031-09	–	–	–	–	2	PP
i.d. 6, 25 mm TC- i.d. 22, 51 mm TC	18-1012-69	18-1012-69	18-1012-69	–	–	2	PP
i.d. 10, 25 mm TC – 3/4"-20 UNF threaded	–	–	–	18-1012-68	18-1012-68	2	PP
i.d. 10, 25 mm TC- i.d. 14, 51 mm TC	–	–	–	18-1027-25	18-1027-25	2	PP
i.d.14, 51 mm TC- i.d. 22, 51 mm TC	–	–	–	–	18-1027-26	2	PP
Clamp 25 mm	18-1001-31	18-1001-31	18-1001-31	18-1001-31	18-1001-31	1	SS 304
Clamp 51 mm	44-7134-01	44-7134-01	44-7134-01	44-7134-01	44-7134-01	1	SS 304
Gasket 25 mm i.d. 6 mm	18-0019-27	18-0019-27	18-0019-27			2	EPDM
Gasket 25 mm i.d. 6 mm	18-0019-28	18-0019-28	18-0019-28			2	PTFE
Gasket 25 mm i.d. 10 mm	–	–	–	18-1035-79		2	EPDM
Gasket 25 mm i.d. 10 mm	–	–	–	18-1012-40		2	PTFE
Gasket 25 mm i.d. 12 mm	–	–	–	–	18-0200-00	2	EPDM
Gasket 25 mm i.d. 12 mm					44-5506-20	2	PTFE
Gasket 51 mm i.d. 10 mm				18-1012-88	18-1012-88	5	EPDM
Gasket 51 mm i.d. 14 mm				–	18-1017-57	5	EPDM
Gasket 51 mm i.d. 22 mm	44-7133-01	44-7133-01	44-7133-01	44-7133-01	44-7133-01	5	EPDM
Gasket 51 mm i.d. 22 mm	44-5512-03	44-5512-03	44-5512-03	44-5512-03	44-5512-03	2	PTFE
Blind flange 25 mm incl gasket	18-1001-25	18-1001-25	18-1001-25	18-1001-25	18-1001-25	1	SS 304/EPDM
Blind flange 51 mm incl gasket	44-7135-01	44-7135-01	44-7135-01	44-7135-01	44-7135-01	1	SS 304/EPDM
Torque wrench	18-0251-37	18-0251-37	18-0251-37	18-0251-37	18-0251-37	1	SS 304
12-point opening socket	18-1031-03	18-1031-04	18-1031-04	18-1031-05	18-1105-31	1	SS 304
Allen key	18-1030-98	18-1030-98	18-1030-98	18-1030-98	18-1030-98	1	SS 304
Packing device glass[1]	18-1104-75	18-1113-33	18-1104-77	18-1108-16	–	1	Glass
Packing device[1]	–	–	–	–	18-1105-32	1	SS 316
Media stirrer (80 mm Ø)	18-1149-80	18-1149-80	18-1149-80	–	–	1	–
Media stirrer (150 mm Ø)	–	–	–	18-1149-81	18-1149-81	1	–

[1] The packing device for BPG 100-200 consists of a 380 mm high glass tube, flanges, rods, O-rings in EPDM, nuts and screws. The packing device for BPG 300 consists of a 380 mm high glass tube, flanges, rods, O-rings in EPDM, nuts and a clamp. The packing device for BPG 450 consists of a 300 mm high stainless steel tube, O-rings, nuts and a clamp.

[2] 25 mm TC.

[3] 51 mm TC.

[4] 2×25, 1×51 mm TC.

[5] BPG 100 - 8 bar, BPG 140-200 - 6 bar, BPG 350 - 4 bar.

Spare parts for BPG columns

Spare part	BPG 100	BPG 140	BPG 200	BPG 300	BPG 450	Qty/pack	Material
Column tube 500	18-0251-01	18-1112-95	18-1152-01	18-1012-28	18-1103-14	1	Borosilicate glass
Column tube 750	18-0251-02	–	18-1152-02	18-1012-29	18-1103-15	1	Borosilicate glass
Column tube 950	18-0251-03	18-1112-96	18-1152-03	18-1012-30	–	1	Borosilicate glass
Column tube 1000	–	–	–	–	18-1103-16	1	Borosilicate glass
Flange O-ring	18-8494-01	18-1113-06	18-8489-01	18-1012-26	18-1105-33	2	EPDM
Flange O-ring	18-0019-41	18-1113-07	18-0019-51	18-1012-27	18-1117-67	1	FEP
Adaptor O-ring	18-8475-01	18-1113-10	18-0275-01	18-1012-51	18-1017-47*	2	EPDM
Adaptor O-ring	18-0019-40	18-1113-11	18-0019-50	18-1012-52	18-1117-66	1	FEP
U-shaped seal	–	–	–	–	18-1104-40	1	EPDM
U-shaped seal	–	–	–	–	18-1117-55	1	PFR
Bed support, adaptor	18-1103-04	18-1112-99	18-0252-56	18-1012-53	18-1104-34*	2	PP
Bed support, end-piece	18-0251-55	18-1112-98	18-0252-55	18-1012-36	18-1104-35*	2	PP
Bed support, 10 µm, adaptor	18-1103-05	18-1113-03	18-0252-76	18-1012-55	18-1017-46*	2	PA
Bed support, 10 µm, end-piece	18-0251-77	18-1113-02	18-0252-77	18-1012-35	18-1103-18*	2	PA
Bed support, 12 µm, adaptor	18-1148-37	18-1148-39	18-1148-41	18-1148-43	18-1148-45*	2	PEEK
Bed support, 12 µm, end-piece	18-1148-38	18-1148-40	18-1148-42	18-1148-44	18-1148-46*	2	PEEK
Bed support, 23 µm, adaptor	18-1103-08	18-1113-01	18-9253-01	18-1012-54	18-1001-62*	2	PP
Bed support, 23 µm, end-piece	18-9252-01	18-1113-00	18-9254-01	18-1012-34	18-1103-19*	2	PP
Bed support, 54 µm adaptor	18-1126-96	18-1126-98	18-1127-00	18-1127-02	18-1127-04*	2	PP
Bed support, 54 µm end-piece	18-1126-97	18-1126-99	18-1127-01	18-1127-03	18-1127-05	2	PP

* One per pack

Material abbreviations: EPDM=ethylene propylene diene, FEP=fluoroethenepropene, FPM=fluorocarbon rubber, PA=polyamide, PFR=perfluor rubber, PP=polypropylene, PTFE=polytetrafluoroethene, PVC=polyvinyl chloride, SS=stainless steel.

Literature

Data Files	Code No.
BPG Columns 100, 140, 200, 300 and 450 series	18-1115-23
Application Notes	
Sanitization of BPG Columns	18-1020-86
Sanitization of BPG 450 Column	18-1117-76

Documentation to support validation available on request. Contact your local GE Healthcare office.

Chromaflow columns

Chromaflow columns represent an innovative development in process scale chromatography resulting in improved process reliability, safety and economics.

With Chromaflow columns, packing, operation, unpacking and cleaning can be done without removing the lid or adaptor – all due to the design of the nozzle in both the top and bottom end-pieces. With the establishment of packing protocols for individual media, large-scale chromatography is more convenient, scalable and safer for both the operators and the product. Chromaflow columns are intended for GMP production. Materials of manufacture and column design, which are consistent over all scales, meet the demands of regulatory authorities for cGMP facilities producing biopharmaceuticals.

Chromaflow range

- Diameters start at 300 mm and end at 2000 mm.
- Design principle is common to all column dimensions making scale-up a simple operation.
- 3 bar pressure rating as standard and up to 5 bar as custom made.
- Transparent, high quality cast acrylic or electropolished stainless steel tube.
- Hygienic design tested in microbial challenge studies.
- Packing stations simplify packing and unpacking.
- All polymeric materials are approved according to USP Class VI tests for toxicity.
- Full documentation package Validation support documentation available on request.
- Documentation to support validation delivered with the product.

For customized Chromaflow columns, please contact your local representative.

Properties of Chromaflow columns

Design specifications	
Design temperature	4–30°C
Operating pressure	3 bar
CE-directive compliance	PED/ATEX100
Design standard	GE Healthcare GEP
Surface finishes, stainless steel	
Internal wetted	< 0.5 µm Ra EP
Non-wetted parts	< 3 µm Ra EP

Material specifications	
Tube	Acrylic (PMMA)/316L
Distributor plates	Polypropylene
Bed supports	Polyethylene/316L
Seals	FEP encapsulated silicone & EPDM
Nozzle body	Polypropylene
Nozzle tube	PEEK 450 G/316L
Nozzle tip	PEEK 450G
Stand	316

For more information contact your GE Healthcare representative.

Principle of operation

Nozzles sit in both the top and bottom of the column allowing packing in either an upward or downward direction. There are three nozzle positions: mid-position, for priming and packing; retracted, for running; and fully extended into the column for unpacking and cleaning. The nozzle also enables isolation of slurry lines from the mobile phase during operation, allowing removal of residual medium and cleaning of the slurry lines independently of the rest of the column.
In the example opposite, packing is via the lower nozzle with upward flow.

Packing position

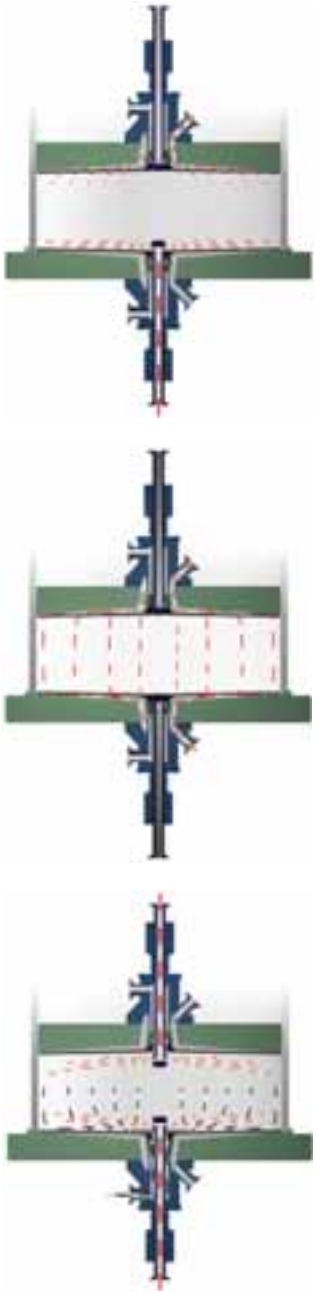
The bottom nozzle extends part of the way (mid position) into the column. The top nozzle is fully retracted. Slurry enters the column via the bottom nozzle and excess liquid exits via the top mobile phase outlet. After packing, the slurry lines are isolated from the mobile phase and can be cleaned independently from the rest of the column.

Running position

The top and bottom nozzles are retracted. Mobile phase enters the column directly into an annulus immediately behind the bed support. The annulus is cut through at an angle to ensure that the linear flow rate is kept constant during distribution of the mobile phase across the bed.

Unpacking position

In this position, both bottom and top nozzles are fully extended into the column, thereby exposing a third passage through which medium leaves the column. Cleaning solution can be pumped through the nozzles and sprayed into the column. In this way, the column is easily and effectively cleaned without exposing the interior or the medium to the outside, or without dismantling the column.



Ordering information

Chromaflow columns with acrylic tubes	Bed support 10 mm SS sinter	Bed support 20 mm SS sinter	Bed support 20 mm PE sinter
I.d. 400 mm Man. nozzle			
Stroke length 100-300	18-1150-40	18-1159-40	18-1161-40
Stroke length 200-400	18-1157-42	18-1159-42	18-1161-42
Stroke length 300-500	18-1157-44	18-1159-44	18-1161-44
I.d. 400 mm Auto. nozzle			
Stroke length 100-300	18-1157-41	18-1159-41	18-1161-41
Stroke length 200-400	18-1157-43	18-1159-43	18-1161-43
Stroke length 300-500	18-1157-45	18-1159-45	18-1161-45
I.d. 400 mm SFP* Man. nozzle			
Stroke length 100-300	18-1170-53	18-1176-12	11-0011-85
Stroke length 200-400	11-0011-80	11-0011-83	11-0011-86
Stroke length 300-500	11-0011-82	11-0011-84	11-0011-87
I.d. 400 mm SFP Auto. nozzle			
Stroke length 100-300	11-0011-89	11-0011-91	11-0011-94
Stroke length 200-400	11-0011-88	11-0011-92	11-0011-95
Stroke length 300-500	11-0011-90	11-0011-93	11-0011-96
I.d. 600 mm Man. nozzle			
Stroke length 100-300	18-1150-60	18-1159-60	18-1161-60
Stroke length 200-400	18-1157-62	18-1159-62	18-1161-62
Stroke length 300-500	18-1157-64	18-1159-64	18-1161-64
I.d. 600 mm Auto. nozzle			
Stroke length 100-300	18-1157-61	18-1159-61	18-1161-61
Stroke length 200-400	18-1157-63	18-1159-63	18-1161-63
Stroke length 300-500	18-1157-65	18-1159-65	18-1161-65
I.d. 800 mm Man. nozzle			
Stroke length 100-300	18-1150-80	18-1159-80	18-1161-80
Stroke length 200-400	18-1157-82	18-1159-82	18-1161-82
Stroke length 300-500	18-1157-84	18-1159-84	18-1161-84
I.d. 800 mm Auto. nozzle			
Stroke length 100-300	18-1157-81	18-1159-81	18-1161-81
Stroke length 200-400	18-1157-83	18-1159-83	18-1161-83
Stroke length 300-500	18-1157-85	18-1159-85	18-1161-85
I.d. 1000 mm Man. nozzle			
Stroke length 100-300	18-1150-10	18-1160-10	18-1162-10
Stroke length 200-400	18-1158-12	18-1160-12	18-1162-12
Stroke length 300-500	18-1158-14	18-1160-14	18-1162-14
I.d. 1000 mm Auto. nozzle			
Stroke length 100-300	18-1158-11	18-1160-11	18-1162-11
Stroke length 200-400	18-1158-13	18-1160-13	18-1162-13
Stroke length 300-500	18-1158-15	18-1160-15	18-1162-15

For column specifications other than listed in the table, please contact your local GE Healthcare representative.
* SFP = Small Flow Path on mobile phase, only available on 400 mm i.d. columns.

Options to the standard configuration

Details	Description
Casters	For columns with a maximum diameter up to 1000 mm.
Nozzle pipings	Extension pipings for the Mobile phase inlet top and Slurry outlet top (avoids tubing getting bent)
Nozzle control	The nozzle can be controlled either by the Chromaflow Nozzle control unit or the Chromaflow Packing station

Chromaflow Packing stations

Chromaflow Packing station Pack 50	18-1163-74
Chromaflow Packing station Pack 100	18-1162-08
Chromaflow Packing station Pack 200	Custom order
Chromaflow Packing station Pack 400	Custom order

Chromaflow Packing station selection guide

Packing Station	Min l/min	Max l/min
Pack 50	10	50
Pack 100	30	100
Pack 200	60	200
Pack 400	100	400

Chromaflow MKIII caster kits

Casters to 400-600 mm MKIII columns	18-1171-51
Casters to 800-1000 mm MKIII columns	18-1171-52

Chromaflow Nozzle control unit

Nozzle control unit	18-1164-61

Chromaflow Nozzle pipings

Chromaflow Nozzle piping 400 1/2"	18-1172-01
Chromaflow Nozzle piping 400 3/4"	18-1172-00
Chromaflow Nozzle piping 400 1"	18-1171-99
Chromaflow Nozzle piping 600 1/2"	18-1172-06
Chromaflow Nozzle piping 600 3/4"	18-1172-05
Chromaflow Nozzle piping 600 1"	18-1172-04
Chromaflow Nozzle piping 800 1/2"	18-1171-94
Chromaflow Nozzle piping 800 3/4"	18-1171-93
Chromaflow Nozzle piping 800 1"	18-1171-92
Chromaflow Nozzle piping 1000 1/2"	18-1172-09
Chromaflow Nozzle piping 1000 3/4"	18-1172-08
Chromaflow Nozzle piping 1000 1"	18-1172-07

Accessories for Chromaflow columns

Accessory	Code No.	Qty/pack	Material
Valves			
4-port 2-way, i.d. 10 mm, 25 mm TC	18-1012-56	1	SS 316L/PTFE
4-port 4-way, i.d. 10 mm, 25 mm TC	18-1012-57	1	SS 316L/PTFE
3-port 2-way, i.d. 15 mm, 25 mm TC	44-5499-90	1	SS 316L/PTFE
4-port 4-way, i.d. 20 mm, 51 mm TC	44-2302-01	1	SS 316L/PTFE
3-port 2-way, i.d. 22 mm, 51 mm TC	44-1583-01	1	SS 316L/PTFE
3-port 2-way, i.d. 35 mm, 51 mm TC	44-5494-65	1	SS 316L/PTFE
Valve sealing washer fits 10 mm 2 and 4-way valves	18-1128-69	2	PTFE
Tubing with sanitary fitting 25 mm TC			
i.d. 10 mm, 900 mm	18-1012-62	1	PVC
i.d. 10 mm, 1400 mm	18-1012-63	1	PVC
i.d. 10 mm, 1700 mm	18-1012-64	1	PVC
i.d. 10 mm, 2000 mm	18-1012-87	1	PVC
i.d. 14 mm, 750 mm	18-1027-28	1	PVC
i.d. 14 mm, 1800 mm	18-1027-29	1	PVC
Tubing with sanitary fitting 51 mm TC			
i.d. 19 mm, 900 mm	28-4042-30	2	PVC
i.d. 19 mm, 1400 mm	28-4042-35	2	PVC
i.d. 19 mm, 2000 mm	28-4042-32	2	PVC
i.d. 19 mm, 4000 mm	28-4042-33	2	PVC
Clamp gasket			
25 mm i.d., 10 mm	18-1035-79	2	EPDM
25 mm i.d., 12 mm	18-0200-00	2	EPDM
51 mm i.d., 22 mm	44-7133-01	5	EPDM
51 mm i.d., 38 mm	44-0515-01	5	EPDM
Clamp 25 mm	18-1001-31	1	SS 304
Clamp 51 mm	44-7134-01	1	SS 304
Blind flange 25 mm incl. gasket	18-1001-25	1	SS 304/EPDM
Blind flange 51 mm incl. gasket	44-7135-01	1	SS 304/EPDM
Safety valve, 3 bar, 51 mm TC	18-5738-01	1	SS 316/EPDM
Safety valve, 5 bar, 51 mm TC	44-5498-97	1	SS 316/EPDM
T-junction i.d. 10 mm, 2 × 25 mm, 1 × 51 mm TC	18-1003-63	1	SS 316
T-junction i.d. 22 mm, 3 × 51 mm TC	44-5509-89		SS 316
Castors, assembly kit 400-600	18-1171-51	*	
Castors, assembly kit 800-1000	18-1171-52	*	
Pressure sensor i.d. 10 mm 25 mm TC	44-0507-02	1	SS 316
Pressure sensor i.d. 22 mm 51 mm TC	44-0507-03	1	SS 316
Connectors			
i.d. 10, 25 mm TC-3/4"-20 UNF threaded	18-1012-68	2	PP
i.d. 10, 25 mm TC-i.d. 14, 51 mm TC	18-1027-25	2	PP
i.d. 14, 51 mm TC-i.d. 22, 51 mm TC	18-1027-26	2	PP
i.d. 22, 51 mm TC – i.d. 10, 25 mm TC	18-1174-11	1	PP
i.d. 22, 51 mm TC – i.d. 14, 25 mm TC	18-1174-12	1	PP

* The kit contains a complete set for a column
Material abbreviations: EPDM=ethylene propylene diene, PP=polypropylene, PTFE=polytetrafluoroethene, PVC=polyvinyl chloride, SS=stainless steel

Literature

Data File	Code No.
Chromaflow columns	18-1138-92
Application Note	
Sanitization of Chromaflow 400 column	18-1118-85

Documentation to support validation available on request. Contact your local GE Healthcare office.

FineLINE columns

The FineLINE range of columns has been developed for use with all SOURCE media. The novel, hydraulic packing method packs SOURCE in a matter of minutes, giving densely packed beds and very high packing efficiencies: more than 22 000 plates/m with SOURCE 15 and more than 11 000 plates/m with SOURCE 30.

FineLINE Pilot 35 is well-suited for both downscaling from the larger FineLINE columns and upscaling from laboratory RESOURCE and ÄKTAdesign columns. This 35-mm inner diameter column has a tube manufactured from calibrated borosilicate glass. FineLINE Pilot 35 can also be run on ÄKTAexplorer.

The larger FineLINE 70, 100P, 200P and 350P columns are intended for scale-up work and small-scale production. Column tubes are manufactured in electropolished stainless steel and are available in two tube lengths: 350 mm and 700 mm.

FineLINE range

- Standard inner diameters of 35, 70, 100, 200 mm and 350P.
- Optimized for use with all SOURCE media.
- Proven single inlet/outlet distribution with special multilayer bed supports for uniform flow at low back pressures.
- Very easy and fast to pack.
- Materials include electropolished stainless steel, calibrated borosilicate glass and EPDM.
- All polymeric materials are approved according to USP class VI tests for toxicity.
- Documentation to support validation delivered with the product.

Overview of FineLINE columns

Column	Tube inner diam (mm)	Tube height (mm)	Cross sectional area (cm^2)	Bed height min (mm)	Bed height max (mm)	Bed vol min (ml)	Bed vol max (ml)	Design pressure (bar)
FineLINE Pilot 35	35	330	10	30	150	29	144	20
FineLINE 70	70	350	38	30	150	115	577	20
FineLINE 70L	70	700	38	50	300	192	1155	20
FineLINE 100P	100	350	79	30	150	236	1178	20
FineLINE 100LP	100	700	79	50	300	393	2355	20
FineLINE 200P	200	350	314	30	150	942	4710	20
FineLINE 200LP	200	700	314	50	300	1570	9420	20
FineLINE 350P	350	350	962	30	150	2884	14424	20
FineLINE 350LP	350	700	962	50	300	4808	28848	20

What do I need?

The stand for FineLINE 70/70L and FineLine 100P/100LP has adjustable feet. Wheels with brakes are available as an accessory.

The stand for FineLINE 200P/200LP has wheels with brakes as standard.

Useful spare parts

Bed supports

Columns are delivered with 2-µm nets; 10-µm nets are also available.

Seals

Order solvent-resistant seals (O-ring kit PFR) if the EPDM O-rings supplied with the columns are not compatible with the solvent to be used.

Spare parts to keep on site

A complete set of O-rings.

FineLINE Pilot 35
Complete set of O-rings, flanging start-up, extra tubing and connectors.

Isolating the column after packing

We recommend using stainless steel valves 2- or 4-way with i.d. 6 mm to close off the top and bottom of the column and prevent contamination of the bed. For storage purposes, the 25-mm blind flanges with clamps and gaskets can be used to seal off the column.

For FineLINE Pilot 35, an extra SRV-1 valve is inserted to close of the bottom of the column. The stop plug for the upper column inlet is supplied with the column.

Connecting the column to your system

Clamps and gaskets with i.d. 6 mm are required to connect the 25-mm sanitary flanged inlet/outlet to either valves or tubing of the same type. Preflanged tubing with i.d. 6 mm is available from GE Healthcare.

FineLINE Pilot 35 is delivered with flanged 1.2 mm i.d. propylene tubing and M6 connectors. A separate tubing kit is needed to connect the column to ÄKTAdesign systems.

Assembly/disassembly of column

Standard wrenches are recommended in a non-explosive environment.
In potentially explosive atmospheres, only tools and protective equipment specially adapted to that environment should be used for operation and maintenance.

Note: Standard wrenches are not supplied with the column, except for FineLINE Pilot 35.

Useful column accessories

Pressure gauge

We recommend fitting a pressure gauge capable of measuring a negative pressure of –1 bar at the top mobile phase connection to indicate the pressure in the column. This monitors the operating pressure and ensures that the correct axial compression packing pressure is set when packing the column.

Pressure relief valve

Required for the packing procedure. It is connected between the pump and the hydraulic inlet to ensure flow delivery at constant pressure. A suitable pressure relief valve designated RL4 is available.

Note: The valve is not supplied with the column and should therefore be ordered separately.

As the pressure relief valve is just required when packing the column, only one valve will generally be needed irrespective of the number of columns in use.

(A manometer is seldom needed for FineLINE Pilot 35 since the pressure-relief valve is preset to 10 bar).

Ordering information

Column	Code No.
FineLINE Pilot 35	18-1102-02
Pressure Relief Valve	18-1110-90
FineLINE 70	18-1152-98
FineLINE 70L	18-1152-99
FineLINE 100P	11-0027-98
FineLINE 100LP	11-0027-99
Stand 100	18-1031-10
FineLINE 200P	11-0031-14
FineLINE 200LP	11-0031-15
Stand 200	18-1031-20
Pressure Relief Valve	18-1105-36
FineLINE 350P EPDM 2 µm	11-0027-90
FineLINE 350P EPDM 10 µm	11-0027-91
FineLINE 350P PFR 2 µm	11-0027-92
FineLINE 350P PFR 10 µm	11-0027-93
FineLINE 350P PFR 2 µm Oligo	11-0027-94
FineLINE 350P PFR 10 µm Oligo	11-0027-95
FineLINE 350LP EPDM 2 µm	11-0027-84
FineLINE 350LP EPDM 10 µm	11-0027-85
FineLINE 350LP PFR 2 µm	11-0027-86
FineLINE 350LP PFR 10 µm	11-0027-87
FineLINE 350LP PFR 2 µm Oligo	11-0027-88
FineLINE 350LP PFR 10 µm Oligo	11-0027-89

Accessories for FineLINE Pilot 35 column

Designation	Code No.	Qty/ pack	Material
Tubing Kit for ÄKTAexplorer	18-1121-65	1	-
Tubing Connector, SRTC2	19-2143-01	5	PEEK
Tubing Connector	19-7476-01	5	PP
Tubing D-flanged i.d. 1.2 mm, 420 mm	18-1102-20	1	ETFE/PEEK/PP
Tubing D-flanged i.d. 1.2 mm, 750 mm	18-4546-01	1	ETFE/PEEK/PP
Tubing i.d 1.2 mm, 2000 mm	19-4370-01	1	ETFE
Stop Plug	18-1102-21	1	-
Domed Nut M6	18-2450-01	4	PP
Flanging/Start up Kit 120 V	18-4603-70	1	-
Flanging/Start up Kit 220 V	18-4603-71	1	-
Flanging Tip Kit i.d. 1.2 mm	18-4597-01	1	-
Pressure Relief Valve	18-1110-90	1	SS 316/ETFE/ PEEK/PP
On/Off Valve i.d. 1.5 SRV-1	19-2145-01	1	FP
Valve SRV-3	18-1110-95	1	FP
O-rings 28.3 × 2.6 mm*	18-1102-15	1	PFR

*Adaptor filter rings in PFR.

Spare parts for FineLINE Pilot 35 column

Designation	Code No.	Qty/pack	Material
Glass tube	18-1102-16	1	Borosilicate glass
Adaptor bed support 2 µm	18-1102-10	1	PP/SS 316L
Bottom bed support 2 µm	18-1102-11	1	PP/SS 316L
*Sealing Kit comprising:	18-1102-12	1	EPDM
-O-ring 39.2 × 1.6		1	
-O-ring 28.25 × 2.62		4	
-O-ring 12.3 × 2.4		1	
-O-ring 19.2 × 3		1	
-O-ring 3.6 × 1.6		2	

* includes all O-rings for FineLINE Pilot 35 column.

Accessories for FineLINE 70/70L, 100P/100LP and 200P/200LP columns

Designation	Code No.	Qty/pack	Material
O-ring Kit RPC FineLINE 70/70L	18-1155-43	1	
O-ring Kit RPC FineLINE 100/100L[1]	18-1105-45	1	
O-ring Kit RPC FineLINE 200/200L[2]	18-1106-23	1	
Set of spare gaskets for the pressure relief valve	18-1105-52	1	SS 316L/FPM
Air trap complete, FineLINE 100/200[4,5]	18-1102-96	1	SS 304/316/Glass/EPDM
Air trap complete, FineLINE 200/200L[4,5]	18-1102-97	1	SS 304/316/Glass/EPDM
Manometer kit[6]	18-1031-07	1	SS 304/316/EPDM
Valves[5]			
4-port, 2-way	18-5757-01	1	SS 316L/PTFE
4-port, 4-way	18-5758-01	1	SS 316L/PTFE
Hydraulic inlet valve (Ball valve)	18-1105-37	1	SS 316L/PTFE
Valve sealing washer[3]	18-1128-69	2	PTFE
Tubing with sanitary fitting i.d. 6 mm[5]			
30 cm	18-0005-42	1	PVC
75 cm	18-0005-43	1	PVC
125 cm	18-0005-44	1	PVC
150 cm	18-0005-45	1	PVC
200 cm	18-0005-47	1	PVC
Connectors (see p 78)			
i.d. 6, 25 mm clamp-3/4"-20 UNF threaded	18-1012-67	2	PP
i.d. 6, 25 mm clamp-6 mm threaded	18-0251-98	2	PP
i.d. 6, 25 mm clamp-M6 threaded	18-1031-09	2	PP
i.d. 6, 25 mm TC-id 22, 51 mm TC	18-1012-69	2	PP
Clamp 25 mm	18-1001-31	1	SS 304
Clamp 25 mm	44-0568-01	12	SS 304
Gaskets 25 mm i.d. 6 mm	18-0019-27	2	EPDM
Gaskets 25 mm i.d. 6 mm	18-0019-28	2	PTFE
Blind flange 25 mm incl. gasket	18-1001-25	1	SS 304/EPDM
Clamp 51 mm	44-7134-01	1	SS 304
Gaskets 51 mm i.d. 22 mm	44-7133-01	5	EPDM
Gasket 51 mm i.d. 22 mm	44-5512-03	2	PTFE
Castors	18-1001-09	1	–

[1] Includes
- One O-ring 104.33 × 3.53 — 18-1105-50 — PTFE
- One O-ring 91.67 × 3.53 — 18-1105-49 — PFR
- Two O-rings 5.3 × 2.4 — 18-1105-51 — PFR

[2] Includes
- One O-ring 202.79 × 3.53 — 18-1106-30 — PFR
- One O-ring 187.3 × 6.99 — 18-1106-29 — PFR
- Two O-rings 7.3 × 2.4 — 18-1106-31 — PFR

[3] Fits 18-5757-01 and 18-5758-01.
[4] Maximum working pressure 8 bar.
[5] 25 mm TC.
[6] 51 mm TC.

Spare parts for FineLINE 70/70L, 100P/100LP, 200P/200LP and 350P/350LP columns

	FineLINE					
Description	70/70L	100P/100LP	200P/200LP	350P/350LP	Quantity	Material
	Code No.					
Bed support, adaptor complete, 2 mm	18-1153-61	11-0034-04	11-0034-06	11-0034-08	1	SS 316 L
Bed support, adaptor complete, 10 mm	18-1153-67	11-0034-72	11-0034-74	11-0034-10	1	SS 316 L
Bed support, end piece complete, 2 mm	18-1153-62	11-0034-05	11-0034-07	11-0034-09	1	SS 316 L
Bed support, end piece complete 10 mm	18-1153-68	11-0034-73	11-0034-75	11-0034-11	1	SS 316 L
O-ring 104.37 × 3.53		18-1103-89			3	EPDM
O-ring 104.37 × 3.53		18-1105-50			1	PTFE
O-ring 202.79 × 3.53			18-8489-01		2	EPDM
O-ring 202.79 × 3.53			18-1106-30		1	PFR
O-ring 5.3 × 2.4		18-1103-92			5	EPDM
O-ring 5.3 × 2.4		18-1105-51			2	PFR
O-ring 7.3 × 2.4			18-1103-90		5	EPDM
O-ring 7.3 × 2.4			18-1106-31		2	PFR
O-ring 64.5 × 3		18-1105-48	18-1105-48		1	EPDM
O-ring 91.67 × 3.53		18-1103-91			2	EPDM
O-ring 91.67 × 3.53		18-1105-49			1	PFR
O-ring 187.3 × 6.99			18-1106-26		1	EPDM
O-ring 187.3 × 6.99			18-1106-29		1	PFR
Piston seal	18-1039-56	18-1139-56	18-1106-28		1	EPDM
O-ring 350 × 5				18-1153-72	1	EPDM
O-ring 350 × 5				18-1153-76	1	PFR
O-ring 15.2 × 3.5				18-1153-74	2	EPDM
O-ring 15.2 × 3.5				18-1153-78	2	PFR
O-ring 55.35 × 3.53				18-1153-73	1	EPDM
O-ring 55.35 × 3.53				18-1153-77	1	PFR
O-ring 329.5 × 6.99				18-1153-75	1	EPDM
O-ring 329.5 × 6.99				18-1153-79	1	PFR
Piston seal				18-1149-99	2	EPDM

Material abbreviations: EPDM=ethylene propylene diene, ETFE=ethylene tetrafluoroethylene, FP=fluoroplastic, PEEK=polyetheretherketone, PFR=perfluor rubber, PP=polypropylene, PTFE=polytetrafluoroethene, PVC=polyvinyl chloride, SS=stainless steel

Photo: Courtesy of Avecia, UK.

Literature

Data File	Code No.
FineLINE Pilot 35 Column	18-1104-95
FineLINE 70/70L, 100/100L, 200/200L	18-1130-00
Application Note	
Scaling up high performance chromatography on SOURCE media and FineLINE column	18-1117-49

Documentation to support validation available on request. Contact your local GE Healthcare office.

BioProcess MPLC and HPLC columns

BioProcess MPLC and HPLC columns comprise a family of stainless steel process-scale columns designed for full-scale production of small molecules, peptides, and proteins using medium- and high-pressure chromatography.

MPLC and HPLC columns simplify chromatographic procedures and offer:

- Leak detection system.
- Uniform distribution of the mobile phase.
- Easy packing with automated set-up.
- Extensive documentation including Test and Material certificates.
- Construction materials resistant to the solvents used in reversed phase chromatography.
- A wide range of dimensions for easy scale-up.

General column description

The columns are available in a broad range of dimensions with variable bed heights, which provides a wide choice of bed volumes. The columns withstand temperatures up to 50°C, (jackets are optional to ensure constant temperature) and employ dynamic axial compression that uses liquid as the compression medium. Dynamic axial piston pressure eliminates the formation of voids or channels in packed beds. A specially-designed flow distribution system fitted at both the piston end and the bottom of the column ensures the uniform distribution of the mobile phase across the area of the packed bed.

Columns are manufactured according the requirements of the pressure equipment directive for Europe (PED) or that of North America (ASME). Columns can also be manufactured according to ATEX or Class 1, Div. I or II directives to assure the highest security in potentially explosive atmospheres. The columns can be manufactured to GAMP4 as an option.

For information on BioProcess MPLC and HPLC columns, contact your local GE Healthcare representative.

MPLC columns

MPLC columns are a family of stainless steel, medium-pressure, process-scale columns. The dynamic axial compression packing method efficiently packs media like SOURCE. BioProcess MPLC columns are pressure rated for operation at up to 20 bar (optional to 30 bar). Materials of construction include AISI 316L stainless steel, PEHD, FEP encapsulated Viton, and PTFE.

BioProcess MPLC columns are supplied with a control box, safety valve, pressure gauge, two mobile phase valves, and a slurry valve. Optional components include materials in duplex stainless steel, column jackets, and electronic indication of piston position.

Slurry units

Slurry units raise the efficiency of filling the BioProcess MPLC column. The units come in various sizes and consist of a stationary vessel with a speed-controlled mixer in the center for preparing the media in slurry form. The units employ an air-driven double diaphragm pump to deliver the slurry directly into the column.

Compression units

Compression units are available to assist in maintaining column compression. The unit consists of a stainless steel tank mounted on wheels and is equipped with a pneumatic pressure pump driven by an air pressure of 5 to 6 bar, which can compress the column to a pressure of 20 bar.

HPLC columns

HPLC columns are a family of stainless steel, high-pressure, process-scale columns. Their well-proven design simplifies packing and ensures the speedy, reliable, and convenient purification of small molecules and peptides. BioProcess HPLC columns are pressure rated for operation at up to 100 bar. Materials of construction include AISI 316L and PTFE, and the sanitary design includes Quick Connections.

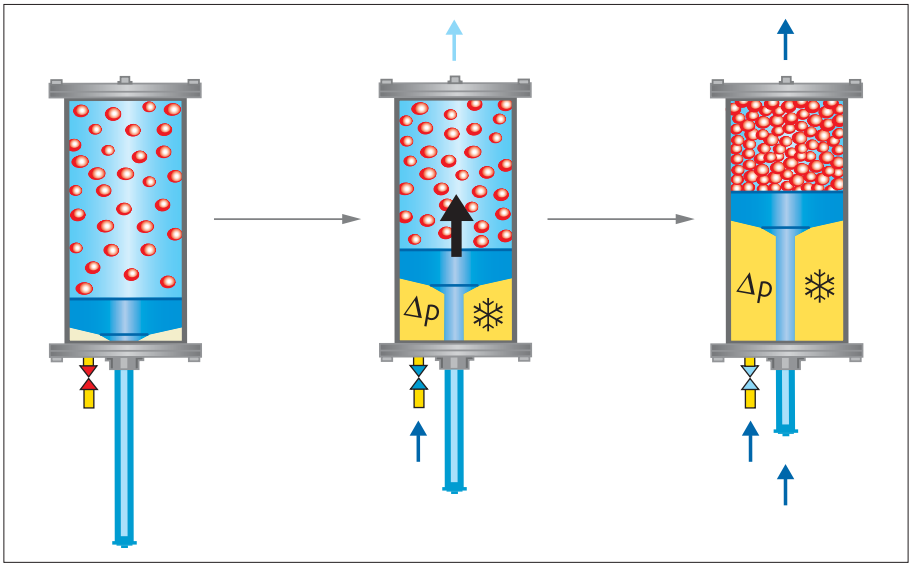
BioProcess HPLC columns are delivered with mobile phase and compression valves and a frame-mounted compression station (stand) that includes a pump, safety valve, pressure gauge, valves and a regulator. Optional components include materials in duplex stainless steel, column jackets, and electronic indication of piston position.

Slurry units

For BioProcess HPLC columns, various sizes of rotating slurry units that fit under the column are available. The units consist of a rotary tank for preparing the chromatography medium in slurry form, and an air-driven double diaphragm pump for pumping slurry directly into the column.

Principle of operation

BioProcess MPLC and HPLC columns are easy to fill with chromatography medium and are simple to pack. Filling the column is facilitated by the accessory slurry unit that prepares the medium in a slurry form and pumps it directly into the column. Compression liquid is then pumped into the hydraulic chamber above the column adapter to move the adapter and compress the media chamber. An automated packing set-up packs the medium in minutes with precise pressure regulation, thereby avoiding crushing the beads. This also results in a homogeneous bed with good contact with the liquid distributor plate.



The axial compression packing method generates homogenous beds and allows very short working bed heights. Note that the method illustrated here applies to HPLC columns only.

Table 1. Properties of selected BioProcess MPLC Columns. All models operate at up to 20 bar (optional 30 bar).

Designation	Size D × L (mm)	Cross-section (cm^2)	Max. bed vol. (L)	Overall column height in process position (mm)	Dry weight (kg)	Footprint (mm^2)
MPLC 100/700	100 × 700	78.5	5.5	2150	100	510 × 580
MPLC 200/700	200 × 700	314	22	2150	150	510 × 580
MPLC 300/700	300 × 700	706	49.4	2150	200	585 × 670
MPLC 350/700	350 × 700	962	67.3	2150	275	630 × 710
MPLC 400/700	400 × 700	1256	87.9	2150	350	670 × 760
MPLC 450/700	450 × 700	1590	111.3	2275	450	815 × 930
MPLC 500/700	500 × 700	1963	137.4	2300	600	850 × 975
MPLC 600/700	600 × 700	2827	198	2300	800	930 × 1060
MPLC 700/700	700 × 700	3848	269	2350	1100	980 × 980
MPLC 800/700	800 × 700	5026	352	2350	1500	1425 × 1425
MPLC 900/700	900 × 700	6276	439	2350	2000	1425 × 1425
MPLC 1000/700	1000 × 700	7854	550	2400	2500	1500 × 1500
MPLC 1100/700	1100 × 700	9498	665	2450	3100	1575 × 1575
MPLC 1200/700	1200 × 700	11310	792	2500	3800	1650 × 1650

Table 2. Properties of selected BioProcess HPLC Columns. All models operate at up to 100 bar.

Description	Column tube D × L (mm)	Cross-section (cm^2)	Max bed vol. (L)	Overall column height process position, (mm)	Dry weight, incl. frame (kg)	Footprint (mm^2)
HPLC 50/700	50 × 700	19.6	1.4	2100	100	650 × 650
HPLC 75/700	75 × 700	44.2	3.1	2100	150	650 × 650
HPLC 100/700	100 × 700	78.5	5.5	2200	200	800 × 800
HPLC 150/700	150 × 700	176.7	12.4	2200	250	800 × 800
HPLC 200/700	200 × 700	314.2	22	2200	300	860 × 860
HPLC 250/700	250 × 700	490.9	34.4	2200	375	860 × 860
HPLC 300/700	300 × 700	706.8	49.5	2400	475	1000 × 1000
HPLC 450/700	450 × 700	1590	111.3	2800	650	1600 × 1600
HPLC 600/700	600 × 700	2827.4	197.9	2800	1000	1600 × 1600

Table 3. Materials of main components

Component	Material	In contact with process
Column tube	Stainless Steel 316L	Yes
Column lids	Stainless Steel 316L	No
Adaptor	Stainless Steel 316L	Yes
Adaptor rod	Stainless Steel 316L	Yes
Distributor	PE / PTFE	Yes
Bed support	Stainless Steel 316L	Yes
Seals	FEP encapsulated Vitron / PTFE / PEHD	Yes
Valves	Stainless Steel 316L	Yes

PE = polyethylene, FEP = fluoroethenepropene, PTFE = polytetrafluoroethene, PEHD = polyethylene high density.

Table 4. Chemical resistance of BioProcess MPLC and HPLC columns. Note the table is to be used as a guide only. The data are compiled from several published sources, not from actual tests on column components.

Chemical	SS 316L	PTFE
Acetic acid 20%	+	+
Acetic acid 80%	+	+
Acetone	+	+
Acetonitrile	+	+
Chloroform	+	+
Ethanol	+	+
Formaldehyde	+	+
Hydrochloric acid	-	+
Hydrogen peroxide	+	+
Isopropyl alcohol	+	+
Methanol	+	+
Nitric acid	+	+
Phosphoric acid <40%	(+)	+
Phosphoric acid >40%	-	+
Sodium chloride	+[1]	+
Sodium hydroxide	+	+

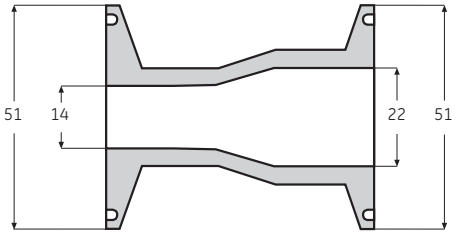
+Resistant, (+) Limited resistance, - Not recommended
[1] NaCl can cause corrosion on stainless steel at pH < 5. Do not use NaCl in storage solutions

Literature

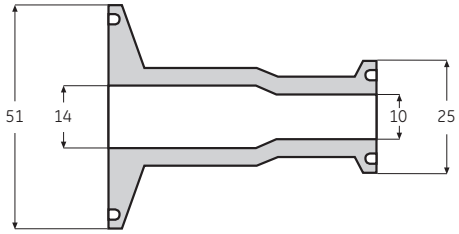
Brochure	Code No.
"More Pressure, Less Worry"	11-0007-13
Data Files	
BioProcess HPLC Columns	18-1167-75
BioProcess MPLC Columns	18-1167-74

A guide to plastic connectors for process-scale columns

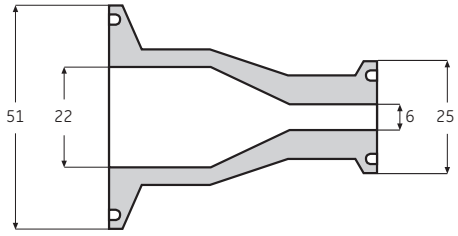
Connector i.d. 14, 51 mm TC-i.d. 22, 51 mm TC
Code No. 18-1027-26



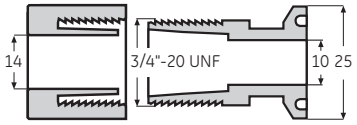
Connector i.d. 14, 51 mm TC-i.d. 10, 25 mm TC
Code No. 18-1027-25



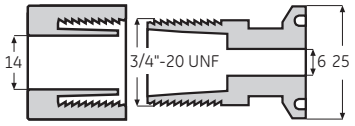
Connector i.d. 22, 51 mm TC-i.d. 6, 25 mm TC
Code No. 18-1012-69



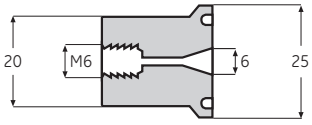
Connector 3/4"-20 UNF-i.d. 10, 25 mm TC
Code No. 18-1012-68



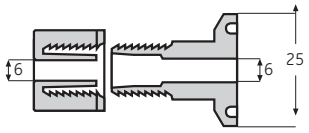
Connector 3/4"-20 UNF-i.d. 6, 25 mm TC
Code No. 18-1012-67



Connector M6-i.d. 6, 25 mm TC
Code No. 18-1031-09

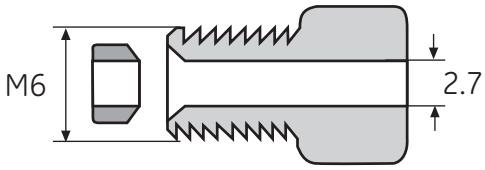


Connector i.d. 6 mm-i.d. 6, 25 mm TC
Code No. 18-0251-98

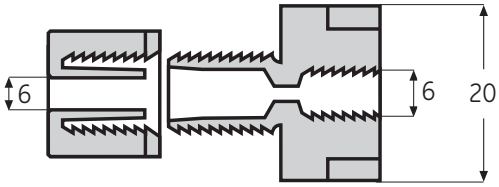


1 inch = 25 mm

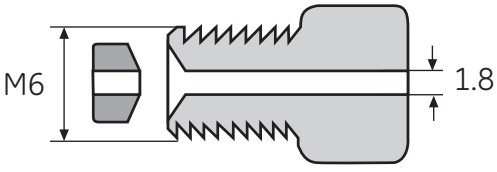
UNF = Standard for finer pitch which fits a lot of female connectors



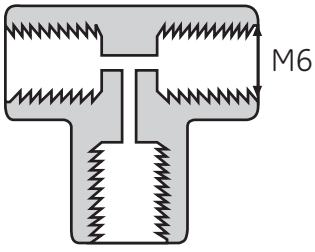
Connector i.d. 2.7 mm – M6
Code No. 18-4652-01



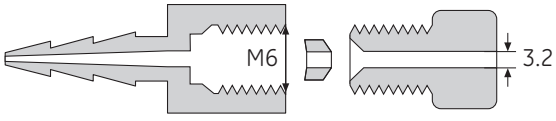
Connector i.d. 3 mm – M6 – Jaco 6 mm
Code No. 18-4603-89



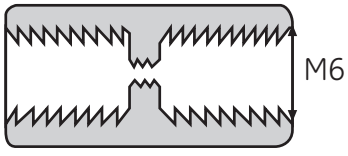
Connector i.d. 1.8 mm – M6
Code No. 19-7476-01



Connector SRTC-3 M6-M6
Code No. 19-2144-01



Connector i.d. 3.8 mm – M6
Code No. 18-1124-16



Connector SRTC-2 M6-M6
Code No. 19-2143-01

Chromatography systems

ÄKTAprocess
BioProcess MPLC/HPLC
Customized Bioprocess Solutions
CBS DeltaV
UNICORN control

ÄKTAprocess system

ÄKTA platform enters production-scale chromatography

ÄKTAprocess is an automated liquid chromatography system built for process scale-up and large-scale biopharmaceutical manufacturing. The proven design has been verified during development and can be user configured to meet specific process demands. It is the obvious choice of system to use when scaling up processes developed on smaller ÄKTAexplorer and ÄKTApilot systems.

- Versatile user-configuration with UNICORN control.
- Post-purchase configuration increasing usability and lifespan.
- Traceable USP Class VI materials.
- Full regulatory documentation and services.
- One-inch tubing size now available.

Versatile user-configuration

ÄKTAprocess offers a versatile platform providing thousands of configuration possibilities. The system is available in three flow rate ranges that extend up to 1800 l/h for large volume manufacturing. The compact design with a built-in computer allows the system to fit neatly into a plant. ÄKTAprocess can be constructed in either electropolished stainless steel or polypropylene, depending on your process conditions and plant requirements.

The systems can be configured to develop gradients at any flow rate with feedback loop technology. This ensures thorough mixing of liquids/solvents without air bubbles so that even challenging gradients can be created with 2% accuracy. The UNICORN software allows standalone operation or integration into any plant-wide control system. Additional configurations include, for example, the choice of extra inlets and outlets, the type and quantity of selected monitors, and isocratic versus gradient functionality.

Sanitary design

ÄKTAprocess has a number of features that make sanitization with 1 M sodium hydroxide simple and effective. UNICORN allows automated cleaning-in-place (CIP) and a new type of air trap makes CIP more efficient. All wetted parts can be changed to prevent cross-contamination when the system is used for campaigning.

In a sanitization study, the system was subjected to high level of microbial challenge organisms (1×10^6 Colony Forming Units CFU/ml). The yeast *Pichia pastoris* was used for antimicrobial testing. The results show that the system is sanitized effectively and that the numbers of viable organisms are efficiency reduced.

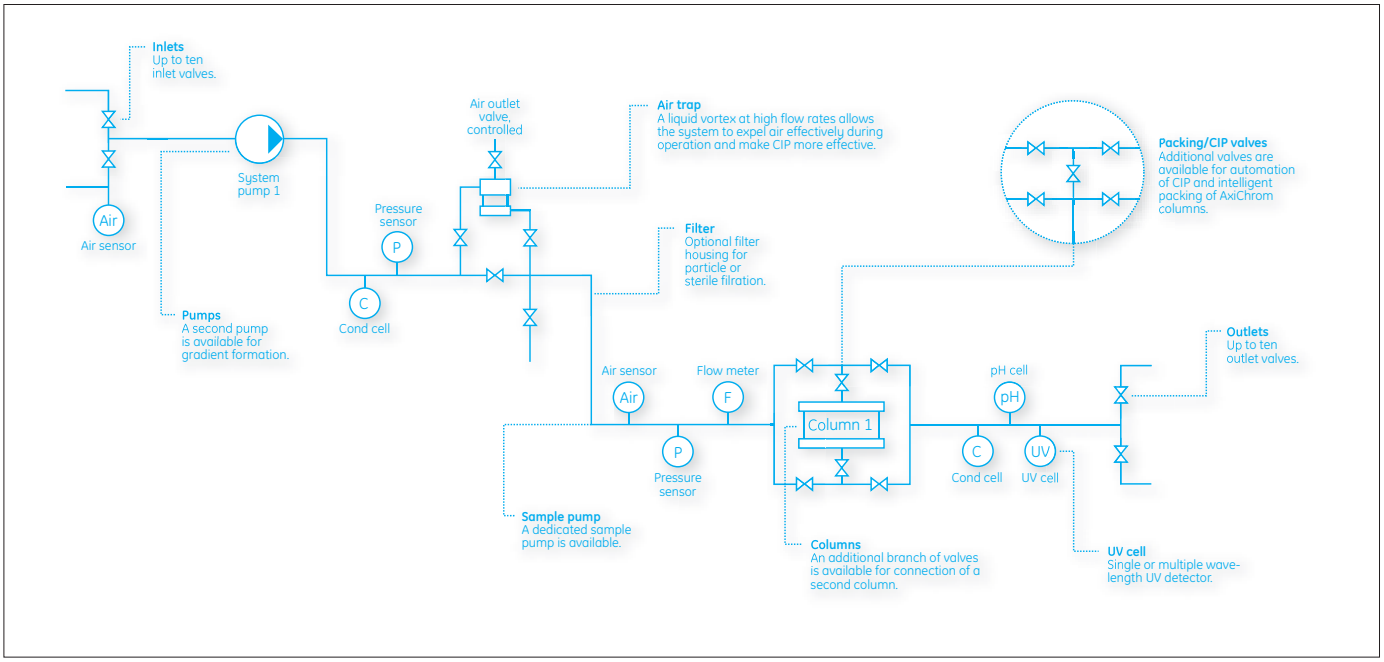


Fig 1. The liquid flow path.

Validatable control with UNICORN software

UNICORN software is a single familiar interface for both chromatography and membrane separations that provides efficient control of process, flexible method programming, extensive data evaluation, and powerful reporting functionality. Improved and cost-effective process security is now provided as a standard. The system control unit, CU 960, allows process operation even if communication with system computer and UNICORN is lost either physically or due to operating system faults.

For integration purposes, UNICORN communicates with control systems within the plant via OLE for Process Control (OPC). OPC supports application area such as data access for real time values and security control to protect sensitive information.

Safety stock of spare parts and consumables

Securing the supply of spare parts and consumables ensures maximum uptime of your ÄKTAprocess system. Our safety stock agreements for ÄKTAprocess can be tailored to meet your unique availability needs.

Table 1. System specifications.

System specifications	System flow rate
6 mm i.d. PP*	4–180 l/h
3/8" o.d. (7.7 mm i.d.) SS†	4–180 l/h
10 mm i.d. PP	13–600 l/h
½" o.d. (9.4 mm i.d.) SS	13–600 l/h
1" o.d. (20.4 mm i.d.) PP	45–1800 l/h
1" o.d. (22.1 mm i.d.) SS	45–1800 l/h
UV wavelength range	Single (280 nm) or multiple wavelengths
pH range	0–14 (spec. valid between 2 and 12)
Conductivity range	1 mS/cm to 200 mS/cm
Ingress protection, cabinet electrical	NEMA 4X / IP 56
Electrical standards	UL 508A, EN 61010-1
Tubing size	PP: 6 mm, 10 mm, SS: 3/8" and ½"
Skid size	
6 mm, 10 mm, 3/8" and 1/2"	(W×D×H): 850 mm × 1205 mm × 1670 mm (D=750 mm if monitor and keyboard included)
1" PP and SS	(W×D×H): 1050 mm × 1730 mm × 1900 mm (D=2275 mm if monitor and keyboard included)

* PP = polypropylene,
† SS = 316 L stainless steel.

Table 2. Operating conditions.

Operating pressure and temperature	
PP (6 mm, 10 mm, and 1")	6 bar (max 40°C)
SS (3/8" and ½")	10 bar (max 40°C)
SS (1")	6 bar (max 40°C)
Surrounding temperature:	2–30°C
Applied solutions:	PP systems: 4–60°C (max 3 bar at 40–60°C)
Applied solutions:	SS systems: 4–80°C (max 3 bar at 40–60°C and max 1 bar at 60–80°C)

Literature	
Data File	
ÄKTAprocess	11-1135-43

BioProcess MPLC/HPLC systems

BioProcess MPLC/HPLC systems comprise a family of stainless steel, liquid chromatography systems for use in process-scale applications where high pressures (20 to 80 bar) are required. Reliable 24 hour-a-day unattended operation contributes to cost-effective processing, all the way from solvent introduction to final fractionation. BioProcess MPLC/HPLC systems simplify chromatographic procedures and offer:

- UNICORN system control, OPC available.
- Precise control of gradient with feedback (Type II system only).
- Compact, modular and sanitary design.
- Multi-product processing, prepared for automated CIP.
- Compatible MPLC and HPLC columns.

General system description

BioProcess MPLC/HPLC systems employ well-proven design solutions that, together with compatible BioProcess MPLC and HPLC columns, ensure the speedy, reliable and convenient process-scale purification of small molecules, peptides and proteins. Such system/column combinations are particularly suitable for processes using reversed phase chromatography (RPC) media. All systems are compact, modular and mobile. The compactness minimizes the floor space needed, and the modularity/mobility permits the easy expansion of current processing units or relocation to new facilities.

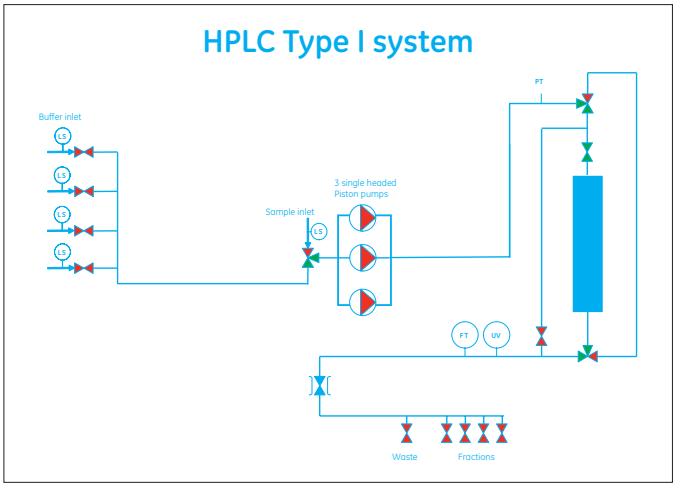
Systems are mounted on stainless steel frames with protective glass doors. Two configurations are available, both of which offer many standard features to match specific needs. For example, the feed pump is a triple-headed diaphragm pump that generates a uniform flow. In addition, the pump construction ensures protection from external contamination. Air sensors on all solvent inlet and sample lines prevent the system from running dry by detecting when levels are low. The piping system is constructed of 316L stainless steel. To ensure a stable UV-signal, a back-pressure valve is mounted after the UV flow cell. This placement eliminates degassing of the mobile phase in the flow cell itself. All systems have four inlet solvent valves and five fractionation valves as standard. To protect the column, a pressure transmitter is fitted before the column as standard and is available after the column as an option. In addition, the diaphragms in the pump are protected with pressure switches that interrupt the system in the case of rupture.

All analog signals, including pressure, pH, UV, near infrared spectrum (NIR), conductivity and flow rate, are monitored throughout the run and are automatically compiled in a batch report for full documentation.

Explosion-proofed options are available for all configurations. Systems can be manufactured according to ATEX or Class 1, Div. I or II Directives, or GAMP 4.

BioProcess MPLC/HPLC system – Type I

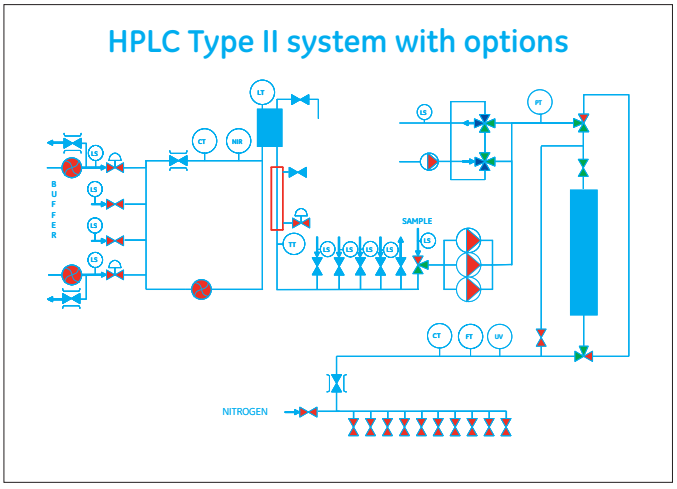
BioProcess MPLC/HPLC system – Type I is straightforward to use. The standard configuration includes 4 inlet lines, a pressure transmitter, a flow meter after the column, a UV detector, and 5 fractionation valves. All systems are controlled by UNICORN software. Several additional features/components are available to ensure that systems match specific needs. These options include:



- Extra inlet solvent lines.
- 5 extra fractionation valves.
- Temperature control before and/or after the column.
- Conductivity meter after the column.
- Pressure sensor after the column.
- pH meter before and after the column.
- Refractive index detector for fractionation.
- Valve feedback.
- Filter module.
- Injection loop for sample application.
- Heat exchanger.

BioProcess MPLC/HPLC system – Type II

BioProcess MPLC/HPLC system – Type II is an advanced gradient system that blends solvents continuously. Blending control is based on conductivity, NIR, or refractive index of the solvents, which results in very accurate and reproducible gradients. A bubble trap in the gradient system ensures that the mobile phase is free of air.



The standard configuration includes four inlet lines, a gradient blending loop with conductivity measurement or NIR detection, a bubble trap, pressure transmitter, flow meter after the column, UV detector, and 5 fractionation valves. All systems are controlled by UNICORN software. Several additional features/components are available to ensure that systems match specific needs. These options include:

- Extra inlet solvent lines.
- 5 extra fractionation valves.
- Magnetic coupling of circulation pump.
- Temperature control before and/or after the column
- Conductivity meter in gradient blending system or after the column.
- Pressure transmitter after the column.
- pH meter before and after the column.
- Refractive index detector for fractionation or gradient blending system.
- Valve feedback.
- Filter module.
- Injection loop for sample application.
- Heat exchanger.

Technical information

BioProcess MPLC and HPLC systems are engineered to comply with the technical performance demands placed on equipment operated at pressures up to 20 bar (MPLC system) or 80 bar (HPLC system) in industrial processing. The systems are manufactured to customer order and range from skid sizes of 1200 × 200 × 700 mm. Table 1 gives a brief technical summary.

Table 1. Technical summary.

Materials of construction:	stainless steel AISI 316 L
Standard operating pressure:	up to 20 bar (MPLC), 80 bar (HPLC)
Optional operating pressure:	up to 30 bar (MPLC), 150 bar (HPLC)
Flow velocity:	up to 20 000 l/h (MPLC), up to 3000 l/h (HPLC)
No. of buffer inlets:	4 (6 as option)
No. of fractionation valves:	5 (10 as option)
Gradient:	mixing of 2 solvents
Related equipment:	MPLC and HPLC columns, and slurry tanks

Compatible BioProcess columns

A wide range of BioProcess MPLC and HPLC columns matches the performance capabilities of the above systems. Their well-proven design simplifies filling and packing. Together with the systems, the columns ensure fast and efficient process-scale purification.

Validation support

Fast Trak Biopharma services can assist with training course and validation procedures for BioProcess MPLC/HPLC systems. See page 140.

Ordering information

For further technical details, please contact your local representative.

Literature

Data File

BioProcees MPLC/HPLC Systems	18-1167-77

Application Note

Factors affecting the accuracy and reproducibility of gradient formation for preparative liquid chromatography	11-0012-40

Brochure

More pressure – less worry	11-0007-13

Customized Bioprocess Solutions

For some applications only customized solutions fit the bill. Through its Customized Bioprocess Solutions (CBS) group, GE Healthcare can offer a wide range of engineered solutions for chromatography, membrane filtration and oligonucleotide synthesis. The CBS group has more than 20 years' experience of engineering systems and columns to meet customer's application needs, specifications, and regulatory requirements. The choice of components, materials, manufacturing methods and system configuration are made by the customer in consultation with our engineers to ensure performance and compatibility. Choice of control software includes DeltaV, UNICORN, PLC or any other requirement. Auxiliary equipment can also be manufactured according to specifications.

A key element of GE Healthcare's offering is its service organization. Service agreements ensure rapid service and replacement spare parts delivered within 48 hours minimize expensive downtime.

For more information, please contact your local GE Healthcare representative or visit the CBS homepage **www.gehealthcare.com/cbs**

CBS DeltaV Standard Control Platform

CBS DeltaV Standard Control Platform is a flexible control software that simplifies process automation of protein purification by industrial-scale chromatography. The control platform employs Emerson DeltaV software, which has a solid track record of providing excellent control capability in the pharmaceutical and biotechnology industries.

Benefits of the CBS DeltaV Standard Control Platform include:

- Efficient and dedicated control solutions for chromatography purification of proteins.
- Flexible operation (recipe) development and assessment.
- Extensive analytical functions for chromatography data with UNICORN Evaluation.
- Full integration with existing DeltaV systems.
- Extensive support (e.g., audit trails) for regulatory support compliance.

For more information on CBS DeltaV Standard Control Platform, see datafile: 28-4074-95

UNICORN control

UNICORN is the control system for real-time control of protein purification unit operations (column packing, chromatography and filtration) from laboratory bench, through development, to full-scale production. UNICORN is used world-wide in over a thousand laboratories and controls hundreds of process development and production systems.

UNICORN control system meets the needs of full-scale production with manufacturing systems, while maintaining the flexibility needed for method and process development with the range of systems in the ÄKTA family.

This flexibility allows quick and simple transition from one stage of a project to the next. Clinical trial equipment can be turned into a final production installation overnight. Documentation and operator-interface remain consistent from one step to the next and re-investment and validation requirements are reduced to a minimum. UNICORN can also be adapted to control other liquid handling process units, or to connect to other control systems in a plant via the OPC interface.

Among the many features of UNICORN are easy method programming, powerful functions for method assessment, a dynamic display to keep you posted on process status, and the configurable user-access profiles to keep your methods secure. In addition, UNICORN can simultaneously supervise up to four liquid handling units from a single work-station, independently or in a pre-programmed sequence. Full validation support for the control system software is available to help speed your product to market.

The software consists of separate modules for method programming, system control and data evaluation.

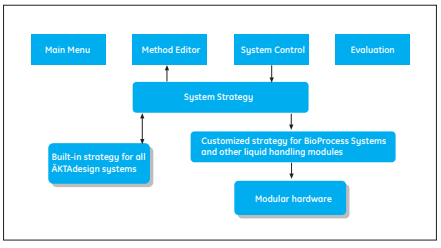
Easy method programming

Most complex valving sequences are handled through valve macros. Programming can be done in time, volume or column volume base.

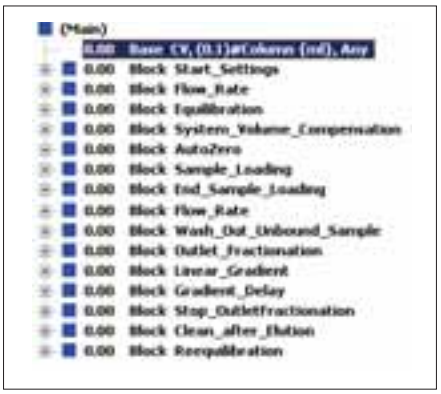
Automatic scouting of important separation variables is easily performed. Conditional responses to specific monitor signals (UV, conductivity, pH, pressure and air) are established through simple WATCH commands.

Real-time process monitoring

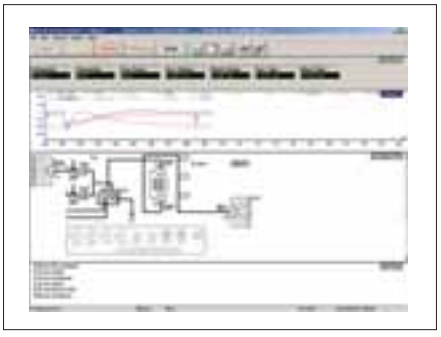
As the chromatography run progresses, selected monitor signals are displayed numerically or as trend curves. The process picture with actual flow path and the continuously updated logbook can be displayed.



UNICORN architecture.



Method text editor.



UNICORN control module.

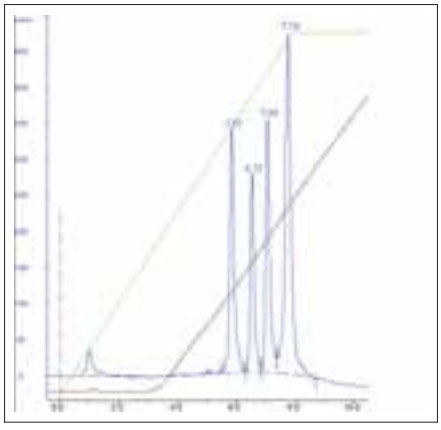
Real-time control

Up to four systems can be connected to one UNICORN workstation where individual controllers handle the real-time control of each system. Data evaluation or methods programming can be done while the systems are running.

The control unit CU 950 (Ethernet and USB) provides a high degree of security for control and data. The unit secures started runs even if the local PC and communication is disrupted. CU 950 Advanced also contains an internal memory that collects data in case of communication failure.

Extensive data evaluation

All monitor data are stored in a Result File for storage and evaluation. Extensive data processing routines include curve smoothing, differentiation, normalization, baseline calculation, peak integration and height equivalent to a theoretical plate (HETP) calculations.



Evaluation procedures can be retrieved from a programmed method to process data and generate reports as part of an automated procedure.

Batch documentation

Along with the chromatographic results of each run, the Result File also includes the programmed method, start protocols, notebooks and the logbook. These files are protected and cannot be manipulated. Processed data generated from an evaluation procedure are stored in the Result File, but separate from the original data.

Start protocols are user-defined questions that must be answered before a run can be started. Questions can vary between simple operator prompts to those requiring mandatory answers and authorized approval.

Notebooks permit additional text to be included in the process documentation. Separate files are generated for method notes, start notes, run notes, and evaluation notes. These notes can be entered at the designated time and cannot be altered after the run is complete.

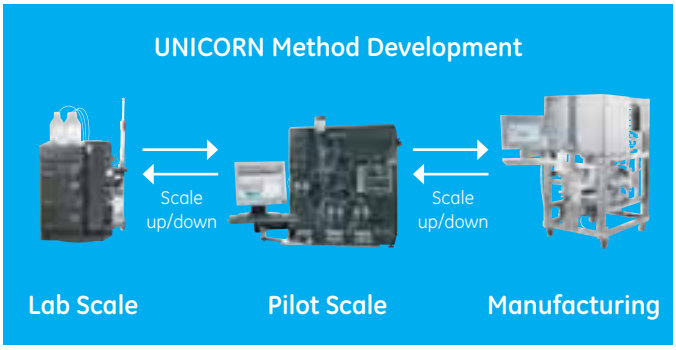
All programmed and manual events occurring during the run, including alarms and warnings, are documented in the logbook and cannot be altered.

Security

UNICORN provides a system for password authorization and access control. Operators log in by name and password. The user profile includes an access level that defines system functions available to each operator.

Scalability

Using UNICORN for method or process development on ÄKTAdesign systems simplifies scale-up to BioProcess system. Personnel retraining is minimized and continuity exists in batch documentation and report generation.



UNICORN methods can be transferred between systems at different scales.

Validation support

UNICORN is fully compliant with 21 CRF Part 11 and is extensively documented for validation purposes.

A Validation Support File is available describing our software development model including routines and test models.

Installation and Operational Qualification Documentation packages consisting of preprinted forms and test methods are also available (see p 140).

OPC Connectivity

The UNICORN OPC server provides a standardized integration interface to support integration between UNICORN and other software systems such as laboratory information systems (LIMS) and manufacturing execution systems like DCS and MES. OPC enables open connectivity via open standards created in collaboration with a number of worldwide leading automation manufacturers, including Microsoft.

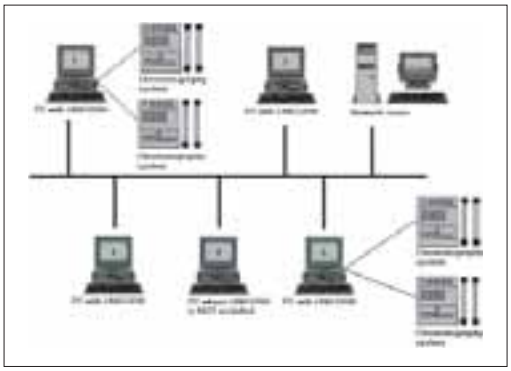
UNICORN OPC server supports the following four areas:

- UNICORN OPC Data Access gives access to all process data (e.g., real time values, valve status, process step information and commands).
- UNICORN Alarm & Events server informs an OPC client application that a system parameter has exceeded an upper or lower limit value. The UNICORN Alarm & Events server also provides information about the process (LogBook).
- UNICORN Historical Data Access allows any OPC client application access to the entire batch result generated by UNICORN.
- UNICORN OPC Security controls client access to the UNICORN OPC DA, A&E and HDA to protect sensitive information and to guard against unauthorized modification of process parameters. This is an important security feature.

Network support

Network support allows control and monitoring of systems from any connected UNICORN workstation, subject to access rights defined by the system administrator. UNICORN is specifically designed for Windows networks operating system control. The figure below illustrates how it can be applied in a fully networked system. This facility gives a larger number of operators access to what is happening. Nevertheless, security is still very controlled and subject to strict user-defined access rights.

Network support also enables results to be automatically saved on a server. Evaluation and generation of reports can then be made locally or at a remote PC.



UNICORN network allows sharing of systems and a central location for data storage.

Computer and networking specifications
System Recommendations for UNICORN v. 5.11

Workstation
PC – Pentium 4, 1.5 GHz or higher.
256 Mb (1 system) 512 Mb (more than 1 system).
500 Mb disk space available at all times.
NTFS file system

Controller
CU-900 requires 1/2 length PCI slot
CU-950 USB requires USB 1.1 Port.
CU-950 Advanced requires a 10 Mbit network interface card.

Network server
Microsoft Windows 2003 Server, TCP/IP.

Operating system
Windows 2000 SP4 or later and Windows XP Professional SP1 or later.

Ordering information

Please contact your local GE Healthcare sales office.

Literature

Data File	Code No.
UNICORN control system	18-1111-20
Validation support and service	18-1104-73
Validation Support File UNICORN 5.1	11-0029-16

Information on OPC-based integration

Application Note	
DeltaV* integration	04-0021-64
iFix integration	04-0030-58
MS SQL Server integration	04-0030-59
InTouch integration	04-0030-60
Data File	
OPC	11-0004-15
Manual	
OPC	04-0023-04

* DeltaV is a trademark owned by Fisher-Rosemount Systems, Inc.

Products for process development

Prepacked columns
Custom-packed columns
ÄKTAexplorer
ÄKTApilot

Products for process development

GE Healthcare supports the migration of a method from the laboratory bench through process development to full-scale production. For lab research, media screening, method scouting and small-scale optimization, there are prepacked columns for every chromatographic technique.

Recent additions include two PlasmidSelect Xtra kits containing prepacked columns for developing and monitoring processes for purifying high-quality supercoiled plasmid DNA, and new HiTrap columns packed with Capto adhere, a new medium for post-Protein A purification of monoclonal antibodies.

ÄKTAexplorer and ÄKTApilot are members of the ÄKTAdesign family of chromatography systems and are well-suited for process development.

As well as operating a wide range of prepacked columns, FineLINE Pilot 35 column can also be connected to ÄKTAexplorer.

FineLINE 70 and BPG 100 can be connected to ÄKTApilot. The control system for ÄKTAdesign systems is UNICORN, which can also be used for pilot-scale systems and full production. Having a common control platform allows quick and simple transfer of methods to pilot- and process-scales. UNICORN combines the flexibility needed for method and process development with the stringent requirements for commercial manufacture of biopharmaceuticals.

ÄKTAexplorer and ÄKTApilot are also supported by Fast Trak with Installation Qualification and Operation Qualification (IQ/OQ) documentation packages.

If the combination of media and column you are looking for is not listed on the following pages, please refer to Custom Packed Laboratory Columns at GE Healthcare.
Further details about prepacked columns can be found in *Products for life sciences 2007*.

Affinity columns for ÄKTAdesign systems

Ordering information

Product	Quantity	Code No.
GSTPrep FF 16/10	1 × 20 ml	17-5234-01
GSTrap 4B	5 × 1 ml	28-4017-45
GSTrap 4B	100 × 1 ml*	28-4017-46
GSTrap 4B	1 × 5 ml	28-4017-47
GSTrap 4B	5 × 5 ml	28-4017-48
GSTrap 4B	100 × 5 ml*	28-4017-49
GSTrap FF	2 × 1 ml	17-5130-02
GSTrap FF	5 × 1 ml	17-5130-01
GSTrap FF	100 × 1 ml*	17-5130-05
GSTrap FF	1 × 5 ml	17-5131-01
GSTrap FF	5 × 5 ml	17-5131-02
GSTrap FF	100 × 5 ml*	17-5131-05
GSTrap HP	5 × 1 ml	17-5281-01
GSTrap HP	100 × 1 ml*	17-5281-05
GSTrap HP	1 × 5 ml	17-5282-01
GSTrap HP	5 × 5 ml	17-5282-02
GSTrap HP	100 × 5 ml*	17-5282-05
HisPrep FF 16/10	1 × 20 ml	17-5256-01
HisTrap FF	5 × 1 ml	17-5319-01
HisTrap FF	100 × 1 ml*	17-5319-02
HisTrap FF	5 × 5 ml	17-5255-01
HisTrap FF	100 × 5 ml*	17-5255-02
HisTrap FF crude	5 × 1 ml	11-0004-58
HisTrap FF crude	100 × 1 ml*	11-0004-59
HisTrap FF crude	5 × 5 ml	17-5286-01
HisTrap FF crude	100 × 5 ml*	17-5286-02
HisTrap HP	5 × 1 ml	17-5247-01
HisTrap HP	100 × 1 ml*	17-5247-05
HisTrap HP	1 × 5 ml	17-5248-01
HisTrap HP	5 × 5 ml	17-5248-02
HisTrap HP	100 × 5 ml*	17-5248-05

Order online at www.gehealthcare.com/orderonline
* Pack size available by special order.

Ordering information

Product	Quantity	Code No.
HiTrap Benzamidine FF (high sub)	2 × 1 ml	17-5143-02
HiTrap Benzamidine FF (high sub)	5 × 1 ml	17-5143-01
HiTrap Benzamidine FF (high sub)	1 × 5 ml	17-5144-01
HiTrap Blue HP	5 × 1 ml	17-0412-01
HiTrap Blue HP	1 × 5 ml	17-0413-01
HiTrap Chelating HP	5 × 1 ml	17-0408-01
HiTrap Chelating HP	1 × 5 ml	17-0409-01
HiTrap Chelating HP	5 × 5 ml	17-0409-03
HiTrap Chelating HP	100 × 5 ml*	17-0409-05
HiPrep 16/10 Heparin FF	1 × 20 ml	17-5189-01
HiTrap Heparin HP	5 × 1 ml	17-0406-01
HiTrap Heparin HP	1 × 5 ml	17-0407-01
HiTrap Heparin HP	5 × 5 ml	17-0407-03
HiTrap IgM Purification HP	5 × 1 ml	17-5110-01
HiTrap IgY Purification HP	1 × 5 ml	17-5111-01
HiPrep IMAC FF 16/10	1 × 20 ml	17-0921-06
HiTrap IMAC FF	5 × 1 ml	17-0921-02
HiTrap IMAC FF	5 × 5 ml	17-0921-04
HiTrap IMAC HP	5 × 1 ml	17-0920-03
HiTrap IMAC HP	5 × 5 ml	17-0920-05
HiTrap MabSelect SuRe	5 × 1 ml	11-0034-93
HiTrap MabSelect SuRe	1 × 5 ml	11-0034-94
HiTrap MabSelect SuRe	5 × 5 ml	11-0034-95
HiTrap MabSelect	5 × 1 ml	28-4082-53
HiTrap MabSelect	1 × 5 ml	28-4082-55
HiTrap MabSelect	5 × 5 ml	28-4082-56
HiTrap MabSelect Xtra	5 × 1 ml	28-4082-58
HiTrap MabSelect Xtra	1 × 5 ml	28-4082-60
HiTrap MabSelect Xtra	5 × 5 ml	28-4082-61
HiTrap NHS-activated HP	5 × 1 ml	17-0716-01
HiTrap NHS-activated HP	1 × 5 ml	17-0717-01
HiTrap Protein A HP	2 × 1 ml	17-0402-03
HiTrap Protein A HP	5 × 1 ml	17-0402-01
HiTrap Protein A HP	1 × 5 ml	17-0403-01
HiTrap Protein A HP	5 × 5 ml	17-0403-03
HiTrap Protein G HP	2 × 1 ml	17-0404-03
HiTrap Protein G HP	5 × 1 ml	17-0404-01
HiTrap Protein G HP	1 × 5 ml	17-0405-01
HiTrap Protein G HP	5 × 5 ml	17-0405-03
HiTrap rProtein A FF	2 × 1 ml	17-5079-02
HiTrap rProtein A FF	5 × 1 ml	17-5079-01
HiTrap rProtein A FF	1 × 5 ml	17-5080-01
HiTrap rProtein A FF	5 × 5 ml	17-5080-02
HiTrap Streptavidin HP	5 × 1 ml	17-5112-01

Order online at www.gehealthcare.com/orderonline
* Pack size available by special order.

Chromatofocusing columns for ÄKTAdesign systems

Ordering information		
Product	Quantity	Code No.
Mono P 5/50 GL*	1	17-5170-01
Mono P 5/200 GL*	1	17-5171-01

Order online at www.gehealthcare.com/orderonline
* Column not suitable for use with ÄKTAprime plus chromatography system. Please contact us for assistance with selection of columns for ÄKTAprime plus.

Desalting columns for ÄKTAdesign systems

Ordering information		
Product	Quantity	Code No.
HiPrep 26/10 Desalting	1 × 53 ml	17-5087-01
HiPrep 26/10 Desalting	4 × 53 ml	17-5087-02
HiTrap Desalting	5 × 5 ml	17-1408-01
HiTrap Desalting	100 × 5 ml*	11-0003-29

Order online at www.gehealthcare.com/orderonline
*Pack size available by special order.

Gel filtration columns for ÄKTAdesign systems

Ordering information		
Product	Quantity	Code No.
HiLoad 16/60 Superdex 30 pg	1 × 120 ml	17-1139-01
HiLoad 16/60 Superdex 75 pg	1 × 120 ml	17-1068-01
HiLoad 16/60 Superdex 200 pg	1 × 120 ml	17-1069-01
HiLoad 26/60 Superdex 30 pg	1 × 320 ml	17-1140-01
HiLoad 26/60 Superdex 75 pg	1 × 320 ml	17-1070-01
HiLoad 26/60 Superdex 200 pg	1 × 320 ml	17-1071-01
HiPrep 16/60 Sephacryl S-100 HR	1 × 120 ml	17-1165-01
HiPrep 16/60 Sephacryl S-200 HR	1 × 120 ml	17-1166-01
HIPrep 16/60 Sephacryl S-300 HR	1 × 120 ml	17-1167-01
HiPrep 26/60 Sephacryl S-100 HR	1 × 320 ml	17-1194-01
HiPrep 26/60 Sephacryl S-200 HR	1 × 320 ml	17-1195-01
HiPrep 26/60 Sephacryl S-300 HR	1 × 320 ml	17-1196-01

Order online at www.gehealthcare.com/orderonline

Ordering information		
Product	Quantity	Code No.
Superdex 75 10/300 GL*	1	17-5174-01
Superdex 200 10/300 GL*	1	17-5175-01
Superdex Peptide 10/300 GL*	1	17-5176-01
Superdex 200 5/150 GL*†	1	28-9065-61
Superose 6 10/300 GL*	1	17-5172-01
Superose 12 10/300 GL*	1	17-5173-01

Order online at www.gehealthcare.com/orderonline
* Column not suitable for use with ÄKTAprime plus chromatography system. Please contact us for assistance with selection of columns for ÄKTAprime plus.
† Short gel filtration column for fast screening of conditions during optimization.

Hydrophobic interaction chromatography columns for ÄKTAdesign systems

Ordering information		
Product	Quantity	Code No.
HiPrep 16/10 Butyl FF	1 × 20 ml	17-5096-01
HiPrep 16/10 Octyl FF	1 × 20 ml	17-5097-01
HiPrep 16/10 Phenyl FF (high sub)	1 × 20 ml	17-5095-01
HiPrep 16/10 Phenyl FF (low sub)	1 × 20 ml	17-5094-01
HiLoad 16/10 Phenyl Sepharose HP	1 × 20 ml	17-1085-01
HiLoad 26/10 Phenyl Sepharose HP	1 × 53 ml	17-1086-01
HiTrap HIC Selection Kit	7 × 1 ml	28-4110-07
HiTrap Butyl HP	5 × 1 ml	28-4110-01
HiTrap Butyl HP	5 × 5 ml	28-4110-05
HiTrap Butyl-S FF	5 × 1 ml	17-0978-13
HiTrap Butyl-S FF	5 × 5 ml	17-0978-14
HiTrap Butyl FF	5 × 1 ml	17-1357-01
HiTrap Butyl FF	5 × 5 ml	17-5197-01
HiTrap Octyl FF	5 × 1 ml	17-1359-01
HiTrap Octyl FF	5 × 5 ml	17-5196-01
HiTrap Phenyl FF (high sub)	5 × 1 ml	17-1355-01
HiTrap Phenyl FF (high sub)	5 × 5 ml	17-5193-01

Order online at www.gehealthcare.com/orderonline

Ordering information		
Product	Quantity	Code No.
HiTrap Phenyl FF (low sub)	5 × 1 ml	17-1353-01
HiTrap Phenyl FF (low sub)	5 × 5 ml	17-5194-01
HiTrap Phenyl HP	5 × 1 ml	17-1351-01
HiTrap Phenyl HP	5 × 5 ml	17-5195-01
RESOURCE ETH	1 × 1 ml	17-1184-01
RESOURCE HIC Test Kit	3 × 1 ml	17-1187-01
RESOURCE ISO	1 × 1 ml	17-1185-01
RESOURCE PHE	1 × 1 ml	17-1186-01
SOURCE 15PHE 4.6/100 PE*	1	17-5186-01

Order online at www.gehealthcare.com/orderonline
* Column not suitable for use with ÄKTAprime plus chromatography system. Please contact us for assistance with selection of columns for ÄKTAprime plus.

Ion exchange columns for ÄKTAdesign system

Ordering information		
Product	Quantity	Code No.
HiLoad 16/10 Q Sepharose HP	1 × 20 ml	17-1064-01
HiLoad 16/10 SP Sepharose HP	1 × 20 ml	17-1137-01
HiLoad 26/10 Q Sepharose HP	1 × 53 ml	17-1066-01
HiLoad 26/10 SP Sepharose HP	1 × 53 ml	17-1138-01
HiPrep 16/10 ANX FF (high sub)	1 × 20 ml	17-5191-01
HiPrep 16/10 CM FF	1 × 20 ml	17-5091-01
HiPrep 16/10 DEAE FF	1 × 20 ml	17-5090-01
HiPrep 16/10 Q FF	1 × 20 ml	17-5190-01
HiPrep 16/10 Q XL	1 × 20 ml	17-5092-01
HiPrep 16/10 SP FF	1 × 20 ml	17-5192-01
HiPrep 16/10 SP XL	1 × 20 ml	17-5093-01
HiTrap IEX Selection Kit	7 × 1 ml	17-6002-33
HiTrap ANX FF (high sub)	5 × 1 ml	17-5162-01
HiTrap ANX FF (high sub)	5 × 5 ml	17-5163-01
HiTrap Capto MMC	5 × 1 ml	11-0032-73
HiTrap Capto MMC	5 × 5 ml	11-0032-75
HiTrap Capto Q	5 × 1 ml	11-0013-02
HiTrap Capto Q	5 × 5 ml	11-0013-03
HiTrap Capto ViralQ	5 × 5 ml	28-9078-09
HiTrap Capto S	5 × 1 ml	17-5441-22
HiTrap Capto S	5 × 5 ml	17-5441-23
HiTrap Capto adhere	5 × 1 ml	28-4058-44
HiTrap Capto adhere	5 × 5 ml	28-4058-46
HiTrap CM FF	5 × 1 ml	17-5056-01
HiTrap CM FF	5 × 5 ml	17-5155-01
HiTrap DEAE FF	5 × 1 ml	17-5055-01
HiTrap DEAE FF	5 × 5 ml	17-5154-01
HiTrap Q FF	5 × 1 ml	17-5053-01
HiTrap Q FF	5 × 5 ml	17-5156-01
HiTrap Q HP	5 × 1 ml	17-1153-01
HiTrap Q HP	5 × 5 ml	17-1154-01
HiTrap Q XL	5 × 1 ml	17-5158-01
HiTrap Q XL	5 × 5 ml	17-5159-01
HiTrap SP FF	5 × 1 ml	17-5054-01
HiTrap SP FF	5 × 5 ml	17-5157-01
HiTrap SP HP	5 × 1 ml	17-1151-01
HiTrap SP HP	5 × 5 ml	17-1152-01
HiTrap SP XL	5 × 1 ml	17-5160-01
HiTrap SP XL	5 × 5 ml	17-5161-01

Order online at www.gehealthcare.com/orderonline

Ordering information		
Product	Quantity	Code No.
Mini Q 4.6/50 PE*	1	17-5177-01
Mini S 4.6/50 PE*	1	17-5178-01
Mono Q 4.6/100 PE*	1	17-5179-01
Mono Q 5/50 GL*	1	17-5166-01
Mono Q 10/100 GL*	1	17-5167-01
Mono Q HR 16/10	1	17-0506-01
Mono S 4.6/100 PE*	1	17-5180-01
Mono S 5/50 GL*	1	17-5168-01
Mono S 10/100 GL*	1	17-5169-01
Mono S HR 16/10*	1	17-0507-01
RESOURCE Q	1 × 1 ml	17-1177-01
RESOURCE Q	1 × 6 ml	17-1179-01
RESOURCE S	1 × 1 ml	17-1178-01
RESOURCE S	1 × 6 ml	17-1180-01
SOURCE 15Q 4.6/100 PE*	1	17-5181-01
SOURCE 15S 4.6/100 PE*	1	17-5182-01

Order online at www.gehealthcare.com/orderonline
*Column not suitable for use with ÄKTAprime plus chromatography system.
Please contact us for assistance with selection of columns for ÄKTAprime plus.

Reversed phase chromatography columns for ÄKTAdesign system

Ordering information		
Product	Quantity	Code No.
RESOURCE RPC 1 ml	1	17-1181-01
RESOURCE RPC 3 ml*	1	17-1182-01
SOURCE 5RPC ST 4.6/150*	1	17-5116-01
SOURCE 15RPC ST 4.6/100*	1	17-5068-01
µRPC C2/C18 ST 4.6/100*	1	17-5057-01

Order online at www.gehealthcare.com/orderonline
*Column not suitable for use with ÄKTAprime plus chromatography system.
Please contact us for assistance with selection of columns for ÄKTAprime plus.

Prepacked columns for purification of high-quality plasmid DNA

Ordering information		
Product	Quantity	Code No.
PlasmidSelect Xtra Starter Kit	1	28-4052-68
PlasmidSelect Xtra Screening Kit	1	28-4052-69

Selection Kits

In addition to the individual columns, there a number of selection kits available. These kits usually contain three to seven prepacked columns that enable you to quickly screen potential media.

IEX Selection Kit

Eight different Sepharose media differentiated by process stage

For Capture, Q Sepharose Big Beads and SP Sepharose Big Beads in 50-ml packs. For Intermediate Purification, Q Sepharose Fast Flow, SP Sepharose Fast Flow, CM Sepharose Fast Flow, and DEAE Sepharose Fast Flow in 50-ml packs. For Polishing, Q Sepharose High Performance and SP Sepharose High Performance in 1-ml prepacked HiTrap columns.

HiTrap IEX Selection Kit (17-6002-33)

Seven different ion exchange ligands on Sepharose Fast Flow and Sepharose XL enable fast and easy screening

Contains seven 1-ml HiTrap columns prepacked with SP Sepharose Fast Flow, Q Sepharose Fast Flow, CM Sepharose Fast Flow, DEAE Sepharose Fast Flow, ANX Sepharose 4 Fast Flow (high sub), SP Sepharose XL and Q Sepharose XL as well as connectors and instructions.

HiTrap HIC Selection Kit (28-4110-07)

For screening different HIC media and experimental conditions

Contains seven 1-ml HiTrap columns prepacked with Phenyl Sepharose High Performance, Phenyl Sepharose 6 Fast Flow (high sub), Phenyl Sepharose 6 Fast Flow (low sub), Butyl Sepharose High Performance, Butyl Sepharose 4 Fast Flow, Butyl-S Sepharose 6 Fast Flow, Octyl Sepharose 4 Fast Flow, connectors and instructions.

RESOURCE HIC Test Kit (17-1187-01)

Fast, high resolution purification of proteins and peptides. The different selectivities in the kit cover a wide range of applications

Contains three 1-ml columns: RESOURCE ETH, RESOURCE ISO, RESOURCE PHE.

PlasmidSelect Xtra platform kits

PlasmidSelect Xtra Starter Kit (28-4052-68)

Fast and convenient process development

Contains one HiPrep 26/10 Sepharose 6 FF column (53 ml), one HiTrap PlasmidSelect Xtra column (5 ml) and one HiTrap SOURCE 30Q column (5 ml) plus accessories. Does not include buffers.

PlasmidSelect Xtra Screening Kit (28-4052-69)

Quick and easy analysis with an ÄKTAdesign system

Contains five 5-ml HiTrap Sepharose HP and five 1-ml HiTrap PlasmidSelect Xtra columns plus accessories. Does not include buffers.

Custom-packed laboratory columns

Custom products adapt the exact combination of media and column to solve specific purification problems. With years of experience in chromatography and column packing, you can rely on the Custom Products group to tailor a solution to fit your separation objectives and save you time. The group works with you from the initial discussions right through to delivery, establishing your needs and sorting through the choices.

- Each custom column is packed and tested under stringent ISO 9001 standards.
- A result of analysis and user instruction that describe the column performance is supplied with the column.
- Delivery time is between two and four weeks, depending on media and column specifications.

GE Healthcare offers the largest selection of prepacked columns and bulk media available, encompassing most liquid chromatography techniques. However, should you require a special configuration – contact the Custom Products group through your local GE Healthcare office to discuss your ideas and receive a free quotation.

Systems for method and process development

ÄKTAexplorer

ÄKTAexplorer is part of the ÄKTAdesign range of liquid chromatography systems and designed for fast method development and optimization of any biomolecular purification using one working platform for all techniques and samples.

Flexibility from laboratory to production

- Easy system modification.
- Fast, trouble-free transfer of methods to production scale.

Easy, safe selection of columns optimally suited to each purification

- Comprehensive column library for support of HiTrap, RESOURCE, Tricorn, HiPrep and HiLoad. Also supports FineLINE Pilot 35 and XK columns.

Fast systematic method optimization

- Automatic media screening.
- Vary any run parameter in automated scouting schemes.

ÄKTAexplorer systems are designed for all liquid chromatography techniques and offer a range of operating scales that previously required several systems or system configurations. For example, it is possible to configure a system with valves for multiple-sample testing, column switching, flow reversal, eluent scouting, etc.

New functions to enhance system capabilities or to create new system configurations are easily added. Functions, consisting of hardware components and software instructions, are selected, installed, and implemented by the user. Method optimization and process development on chromatographic systems often include systematic variation of the key run parameters, such as media selection, binding and elution buffers, or safe sample loading using air sensors.

UNICORN control software includes scouting schemes within each general method that eliminates the need for creating new methods for each set of parameters. The method wizard minimizes time spent in method programming, and supports the most common scouting procedures such as:

- Automatic media screening.
- Automatic eluent pH scouting.

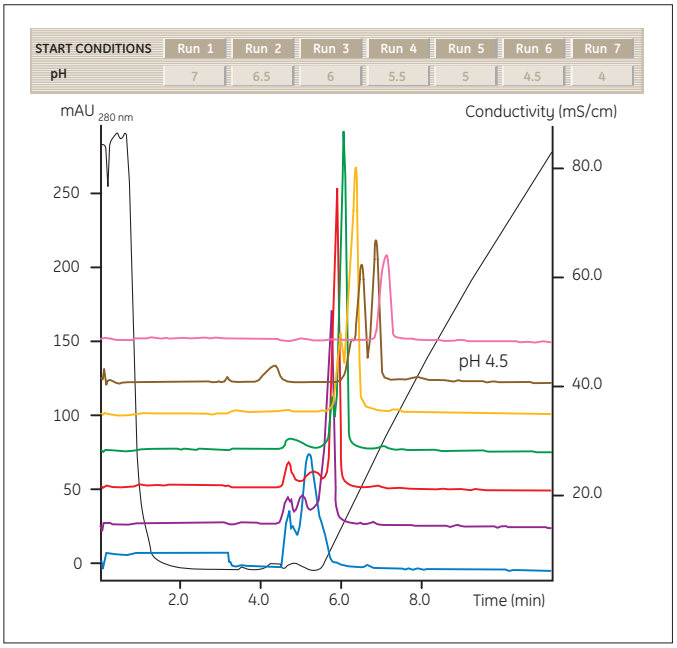
ÄKTAexplorer also includes a function, BufferPrep, which increases the speed and the reliability of results by eliminating the time-consuming manual buffer preparation and titration usually needed for every pH range.

UNICORN control system is used at all scales of operation from laboratory bench to full production. UNICORN combines the flexibility needed for method and process development with the stringent requirements for commercial manufacture of biopharmaceutical products on production chromatography systems.

ÄKTAexplorer systems are available in different standard configurations to suit most purification needs, but are easily modified if required. Systems can be used for flow rates up to 100 ml/min (at 10 MPa) to ensure minimized runtime at maximum flow rates, or at 10 ml/min (25 MPa pressure) for applications using columns with higher back pressure and resolution.

A method can be created in ÄKTAexplorer in under 3 minutes.

Scouting, developing and optimizing methods for all liquid chromatography techniques are the strengths of the different ÄKTAexplorer systems available. Broad capabilities and flexibility, high levels of automation, simple user interface, and accurate, reproducible and reliable operation makes these the perfect systems for laboratories involved in pre-production method scouting or in developing and optimizing methods.



Automatic pH scouting on ÄKTAexplorer 100 using the method wizard.

ÄKTAexplorer 100 and FineLINE Pilot 35

FineLINE Pilot 35 column can be connected to any of the ÄKTAdesign systems that has a pump capacity of 100 ml/min provided the appropriate tubing kit is used (see below). This kit needs to be ordered separately.

Prepacked columns for ÄKTAexplorer

Suitable columns for use with ÄKTAexplorer are listed at the beginning of this section.

For detailed information about ÄKTAexplorer systems, or the other systems in the ÄKTAdesign platform, please refer to GE Healthcare *Products for life sciences 2007*, or ÄKTAexplorer chromatography systems data file, Code No. 18-1124-09.

Ordering information

Product	Code No.
ÄKTAexplorer 100	18-1112-41
ÄKTAexplorer 100 Air	18-1403-00
ÄKTAexplorer 10	18-1300-00
ÄKTAexplorer 10S	18-1145-05
Tubing kit for FineLINE	18-1115-74

ÄKTApilot system

ÄKTApilot is a high-performance, automated liquid chromatography system designed for process development, process scale-up, scale-down and small-scale production. The system has the capacity to purify from milligrams to tens of grams of product and is biocompatible, hygienic and sanitizable. ÄKTApilot meets all GLP and cGMP demands for Phase I–III in drug development and final-scale production.

- Hygienic design
  - enables purification of microbial-free and contaminant-free products.
- High dynamic capacity
  - flow capacity 4 to 400 ml/min with 0 to 100% gradient.
  - 4 to 800 ml/min flow with limited gradient.
  - possibility to purify 10 g product per cycle.
- Built-in and EVB sanitary fraction collection valves for
  - maximum use of bench space.
  - a complete purification package in one system.
- Fast and convenient start with UNICORN
  - Method Wizard for easy programming.
  - preprogrammed sanitization method and column lists.
  - constant pressure regulation of flow rate during sample application and during column packing.
- Validation support
  - IQ/OQ documentation available.
  - UNICORN supports FDA 21 CFR part 11 for Electronic Signatures and Electronic Records.
  - Supported with hardware product documentation to simplify validation.
- Bench top design
  - fits in small areas
  - easily moved and serviced.
- All wetted parts are externally mounted and are easily changeable for
  - convenient product change-over when campaigning
  - simplified cleaning validation.

The sanitary system for rapid process development and small-scale production

The system consists of the ÄKTApilot separation unit, a computer including a flat-screen monitor and UNICORN control system. UNICORN ensures quick, simple communication between systems and users and meets the stringent control and data handling procedures of modern production and laboratory facilities. Method wizards provide easy method generation. Optimized methods are transferred easily from laboratory to production scale.

In addition to the two outlet fraction valves, you can connect four extra EVB 988 valves (External Valve Block). Two extra EVB 981 inlet valves can also be connected on the outlet valve rack.

Trouble-free sanitization

ÄKTApilot system is easily sanitized with 1 M sodium hydroxide (NaOH). Microbial challenge tests that subject the system to infection with solutions containing three strains of bacteria recommended by the United States Pharmacopoeia (USP 25), and a strain of yeast commonly found in production environments gave 6 log reduction results that fulfill the USP 25 requirements.

Ordering information

Product	Code No.
ÄKTApilot	18-1170-63
Additional items	
EVB 981 (Inlet)	28-4079-75
EVB 988 (Outlet)	28-4079-78
EVB Rack	28-4079-72
CIP Manifold	28-4009-03
ÄKTApilot Tubing Kit Column	18-1167-68
ÄKTApilot Valve Membrane CPL	18-1169-10
ÄKTApilot Elbow 90 TC25 Short	18-1169-19
ÄKTApilot TUBE S7 CPL	18-1169-71
ÄKTApilot TUBE S8 CPL	18-1169-75
Wetted parts kit	18-1171-07
O-ring, top air trap	18-1169-12
Connector M6 fem. – 5/16 fem.	18-1169-17
Connector M6 fem. – 5/16 male	18-1169-16
Clamp TC 25	18-1169-18
Connector TC – 5/16 fem.	18-1169-22
Connector TC – 5/16 male	18-1169-23
TC-gasket 25/4 mm	18-1169-24
TC-gasket 25/6.5 mm	18-1169-25
T-connector 5/16 – 24	18-1170-59
Connector 5/16 fem. – 5/16 fem.	18-1173-51
Data Files	
ÄKTApilot	18-1167-90
UNICORN Control System	18-1156-35

Filtration

Cross flow filtration

- Hollow fiber cartridges
- Kvick cassettes and holders
- Systems

Normal flow filtration

- ULTA cartridges

Filtration

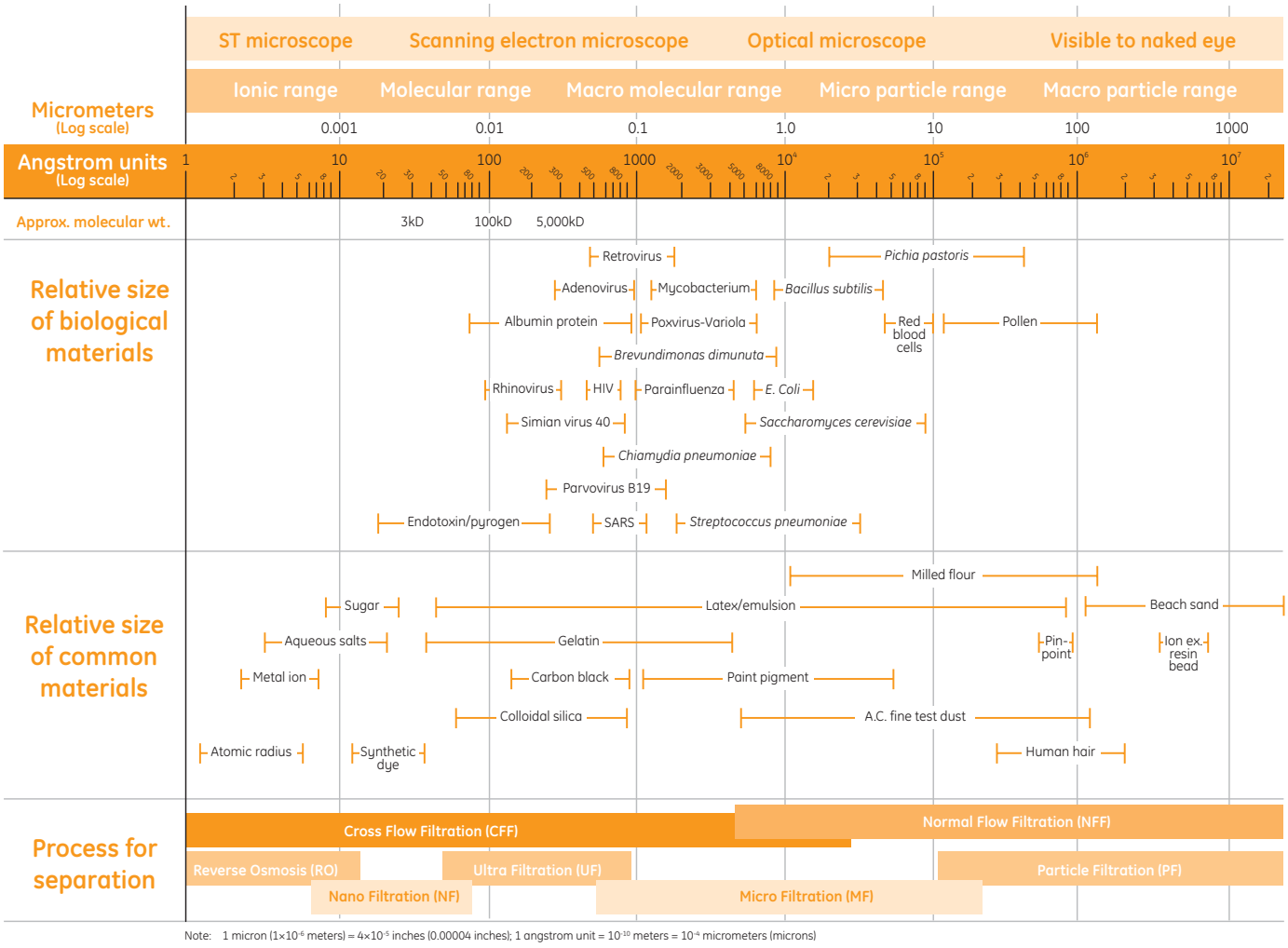
Cross flow filtration (CFF), normal ("dead-end") flow filtration (NFF), and chromatographic separations are all frequently required in the purification process of biological fluids. CFF and NFF are "positive barrier" separations and thus complement chromatography.

GE Healthcare provides filtration solutions and support for integrated bioprocessing applications at every step and every scale of the drug development, validation and manufacturing process.

The following classes of filtration products are available:

- **Hollow Fiber:** Hollow Fiber Cartridges & Systems.
- **Cassettes:** Kvick Cassettes, Holders & Systems – (flat sheet membrane devices).
- **Normal Flow:** ULTA Normal Flow Cartridges & Hardware.

The above classes comprise membranes and systems that provide optimum membrane packing density, ease of validation, and reliable scale up from laboratory to production volumes.



Note: 1 micron (1×10^{-6} meters) = 4×10^{-5} inches (0.00004 inches); 1 angstrom unit = 10^{-10} meters = 10^{-4} micrometers (microns)

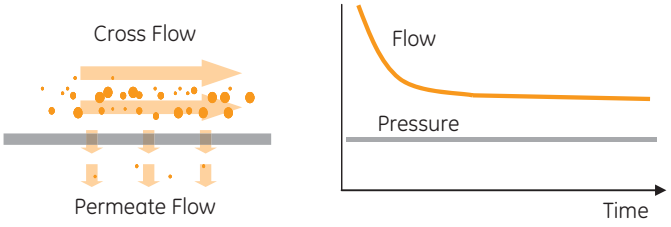
GE Healthcare's products span a wide range of filtration applications.

Filtration – how it works

Membrane filters retain matter primarily due to size differences between the molecules and the pores in the membrane. The precise nature of GE Healthcare's porous synthetic membranes used in the CFF product range makes them ideal for bioprocess purification and recovery. The key advantage of a positive barrier is GE Healthcare's advanced void-free technology, which allows optimal performance with a wide variety of feed stream constituents. Our manufacturing technology provides sharp cut-off to enhance clarification and fractionation applications. Our filters are engineered specifically for accurate linear scale-up, and our family of CFF and NFF devices offers consistent performance, excellent durability, and ease of use.

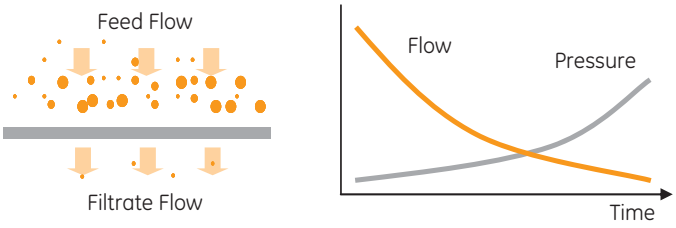
The GE Healthcare array of CFF and NFF filtration devices.

How cross flow membranes work



The feed stream moves parallel to the membrane surface (cross flow) and purified liquid passes through the membrane (permeate). Most of the particulates and aggregates are carried away by the cross flow.

How normal or dead-end flow filters work



The feed stream moves perpendicular to the membrane and purified liquid passes through the membrane (filtrate). Particulates and aggregates remain behind as 'filter cake', reducing flow and/or increasing pressure over time.

Cross flow filtration vs. Normal flow filtration

Both technologies purify bioprocess solutions by removing contaminates with a fixed porous medium, yet each format has unique advantages. Generally, normal flow filters (NFF) are used where clarification and/or bio-burden reduction is desired in relatively low solid streams, for protecting or enhancing downstream operations, or when final polishing is required to achieve sterility. Cross flow filters (CFF) are best suited for higher solids, more viscous feed solutions, and/or where concentration or purification of cells or target species is desired.

The guide below provides further information. Where functional needs overlap, a GE Healthcare Filtration Specialist can help you find the optimum configuration for your specific operation.

Guide to selecting Normal flow or Cross flow filtration

	NFF	CFF
MF Range	×	×
UF Range		×
High solids handling		×
Diafiltration		×
Concentration		×
Disposable	×	[1]
Recirculation required		×
Clean & reuse		×
Air applications	×	
Aseptic environment	×	×
Sterile applications	×	
Integrity-testable	×	
Validation guides	×	×
Self-contained available	×	×
SIP	×	×
Autoclavable	×	×

× = suitable for use.

[1] some models available; contact GE Healthcare.

Cross flow filtration

GE Healthcare separation cassettes and cartridges are designed for cross flow (tangential flow) operation. Unlike single pass or normal flow (dead end) filtration, cross flow filtration continuously sweeps the membrane surface by circulating the feed stream across it. This circulation minimizes blinding of the membrane pores and promotes consistent, long-term productivity. It also allows units to be cleaned, stored, and re-used as needed.

As the feed stream is pumped through the cassette or cartridge, the retentate (the materials excluded by the membrane pores) continues through the recirculation loop, while the permeate, including solvent and solutes, is transported through the membrane pores and collected separately.

Cross flow filtration format selection guide

Attribute	Hollow fiber	Cassette
Low binding	Best	Best
Aseptic processing	Best	Good
Reliable liner scale up	Best	Best
High solids	Best	Good
Low solids concentration	Good	Best
Perfusion	Best	NR
Cell clarification	Best	Good
Plasma concentration	Good	Best
Diafiltration	Best	Good
Single use	Good[1]	Good[1]
Laboratory scale	Best	Best
Low hold up	Good	Best
UF	Best	Best
MF	Best	NA
Steam-in-Place	Best	NR
Multiple feed channel heights	Best	Limited

[1] some models available; contact GE Healthcare.

Normal flow filtration

GE Healthcare provides comprehensive normal flow filtration products designed to maximize process efficiency from early-phase product development through to full bioprocess production.

Liquid sterilization

Filters incorporating high-flow membrane formats minimize filtration system sizes while meeting full validation and integrity test requirements.

Bioburden reduction

Extensive range of membrane and depth media products meet individual application requirements.

Clarification

Range of absolute-rated, prefiltration products providing consistent performance with broad chemical compatibility.

Range of Normal flow filtration filters

Formats	Prefilters	Bio-burden reduction*	Sterilizing grade
Flat disc	×	×	×
Syringe filters		×	×
Capsules	×	×	×
10” cartridges	×	×	×
20” cartridges	×	×	×
30” cartridges	×	×	
Pore sizes			
0.1			×
0.2		×	×
0.45		×	
0.65	×		
1.0	×		
3.0	×		
5.0	×		
10.0	×		
20.0	×		

* 1 to 5 Logs

Systems

GE Healthcare filtration systems are engineered with consistent flow paths for straightforward scale-up/scale-down, easing the transition from research to pilot to full production. In addition, GE Healthcare has highly experienced technical resources available for consultation and input into process development.

ÄKTAcrossflow

The purification of biomolecules normally uses filtration to concentrate and wash feed prior to chromatography. ÄKTAcrossflow is a fully automated system for cross flow filtration (ultrafiltration/diafiltration and cell separation) designed for process development and optimization. ÄKTAcrossflow is suitable for installation in a laboratory environment, which reduces facility and infrastructure expenditure. The benchtop system is compact and has a sanitary design with changeable wetted parts.

Hollow fiber cartridge systems

GE Healthcare provides a range of cartridge-based systems, from small systems for laboratory scale to larger-scale systems that are modular in design.

MidJet Systems are compact and self-contained. They use MidGee Cross flow Filters to facilitate rapid processing of volumes up to 200 ml. Low hold-up volumes allow concentration of volumes as small as 2 to 5 ml.

QuixStand Basic Systems are compact, self-contained units designed for Xampler laboratory cartridges for rapid processing of volumes up to 10 liters, plus linear scale up from pilot to process-scale.

FlexStand Basic Systems accommodate Pilot/Process Scale Cartridges from 0.14 to 3.4 m^2 for processing volumes from 5 to 100 liters and more.

GrandStand Pilot/Process Systems are self-contained and designed for MaxCell Large Process Scale Cartridges up to 13 m^2. Process volumes range from 50 to 1000 liters and higher.

Kvick cassette systems

The Kvick Lab separation system uses up to five Kvick Lab cassettes, and includes a 2.5 liter reservoir, rotary-lobe pump, pressure gauges, and necessary valves, piping, connectors, and fittings. The pilot/process scale system can accommodate up to 10 Kvick flow cassettes.

UniFlux systems

UniFlux systems provide a highly flexible means for incorporating filtration solutions into an overall downstream process. Available in 4 sizes (10, 30, 120, and 400 lpm) for pilot to production scales, UniFlux is available as a fully automated version with UNICORN control software, now expanded to encompass filtration as well as chromatography.

Designed to maximize productivity in cross flow filtration, UniFlux works in concert with other GE Healthcare components to provide consistent, repeatable – and validatable – results. UniFlux was developed with input from several GE Healthcare customers with needs ranging from research and development to biopharmaceutical manufacturing, thus helping ensure the relevance of each feature.

All UniFlux systems are skid-mounted, mobile, and can fit through a standard doorway. The automated systems include the following features:

- Rotary-lobe pump for reliable, shear-sensitive operation (diaphragm pump for UniFlux 10).
- Sanitary diaphragm valves.
- Overpressure protection.
- Zero dead-leg piping in stainless steel.
- Product contact material 316L stainless steel.
- Monitoring of all major process parameters.

Automated systems also include the additional benefit of GE Healthcare UNICORN control system. UNICORN software, a single interface for the control of both filtration and chromatography systems, has become a standard in the industry with over 25 000 systems in use, many in approved manufacturing operations. The UNICORN operating system is an extremely powerful tool for process development and production control, providing flexibility to control processes with automatic TMP control or regulated flow control.

Scale-up

In addition to laboratory-scale cross flow devices and systems, GE Healthcare also offers a complete range of products for biopharmaceutical scale-up to pilot and production operations. Hollow fiber ultrafiltration and microfiltration products are supplied as 25 different self-contained cartridge designs ranging from 16 cm^2 to 28 m^2 of effective membrane area.

MidGee, MidGee Hoop and Xampler scale hollow fiber cartridges can be optimized in larger processes by using pilot scale cartridges/process scale cartridges. Steam-in-place hollow fiber cartridge elements for pharmaceutical manufacturing are also available. For complete systems offerings for hollow fiber cartridges, see MidJet, QuixStand, FlexStand or GrandStand.

Like cartridges, Kvick Cassette offerings provide scalability from laboratory through pilot to production scale. Both Kvick Lab System and Kvick Flow System benefit from a design and engineering approach usually reserved for large-scale production equipment.

Automated cross flow systems are available for hollow fiber and Kvick cassettes at laboratory-scale as ÄKTAcrossflow and at pilot/production-scale as UniFlux.

Hollow fiber cartridges

Start AXM/AXH cross flow cartridges

Hollow fiber Start AXM and Start AXH cross flow cartridges.

Start hollow fiber cartridges are comprised of polysulfone (PS)-based membranes of seven UF molecular weight ratings and four MF micron ratings for processing a wide range of cells, viruses, and biomolecules. These membranes exhibit sharp rejection curves, leading to reproducible, precise separations and maximized protein yield. Each of these membranes is identical to membranes in the GE Healthcare's pilot- and process-scale hollow fiber cartridges to ensure relevance of performance data generated by using hollow fiber Start AXM and Start AXH cross flow cartridges.

- Rapid concentration and/or diafiltration of biological solutions and suspensions using an open flow path design.
- Integrated UNF fittings for feed, and retentate permeate connections allows direct connection to ÄKTAcrossflow system.
- Membrane area of 40 cm^2 (AXH) or 50 cm^2 (AXM) allows direct performance comparison when evaluating multiple membrane pore sizes.
- Standard path lengths of 30 and 60 cm enables accurate scale-up and scale-down studies.

Hollow fiber Start AXM and Start AXH cross flow cartridges are self-contained, disposable filtration devices. They enable process development and optimization of ultrafiltration (UF) and microfiltration (MF) operations for cell processing and upstream clarification of biopharmaceutical solutions.

The cartridges are designed for small scale processing, rapid laboratory concentration, and/or diafiltration of biological solutions at research-scale volumes with convenience and speed. The cartridges are easy to use and minimize membrane polarization due to the "sweeping action" generated by a recirculation pump. Typical application areas for Start cross flow cartridges include cell harvesting and washing, clarification of lysates and cell cultures, and concentration, diafiltration, and purification of monoclonal antibodies, plasmids, proteins, viruses, vaccines, colloids, and plasma.

Ordering information

Product	Quantity	Code No.
Start AXM (UFP-3-C-2U)	12	11-0005-43
Start AXM (UFP-10-C-2U)	12	11-0005-44
Start AXM (UFP-30-C-2U)	12	11-0005-45
Start AXM (UFP-100-C-2U)	12	11-0005-46
Start AXM (UFP-300-C-2U)	12	11-0005-47
Start AXM (UFP-500-C-2U)	12	11-0005-48
Start AXM (UFP-500-E-2U)	6	11-0005-49
Start AXM (UFP-750-E-2U)	6	11-0005-50
Start AXM (CFP-1-E-2U)	6	11-0005-51
Start AXM (CFP-2-E-2U)	6	11-0005-52
Start AXM (CFP-4-E-2U)	6	11-0005-53
Start AXM (CFP-6-D-2U)	8	11-0005-54
Start AXH (UFP-3-C-H24U)	4	11-0005-37
Start AXH (UFP-10-C-H24U)	4	11-0005-38
Start AXH (UFP-30-C-H24U)	4	11-0005-39
Start AXH (UFP-100-C-H24U)	4	11-0005-40
Start AXH (UFP-300-C-H24U)	4	11-0005-41
Start AXH (UFP-500-C-H24U)	4	11-0005-42

Technical specifications

	Start AXM	Start AXH
Diameter	0.6 cm (0.25 in)	0.3 cm (0.125 in)
Path length	30 cm (12 in)	60 cm (24 in)
Connections		
Feed/retentate	UNF fitting	UNF fitting
Permeate	UNF fitting	UNF fitiing
Membrane area (nominal)	50 cm^2 (7.75 in^2)	40 cm^2 (6.2 in^2)
Hold-up volume (nominal)		
Lumen side	1–1.5 ml	< 1 ml
Shell side	1 ml	< 1 ml
Materials of Construction		
Hollow fibers	Polysulfone	Polysulfone
Housing components	Polysulfone	Polysulfone
Potting	Epoxy	Epoxy
Fitting caps	Vinyl	Vinyl

MidGee cross flow cartridges

MidGee Cross flow cartridges are for biological solution volumes up to 200 ml.

- Rapid concentration and/or diafiltration of critical biological solutions and suspensions.
- Ultrafiltration pore sizes from 1000 to 750 000 NMWC, microfiltration pore sizes from 0.1 to 0.65 microns.
- Maximum product recovery due to cross flow design.
- Sealed system permits convenient, continuous hands-free diafiltration.
- Contaminating proteins and electrolytes can be washed through membrane fibers and reduced to undetectable levels.
- Low hold-up volume for concentration of 2 to 5 ml (cartridge hold-up volume 0.5 ml).
- Quick, convenient Luer-Lok connections.

MidGee disposable cross flow cartridges are for small-scale processing, rapid laboratory concentration and/or diafiltration of biological solution volumes up to 200 ml with a convenience and speed impossible to achieve with stirred cells or dialysis tubing.

MidGee cartridges are optimized for use in our compact MidJet cross flow filtration system. Test data can be used to linearly scale up to larger cartridge and system designs or for scale-down process optimization and trouble-shooting experiments.

Ordering information

Product*	Quantity	Code No.
MidGee Cartridge, 0.1 micron, 0.5 mm lumen (CFP-1-C-MM01A)	1	56-4100-60
MidGee Cartridge, 0.2 micron, 0.5 mm lumen (CFP-2-C-MM06A)	1	56-4100-69
MidGee Cartridge,100 kD, 0.5 mm lumen (UFP-100-C-MM01A)	1	56-4100-36
MidGee Cartridge, 100 kD, 1.0 mm lumen (UFP-100-E-MM06A)	6	56-4100-41
MidGee Cartridge, 10 kD, 1.0 mm lumen (UFP-10-E-MM01A)	1	56-4100-16
MidGee Cartridge, 1 kD, 0.5 mm lumen (UFP-1-C-MM06)	6	56-4100-01
MidGee Cartridge,30 kD, 0.5 mm lumen (UFP-30-C-MM01A)	1	56-4100-20
MidGee Cartridge, 30 kD, 1.0 mm lumen (UFP-30-E-MM06A)	6	56-4100-25
MidGee Cartridge, 500 kD, 1.0 mm lumen (UFP-500-E-MM01A)	1	56-4100-56
MidGee Cartridge, 750 kD, 1.0 mm lumen (UFP-750-E-MM06A)	6	56-4108-07

Order online at www.gehealthcare.com/orderonline

** This table shows examples of MidGee cartridges currently available. For complete product lists and ordering information, please contact your local GE Healthcare representative.*

Technical specifications

MidGee Cross Flow Cartridges

Diameter:	0.3 cm (0.125 in.)
Length:	30.8 cm (12.125 in.)
Endfitting connections:	Male Luer-Lok
Permeate connections:	Male Luer-Lok
Membrane area (nominal):	16 to 26 cm^2 (2.3–4.03 in^2)
Hold-up volume (nominal):	
Lumen side:	0.25 ml
Shell side:	0.25 ml
Autoclavable:	All except 1000 NMWC models
Materials of construction:	
Hollow fibers:	Polysulfone
Shell:	Polysulfone
Luer Lok fittings:	Polycarbonate
Potting:	Epoxy

MidGee Hoop cross flow cartridges

MidGee Hoop cross flow cartridges are perfect for scaling trials.

- Rapid concentration and/or diafiltration of critical biological solutions.
- Ultra-compact design.
- Full range of UF/MF pore sizes and lumen diameters.
- 60 cm and 110 cm pathlengths match pilot/production scale designs.
- Autoclavable.
- Require minimal solution volume/pump capacity.
- High product recoveries with minimal shear denaturation.
- No 'wall effects' to distort scale-up projections.

Throughout the R&D process, access to product is often limited. As a result, investigations into optimization of operating conditions are sometimes postponed or avoided entirely. Now scale-up and scale-down using minimum product volumes is easy with our MidGee Hoop cross flow cartridges. Hoop cartridges provide all the critical features of full production scale in a miniature cross flow device, allowing simulation of process parameters – including path length – with minimal solution volume and pump capacity. The uniform flow path design from laboratory to production scale makes hollow fibers the most attractive of the various cross flow configurations for linear scale-up. MidGee Hoop cartridges are optimized for use in our compact MidJet cross flow filtration system, which includes a miniature peristaltic pump with exchangeable saddles to accommodate size 14 and 16 tubing; reservoirs for retentate, diafiltrate and permeate; precision backpressure control valve; and a convenient platform for mounting the cartridge and pump with recesses to accommodate three reservoirs.

Ordering information

Product*	Quantity	Code No.
MidGee Hoop Cartridge, 0.1 micron, 1.0 mm lumen, 60 cm (CFP-1-E-H22LA)	1	56-4100-96
MidGee Hoop Cartridge, 0.2 micron, 1.0 mm lumen, 60 cm (CFP-2-E-H22LA)	1	56-4100-97
MidGee Hoop Cartridge, 0.45 micron, 1.0 mm lumen, 60 cm (CFP-4-E-H22LA)	1	56-4100-98
MidGee Hoop Cartridge, 0.65 micron, 0.75 mm lumen, 60 cm (CFP-6-D-H22LA)	1	56-4100-99
MidGee Hoop Cartridge, 100kD, 0.5 mm lumen, 60 cm (UFP-100-C-H24LA)	1	56-4101-03
MidGee Hoop Cartridge, 100kD, 1.0 mm lumen, 60 cm (UFP-100-E-H22LA)	1	56-4100-92
MidGee Hoop Cartridge, 10kD, 0.5 mm lumen, 110 cm (UFP-10-C-H42LA)	1	56-4101-08
MidGee Hoop Cartridge, 10kD, 1.0 mm lumen, 110 cm (UFP-10-E-H22LA)	1	56-4100-89
MidGee Hoop Cartridge, 300kD, 0.5 mm lumen, 60 cm (UFP-300-C-H42LA)	1	56-4101-15
MidGee Hoop Cartridge, 300kD, 1.0 mm lumen, 60 cm (UFP-300-E-H22LA)	1	56-4100-93
MidGee Hoop Cartridge, 30kD, 0.5 mm lumen, 110 cm (UFP-30-C-H42LA)	1	56-4101-10
MidGee Hoop Cartridge, 30kD, 1.0 mm lumen, 60 cm (UFP-30-E-H22LA)	1	56-4100-90
MidGee Hoop Cartridge, 3kD, 0.5 mm lumen, 60 cm (UFP-3-C-H42LA)	1	56-4101-06
MidGee Hoop Cartridge, 3kD, 1.0 mm lumen, 60 cm (UFP-3-E-H22LA)	1	56-4100-88
MidGee Hoop Cartridge, 500kD, 0.5 mm lumen, 110 cm (UFP-500-C-H42LA)	1	56-4101-17
MidGee Hoop Cartridge, 50kD, 1.0 mm lumen, 60 cm (UFP-50-E-H22LA)	1	56-4100-91
MidGee Hoop Cartridge, 750kD, 1.0 mm lumen, 110 cm (UFP-750-E-H42LA)	1	56-4101-19

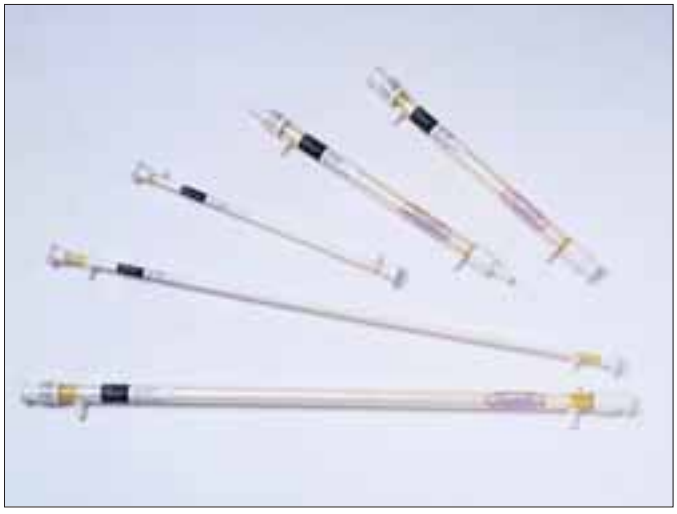
* This table shows examples of MidGee Hoop cartridges currently available. For complete product lists and ordering information, please contact your local GE Healthcare representative.

Technical specifications

MidGee Hoop Cross Flow Cartridges

Diameter:	0.3 cm (0.125 in.)
Length (nominal):	60 cm (23.6 in.)
	110 cm (43.3 in.)
Endfitting connections:	Male Luer-Lok
Permeate connections:	Male Luer-Lok
Membrane area (nominal):	29–73 cm^2 (4.5–11.3 $in.^2$)
Hold-up volume (nominal):	
60 cm model:	0.5 to 1.0 ml each (lumen and shell side)
110 cm model:	0.6 to 2 ml each (lumen and shell side)
Materials of construction:	
Hollow fibers:	Polysulfone
Shell:	Polysulfone
Luer Lok fittings:	Polycarbonate
Potting:	Epoxy

Xampler laboratory cartridges



Xampler cartridges, available for QuixStand and Kvick Lab benchtop systems, can be manifolded together to achieve a wide range of process requirements.

- Nominal flow path lengths of 30 and 60 cm allow optimization of process conditions and assist future scale-up.
- Low flow rate requirements allow the use of smaller pumps.
- Polysulfone membrane minimizes non-specific protein binding and provides high product recovery.
- Range of membrane areas suits different processing needs.
- Offered with Tri-Clamp end fittings for quick and easy aseptic connection.
- Autoclavable (with the exception of 1000 NMWC) devices address the need for small-volume sanitary processing.

Xampler ultrafiltration and microfiltration cartridges are for laboratory scale processing with solution volumes typically ranging from a few hundred milliliters to about five liters. Nominal flow pathlengths are 30 and 60 cm and membrane areas range from 0.01 to 0.14 m^2 (0.12 to 1.5 ft^2). Moreover, they are directly scalable to pilot and process scale cartridges with equivalent pathlengths.

Xampler cartridges have self-contained housings that match QuixStand and Kvick Lab benchtop systems. Vertical operation achieves complete process fluid drainage and maximum product recovery.

Ordering information

Product*	Quantity	Code No.
Xampler Cartridge, 0.1 micron, 0.75 mm lumen, size 3M, autoclavable (CFP-1-D-3MA)	1	56-4101-40
Xampler Cartridge, 0.2 micron, 1.0 mm lumen, size 3X2M, autoclavable (CFP-2-E-3X2MA)	1	56-4101-57
Xampler Cartridge, 0.45 micron, 1.0 mm lumen, size 3M, autoclavable (CFP-4-E-3MA)	1	56-4101-43
Xampler Cartridge, 0.65 micron, 0.75 mm lumen, size 3M, autoclavable (CFP-6-D-3MA)	1	56-4101-44
Xampler Cartridge, 100kD, 0.5 mm lumen, size 3M, autoclavable (UFP-100-C-3MA)	1	56-4101-33
Xampler Cartridge, 10kD, 1.0 mm lumen, size 3M, autoclavable (UFP-10-E-3MA)	1	56-4101-28
Xampler Cartridge, 1kD, 0.5 mm lumen, size 3M (UFP-1-C-3M)	1	56-4101-20
Xampler Cartridge, 300kD, 0.5 mm lumen, size 3M, autoclavable (UFP-300-C-3MA)	1	56-4101-35
Xampler Cartridge, 30kD, 1.0 mm lumen, size 3M, autoclavable (UFP-30-E-3MA)	1	56-4101-30
Xampler Cartridge, 3kD, 0.5 mm lumen, size 3M, autoclavable (UFP-3-C-3MA)	1	56-4101-22
Xampler Cartridge, 3kD, 0.5 mm lumen, size 3M, autoclavable (UFP-3-C-3X2MA)	1	56-4101-45
Xampler Cartridge, 3kD, 1.0 mm lumen, size 3M, autoclavable (UFP-3-E-3MA)	1	56-4101-23
Xampler Cartridge, 500kD, 0.5 mm lumen, size 3M, autoclavable (UFP-500-C-3MA)	1	56-4101-37
Xampler Cartridge, 50kD, 1.0 mm lumen, size 3M, autoclavable (UFP-50-E-3MA)	1	56-4101-32
Xampler Cartridge, 5kD, 0.5 mm lumen, size 3M, autoclavable (UFP-5-C-3MA)	1	56-4101-24

* This table shows examples of Xampler cartridges currently available. For complete product lists and ordering information, please contact your local GE Healthcare representative.

Technical specifications

Xampler Cross Flow Cartridges

Diameter:	
3M, 3X2M:	0.9 cm (0.375 in.)
4, 4M, 4X2M:	1.9 cm (0.75 in.)
Length:	
3M:	31.7 cm (12.5 in.)
3X2M:	63.5 cm (25 in.)
4:	36.2 cm (14.25 in.)
4M:	34.5 cm (13.6 in.)
4X2M:	66 cm (26 in.)
Endfitting connections:	
3M, 3X2M, 4M, 4X2M:	0.5-in. Tri-Clamp
4:	0.375-in. Tubing barb
Permeate connections:	
3M, 3X2M:	0.25-in. Tubing nipple
4, 4M, 4X2M:	0.375-in Tubing nipple
Membrane area (nominal):	110–1400 cm^2 (17–216 $in.^2$)
Hold-up volume (nominal):	
Lumen side:	2–30 ml
Shell side:	5–75 ml
Autoclavable:	All except 1000 NMWC models
Materials of construction:	
Hollow fibers:	Polysulfone
Shell:	Polysulfone
Luer Lok fittings:	Polycarbonate
Potting:	Epoxy
Fiber bundle:	Polypropylene

Lab/Pilot-scale hollow fiber cartridges

To bridge the several steps between research and production volumes, GE Healthcare offers a full range of pilot scale ultrafiltration and microfiltration hollow fiber membrane cartridges. These cartridges feature industry standard 1.5-in Tri-Clamp sanitary feed and retentate fittings. Both 30 and 60 cm flow path lengths are offered with cartridges that provide an order-of-magnitude membrane area span from 0.12 to 1.15 m^2 (1.3 to 12.5 ft^2). Please feel free to contact our Technical Support team for guidance with linear scaling parameters for small volume processing.

GE Healthcare's FlexStand benchtop system product line is designed to suit the entire range of pilot scale cartridges. Two basic models are offered with optional peristaltic or rotary lobe pumps and polysulfone or stainless steel feed reservoirs. These systems can be cart-mounted for ease of movement between the laboratory and the coldroom.

Representative Lab/Pilot Cartridges

Code No.	Model No.	Pore size (NMWC)	Fiber ID (mm)	Membrane area (m^2)	(ft^2)	Nominal flowpath length (cm)
56-4102-26	UFP-1-C-5	1000	0.5	0.20	2.1	30
56-4102-27	UFP-1-E-5	1000	1	0.12	1.3	30
56-4102-28	UFP-3-C-5A	3000	0.5	0.20	2.1	30
56-4102-29	UFP-3-E-5A	3000	1	0.12	1.3	30
56-4102-30	UFP-5-C-5A	5000	0.5	0.20	2.1	30
56-4102-31	UFP-5-E-5A	5000	1	0.12	1.3	30
56-4102-32	UFP-10-B-5A	10 000	0.25	0.375	4	30
56-4102-33	UFP-10-C-5A	10 000	0.5	0.20	2.1	30
56-4102-51	UFP-1-C-6	1000	0.5	0.48	5.2	60
56-4102-52	UFP-3-C-6A	3000	0.5	0.48	5.2	60
56-4102-53	UFP-3-E-6A	3000	1	0.28	3	60
56-4102-54	UFP-5-C-6A	5000	0.5	0.48	5.2	60
56-4102-55	UFP-5-E-6A	5000	1	0.28	3	60
56-4102-56	UFP-10-C-6A	10 000	0.5	0.48	5.2	60
56-4102-57	UFP-10-E-6A	10 000	1	0.28	3	60
56-4102-58	UFP-30-C-6A	30 000	0.5	0.48	5.2	60
56-4102-59	UFP-30-E-6A	30 000	1	0.28	3	60
56-4102-60	UFP-50-C-6A	50 000	0.5	0.48	5.2	60
56-4102-74	UFP-3-C-8A	3000	0.5	0.53	5.7	30
56-4102-75	UFP-10-B-8A	5000	0.25	0.9	9.7	30
56-4102-76	UFP-10-C-8A	10 000	0.5	0.53	5.7	30
56-4102-77	UFP-30-C-8A	30 000	0.5	0.53	5.7	30
56-4102-78	UFP-50-C-8A	50 000	0.5	0.53	5.7	30
56-4102-79	UFP-100-C-8A	100 000	0.5	0.53	5.7	30
56-4102-80	UFP-100-E-8A	100 000	1	0.36	3.9	30
56-4102-70	CFP-1-E-6A	0,1	1	0.28	3	60
56-4102-71	CFP-2-E-6A	0,2	1	0.28	3	60
56-4102-61	CFP-2-G-6A	0,2	1.75	0.23	2.5	60
56-4102-72	CFP-4-E-6A	0,45	1	0.28	3	60
56-4102-73	CFP-6-D-6A	0,65	0.75	0.37	4	60

MaxCell process-scale hollow fiber cartridges

MaxCell cartridges for high-volume, cross flow bioprocessing applications.

- Superior processing economies.
- Streamlined design utilizes space very effectively.

MaxCell cartridges can be manifolded with spacing as close as 18 cm (7 inches) on center for incorporation into a compact membrane separations system. System sizing can be accurately scaled from testing laboratory and pilot scale cartridges, such as MidGee and Xampler cartridges. In addition, MaxCell cartridges can be used in place of other manufacturer's cartridges.

MaxCell cartridge ordering information

Housing size 45

Code No. Ultrafiltration	Model No.	NMWC	Membrane fiber inner diameter mm	Cartridge length cm	Cartridge length in	Membrane area m^2	Membrane area ft^2
56-4104-67	UFP-3-C-45	3000	0.5	39.4*	15.5*	3.5	37
56-4104-68	UFP-5-C-45	5000	0.5	39.4*	15.5*	3.5	37
56-4104-69	UFP-10-C-45	10 000	0.5	39.4*	15.5*	3.5	37
56-4104-70	UFP-30-C-45	30 000	0.5	39.4*	15.5*	3.5	37

Code No. Microfiltration	Model No.	Pore size µm	Membrane fiber inner diameter mm	Cartridge length mm	Cartridge length in	Membrane area m^2	Membrane area ft^2
56-4104-71	CFP-1-E-45	0.1	1	39.4*	15.5*	2.5	27
56-4104-72	CFP-2-E-45	0.2	1	39.4*	15.5*	2.5	27
56-4104-73	CFP-4-E-45	0.45	1	39.4*	15.5*	2.5	27
56-4104-74	CFP-6-D-45	0.65	0.75	39.4*	15.5*	2.8	30

Housing size 65

Code No. Ultrafiltration	Model No.	NMWC	Membrane fiber inner diameter mm	Cartridge length cm	Cartridge length in	Membrane area m^2	Membrane area ft^2
56-4104-75	UFP-3-C-65	3000	0.5	62.5*	24.6*	6.1	66
56-4104-76	UFP-3-E-65	3000	1	62.5*	24.6*	4.4	47
56-4104-77	UFP-5-C-65	5000	0.5	62.5*	24.6*	6.1	66
56-4104-78	UFP-5-E-65	5000	1	62.5*	24.6*	4.4	47
56-4104-79	UFP-10-C-65	10 000	0.5	62.5*	24.6*	4.4	47
56-4104-81	UFP-30-C-65	30 000	0.5	62.5*	24.6*	6.1	66
56-4104-82	UFP-30-E-65	30 000	1	62.5*	24.6*	4.4	47
56-4104-85	UFP-100-C-65	100 000	0.5	62.5*	24.6*	6.1	66
56-4104-86	UFP-100-E-65	100 000	1	62.5*	24.6*	4.4	47
56-4104-87	UFP-300-C-65	300 000	0.5	62.5*	24.6*	6.1	66
56-4104-88	UFP-300-E-65	300 000	1	62.5*	24.6*	4.4	47
56-4104-89	UFP-500-C-65	500 000	0.5	62.5*	24.6*	6.1	66
56-4104-90	UFP-500-E-65	500 000	1	62.5*	24.6*	4.4	47

Code No. Microfiltration	Model No.	Pore size µm	Membrane fiber inner diameter mm	Cartridge length mm	Cartridge length in	Membrane area m^2	Membrane area ft^2
56-4104-92	CFP-1-E-65	0.1	1	62.5*	24.6*	4.4	47
56-4104-93	CFP-2-E-65	0.2	1	62.5*	24.6*	4.4	47
56-4104-94	CFP-4-E-65	0.45	1	62.5*	24.6*	4.4	47

*Add 4.25 in (10.8 cm) for straight adaptors

Housing size 85							
Code No. Ultrafiltration	Model No.	NMWC	Membrane fiber inner diameter mm	Cartridge length cm	in	Membrane area m^2	ft^2
56-4104-95	UFP-3-C-85	3000	0.5	120*	47.3*	13	140
56-4104-96	UFP-3-E-85	3000	1	120*	47.3*	8.8	95
56-4104-97	UFP-5-C-85	5000	0.5	120*	47.3*	13	140
56-4104-98	UFP-5-E-85	5000	1	120*	47.3*	8.8	95
56-4104-99	UFP-10-C-85	10 000	0.5	120*	47.3*	13	140
56-4105-00	UFP-10-E-85	10 000	1	120*	47.3*	8.8	95
56-4105-01	UFP-30-C-85	30 000	0.5	120*	47.3*	13	140
56-4105-02	UFP-30-E-85	30 000	1	120*	47.3*	8.8	95
56-4105-05	UFP-100-C-85	100 000	0.5	120*	47.3*	13	140
56-4105-06	UFP-100-E-85	100 000	1	120*	47.3*	8.8	95
56-4105-08	UFP-500-C-85	500 000	0.5	120*	47.3*	13	140
56-4105-09	UFP-500-E-85	500 000	1	120*	47.3*	8.8	95

*Add 4.25 in (10.8 cm) for straight adaptors

MaxCell cartridge accessories

Code No.	Model No.	Description
56-4107-26	RBMX-16PS-ST	Straight adaptor for MaxCell Cartridge, polysulfone
56-4107-27	RBMX-16PS-EL	Elbow adaptor for MaxCell Cartridge, polysulfone
56-4107-21	RB16-12SS	2-in TC to 1.5-in TC Concentric Adaptor, 316L SS
56-4107-22	RB16-12FNPTSS	2-in TC to 1.5-in female NPT Adaptor, 304 SS
56-4107-23	RB16-16FNPTSS	2-in TC to 2-in female NPT Adaptor, 304 SS
56-4107-28	EL16-16SS	2-in TC elbow, 316LSS
56-4107-37	KAMX-16PS	Straight Adaptor Kit for Installation. Either kit KAMX-16PS or kit KAMX-16EL-PS required for each new MaxCell Cartridge. Contains 2 each: RBMX-16PS-ST straight adaptors, polysulfone cartridge end nuts, polysulfone O-rings, silicone.
56-4107-38	KAMX-16EL-PS	Elbow Adaptor Kit for Installation. Either kit KAMX-16PS or kit KAMX-16EL-PS required for each new MaxCell Cartridge. Contains 2 each: RBMX-16PS-EL elbow adaptors, polysulfone cartridge end nuts, polysulfone O-rings, silicone.
56-4107-70	CL16-LT	2-in TC toggle clamp, 304 SS
56-4106-79	G16S	2-in TC gasket, silicone
56-4107-92	K04ORS	MaxCell O-ring set, 2 each, silicone
56-4107-39	SWR-MX01	MaxCell Wrench Set, standard
56-4107-40	SWR-MX02	MaxCell Wrench Set, applied torque

MaxCell cartridge physical dimensions

Technical specifications						
Housing size	Diameter cm	in	Length cm	in	Endfitting connections	Permeate connections
45	10.8	4.25	39.4*	15.5*	2-in sanitary	1.5-in sanitary
65	10.8	4.25	62.5*	24.6*	2-in sanitary	1.5-in sanitary
85	10.8	4.25	120.0*	47.3*	2-in sanitary	1.5-in sanitary

*Add 4.25 in (10.8 cm) for straight adaptors (2) at retentate ends.

MaxCell cartridge membrane area as a function of housing size and lumen diameter

Housing size	Membrane Fiber inner diameter mm	Membrane area m^2	ft^2
45	0.5	3.5	37
	0.75	2.65	28.5
	1	2.3	25
65	0.5	6.1	66
	1	4.4	47
85	0.5	13	140
	1	9	95

ProCell hollow fiber cartridges

ProCell hollow fiber cartridges of 15 cm (6 inch) diameter are for large production scale processes and are installed inside sanitary stainless steel housings.

- Sanitary design for production scale applications.
- Selection of UF/MF pore sizes and lumen diameters.
- 316 L stainless steel housings.
- Efficient processing of thousands of liters.
- Compact design with low hold-up volume.
- Multiple cartridges can be manifolded into compact production systems.

ProCell hollow fiber cartridges of 15 cm (6-inch) diameter are for large production scale ultrafiltration and microfiltration. Containing up to 28 m^2 (300 ft^2) of membrane area in a single, compact module, these cartridges are well suited to a wide range of bioprocessing applications.

ProCell cartridges are available in two path lengths and in a selection of ultrafiltration nominal molecular weight cut-offs and microfiltration pore sizes, as well as several membrane fiber inner diameters.

ProCell cartridge ordering information

ProCell ultrafiltration cartridges

Code No.	Model No.	NMWC	Membrane fiber ID mm	Membrane area m^2	Membrane area ft^2
56-4105-13	UFP-10-C-154	10 000	0.5	28	305
56-4105-11	UFP-500-E-152	500 000	1	9	97
56-4105-14	UFP-500-E-154	500 000	1	19.5	210

ProCell microfiltration cartridges

Code No.	Model No.	Pore size	Membrane fiber ID mm	Membrane area m^2	Membrane area ft^2
56-4105-12	CFP-2-E-152	0.2µ	1	9	97

ProCell stainless steel housings (one housing required per cartridge)

Code No.	Model No.	Description
56-4106-35	SS-152TC	Housing assembly for ProCell – 152M cartridges 316LSS with 2 each gaskets and 2 each clamps
56-4106-36	SS-154TC	Housing assembly for ProCell – 154M cartridges 316LSS with 2 each gaskets and 2 each clamps

ProCell cartridge and housing accessories

Code No.	Model No.	Description
56-4106-77	G12S	1.5-in TC gasket, silicone
56-4106-79	G16S	2-in TC gasket, silicone
56-4106-88	G48S	6-in TC [schedule 5 pipe gasket], silicone
56-4106-67	CL12	1.5-in TC quick disconnect clamp 304SS
56-4106-70	CL16	2-in TC quick disconnect clamp 304SS
56-4106-74	CL48	6-in TC [schedule 5 pipe] clamp 304SS
56-4106-96	K06ORS	ProCell cartridge O-ring set, 2 each, silicone

ProCell housing physical dimensions*

Technical specifications

Housing size	Diameter** cm	Diameter** in	Length** cm	Length** in	Endfitting connections	Permeate connections
152	16.8	6.6	81	32	2-in TC	1.5-in TC
154	16.8	6.6	139	55	2-in TC	1.5-in TC

*Stainless steel housing dimensions. **Nominal, not for design purposes.

Steam-in-place hollow fiber cartridges

Steam-in-place hollow fiber cartridges/housings (STM style)

- Strong polysulfone cartridge elements.
- Leak-proof, sanitary closure.
- Available in UF and MF pore sizes.

Polysulfone cartridge elements have the strength and integrity to withstand the rigors of steam-in-place operations. Cartridges slip into stainless steel housings for safety and containment. A double O-ring seal at the inlet and outlet of the cartridge element ensures leak-proof, sanitary closure within the housing.

The element design allows quick yet thorough steam penetration of the membranes. Furthermore, all cartridge components are USP 24 Biologicals Test for Plastics Class VI tested. Cartridges are available in both ultrafiltration (UF) and microfiltration (MF) pore sizes in a choice of cartridge lengths.

STM cartridge ordering information

STM ultrafiltration cartridges

Code No.	Model No.		Fiber ID	Membrane area	
		NMWC*	mm	m^2	ft^2
56-4104-12	UFP-10-E-35STM	10 000	1	0.8	8.5
56-4104-13	UFP-30-E-35STM	30 000	1	0.8	8.5
56-4104-14	UFP-100-E-35STM	100 000	1	0.8	8.5
56-4104-15	UFP-500-E-35STM	500 000	1	0.8	8.5
56-4104-21	UFP-10-E-55STM	10 000	1	2.1	23
56-4104-23	UFP-30-E-55STM	30 000	1	2.1	23
56-4104-26	UFP-100-E-55STM	100 000	1	2.1	23
56-4104-27	UFP-500-E-55STM	500 000	1	2.1	23
56-4104-19	UFP-3-C-55STM	3000	0.5	3.25	35
56-4104-20	UFP-10-C-55STM	10 000	0.5	3.25	35
56-4104-22	UFP-30-C-55STM	30 000	0.5	3.25	35
56-4104-24	UFP-50-C-55STM	50 000	0.5	3.25	35
56-4104-25	UFP-100-C-55STM	100 000	0.5	3.25	35

*Nominal molecular weight cutoff

STM microfiltration cartridges

Code No.	Model No.	Pore size	Fiber ID	Membrane area	
		micron	mm	m^2	ft^2
56-4104-16	CFP-1-E-35STM	0.1	1	0.8	8.5
56-4104-17	CFP-2-E-35STM	0.2	1	0.8	8.5
56-4104-18	CFP-4-E-35STM	0.45	1	0.8	8.5
56-4104-28	CFP-1-E-55STM	0.1	1	2.1	23
56-4104-29	CFP-2-E-55STM	0.2	1	2.1	23
56-4104-30	CFP-4-E-55STM	0.45	1	2.1	23
56-4109-25	CFP-6-D-55STM	0.75	1	2.5	27

STM housings and accessories

Code No.	Model No.	Description
56-4106-27	SS-35STM	Housing Assembly for -35STM cartridges, 316L SS with 2 each gaskets and 2 each clamps
56-4106-28	SS-55STM	Housing Assembly for -55STM cartridges 316L SS with 2 each gaskets and 2 each clamps
56-4106-75	G4S	0.5-in TC gasket, silicone
56-4106-77	G12S	1.5-in TC gasket, silicone
56-4106-81	G24S	3-in TC [Schedule 5 pipe] gasket, silicone
56-4106-65	CL4	0.5-in quick disconnect clamp, 304 SS
56-4106-69	CL12	1.5-in quick disconnect clamp, 304 SS
56-4106-71	CL24	3-in [Schedule 5 pipe] clamp, 304 SS
56-4106-90	K02ORS	STM cartridge O-ring set, 8 each, silicone
56-4105-90	VPC4	0.5-in TC permeate condensate drain or vent valve, 316L SS

Technical specifications

Cartridge housing assembly

All housing assemblies are of 316L stainless steel with sanitary construction. The O-ring material is silicone. The retentate and permeate ports are 1.5-in sanitary clamp configuration allowing for quick and easy connection to steam and process piping. In operation, the housing should be piped in a vertical orientation. It is recommended to steam the complete element and housing assembly for 30 minutes at 121 to 123°C and 1 barg (15 psig). Steam should be delivered to both sides of the membrane to ensure full steam penetration and to minimize the delta P across the membrane during the steam sterilization cycle. A 0.5-in sanitary clamp port is positioned on the low point of the housing shell to ensure complete removal of concentrate.

GE Healthcare offers a complete SIP protocol. To ensure that the cycle will support the rigors of a full validation and maximize the cartridge lifetime, GE Healthcare strongly suggests that customers adhere to all recommendations of the SIP protocol.

Kvick cassettes
Kvick Start cassettes

Kvick Start cassettes are for research, product development, lab scale evaluations and process development where starting material is limited.

- UNF fittings for use in the ÄKTAcrossflow instrument and Luer-lok adapters for use in virtually all other crossflow instruments.
- Minimal working volume and minimum hold-up volume gives maximum product recovery.
- USP XXVIII Biological Test for Plastics Class VI compliant.
- Low extractables.
- PES (polyethersulfone) membrane resists a wide range of chemicals.
- Precise, reproducibly selective membranes with a macrovoid-free structure for superior performance.

Kvick Start cassettes maximize product recovery by offering a small-area device capable of handling low working volumes with minimal hold-up. The cassettes offer easy setup and linear scalability to facilitate membrane evaluation trials, product screening, process development work and optimization of UF processes in downstream purification. When manifolded together, they allow concentration or diafiltration of product from less than 15 milliliters to over two liters.

Highly selective membranes provide reproducible and precise separations, thus maximizing yields. The cassettes are provided with UNF fittings for use with ÄKTAcrossflow, and with luer lok adapters for use with other systems. Kvick Start cassettes are available with 50 or 100 square centimeters of membrane surface area and five molecular weight cut-offs (5k, 10k, 30k, 50k, and 100k) to fit a broad range of cross flow applications.

Ordering information

Code number	Model number	Membrane area cm^2	Cassette NMWC	Quantity
11-0006-02	UFEST0005050ST	50	5 kD	1
11-0006-04	UFEST0010050SE	50	10 kD *	1
11-0006-03	UFEST0010050ST	50	10 kD	1
11-0006-05	UFEST0030050ST	50	30 kD	1
11-0006-06	UFEST0050050ST	50	50 kD	1
11-0006-08	UFEST0100050ST	50	100 kD	1
11-0006-61	UFESTCPAK045ST	50 per cassette	5, 10, 10*, 30, 50 and 100 kD	5

* 10 kD Select membrane is a tighter 10 kD membrane and is particularly effective for recombinant proteins.

Technical specifications

Materials of construction:	
Housing:	Urethane
Membrane:	Polyethersulfone
Membrane screen:	Polypropylene
Port Sealer:	Solvent-free urethane (meth)acrylate blend
Inner plates:	Polyester copolymer
Shipping solution:	20–22% glycerin by weight
Retentate hold-up volume:	1.4 ml
Operating Conditions:	
pH range, long term:	Storage 2–13
pH range, short term:	Cleaning 1–14
Maximum operating temperature:	50°C
Maximum inlet pressure:	4 barg (60 psig)
Typical operating cross flow:	27–36 ml/min

Kvick Lab SCU cassette

Ordering information

Code No.	Model No.	Membrane area m^2	Membrane area ft^2	Cassette NMWC	Qty
56-4115-30	UFESC 0010 010 SE	0.11	1.2	10 000*	1
56-4115-31	UFESC 0010 010 ST	0.11	1.2	10 000	1
56-4115-32	UFESC 0030 010 ST	0.11	1.2	30 000	1
56-4115-33	UFESC 0050 010 ST	0.11	1.2	50 000	1
56-4115-35	UFESC 0100 010 ST	0.11	1.2	100 000	1
56-4113-70	KLSC o10 ST	Kvick Lab SCU holder			1

* 10 kD Select membrane is a tighter 10 kD membrane

Kvick SCU cassette specifications

Materials of construction:	
Housing	Polyethersulfone
Membrane	Polyethersulfone
Screen	Polypropylene
Encapsulent	Silicone
Preservative solution	0.1–0.2N NaOH and 20–22% glycerine
Hold-up volume:	1.2 ft^2 – 20 ml

Recommended operating conditions

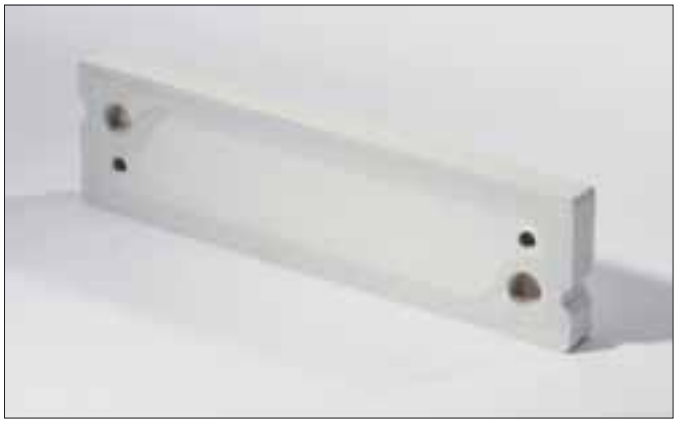
pH range, long-term:	Storage 2 to 13
pH range, short-term:	Cleaning 1 to 14
Maximum operating temperature:	50°C (122°F)
Maximum inlet pressure:	3 barg (45 psig)
Operating cross flow rate:	850 ml/min (1.2 ft^2)

Easy use with minimum hold-up volume and maximum product recovery

- Precise, reproducibly selective membranes.
- Low extractables.
- PES (polyethersulfone) membrane resists a wide range of chemicals.
- Anti-dead space technology.
- 100% integrity tested on delivery.
- Macrovoid-free membrane structure for superior performance.
- Consistent fluid path for linear scale-up.
- USP 24 Biologicals Test for Plastics Class VI compliant.

Kvick SCU cassettes give easy set-up, enhanced clean-ability, minimum product hold-up volume, and optimum membrane selectivity. They are ideally suited for laboratory work with starting volumes of less than 250 milliliters to 25 liters. The self-contained holder does not require cassette installation, thus promoting easy set-up and use.

Kvick Lab cassettes



Ordering information

Code No.	Model No.	Membrane area m^2	Membrane area ft^2	Cassette NMWC	Quantity
56-4112-02	UFELA0005001ST	0.009	0.1	5000	1
56-4112-06	UFELA0010001SE	0.009	0.1	10 000*	1
56-4112-04	UFELA0010001ST	0.009	0.1	10 000	1
56-4112-08	UFELA0030001ST	0.009	0.1	30 000	1
56-4112-10	UFELA0050001ST	0.009	0.1	50 000	1
56-4112-14	UFELA0100001ST	0.009	0.1	100 000	1
56-4113-31	UFELA0005010ST	0.11	1.2	5000	1
56-4113-26	UFELA0010010SE	0.11	1.2	10 000*	1
56-4113-25	UFELA0010010ST	0.11	1.2	10 000	1
56-4113-27	UFELA0030010ST	0.11	1.2	30 000	1
56-4113-28	UFELA0050010ST	0.11	1.2	50 000	1
56-4113-29	UFELA0100010ST	0.11	1.2	100 000	1

* 10 kD Select membrane is a tighter 10 kD membrane

Technical specifications

Fit the following holders:	Kvick lab holders, Kvick packet holders, and other industry standard holders
Materials of construction:	
Membrane:	Polyethersulfone
Screen:	Polypropylene
Encapsulent:	Silicone
Preservative solution:	0.1–0.2 N NaOH and 20–22% glycerine
Hold-up volume:	Approximately 20 ml per 0.09 m^2 (1 ft^2)

Recommended operating conditions

pH range, long term:	Storage 2–13
pH range, short term:	Cleaning 1–14
Maximum operating temperature:	50°C
Maximum inlet pressure:	4 barg (60 psig)
Operating cross flow:	85 ml/min for each 0.009-m^2 (0.1-ft^2) cassette installed
Operating cross flow:	850 ml/min for each 0.11-m2 (1.2-ft^2) cassette installed

The wide range of Kvick Lab cross flow cassette designs can handle almost any application.

- Precise, reproducibly selective membranes.
- Minimum hold-up volume and maximum product recovery.
- Low extractables (silicone versus polyurethane encapsulant).
- PES (polyethersulfone) membrane resists a wide range of chemicals.
- 100% integrity tested on delivery.
- Macrovoid-free membrane structure for superior performance.

The Kvick family of cassettes is designed for easy set-up, enhanced cleanability, minimum product hold-up volume, and optimum membrane selectivity.

Kvick Lab cassettes are for laboratory work with starting volumes of less than 0.5 liters up to 100 liters. They fit exactly into the Kvick Lab cassette holder, and can be retrofitted to other types of holders, allowing existing equipment to benefit from high product recovery and better flux gains.

Kvick Lab cassettes are available with a membrane area of 0.11 m^2 (1.2 ft^2), and six molecular weight cut-offs (5k, 10k select, 10k, 30k, 50k, and 100k) to fit a broad range of cross flow applications.

Kvick Lab cassette holder

Designed for fast assembly, Kvick Lab cassette holder utilizes sanitary connections.

- Capacity of 1 to 5 Kvick Lab cassettes.
- Three forward facing ports for convenience.
- Vertical inlet and outlet flow paths for excellent drainage and product recovery, with less than 30-ml hold-up volume.
- Perfectly sized to fit Kvick Lab cassettes.
- Adjustable stand for ease of use on the laboratory bench.

The Kvick Lab cassette holder is for cross flow membrane separations at volumes from less than 0.5 liters to 25 liters. The holder is easy to set-up and quick and convenient to use. Its design with fewer parts and connections makes assembly very fast. Drainage and product recovery are excellent with less than 30-ml hold-up volume. Together, this holder and Kvick cassettes enable fast and accurate concentration and diafiltration of biological solutions.

Furthermore, trial data can be scaled quickly to larger systems. Product development scale-up is linear from laboratory to production.

Ordering information

Product	Quantity	Code No.
Kvick Lab Holder (KLHR0105000SS)	1	56-4112-79
Accessories		
Diaphragm Valve, stainless steel, 1/2-inch sanitary connections (KFSY01071DV05)	1	56-4112-95
1/2-inch Sanitary Clamp (KFSY0107TCL05)	1	56-4112-85
1/2-inch Sanitary Gasket, EPDM (KFSY0107TCG05)	1	56-4112-86
Kvick Lab Holder torque wrench (KLTW0001)	1	56-4112-84
Kvick Lab Cassette Gasket (KYLAGS001011)	1	56-4113-64
Kvick Lab Cassette Gasket (KYLAGS001033)	3	56-4113-65
In-line pressure gauge, 0–4 barg (0–60 psig) (KLSY0105PGA60)	1	56-4113-07
Kvick Lab Pressure Gauge Kit (KLSY0105PRKIT)	1	56-4113-69
1/2-inch Sanitary to 1/4-inch Hose Barb Adaptor (KLSY0105HB4F01)	1	56-4115-26
1/2-inch Sanitary to 3/8-inch Hose Barb Adaptor (KLSY0105HBF01)	1	56-4113-97

Technical specifications

Kvick Lab cassette holders

Feed, retentate and permeate port fittings:	1/2-in sanitary
Dimensions (W × L × H):	13.2 × 22.6 × 16.7 cm (5.2 × 8.9 × 6.6-in.)
Weight:	7.7 kg (17 lb)
Max. temperature:	121°C (250°F)
Max. operating pressure:	4 bar (60 psi)
Installable membrane area:	0.01–0.55 m^2 (0.11–6.0 ft^2)
System holdup volume:	30 ml
Materials of construction	
Wetted parts:	Polished 316L stainless steel, Ra v 0.8 µm
Nonwetted parts:	Tie rods, washers, stand: Stainless steel
Tie rod nuts:	Bronze

Kvick Flow cassettes

Kvick Flow cassettes are for batch sizes with 5 to 1000 liter starting volumes.

- Precise, reproducibly selective membranes.
- Minimum hold-up volume and maximum product recovery.
- Low extractables.
- PES (polyethersulfone) membrane resists a wide range of chemicals.
- Anti-dead space technology.
- 100% integrity tested on delivery.
- Macrovoid-free membrane structure for superior performance.
- Consistent fluid path for linear scale-up.
- USP 24 Biologicals Test for Plastics Class VI compliant.

Kvick Flow cassettes fit exactly into the Kvick Flow cassette holder, and can be retrofitted into other types of cassette holders, allowing existing equipment to benefit from high product recovery and better flux gains.

Ordering Information

Kvick Flow cassettes

Code No.	Model No.	Membrane area m^2	ft^2	Cassette NMWC	Qty
56-4113-49	UFEFL00050505 S	0.46	5	5000	1
56-4113-50	UFEFL 0010 050 SE	0.46	5	10 000*	1
56-4113-47	UFEFL 0010 050 ST	0.46	5	10 000	1
56-4113-51	UFEFL 0030 050 ST	0.46	5	30 000	1
56-4113-52	UFEFL 0050 050 ST	0.46	5	50 000	1
56-4113-54	UFEFL 0100 050 ST	0.46	5	100 000	1
56-4113-37	UFEFL 0005 250 ST	2.33	25	5000	1
56-4113-39	UFEFL 0010 250 SE	2.33	25	10 000*	1
56-4113-38	UFEFL 0010 250 ST	2.33	25	10 000	1
56-4113-40	UFEFL 0030 250 ST	2.33	25	30 000	1
56-4113-41	UFEFL 0050 250 ST	2.33	25	50 000	1
56-4113-43	UFEFL 0100 250 ST	2.33	25	100 000	1

* 10 kD Select membrane is a tighter 10 kD membrane

Kvick Flow cassette specifications

Fits the following holders:	GE Healthcare Kvick Flow holder and other industry standard holders
Materials of construction:	
Membrane	Polyethersulfone
Screen	Polypropylene
Encapsulant	Silicone
Housing	Polyethersulfone
Preservative solution	0.1–0.2 N NaOH and 20–22% glycerine
Hold-up volume:	1 ft^2 – 20 ml per cassette
Hold-up volume:	5 ft^2 – 30 ml per cassette 25 ft^2 – 150 ml per cassette

Recommended operating conditions

pH range, long term:	Storage 2–13
pH range, short term:	Cleaning 1–14
Maximum operating temperature:	50°C
Maximum inlet pressure:	4 barg (60 psig)
Operating cross flow:	3400 ml/min for each 0.46-m^2 (5-ft^2) cassette installed
Operating cross flow:	17000 ml/min for each 2.33-m^2 (25-ft^2) cassette installed

Kvick Pilot and Process cassettes

For linear scale up to pilot and production scale.

- Precise, reproducibly selective membranes.
- Minimum hold-up volume and maximum product recovery.
- Low extractables.
- PES (polyethersulfone) membrane resists a wide range of chemicals.
- Anti-dead space technology.
- 100% integrity tested on delivery.
- Macrovoid-free membrane structure for superior performance.
- Consistent fluid path for linear scale-up.
- USP 24 Biologicals Test for Plastics Class VI compliant.
- Dimensions that match competitive holders, providing a drop-in-replacement for this size cassette format.

Kvick Pilot and Process cassettes enable linear scale up to pilot and production scale operations, either via multiple Kvick Pilot and Process cassettes or by scaling up from Kvick Pilot to Kvick Process. Pilot cassettes are ideally suited for pilot and small scale production processes with volumes of 500 ml to 100 l. Process cassettes are for pilot and production facilities with starting volumes of 50 liters or greater.

Ordering Information

Kvick pilot cassettes

Code No.	Model No.	Membrane area m^2	Membrane area ft^2	Cassette NMWC	Qty
56-4115-69	UFEPT 0005 025 ST	0.23	2.5	5000	1
56-4115-70	UFEPT 0010 025 SE	0.23	2.5	10 000*	1
56-4115-71	UFEPT 0010 025 ST	0.23	2.5	10 000	1
56-4115-72	UFEPT 0030 025 ST	0.23	2.5	30 000	1
56-4115-73	UFEPT 0050 025 ST	0.23	2.5	50 000	1
56-4115-75	UFEPT 0100 025 ST	0.23	2.5	100 000	1

* 10 kD Select membrane is a tighter 10 kD membrane

Kvick process cassettes

Code No.	Model No.	Membrane area m^2	Membrane area ft^2	Cassette NMWC	Qty
56-4115-55	UFEPR 0005 300 ST	2.79	30	5000	1
56-4115-56	UFEPR 0010 300 SE	2.79	30	10 000*	1
56-4115-57	UFEPR 0010 300 ST	2.79	30	10 000	1
56-4115-58	UFEPR 0030 300 ST	2.79	30	30 000	1
56-4115-59	UFEPR 0050 300 ST	2.79	30	50 000	1
56-4115-63	UFEPR 0100 300 ST	2.79	30	100 000	1

* 10 kD Select membrane is a tighter 10 kD membrane

Kvick Pilot and Process specifications

pH range, long-term:	storage 2 to 13
pH range, short-term:	cleaning 1 to 14
Maximum operating temperature :	50°C (122°F)
Maximum inlet pressure:	4 barg (60 psig)
Typical operating cross flow rate	
30 ft^2:	24 l/min.
2.5 ft^2:	2 l/min.
Holders, Pilot cassettes:	GE Healthcare Kvick Pilot holders and other industry standard holders
Holders, Process cassettes:	GE Healthcare Kvick Process holderand other industry standard holders
Materials of construction	
Membrane:	Polyethersulfone
Screen:	Polypropylene
Encapsulant:	Silicone
Preservative solution:	0.1–0.2 N NaOH and 20–22% glycerin

Kvick Lab packet and Kvick Lab packet holder

Kvick Lab packet

The Kvick Lab packet is the smallest filtration device in the line of Kvick Lab and Kvick Flow ultrafiltration (UF) cassettes from GE Healthcare. The Kvick Lab packet is intended for the concentration and diafiltration of small process volumes ranging from approximately 50 to 2000 ml. Kvick cassettes are constructed of identical materials and have identical flow path geometries to ensure performance scalability and reproducibility across the full product range.

Kvick Lab packets are specifically designed for use by process development engineers who are interested in developing process parameters for an ultrafiltration step that will be transitioned to full manufacturing scale. The packet is well suited to experimentation that will yield concentration and diafiltration process settings for downstream purification of biotechnology products. Kvick lab packets are simple to use and effective for laboratory scientists with a need for rapid ultrafiltration of biomolecules.

Kvick Lab packet holder

The Kvick Lab packet holder is the latest in the GE Healthcare line of design-in tools for crossflow applications involving Kvick cassettes. The Kvick Lab packet holder is a versatile device that houses Kvick lab packets and facilitates their use on ÄKTAcrossflow and on other small-scale crossflow systems.

The holder will support linear cross flow versus pressure drop (ΔP) through the range of 0.7 and 4 barg (10 and 60 psig), indicating the structural strength of the unit. The holder is designed with UNF fittings for direct connection to the GE Healthcare ÄKTAcrossflow system. It also comes with an accessory kit for installation onto systems that use luer-style fittings.

The Packet & Holder combination is designed for:

- Performing crossflow trials in preparation for scale up.
- Working with filters that have the same flow path lengths and geometries as our larger Kvick cassettes.
- Applications that require a surface area for processing larger volumes than is practical by using Kvick Start cassettes (50 cm^2). The holder is designed to also hold one Kvick lab (0.11 m^2) cassette. Many Packet applications will involve 200 to 2000 ml of feed material per Packet (100 cm^2).

Ordering information

Product	Code No.	Model No.	Qty
Kvick Lab packet, 5 kD	56-4112-02	UFELA0005001ST	1
Kvick Lab packet, 10 kDselect	56-4112-06	UFELA0010001SE	1
Kvick Lab packet, 10K kD	56-4112-04	UFELA0010001ST	1
Kvick Lab packet, 30 kD	56-4112-08	UFELA0030001ST	1
Kvick Lab packet, 50 kD	56-4112-10	UFELA0050001ST	1
Kvick Lab packet, 100 kD	56-4112-14	UFELA0100001ST	1
Packet holder	11-0006-70	KLPH001SSU	1
Kvick UNF accessory Kit	11-0006-71	KSP001AKT	1
Kvick lab packet holder torque wrench	56-4112-84	KLTW0001	1

Technical specifications

Materials of construction

Kvick Lab packet:	
Membrane	Polyethersulfone
Screen	Polypropylene
Encapsulant	Silicone
Gasket	Silicone
Preservative solution	0.1–0.2N NaOH and 20–22% glycerin
Kvick Lab packet holder:	
Holder	316L stainless steel with electropolished inner surface with Ra less than 0.63 µm (25 µin) 400 stainless steel threaded posts
Luer lock adapters	Polypropylene
Luer lock adapter gasket	EPDM
UNF block	PEEK

Operating conditions

Long-term storage pH	2–13
Cleaning/sanitization	1–14
Maximum inlet pressure	4 barg (60 psig)
Operating cross flow rate	60 ml/min per 100 cm^2 filter

Literature

Data File for Kvick Lab packet and holder	18-1171-60 AB
User Manual for Kvick Lab packet holder	11-0003-86 AA


UniFlux

Systems
ÄKTAcrossflow system

Automated cross flow filtration for process development.

- Broad range of applications that cover ultrafiltration and microfiltration.
- Flexible operation of either hollow fiber cartridges or cross flow cassettes.
- Thorough and efficient process development with full TMP and flux scouting.
- Single familiar UNICORN interface for both chromatography and membrane separations.
- No disruption to proteins or cells with low shear force pumps that require no cooling.
- Minimum working volume of 25 ml ensures operation of complete processes using filters between 40 cm^2 and 150 cm^2.
- Supported with hardware product documentation to simplify validation.

Membrane separations are normally used to concentrate and wash feed prior to chromatography. ÄKTAcrossflow is a fully-automated system for cross flow filtration (ultrafiltration/diafiltration and cell separation) during process development and optimization. The benchtop system is compact and has a sanitary design with changeable wetted parts. It can be installed in a laboratory, which reduces facility and infrastructure expenditure.

UNICORN control software means one common control platform and user-interface for all scales of operation in filtration and chromatography. Scouting gives automatic support to process development and optimization. Method wizards and pre-programmed cleaning methods provide a high degree of efficiency. UNICORN is compatible with all applicable regulations, including 21 CFR Part 11.

The system is for use with flat sheet cassettes and hollow fibers. A wide range of cross flow devices include MidGee hollow fiber cross flow cartridges and Kvick Start flat sheet cassettes. The cassettes require small working volumes and are well-suited for ultrafiltration and diafiltration process development. The cassettes have a surface are of 50 cm^2 and can be combined for a total surface area of 150 cm^2.

Product	Quantity	Code No.
ÄKTAcrossflow	1	18-1180-00

Technical specifications

Operating range	
Feed flow rate	1–600 ml/min
Transfer flow rate	0.1–200 ml/min
Permeate flow rate	0.1–200 ml/min
Max. system pressure	5.2 bar (75.4 psi)
Min. recirculation volume	less than 25 ml (excluding cartridge)
Detection and control	
Pressure transducers	Less than ± 0.01 bar (1.0 KPa)
TMP control accuracy	Less than ± 0.05 bar (5.0 KPa)
Flow rate and displaced volume:	
transfer and permeate pump	± 0.5%
feed pump	Less than ± 2.0%

Literature

Data File	
ÄKTAcrossflow systems	11-0032-71

MidJet systems

Advanced MidJet System is complete with peristaltic pump, pressure transducers, and a dual digital panel meter. Optional autoclavable reservoirs are shown.

- Rapid processing of volumes up to 200 ml.
- Quick and easy cartridge change out using Luer-Lok fittings.
- Low system hold-up volume for concentration down to 2 to 5 ml (cartridge hold-up volume 0.5 ml).
- Easy scale-up to pilot and process volumes.
- Perfect sizing for MidGee and MidGee Hoop hollow fiber cartridges.
- Attaches to syringe for easy removal of retentate.

MidJet Labscale System enables you to separate, concentrate, and diafilter small volumes (up to 200 ml) of biological solutions. Using hollow fiber cartridges, processing is easy and fast compared to other techniques. In addition, hollow fiber cartridges let you scale your laboratory data linearly to pilot and production-scale systems.

The Basic MidJet System includes a peristaltic pump, reservoirs, tubing, fittings, a back-pressure valve, and a stand to mount the system components. The Advanced MidJet System comprises the basic system plus pressure transducers and displays for precise pressure and flow control. Such control ensures high product recovery and minimal shear denaturation, and provides data for scale-up.

Ordering information

Product	Quantity	Code No.
Basic MidJet System (MDG-3SP)	1	56-4106-37
Advanced MidJet System (MDG-4SP)	1	56-4106-38
Accessories		
MidGee Starter Kit (KMDG-1)	1	56-4105-79
MidGee Reservoir Kit, 175 ml, Autoclavable (KMDG-175R01A)	1	56-4105-86
MidGee Replacement Reservoir Kit, 175 ml, Autoclavable (KMDG-175R02A)	1	56-4105-87
MidJet System Accessory Kit (KMDG-2)	1	56-4105-82

Technical specifications

	Basic MidJet system	Adv. MidJet System
Max. process volume:	200 ml	200 ml
Min. working volume:	2–5 ml	2–5 ml
Pump power requirement:	24 VDC	24 VDC
Max. Recirculation Rate:	size 14 tubing 50 ml/min size 16 tubing 140 ml/min	50 ml/min 140 ml/min
Materials of construction:		
Reservoir:	Polystyrene (std) Polycarbonate (autoclavable)	Polystyrene (std) Polycarbonate (autoclavable)
Reservoir fittings/tubing:	PVC, nylon, silicone	PVC, nylon, silicone
CE Compatible Components:	Yes	Yes
Basic and Advanced MidJet	1 peristaltic recircualtion pump 1 mounting platform 1 backpressure tubing valve 1 accessory kit (includes reservoirs) 1 assembly guide	
Advanced MidJet only	1 digital panel meter	

Kvick Lab systems

Kvick Lab system with feed tank and sanitary rotary-lobe pump for shear-sensitive products.

- Stainless steel jacketed feed tank with multiple ports for process flexibility.
- Low-shear, rotary-lobe pump with touch controls and LCD display.
- Sanitary diaphragm valves and zero dead-leg pressure gauges.
- Protection against over pressurization.
- For Kvick cassettes and hollow fiber cartridges.

Engineered for consistency and precise control, Kvick Lab System is a flexible cross flow laboratory scale separations system. With a complementary 2.5 liter reservoir, pump, pressure gauges, cassette holder, piping, and fittings, the system quick to set up and easy to use.

As with all Kvick products, trial data can be scaled to larger systems. The GE Healthcare range of cross flow equipment is consistent and repeatable across all size ranges to allow linear scale-up on laboratory, pilot and production equipment.

Ordering information

Product	Quantity	Code No.
Kvick Lab System 115 V (KLSY0105 RLPSS15)	1	56-4112-77
Kvick Lab System 220 V (KLSY0105RLPSS20)	1	56-4112-78
Accessories		
Flowmeter Kit, 115 V for Kvick Lab System (KLSY0105FLKIT15)	1	56-4113-66
Flowmeter Kit, 220V for Kvick Lab System (KLSY0105FLKIT20)	1	56-4113-67
Pressure gauge w CPM fitting, 0–4 barg (0–60 psig) (KLSY0105APGA60CPM)	1	56-4113-91
Kvick Lab Pressure Gauge Kit (KLSY0105PRKIT)	1	56-4113-69
Kvick Lab 2 Liter Tank Cover (KLSY0105TC001)	1	56-4113-58
2-inch Sanitary Clear Acrylic Tank Cap (KLSY0105SAC20)	1	56-4113-16
1/2-inch Sanitary to 1/4-inch Hose Barb Adaptor (KLSY0105HB4F01)	1	56-4115-26
1/2-inch Sanitary to 3/8-inch Hose Barb Adaptor (KLSY0105HBF01)	1	56-4113-97
1/2-inch Sanitary CPM Fitting (KLSY010CPM05)	1	56-4113-92
CPM O-ring (KFSY0107CPMORI)	6	56-4113-89
Clamps		
1/2-inch Sanitary Clamp (KFSY0107TCL05)	1	56-4112-85
2-inch Sanitary Clamp (KLSY0105TCL20)	1	56-4113-12
6-inch Sanitary Clamp (KYSL0105TCL60)	1	56-4113-13
Gaskets		
1/2-inch Sanitary Gasket, EPDM (KFSY0107TCG05)	1	56-4112-86
3/4-inch Sanitary Gasket, EPDM (KYSL0105TCG10)	10	56-4113-17
Kvick Lab Cassette Gasket (KYLAGS001011)	1	56-4113-64
Kvick Lab Cassette Gasket (KYLAGS001033)	3	56-4113-65
2-inch Sanitary Gasket, EPDM (KLSY0105TCG20)	1	56-4113-18
6-inch Sanitary Gasket, EPDM (KYSL0105TCG60)	1	56-4113-19
Valves		
Diaphragm Valve, stainless steel, 1/2-inch sanitary connections (KFSY01071DV05)	1	56-4112-95
Dual Diaphragm Diverter Valve, stainless steel (KLSY0105DDV05)	1	56-4113-08
Related products		
Kvick Lab Holder (KLHR0105000SS)	1	56-4112-79
Kvick Lab Holder torque wrench (KLTW0001)	1	56-4112-84

Technical specifications

Kvick Lab Systems	
Feed, retentate and permeate port fittings:	1/2 in. sanitary
Dimensions, approximate (W × L × H):	38 × 61 × 53 cm (15 × 24 × 21in.)
Weight, approximate:	68 kg (150 lb)
Max. operating temperature:	60°C (140°F)
Max. temperature:	121°C (250°F)
Max. inlet pressure:	4 bar (60 psi)
Installable membrane area:	0.01 to 0.55 m^2 (0.11 to 6.0 ft^2)
System holdup volume:	v 30 ml
Materials of construction Wetted parts:	Polished 316L stainless steel, Ra v 0.8 µm

QuixStand systems

Versatile QuixStand system accommodates Xampler cartridge sizes 3M, 3X2M, 4, 4M, and 4X2M.

- Rapid processing of volumes up to 10 liters.
- Quick, easy cartridge change-out.
- Low hold-up volume allows concentration to as low as 30 to 50 ml.
- Reservoir can be pressurized for gentle recirculation of labile solutions.
- Accommodates Xampler cartridge sizes 3M, 3X2M, 4, 4M, and 4X2M.

QuixStand benchtop system is a compact, laboratory-scale separation system that uses GE Healthcare membrane cross flow filtration cartridges. Fitted with a hollow fiber cartridge, QuixStand gives quick, efficient concentration and diafiltration of a wide range of biological solutions. The system rapidly processes solution volumes up to 10 liters. As well as concentrating to volumes as low as 30 to 50 ml, the low hold-up design provides speed, efficiency and true scale-up data impossible to achieve using conventional dialysis or stirred cells.

The basic QuixStand system consists of a cartridge support stand, inlet and outlet pressure gauges, and 400 ml and 1 liter reservoirs. The self-contained system also incorporates a precision back-pressure control valve and a convenient sampling/drain valve. An optional peristaltic pump with a nominal maximum recirculation rate of 2 liters/minute is available.

Ordering information

Product	Quantity	Code No.
QuixStand in Case (KCQSM03SP)	1	56-4108-05
QuixStand System (QSM-02S)	1	56-4107-41
QuixStand System, 50 Hz pump (QSM-02SP/50)	1	56-4107-77
QuixStand System, Sanitary (QSM-03S)	1	56-4107-42
QuixStand System, Sanitary, 50 Hz pump (QSM-03SP/50)	1	56-4107-78
QuixStand System, Autoclavable (QSM-04SA)	1	56-4107-43
QuixStand System, Autoclavable, 50 Hz pump (QSM-04SAP/50)	1	56-4107-79
Accessories		
QuixStand Reservoir Kit, 0.4 l (KQRVA-0.4)	1	56-4107-48
QuixStand Reservoir Kit, 1 l (KQRVA-1.0)	1	56-4107- 49
QuixStand Accessory Kit (QAK-2)	1	56-4107-50
QuixStand Reservoir, 2.5 l (QRV-2.5)	1	56-4107-47
QuixStand Carrying Case (QSM-CC)	1	56-4109-57
QuixStand Reservoir Replacement Cap (QSM-RCP)	1	56-4107-51
Peristaltic pump dual voltage (PRP-09WM)	1	56-4106-53

Technical specifications

	Basic QuixStand system	Adv. QuixStand system
Max. process volume:	10 l	10 l
Min. working volume:	n/a	30–50 ml
Pump power requirement:	n/a	110V/60 Hz or 220 V/50 Hz
Max. recirculation rate:	size 17 tubing n/a 1.4 l/min	size 18 tubing n/a 2.0 l/min
CE Compatible	n/a	Yes

Components:
Basic and Advanced QuixStand
1 cartridge stand
2 support rods
2 pressure guages, 0–2 bar (0–30 psi)
1 backpressure tubing valve
1 reservoir kit (includes 400 ml and 1 l reservoirs)
1 sample/drain valve
1 accessory kit
1 assembly guide
Advanced QuixStand only
1 peristaltic recirculation pump
1 system stand

FlexStand benchtop pilot system

Versatile processing system with a compact, modular design.

- Accommodates a variety of cartridge sizes up to 3.5 m^2 (37 ft^2).
- Process volumes from 5 to 100 liters and more.
- Quickly change from lab to pilot scale.
- Stainless steel fittings and USP XXIV Class 6 polymers/ elastomers ensure compatibility with cleaning regimens.
- 316L stainless steel wetted surfaces ensures compatibility with process and cleaning fluids.
- Sturdy base holds cartridges in vertical position and allows maximum product recovery.

FlexStand benchtop pilot system accommodates GE Healthcare laboratory cartridges as well as up to 2-inch diameter pilot-scale cartridges with 1.5-inch Tri-Clamp fittings.

The standard pilot system is a compact, sanitary device with autoclavable pressure gauge, pinch-type backpressure valve, tubing connector kit and associated gaskets and clamps. It takes up minimal bench space and is easily moved from laboratory to cold room.

Various pump and reservoir options create a versatile processing system capable of concentration and/or diafiltration of process volumes ranging from 5 to 100 liters or more.

FlexStand benchtop pilot systems

Code No.	Part No.	Description
56-4107-54	FS-01S	Standard FlexStand Benchtop Pilot Cartridge Support Assembly with 1.5-in Tri-Clamp connections.
Includes:		Qty Description
		1 Stand and support rods
		1 Pressure gauge, back mount, 0–4 barg (0–60 psig), mechanically dampened
		1 Backpressure valve, pinch-type
		1 Blank-off cap
		6 Clamp, 1.5-in sanitary
		6 Gasket, 1.5-in sanitary, silicone
		1 Tubing connector kit [KTC-2]
		1 Assembly guide
56-4107-55	FS-03LVS	Low void volume FlexStand Benchtop Pilot Cartridge Support Assembly with fractional Tri-Clamp connections. Includes:
		Qty Description
		1 Stand and support rods
		1 Pressure gauge, back mount, 0–4 barg (0–60 psig), mechanically dampened
		1 Backpressure valve, pinch-type
		1 Blank-off cap
		6 Clamp, fractional sanitary
		6 Gasket, fractional sanitary, silicone
		1 Tubing connector kit [KTC-FS-03VS]
		1 Assembly guide

FlexStand benchtop pilot processing systems

Code No.	Part No.	Description
56-4107-56	FS-02RLP	Standard FlexStand Benchtop Pilot Cartridge Support Assembly with 1.5-in Tri-Clamp connections, rotary lobe pump. Includes:
		Qty Description
		1 Stand and support rods with manifold
		2 Pressure gauge, back mount, 0–4* barg (0–60 psig), mechanically dampened
		1 Rotary lobe recirculation pump, FlowTech LABTOP® 350 with low point drain
		1 Gear box for LABTOP 350 pump
		1 Diaphragm valve, 1.5-in sanitary (retentate)
		1 Diaphragm valve, fractional sanitary (drain)
		1 High pressure shut-off switch
		1 Tubing connector kit [KTC-2]
		1 Set of clamps, gaskets, piping, tubing
		1 Assembly guide
56-4107-57	FS-02RLP/50	Same as FS-02RLP except with 220 v 50 Hz electrical system
56-4107-58	FS-04LVS-RLP	Low void volume FlexStand Benchtop Pilot Cartridge Support Assembly with fractional Tri-Clamp connections, rotary lobe pump. Includes:
		Qty Description
		1 Stand and support rods with manifold
		2 Pressure gauge, back mount, 0–4* barg (0–60 psig), mechanically dampened
		1 Rotary lobe recirculation pump, FlowTech LABTOP 250 with low point drain
		1 Gear box for LABTOP 250 pump
		2 Diaphragm valve, fractional sanitary
		1 High pressure shut-off switch
		1 Tubing connector kit [KTC-FS-03VS]
		1 Set of clamps, gaskets, piping, tubing
		1 Assembly guide
56-4107-59	FS-04LVS-RLP/50	Same as FS-04LVS-RLP except with 220 v 50 Hz electrical system

*0–2 barg (0–30 psig) gauges may be substituted

FlexStand benchtop pilot options

Pumps, rotary lobe

FlowTech LABTOP rotary lobe pumps incorporate variable-speed drive and a manual control system. LABTOP 250 pumps have a vertical pump head, fractional Tri-Clamp fittings and produce approximately 10 lpm at 25 psig. LABTOP 350 pumps have a low point drain port, 1.5-in Tri-Clamp fittings and produce approximately 30 lpm at 25 psig.

Code No.	Part No.	Description
56-4106-39	RLP-250FT	LABTOP 250, Teflon rotors
56-4106-54	RLP-250FT-HPS	LABTOP 250, Teflon rotors, high pressure shut-off
56-4106-40	RLP-250FT/50	LABTOP 250, Teflon rotors, 220 v 50 Hz
56-4106-55	RLP-250FT/50-HPS	LABTOP 250, Teflon rotors, 220 v 50 Hz, high pressure shut-off
56-4106-41	RLP-250FT/SS	LABTOP 250, stainless steel rotors
56-4106-56	RLP-250FT/SS-HPS	LABTOP 250, stainless steel rotors, high pressure shut-off
56-4106-42	RLP-250FTSS/50	LABTOP 250, stainless steel rotors, 220 v 50 Hz
56-4106-57	RLP-250FTSS/50-HPS	LABTOP 250, stainless steel rotors, 220 v 50 Hz, high pressure shut-off
56-4106-43	RLP-350DPFT	LABTOP 350, stainless steel rotors
56-4106-58	RLP-350DPFT-HPS	LABTOP 350, stainless steel rotors, high pressure shut-off
56-4106-44	RLP-350DPFT/50	LABTOP 350, stainless steel rotors, 220 v 50 Hz
56-4106-59	RLP-350DPFT/50-HPS	LABTOP 350, stainless steel rotors, 220 v 50 Hz, high pressure shut-off
56-4107-60	YS-01-12TCSS	"Y" strainer for RLP-350DPFT suction protection, 1.5-in Tri-Clamp

Pumps, peristaltic

Masterflex peristaltic pumps incorporate variable-speed drive and a manual control system. Masterflex Easy-Load pump heads deliver up to 13 lpm.

Code No.	Part No.	Description
56-4106-45	PRP-01MF	Masterflex peristaltic pump with Easy-Load head, tubing
56-4106-46	PRP-01MF/50	Masterflex peristaltic pump with Easy-Load head, tubing, 220 v 50 Hz
56-4106-47	KPRP-02MF	Dual head add-on kit for PRP-01MF and PRP-01MF/50. Provides flow rates up to 26 lpm. Includes Easy-Load head, tubing, clamps, Y-connectors and mounting hardware.
51-4106-22	PTPM12	Peristaltic pump tubing – Bioprene size 82, 12.7 mm (0.5 in) ID, 7.6 m (25 ft)
51-4106-23	PTSL12	Peristaltic pump tubing – silicone size 82, 12.7 mm (0.5 in) ID, 7.6 m (25 ft)
56-4106-24	FTTY06	Flexible tubing – Tygon S-50-HL, 6.3 mm (0.25 in) ID, 15.2 m (50 ft)
56-4106-25	FTTY09	Flexible tubing – Tygon S-50-HL, 9.5 mm (0.375 in)
56-4106-26	FTTY12	Flexible tubing – Tygon S-50-HL, 12.7 mm (0.5 in) ID, 15.2 m (50 ft)

Reservoirs

All polysulfone reservoir kits come with associated supports, gaskets, clamps and adaptors. Sealable-top reservoirs are for use with diafiltration operations

Code No.	Part No.	Description
56-4107-63	TK01-30SS	Stainless steel tank, ASME code, adjustable legs, 30-liter capacity, sanitary ports for retentate return, vent filter and continuous diafiltration. Withstands up to 275°C for steam sterilization Electropolished.
56-4107-66	RVK-1	2-Liter polysulfone reservoir kit with open top, graduated. Not autoclavable.
56-4107-67	FRV-2A	2-Liter polysulfone reservoir kit with sealable top. Autoclavable.
56-4107-68	FRV-PPK-2A	Replacement 2-liter polysulfone reservoir. Autoclavable.
56-4107-70	FRV-5A	5-Liter polysulfone reservoir kit with sealable top. Autoclavable.
56-4107-71	FRV-PPK-5A	Replacement 5-liter polysulfone reservoir. Autoclavable.
56-4107-69	FRV-CP2/5A	Replacement cap for 2- and 5-liter polysulfone reservoirs. Autoclavable.

Other options

Code No.	Part No.	Description
56-4107-62	KFSM04	Conversion kit to change standard FlexStand to low void volume assembly
56-4107-61	KFSM12	Conversion kit to change low void volume FlexStand to standard assembly
56-4107-64	KTC-2	Tubing connector kit for FS-01S
56-4107-65	KTC-FS-03VS	Tubing connector kit for FS-03LVS
56-4106-03	PG-TCP30	Pressure gauge, 0–2 barg (0–30 psig), mechanically dampened, autoclavable
56-4106-04	PG-TCP60	Pressure gauge, 0–4 barg (0–60 psig), mechanically dampened, autoclavable
56-4106-06	PG-TCV30P30	Vacuum/pressure gauge -2 to 2 barg (-30 to 30 psig), mechanically dampened, autoclavable
56-4107-72	KDV-F1	Drain valve kit for FS-01S, includes custom tee, sanitary plug valve, gasket and clamp
56-4107-73	KPCM-1	Manual permeate control kit, includes vacuum/pressure gauge, backpressure valve, supports, adaptors, clamps and gaskets
56-4105-92	VDM-6SS	Diaphragm valve, fractional Tri-Clamp, stainless steel
56-4105-93	VDM-12SS	Diaphragm valve, 1.5-in Tri-Clamp, stainless steel
56-4105-91	VBF12	Butterfly valve, 1.5-in Tri-Clamp, stainless steel, silicone seat
56-4105-95	HX12-L1-8	Heat exchanger, 1.5-in Tri-Clamp, 5.1 cm diameter, 34 cm long
56-4105-96	HX12-L2-9	Heat exchanger, 1.5-in Tri-Clamp, 5.1 cm diameter, 63 cm long
56-4107-76	SSCRT-RLP	Heavy-duty stainless steel cart with locking castors

Grandstand Pilot / Process cross flow filtration systems

GrandStand Systems are self-contained manual cross flow filtration systems designed to support a wide selection of GE Healthcare Hollow Fiber Ultrafiltration and/or Microfiltration Cartridges. The systems can handle process volumes from 50 to 1000 liters or more.

Two standard systems are available, capable of accommodating one or two MaxCell process scale cartridges. The inclusion of a variable frequency drive on the recirculation pump allows smaller cartridges to be run on either system by adjusting pump output to lower flow rates. A polypropylene Clean-In-Place tank and 30-mesh Y-strainer are included. Sanitary extensions are in place for connection to tanks or other process components. This system is intended to operate independently with no sequencing or interfacing with other process components.

Basic System features include:

- Compact system support for one or two MaxCell Size "85" membrane cartridges.
- Rapid changeover for different length membrane cartridges and/or different molecular weight cut-off membranes.
- Sanitary rotary lobe recirculation pump with variable speed control.
- 316L SST wetted parts.
- 316L SST diaphragm valves with position indicators for flow/pressure control.

Code No.	Catalog No.	Description
56-4114-94 Includes:	GS1RLP450	Grandstand Single Position Cross Flow Filtration System • 304 SS Frame with sanitary casters • Support and manifold for one Maxcell Cartridge (Up to 13 m^2 (140 ft^2) membrane area) • Sanitary rotary lobe pump: 120 lpm capacity • 5 HP Variable frequency drive • Manual sanitary diaphragm valves • Sanitary pressure indicators on feed and retentate side of HF cartridges • High pressure shut-off switch • 30 mesh strainer on pump inlet • 18 gallon polypropylene tank for CIP • 316 SS interconnecting piping • EPDM, silicone gaskets
56-4108-13 includes:	GS1RLP550	Grandstand Dual Position Cross Flow Filtration System • 304 SS frame with sanitary casters • Supports and manifold for two Maxcell Cartridges (up to 26 m^2 (280 ft^2) membrane area) • Capability to run just one cartridge if desired. • Sanitary rotary lobe pump: 400 lpm capacity. • 7.5 HP variable frequency drive • Manual sanitary diaphragm valves • Sanitary pressure indicators on feed and retentate side of HF cartridges • High pressure shut-off switch • 30 mesh strainer on pump inlet • 30 gallon polypropylene tank for CIP • 316 SS interconnecting piping • PDM, silicone gaskets

UniFlux systems

The UniFlux series is a standard line of membrane separations filtration systems that utilizes UNICORN software for full automation with data logging capabilites of the entire cross flow process.

- Available in 4 sizes (10, 30, 120, and 400 lpm) for pilot to production-scales.
- Fully automated using UNICORN control software.
- Maximizes productivity in cross flow filtration.
- Consistent, repeatable, and validatable results.
- Developed using input from biopharmaceutical manufacturers.

UniFlux membrane separation systems incorporate cross flow membranes and high performance hardware in a single system. The systems are configured to operate hollow fiber cartridges ideal for microfiltration applications such as cell clarification/harvesting, or cassettes for ultrafiltration applications, such as protein concentration and diafiltration in downstream unit operations.

Automated configurations use a membrane separations-specific version of GE Healthcare UNICORN control system. UNICORN supports FDA 21 CFR Part 11 compliant software in a form familiar to many operators conversant with GE Healthcare chromatography systems from bench-top ÄKTAdesign to production-scale ÄKTAprocess.

Uniflux Systems & Accessories

System	Description
UniFlux 30 AH	CFF system for Hollow fiber, 60 lpm
UniFlux 120 AH	CFF system for Hollow fiber, 120 lpm
UniFlux 400 AH	CFF system for Hollow fiber, 400 lpm
UniFlux 10 AC	CFF system for Kvick lab cassette, 10 lpm
UniFlux 30 AC	CFF system for Kvick flow cassette, 60 lpm
UniFlux 120 AC	CFF system for Kvick flow cassette, 120 lpm
UniFlux 400 AC	CFF system for Kvick flow cassette, 400 lpm
Accessories	**Description**
UniFlux 10 UV	Permeate UV sensor
UniFlux 30 UV	Permeate UV sensor
UniFlux 120 UV	Permeate UV sensor
UniFlux 400 UV	Permeate UV sensor
UniFlux 10 Transfer pump	Transfer pump, 2.3 lpm
UniFlux 30 Transfer pump	Transfer pump, 19 lpm
UniFlux 120 Transfer pump	Transfer pump, 19 lpm
UniFlux 400 Transfer pump	Transfer pump, 60 lpm
UniFlux 10 Permeate control pump	Permeate control pump, 2.3 lpm
UniFlux 30 Permeate control pump	Permeate control pump, 19 lpm
UniFlux 120 Permeate control pump	Permeate control pump, 19 lpm
UniFlux 400 Permeate control pump	Permeate control pump, 60 lpm
UniFlux 10 Conversion Cass to HF	Kit for conversion from cassette to Hollow fiber system
UniFlux 30 Conversion Cass to HF	Kit for conversion from cassette to Hollow fiber system
UniFlux 120 Conversion Cass to HF	Kit for conversion from cassette to Hollow fiber system
UniFlux 400 Conversion Cass to HF	Kit for conversion from cassette to Hollow fiber system
UniFlux 30 Conversion HF to Cass	Kit for conversion from Hollow fiber to cassette system
UniFlux 120 Conversion HF to Cass	Kit for conversion from Hollow fiber to cassette system
UniFlux 400 Conversion HF to Cass	Kit for conversion from Hollow fiber to cassette system
UniFlux 30 Spool kit 35	Spool piece for size 35 Hollow fiber cartridge
UniFlux 30 Spool kit 75	Spool piece for size 75 Hollow fiber cartridge
UniFlux 120 Spool kit 35	Spool piece for size 35 Hollow fiber cartridge
UniFlux 120 Spool kit 75	Spool piece for size 75 Hollow fiber cartridge
UniFlux 400 Spool kit 45	Spool piece for size 45 Hollow fiber cartridge
UniFlux 400 Spool kit 85	Spool piece for size 85 Hollow fiber cartridge

Literature

Data File	
UniFlux membrare separation systems	18-1177-25

System performance

System size		10 LPM	30 LPM	120 LPM	400 LPM
Hollow fiber membranes					
No. of cartridges		1	1	2	up to 4
Min / Max area	ft^2	1.3/5.2	3.9/65	19.8/130	108/560
	m^2	0.12/0.48	0.36/6	1.8/12	10/52
Cartridge size		5, 6	35, 55, 75	35, 55, 75	45, 65, 85
Lumen diameter		Consult your GE Healthcare representative for application specific information.			
Cassette membranes					
No. cassette holders		1	1	2	6
Min / Max cassettes		1/5 Kvick Lab	1/10 Kvick Flow	2/20 Kvick Flow	6/60 Kvick Flow
Min / Max area	ft^2	1.2/6	5/50	10/100	30/300
	m^2	0.11/0.55	0.46/4.6	0.92/9.2	2.76/27.6

System specifications

System size		10	30	120	400
Max recirculation flow rate		10 lpm @ 4 bar	60 lpm @ 4 bar	120 lpm @ 4 bar	400 lpm @ 4 bar
Min recirculation flow rate		0.5 lpm @ 4 bar	3 lpm @ 4 bar	12 lpm @ 4 bar	40 lpm @ 4 bar
Feed connection, TC		3/4"	1"	1 1/2"	3"
Retentate connection, TC		3/4"	1"	1 1/2"	2"
Permeate connection, TC		3/8"	1/2"	3/4"	1"
Jacketed feed tank capacity	liter	5	N/A	N/A	N/A
System dimensions (W × L × H)	mm	1010 × 880 × 1770*	880 × 1500 × 1800*	880 × 1500 × 1800*	890 × 1700 × 1800
Cassette membrane cart dimensions (W × L × H)	mm	N/A	N/A	N/A	920 × 1410 × 1820

* If a transfer or permeate control pump is used, the system length will increase by to 300 mm.

Utility requirements		
Compressed air		6–10 Barg (87–145 psig) 0.12–10 SCFM. Dry particle free, non-condensing
Power requirements		
Pump, hydraulic unit	30–400 lpm	3-Phase, 400/480 VAC; 50/60 Hz; 10A to 30A
	10 lpm	1-Phase; 110/230 VAC; 50/60 Hz; 16/10A
Control system hardware		1-Phase; 110/230 VAC; 50/60 Hz; 16A
Materials of construction		
Wetted materials	30–400 lpm	316L/ N08904 (EN 1.4539) / PTFE / PFA / Glass / EPDM / SiC / PEEK / Hastelloy C22 / Polypropylene / Pt-cured Silicone (Only on Hollow fiber system), UV option: Quartz glass, Transfer/permeate control pump option: STA-PURE, PVDF
	10 lpm	316L / Glass / EPDM / PTFE / Silicone / Al_2O_3 / PFA / Kynar® / Titanium / Santoprene / Polypropylene / Buna UV option: Fused quartz, Transfer/permeate control pump option: STA-PURE, PVDF, Santroprene (depending on hose)
Frame		316 stainless steel

Normal flow filtration

New

ULTA Prime CG

Liquid column guard filters for reducing bioburden and prefiltering upstream solutions.

- Can be repeatedly steam sterilized *in situ*, autoclaved at up to 130°C, or sanitized with hot water at up to 90°C.
- Compatible with a wide range of chemicals.
- Materials conform to the relevant biological safety requirements of 21CFR Part 177 and current USP Plastics Class VI - 121°C and ISO10993 equivalents.
- Meet current USP quality standards for oxidizable substances.
- Aqueous extracts from ULTA Prime CG contain <0.125 EU/ml when tested in accordance with the standard (LAL) test for endotoxins.
- Effluent quality conforms to the requirements of USP 28<643>(TOC) and USP 28<645> (conductivity).
- Full pharmaceutical validation guide available on request.

ULTA Prime CG filter cartridges and capsules are specifically designed for bioburden control and particle retention in a variety of pH ranges and feed streams. They can act immediately before chromatography columns and prefilter solutions upstream of the sterilizing grade filter. For general bioburden control, they give log reduction of bacteria when sterility is not required.

The cartridges are validated to give an LRV > 5 when challenged with *Brevundimonas diminuta* in accordance with methods specified in ASTM F838-05 (10^7 organisms/cm^2 minimum).

Pleated polyethersulfone (PES) membranes combined with thermal-bonded construction in both capsule and cartridge formats ensure low extractables and quick flush-up devices. All products are 100% integrity tested before release and are shipped with a certificate of quality. Filters are flushed with pharmaceutical-grade purified water prior to packaging.

Technical specifications

Filtration area	0.54 m^2 (5.8 ft^2) per 250 mm (10 inch) module.
Recommended operating conditions	Up to 70°C (158°F) continuous operating temperature and higher short-term temperatures during CIP.
Materials of construction	
Filtration membrane	Polyethersulphone
Prefilter layer	Polyester
Upstream support	Polyester
Downstream support	Polyester
Inner support core	Polypropylene
Outer protection cage	Polypropylene
End caps	Nylon
End cap insert	316 stainless steel
Standard o-ring / gaskets	Silicone

Literature

Data file	
ULTA Prime CG	28-9094-69
Validation guide	
ULTA Prime CG capsule and cartridge pleated filters	28-9094-73

For more information on this product, contact your local GE Healthcare representative.

ULTA Prime GF New

Liquid filter cartridges for clarifying, stabilizing and reducing bioburden in aqueous solutions, media and biologicals.

- High dirt-holding capacity and exceptional flow performance compared with polypropylene filters.
- Compatible with a wide range of chemicals.
- Cartridges can be repeatedly steam sterilized *in situ*, autoclaved at up to 121°C, or sanitized with hot water at up to 90°C. Capsules can be repeatedly autoclaved up to 121°C.
- Materials conform to the relevant biological safety requirements of 21CFR Part 177 current USP Plastics Class VI – 121°C and ISO10993 equivalents. (Low concentrations of surfactant maybe present).
- Full pharmaceutical validation guide available on request.

ULTA Prime GF cartridges utilize a glass microfiber filter medium encased within an upstream polypropylene mesh and a downstream non-woven filter support material. ULTA Prime GF filter cartridges are dimensionally stable with no media migration. The pleat pack is supported by an inner polypropylene core and outer polypropylene cage, heat-bonded to polypropylene end caps. The hydrophilic nature of ULTA Prime GF filter cartridges also makes them suitable for gravity-fed systems.

Retention characteristics have been determined through controlled laboratory tests challenging with a standard aqueous suspension of ACFTD (AC Fine Test Dust) using on-line laser particle counters.

Technical specifications

Filtration area	Up to 0.6m^2 (6.3ft^2) per 250 mm (10 inch) module.
Recommended operating conditions	Recommended operating conditions Up to 70°C (158°F) continuous operating temperature and higher short-term temperatures during CIP. Capsules may be operated up to a temperature of 40°C (104°F) at line pressures up to 5.0 barg (72 psi) for liquids and 4.0 bar (58 psi) in air/gas.
Materials of construction	
Filtration media	Glass Microfiber
Prefilter layer	Polyester
Upstream support	Polypropylene
Downstream support	Polypropylene
Inner support core	Polypropylene
Outer protection cage	Polypropylene
End caps	Polypropylene
End cap insert	316 stainless steel
Standard o-ring / gaskets	Silicone/EPDM
Capsule body	Polypropylene
Capsule vent seals	Silicone
Filling bell	Polycarbonate

Literature

Data file	
ULTA Prime GF	11-0026-26
Validation guide	
ULTA Prime GF capsule and cartridge filters	28-9094-72

For more information on this product, contact your local GE Healthcare representative.

ULTA Prime PP

New

Liquid filter cartridges for clarifying and prefiltering in biopharmaceutical and ultrapure applications.

- Cartridges can be repeatedly steam sterilized *in situ*, autoclaved at up to 135°C, or sanitized with hot water at up to 90°C. Capsules can be repeatedly autoclaved up to 135°C.
- Compatible with a wide range of chemicals.
- Materials conform to the relevant biological safety requirements of 21CFR Part 177 and current USP Plastics Class VI - 121°C and ISO10993 equivalents.
- Full pharmaceutical validation guide available on request.

The all-polypropylene construction of ULTA Prime PP cartridges ensures a wide range of chemical compatibility and makes them particularly suitable for filtering viscous and aggressive and chemicals and solvents. Cartridges do not hydrolyze in aggressive solutions and thus do not contaminate process fluids.

Filter media of continuously-graded fiber density provide progressively finer particulate retention throughout the depth of the media. This, combined with optimized media pleating density, gives ULTA Prime PP cartridges exceptional lifetime performance.

Retention characteristics have been determined by a single-pass technique using suspensions of ISO 12103 Part 1 A2 Fine and A4 Coarse test dust in water.

Technical specifications

Filtration area	Up to 0.6m^2 (6.3ft^2) per 250 mm (10 inch) module.
Recommended operating conditions	Recommended operating conditions Up to 70°C (158°F) continuous operating temperature and higher short-term temperatures during CIP. Capsules may be operated up to a temperature of 40°C (104°F) at line pressures up to 5.0 barg (72 psi) for liquids and 4.0 bar (58 psi) in air/gas.
Materials of construction	
Filtration media	Glass Microfiber
Prefilter layer	Polyester
Upstream support	Polypropylene
Downstream support	Polypropylene
Inner support core	Polypropylene
Outer protection cage	Polypropylene
End caps	Polypropylene
End cap insert	316 stainless steel
Standard o-ring / gaskets	Silicone/EPDM
Capsule body	Polypropylene
Capsule vent seals	Silicone
Filling bell	Polycarbonate

Literature

Data file	
ULTA Prime PP	11-0012-07
Validation guide	
ULTA Prime PP capsule and cartridge filters	28-9094-71

For more information on this product, contact your local GE Healthcare representative.

Fast Trak BioPharma services

Fast Trak BioPharma Services provides practical support and advice to the developer of biotech products, in particular biopharmaceuticals. We can help you plan, implement and document downstream purification processes, from start-up to routine production, as well as train your personnel.

The services described here are supported by experts in a wide range of relevant specialist fields both from within GE Healthcare and from a network of outside suppliers.

Validation

Validation is a key activity integrated into the development and implementation of a downstream process.
Fast Trak Validation staff continuously monitor world-wide regulatory trends and, together with the Fast Trak network of advisory consultants, provide a wealth of specialist knowledge relevant to your specific biotech project. We can help you design, document and implement downstream purification processes, thus simplifying the journey to market. The end results are time-savings and cost-efficiency.

Validation Documentation

- System and Column Installation and Operational Qualification packages (IQ/OQs).
- Change Control Protocols (CCPs) for software updates and other modifications.
- Standard Operating Procedures (SOPs) for UNICORN controlled systems and Process columns.

Installation Qualification and Operational Qualification (IQ/OQ)

Fast Trak can help you get new equipment quickly into operation in your facility. Our IQ/OQ document packages are developed according to all current and relevant US FDA and European EMEA guidelines and regulations. They are available for a wide range of systems and columns including ÄKTApilot, ÄKTAcrossflow, ÄKTAexplorer, ÄKTAprocess, ÄKTApurifier, ÄKTAFPLC, BioProcess Chromatography and UniFlux Membrane systems, OligoProcess and ÄKTA oligopilot Systems, as well as BPG, Chromaflow and BioProcess columns.

The documents are always system-specific, indicating the correct number of valves, tag numbers, etc. They are also designed so that values can only be entered in permitted areas, thereby securing valuable system information.

Each IQ/OQ document consists of printed forms, detailed test protocols and “expected results”. There are also descriptions of the software program and hardware components for UNICORN, which are necessary for validating the control system.

Change Control Protocols (CCPs)

CCP document packages are available for a range of systems for upgrading UNICORN software and for other system modifications. The documents are intended for companies working in a regulated environment and describe procedures for upgrading GE Healthcare systems in a controlled manner. In this way, changes to software and hardware systems will be carefully evaluated, verified, documented and reviewed.

Performance of IQ/OQ and CCP

In addition to providing IQ/OQ and CCP documentation packages, we have Service Engineers who can execute the IQ/OQ and CCP testing for your company. This will save valuable time and prepare you for process validation. Our engineers are specially trained and certified to perform these procedures. On completion of the testing, all requisite documentation is completed and handed over.

Standard Operating Procedures (SOPs)

Fast Trak offers SOPs for all important functions in a UNICORN controlled computer system, as well as for column packing. SOPs describe how to use and maintain the system and equipment during regular operation. They need to be in place for systems and equipment used in a regulated environment according to cGMP.

SOPs are offered in sets of related documents as hard copy or in Microsoft Word. The electronic copy can be used to modify or customize the template SOPs. The benefits of using these template SOPs are shorter implementation time, reduced development costs, and fewer regulatory setbacks.

For further information about these packages, and for assistance with your IQ/OQ and CCP procedures or validation support, please see *Data File, 18-1117-32* or contact your nearest Fast Trak Center or GE Healthcare office.

IQ/OQ and CCP documentation

IQ/OQ documentation	Code No.
IQ/OQ BioProcess LPLC system, customized	44-8100-03
IQ/OQ BioProcess LPLC system, standard	44-8100-40
IQ/OQ BioProcess LPLC system with PLC	44-8100-50
IQ/OQ BioProcess MPLC/HPLC system, isocratic PLC	44-8100-70
IQ/OQ BioProcess MPLC/HPLC system, gradient PLC	44-8100-71
IQ/OQ BioProcess MPLC/HPLC system, isocratic UNICORN	44-8100-74
IQ/OQ BioProcess MPLC/HPLC system, gradient UNICORN	44-8100-75
IQ/OQ BioProcess system MPLC/HPLC Pilot	44-8100-81
IQ/OQ BioProcess Column LPLC/MPLC	44-8100-72
IQ/OQ BioProcess Column HPLC	44-8100-73
IQ/OQ OligoProcess system	44-8100-08
IQ/OQ OligoPilot 400 system	44-8100-80
IQ/OQ ÄKTA oligopilot system	44-8100-43
IQ/OQ OligoProcess PPSM system	44-8100-53
IQ/OQ ÄKTAexplorer	44-8100-11
IQ/OQ ÄKTApurifier	44-8100-13
IQ/OQ ÄKTA$_{FPLC}$	44-8100-23
IQ/OQ ÄKTAprime	44-8100-44
IQ/OQ ÄKTApilot	44-9100-49
IQ/OQ ÄKTAcrossflow system	44-8100-77
IQ/OQ ÄKTAprocess system	44-8100-61
IQ/OQ UniFlux Automated system, standard	44-8200-58
IQ/OQ UniFlux Automated system, customized	44-8200-59
IQ/OQ Kvick Benchtop system	44-8200-03
IQ/OQ Membrane Benchtop system	44-8200-06
IQ/OQ Chromaflow column	44-8100-12
IQ/OQ BPG column	44-8100-24
IQ/OQ BPSS column	44-8100-28
IQ/OQ STREAMLINE column	44-8100-14
IQ/OQ FineLINE column	44-8100-29
IQ/OQ Packing station/Pressure vessel	44-8100-35
IQ/OQ BioProcess LPLC/MPLC column	44-8100-72
IQ/OQ BioProcess HPLC column	44-8100-73
IQ/OQ Slurry tank	44-8100-76
IQ/OQ Control Cab ETTAN LC	44-8101-02
CCPs Change Control Protocols	
CCP/UNICORN upgrade BioProcess system	44-8100-25
CCP/UNICORN upgrade OligoProcess system	44-8100-37
CCP/UNICORN upgrade ÄKTA oligopilot	44-8100-38
CCP/UNICORN upgrade ÄKTAexplorer	44-8100-30
CCP/UNICORN upgrade ÄKTA$_{FPLC}$	44-8100-32
CCP/UNICORN upgrade ÄKTApurifier	44-8100-34
CCP/UNICORN upgrade ÄKTAprime	44-8100-39
CCP/UNICORN upgrade ÄKTApilot	44-8100-52
CCP/UNICORN upgrade ÄKTAcrossflow system	44-8100-79
CCP/UNICORN upgrade OligoPilot II system	44-8100-54
CCP/UNICORN upgrade UniFlux system	44-8100-82

Standard Operating Procedures

SOP for backup	44-8102-02
SOP for restore	44-8102-03
SOP for revalidation	44-8102-04
SOP for log book	44-8102-08
SOP for system security	44-8102-09
SOP for audit trail	44-8102-10
SOP BioProcess system, wetted parts replacement	44-8102-11
SOP ÄKTApilot system, wetted parts replacement	44-8102-13
SOP Chromaflow packing	44-8102-12

Process development service

Fast Trak supports companies by helping with hands-on process development, scaling-up and scaling-down, assessment of purification protocols and trouble-shooting for both cross flow filtration and chromatography techniques. Fast Trak can also assist in the use of Custom Designed Media (CDM).

At our main centers in the USA, Germany, Sweden, and China, we have fully-equipped laboratories and highly educated personnel with many years of experience in industrial downstream purification.

Fast Trak process development projects can be run at your facilities or at a Fast Trak center if you need to supplement your own laboratory and pilot plant capabilities. We have a long history of working with the pharmaceutical industry and work under strictest confidentiality.
Our service can significantly enhance the speed and value of your downstream process development. Typically, the development activity starts at a very early stage, often at the pre-clinical phase. However, even at later stages, such as clinical phase I & II or during second-generation process planning, we can provide the skills to help you develop a cost-efficient, cGMP-compliant manufacturing process.

Typical projects

- Development of protocols for purifying products such as monoclonal antibodies, viruses, vaccines, plasmids, peptides, oligonucleotides and proteins from recombinant or natural sources, based on chromatography and cross flow filtration techniques.
- Optimization of a unit operation as well as a complete process.
- Packing different chromatography media in GE Healthcare columns with qualification protocols.
- Screening different chromatography media or filtration modules for specific unit operations.
- Trouble-shooting an existing process.
- Process scale-up and assessment of hardware requirements.

Consulting

Both newly started and well-established biopharmaceutical companies are challenged by the demands of regulatory agencies and the need to assure product quality and safety. You must also be able to withstand the economic and time pressures associated with developing a new drug. Fast Trak staff can save you time and money by providing useful advice on a range of topics.

We can help you:

- Understand the latest regulatory trends.
- Perform internal audits.
- Plan process and system validation.
- Review the status of purification development projects.

Typically, we arrange a first visit to define the nature and scope of the activity, time-lines and deliverables. Follow-up may require deeper discussions, on-site reviews and generation of reports with descriptive sections and recommendations.

Don't risk delays at the end of a project. Call in the experts as early as possible.

Education and courses

Fast Trak Courses help educate and train your personnel in downstream purification processes. They are designed for research, development and production staff. Hands-on training courses and laboratory exercises are run at our regional Fast Trak centers or they can by customized and run at your premises.

All courses programmes undergo continuous improvement, for example the MAB1 course now includes extensive practical work, and a new UNICORN class for ÄKTAcrossflow has been introduced (SYS3). Visit the web for the latest information about our standard course content and schedules in North America, Europe and Asia: **www.gehealthcare.com/fasttrak**

Standard courses

MEM1

Membrane separations. A three-day practical course on membrane separation techniques in downstream processing.

MAB1

Monoclonal antibody purification. A three and a half-day practical course on the downstream processing of antibody molecules using chromatographic techniques.

DEV1

Development of chromatographic methods. A three-day basic hands-on course on chromatographic techniques suitable for production-scale biomolecule purification.

DEV2

Development of chromatographic processes. A five-day hands-on course for people with basic experience to improve their knowledge in downstream process development.

DEV4

Scale-up and technical transfer. A three-day hands-on course focused on designing and scaling up a laboratory scale process to production.

COL1

Large-scale column packing. A three-day practical course on packing, qualifying and maintaining production chromatography columns.

SYN1s and SYN1p

Oligonucleotide Synthesis and Purification in an industrial environment. A two to four-day practical workshop providing the knowledge required to design and optimize a complete process for the chemical synthesis and work-up of synthetic oligonucleotides.

SYS1 and SYS2

System Control using UNICORN in an industrial environment. Courses on UNICORN control software ensure that your UNICORN controlled ÄKTA or BioProcess system performs in an optimal way. The courses are on two levels; a two-day basic and a three-day advanced course.

SYS3

UNICORN for cross flow filtration systems. A two-day intensive course on how to control an ÄKTAcrossflow system.

Web-based courses

e-SYS1

Online training for basic control of ÄKTAexplorer and ÄKTApurifier using UNICORN. The course is fully interactive and can be completed at your own pace. Animations, audio instructions and interactive exercises are included to present system control, basic and advanced programming and report generation.

Customized modules

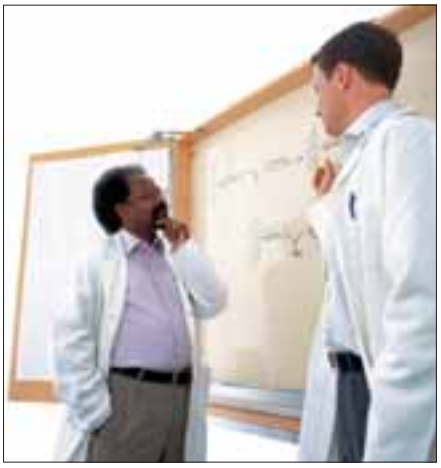
Customized training modules can deal with specific practical or theoretical topics within downstream processing. They are an excellent way to increase the efficiency of your team and to train personnel to comply with ISO 9000 and GMP requirements. Modules can be given at a Fast Trak training center or at your facilities, depending on the equipment involved.

Lectures or experiments may be used in different combinations, and other topics may be included to match your specific requirements. English is the language for most of our standard courses, but we can offer customized modules in a variety of languages.

The format may be a seminar open to everybody in your company, or a strictly confidential discussion of your specific work. Please contact your nearest Fast Trak center or your local GE Healthcare office.

Fast Trak Centers

Fast Trak services, including education, consulting, validation and regulatory support, are available from GE Healthcare throughout the world via our Fast Trak Centers. Contact a center listed here or your nearest GE Healthcare office.



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Administration
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Online support

Regulatory Support Files online

GE Healthcare pioneered the development of Regulatory Support Files to provide customers with detailed information about performance, stability, extractable compounds, and analytical methods for BioProcess media. This information is an invaluable starting point for process development and validation, for preparing Standard Operating Procedures and quality control, and as support for clinical and marketing applications to regulatory agencies. GE Healthcare has over 15 years of experience in providing customers with Regulatory Support Files.

GE Healthcare offers this regulatory support online, including the following features:

- Direct access to Regulatory Support Files.
- Email notification of updates when updates are published.
- Downloadable files in Adobe Acrobat (.pdf) format.
- Online subscription to Regulatory Support Files.
- Sharing subscriptions with colleagues.

As some of the information is proprietary, Regulatory Support Files are available only after signing a Secrecy agreement.

www.gehealthcare.com/rsf

Technical support online

Users of GE Healthcare´s columns and systems may need quick and easy access to information regarding their equipment. To meet these needs GE Healthcare has developed an efficient and enhanced support site on the internet.

From its initial focus on standard process-scale columns and systems, the site will expand to cover laboratory-scale equipment as well.

When entering the technical support site you quickly get access to detailed information regarding:

- Spare parts for columns, packing stations and systems.
- Accessories necessary for packing and running columns.
- Columns and systems recommended for your scale and selected medium.
- Column packing.
- A troubleshooting section will guide you to solutions for specific issues.

www.gehealthcare.com/purification_techsupport

System and column support

Installation

BioProcess Service engineers deliver and assemble your system, perform installation tests and get it ready for operation.

Validation

Installation Qualification & Operational Qualification – IQ/OQ

We can help certify your system and its operation with our IQ/OQ services. GE Healthcare's document packages (from FastTrak) and qualification services cover cGMP requirements and can include CFR 21 Part 11 verification (optional). Our engineers are fully trained on the complexities of both hardware and software and are efficient, quick and precise. Initial certification and annual cGMP training keeps them current on the latest cGMP regulations and requirements.

Change Control Protocols – CCPs

GE Healthcare can also certify upgrades to your system or UNICORN software in a controlled manner. Engineers ensure that the changes are carefully evaluated, verified, documented and reviewed.

Parts solutions

Critical parts

To minimize downtime, you should keep a stock of critical parts on site. A list of parts to keep in stock can be provided.

Parts locker

If you prefer that we hold a guaranteed stock of critical components on your behalf, ask about our 'Parts locker' option. For a monthly fee, we deliver any designated critical part according to an agreed time-frame.

Service agreements

BioProcess chromatography and filtration offerings

Based on needs, Service agreements for BioProcess systems can include:

- Comprehensive Preventive Maintenance including documentation (scheduled according to system requirements).
- Replacement of wetted components after product change.
- Calibration and function testing.
- Parts coverage (on a part-for-part exchange basis).
- Parts locker with guaranteed delivery times of critical stock.
- Engineer labor and travel coverage with unlimited service calls.
- Guaranteed on-site engineer response: 1-day or 2-day (selective availability).

Column offerings

Column maintenance

Service agreements for columns can include:

- Comprehensive column maintenance including documentation (scheduled as required by the process).
- Parts coverage (on a part-for-part exchange basis).
- Parts locker with guaranteed delivery times of critical stock .
- Engineer labor and travel coverage with unlimited service calls.
- Guaranteed on-site engineer response: 1-day or 2-day (selective availability).

Other column services

- Trouble-shooting.
- Column re-packing (scheduled).
- Column performance evaluation.
- Functional test (IQ/OQ).

Security of supply

Securing the supply of chromatography media is essential to successful biopharmaceutical development and manufacture. As protein-based drugs and/or vaccines progress further along their route-to-market, manufacturers need to be confident that they can produce enough material, on time, for clinical trials and product launches.

The media must be of consistently high quality and delivered on time during all stages of your production cycle. With an annual media production exceeding 450 000 liters/kilograms, GE Healthcare has the media production capacity to meet your needs.

In part, security-of-supply means being certain that you will receive the right quantity of media, manufactured to specified quality levels, and delivered at the right time. Given today's competitive marketplace, there really is no room for unnecessary risks.

Safety stock of chromatography media

Media safety stock agreements offer assurance of a smooth, continuous supply of chromatography media.

A customized media safety stock agreement guarantees:

- Assured media supply chain efficiency.
- Maintained optimum stock levels of media.
- Minimized downtime and product loss due to an incident occurring during development, campaign production or regular production.
- Minimized cash layout (transfer cost from balance sheet to profit and loss account).
- Simplified management of consumption fluctuations of production material during therapeutic and clinical trials.
- Help in meeting security and safety demands of regulatory agencies and insurance companies.

GE Healthcare maintains full responsibility for effective media stocking, rotation, and rapid supply during any emergency situations. You choose:

- Stock situation.
- Media products and quantities.
- Maximum shelf life.
- Storage period.
- Commencement date.

Oligosynthesis

Oligonucleotides are a major tool in drug discovery and diagnostic chip technology. They are used in initial research and screening through to target validation and drug production. Developers of oligonucleotide-based drugs have a clear need for regulatory-compliant material to use in pre/early-phase clinical trials. Similarly, companies involved in molecular diagnostics need cost-effective oligonucleotide-based probes to include in commercial kits. Oligonuleotides synthesized on our instruments and supports are currently in several clinical trials.
All our synthesizers are based on flow-through columntechnology (described opposite). This gives cost-efficient synthesis, creates less waste and allows simple scale-up. It also permits exact control of flow rate and thus fine control of reactions.
All systems are compatible with most synthesis chemistries used today, including RNA synthesis. Recirculation of monomers over the column reactor is included. The common use of UNICORN control software means convenient scale-up from research to full production, and enables use of PAT (Process Analytical Technology) in combination with in-line monitors.

System selection guide	
System	Nominal scale*
ÄKTA oligopilot plus 10	1–50 µmol
ÄKTA oligopilot plus 100	250 µmol – 9 mmol
OligoPilot 400	4–30 mmol
OligoProcess	50–500, 100–1000 mmol (or higher)

* All scale examples used Primer Support 200 loaded at 200 µmol/g, except the lower range in which custom Primer Support 40s was used with ÄKTA oligopilot plus 10. Longer oligos might require a lower loading and thus the corresponding scale is affected.

ÄKTA oligopilot plus

ÄKTA oligopilot plus is a flexible, fully-automated DNA/RNA oligonucleotide synthesizer for use in research, process development and production. This compact, pump-driven system meets the needs of new synthesis chemistries like RNAi and enables cost-efficient, high-quality synthesis.
ÄKTA oligopilot plus employs flow-through reactor technology and features column re-circulation, an important factor when performing RNA synthesis.
It is available in two configurations: ÄKTA oligopilot plus 10 for synthesis in the 1 to 50 µmol range, and ÄKTA oligopilot plus 100 for the range 50 µmol to 9 mmol.

The system is compatible with a range of column reactors, small scale cassettes and pre-packed disposable Oligosynt columns. For larger scale synthesis, the adjustable FineLINE 35 oligo column has been specifically developed to allow synthesis at scales from 250 µmol to 3.8 mmol. Adjustable Column 200 ml enables 9 mmol synthesis.
ÄKTA oligopilot plus is controlled via an external computer using UNICORN software specially designed for production needs.

OligoPilot 400

OligoPilot 400 is specifically developed for synthesizing oligonucleotides in quantities suitable for pre-clinical and early-phase clinical trials.
The system uses flow-through column technology, UNICORN software and comes with the same level of technical support as ÄKTA oligopilot plus and OligoProcess Systems to allow seamless scale-up/down.
Synthesis scale range is from 4 to 30 mmol using column diameters of 70 and 100 mm. As much as 150 gram crude 20-mer oligo per run can be produced with the 100 mm column.

The synthesizer is designed in an integrated manner with reagent bottles and column reactors forming a single unit in the system. The system reduces facility expenditure since it can be installed in a laboratory. The tilted bottle holder allows organized and cost-efficient use of amidite. A rotating column holder that simplifies unpacking of the columns is also included.

Ordering information	
Product	Code No.
ÄKTA oligopilot plus 10	18-1140-42
ÄKta oligopilot plus 100	18-1136-79

For OligoPilot 400 and OligoProcess contact your local representative

OligoProcess

OligoProcess systems are custom-designed for reliable and cost-effective industrial production. They use the same flow-through column technology as the other synthesizers. Production range is from 50 mmol to over 1 mol, or more, of therapeutic oligonucleotides.
The systems are explosion-proof and constructed with industrial grade components that withstand harsh synthesis chemicals. UNICORN control allows rapid scale-up of methods developed on OligoPilot 400.
OligoProcess systems are the world's first, validated industrial scale systems for oligonucleotide production. They are installed and qualified for GMP production by GE Healthcare personnel.

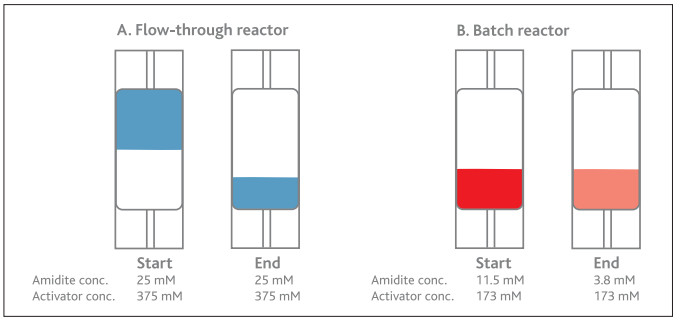
Flow-through technology

The flow-through reactor is a feature common to ÄKTA oligopilot plus, OligoPilot 400 and OligoProcess synthesizers. It is superior to the inefficient batch reactors found in other systems. The better efficiency of a flow-through reactor is due to the way the coupling mixture behaves. The figure illustrates this behavior. Coupling mixture is added to the solid support as a reagent zone (shown in blue) and is pushed through the column as a well-defined zone. Reagents at the front of this zone are consumed by the coupling reaction at a continuous rate. As this zone moves down the reactor, new reagents continuously replace those used. Smooth liquid distribution ensures that coupling efficiencies remain the same, even in different parts of the column. This continuous replacement of consumed reagents by new keeps the concentration constant throughout the zone. Both the amidite concentration and the reaction rate remain the same throughout the reaction.

In a batch reactor, on the other hand, consumed reagents are not replaced. Amidite concentration (red zone) decreases continuously, thus lowering the overall reaction rate. Moreover, flow-through technology delivers three further advantages; its synthesis cycle time is faster, which thus reduces overall production time, it produces less waste and, in combination with high accuracy pumps, it allows more exact control of reagent contact times.

A) Flow-through reactor. The coupling mixture moves down as a reagent zone, continuously replacing reagents consumed by the reaction. The amidite concentration is the same at the end of the reaction as at the beginning.

B) Batch reactor. Reagents consumed by the coupling reaction are not replaced. Amidite concentrations fall to low levels.



The efficiency of the flow-through reactor (A) is superior to that found in a batch reactor (B). At the end of the reaction, when one equivalent has been consumed, the active concentration of amidite in OligoPilot 400 for example, can be more than 6 times higher.

Solid supports

Polystyrene-based supports have been produced by GE Healthcare since the mid-1980's. They allow high scales of synthesis per reaction volume and are suitable for synthesis chemistries that are incompatible or ineffective with glass beads.
These solid supports not only exceed what you can achieve with glass beads, they also enable the synthesis of substantially higher yields of pure full-length products and reduce reagent consumption. A significant cost reduction, in other words.
Our supports are produced in large quantities and are available world-wide via our global distribution network.
For more information visit: **www.primersupport.com**

Primer Support 200

Primer Support 200 is polystyrene-based solid support for synthesizing oligonucleotides. The 30-µm beads are loaded at 200 µmol/g as our standard offering for cost-effective production of therapeutic oligonucleotides (<30 mer). The advantages of this high degree of substitution in the same column volume includelarger-scale synthesis per reaction volume plus lower consumption of reagents and solvents. This can reduce the cost of synthesis by up to 30% compared with conventional controlled-pore glass beads. Primer Support 200 is guaranteed free from BSE/TSE contamination.

- **Cost-effective synthesis**
  Minimal reagent consumption.
  High synthesis scale per reaction volume
  Typically > 125 OD/µmol synthesis scale †.
- **High quality oligonucleotide**
  Typically > 75% full-length †.
  Typically < 4% (n-1) contamination †.
- **Scalable and secure material supply**
  Process development to production-scale synthesis.
  Manufacturing capacities to meet industrial demands.
- **Regulatory support**
  Product support information available for regulatory compliance.
- **For therapeutic oligonucleotide production**
  Reagents and instrumentation for process development. to production Primer Support 200 beads in acetonitrile.

† *Test 20mer sequence used: 5'ATACCGATTAAGCGAAGTTT*

Oligosynt – prepacked disposable columns

Long oligonucleotides (30 to 90 or more bases) are used as probes in analytical or diagnostic methods for applications such as blood testing, gene expression studies and genetic profiling or identification. To ensure optimal purity and yield of long oligonucleotides, GE Healthcare provides Primer Support 200 loaded at nucleoside densities of 40 µmol/g. For convenience and ease of use, the solid support is prepacked in disposable Oligosynt columns that run on ÄKTA oligopilot instruments. Oligosynt combined with ÄKTA oligopilot is well-suited for GMP production of long oligonucleotides.

- **High quality and yield of long oligonucleotides**
  More than 50% pure full-length product ††.
  Less than 4% (n-1) contamination ††.
  More than 300 OD/µmol crude yield ††.
- **Convenience**
  Columns are prepacked and disposable
  UNICORN method templates simplify operation.
  On-column cleavage possibility.
- **Reproducibility and reliability**
  Reproducible performance with each batch of prepacked columns.
  All batches of solid support certified for use in long oligonucleotide synthesis.
- **Long oligonucleotide production**
  Reagents and instrumentation from process development to production syntheses.
  Primer Support regulatory support files available for product registration.
  IQ/OQ installation service available for ÄKTA oligopilot instruments.

†† *Test 60mer sequence used:*
5'ATACCGATTAAGCGAAGTTTATACCGATTAAGCGAAGTTTATACCGATTAAGCGAAGTTT

Custom Primer Support 200

GE Healthcare offers Custom Primer Support 200 to meet your exact needs by coupling with linkers, labels, modified bases, alternative protecting groups or almost any molecule of your choice. The support can be loaded at 20 to 250 µmol/g and delivered in bulk or in prepacked, disposable Oligosynt columns. The A-Z listing at the end of this catalog gives the most frequently requested Custom Primer Support 200 products that are kept in stock for immediate delivery:

Nucleoside Loading µmol/g
DNA (A^{bz}, C^{bz}, G^{ibu}, T): 40, 80, 200
RNA (A^{bz}, C^{bz}, G^{ibu}, U): 40, 80

For more information, please visit **www.primersupport.com** or contact your local GE Healthcare office.

Note: Use of THF-based synthesis reagents from other vendors is NOT recommended for GE Healthcare synthesizers. They may cause irreparable instrument damage.

Cell preparation and processing

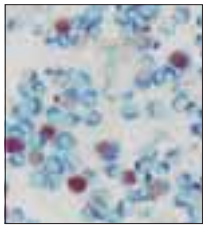
GE Healthcare is one of the world's largest suppliers of density gradient media for cell preparation. Our cell preparation product range is used to isolate lymphocytes, sub-cellular particles and organelles, and large viruses, for example.

Cell preparation using density gradient media is a convenient and reliable technique for isolating and purifying cells, viruses and sub-cellular particles. By centrifuging the cell solution in a medium containing particles that form a sedimentation gradient, cells can be separated according to their density (isopycnic centrifugation) or size (rate zonal centrifugation). Gradients can be either preformed or formed *in situ*. In comparison with other techniques commonly used for cell separation (e.g., fluorescent cell sorters and magnetic beads), density gradient separation offers several important advantages:

- No antibodies or reagents are needed to bind the cells to a matrix. Thus, no such substances risk being carried along with the cells.
- No labeling of the cells is required. Your cells remain in their native state. The technique does not affect their receptors or genetic make-up.
- The method is fast and allows you to work with large volumes.

Ficoll PM400

Ficoll PM400 is a synthetic neutral, highly-branched hydrophilic polymer of sucrose with an average molecular weight of 400 000. It has long been used to form density gradients for separating and isolating eukaryotic cells, organelles and bacterial cells, as a stabilizing agent, and as a preparation medium for isolating lymphocytes. Applications can also be found in defined culture media, nucleic acid hybridization, electrophoresis, and immunological studies.



Ficoll-Paque PREMIUM

Ficoll-Paque PREMIUM is based on Ficoll-Paque PLUS, which has a proven track record as a sterile density medium for the isolation of high yields of mononuclear cells from bone marrow, peripheral blood, and umbilical cord blood. Ficoll-Paque PREMIUM differs from Ficoll-Paque PLUS in that it is manufactured in a strictly controlled environment compliant with ISO 13485:2003 and in accordance with GMP (Good Manufacturing Practice) guidelines and the recommendations of the United States Pharmacopeia for the manufacture of cell therapy products. ISO 13485 and GMP compliance requires stringency in validation and documentation of manufacturing procedures. For technical specifications see Ficoll-Paque PLUS.

Ficoll-Paque PLUS

Ficoll-Paque PLUS is a ready to use, sterile medium for isolation of lymphocytes in high yield from peripheral blood using a simple and rapid centrifugation procedure. It maintains the viability and a representative distribution of B and T lymphocytes. Endotoxin levels are kept very low (<0.12 EU/ml).

Percoll PLUS

New

Percoll PLUS is a sterile density gradient separation medium with low endotoxin level plus low osmolality, toxicity and viscosity. Percoll PLUS comprises silica particles covalently coated with silane and has the same physical properties and features as Percoll, which is cited in nearly 5000 references.

No antibodies or reagents are needed to bind cells with Percoll PLUS, so cells always stay in their native, natural state. Percoll PLUS is also well-suited for making finally-formulated sterile density gradient solutions. Gradient formulations may even be re-sterilized by autoclaving, which helps save time and money.

Percoll PLUS is particularly useful for clinical research applications where its stability and flexibility help provide reproducible results.

Percoll

Percoll is the density gradient medium of choice for thousands of researchers around the world. Percoll's physical characteristics facilitate its use in separating cells, organelles, viruses, and other subcellular particles.

Percoll is especially useful as a first step to enrich cell populations before attempting finer resolution or extracting nucleic acids.

Percoll is used to separate and isolate lymphocytes, monocytes, erythrocytes, neutrophils, liver cells, leydig cells, spermatozoa, bone marrow cells, macrophages, mast cells, mitochondria, granules, plant organelles and many other cells and organelles.

Separation of human blood cells in a gradient of Percoll. Bottom layer contains red blood cells, the middle band is polymorphonuclear cells and top band is mononuclear cells.

AXP AutoXpress Platform

New

AXP AutoXpress Platform is an automated, functionally-closed, sterile system that reduces cord blood volume to a precise 20 ml in less than 40 min, while retaining more than 97% mononucleated cells (MNCs)*. The platform is comprised of the AXP device, docking station, processing set, and XpressTRAK software that assists cGMP and cGTP compliance. A range of accessories is also available.

The microprocessor-controlled AXP device is self-powered by a NiMH battery that is recharged from a docking station concurrent with data downloading. It contains flow-control optical sensors that separate a concentrated MNC fraction of uniform volume (nominally 20 ml). The device fits into standard, refrigerated blood bank centrifuge buckets. Six units of cord blood can be processed at one time.

AXP AutoXpress platform captures data essential for quality assurance and compliance with current good tissue practices (cGTP). XpressTRAK software tracks and documents each cord blood unit's separation data during and after centrifugation.

- Consistently high recoveries of stem-cell rich, MNC cells from cord blood*.
- Simultaneous processing of multiple cord blood units.
- Sterile sample collection through integrated sample pillows.
- Quick and accurate data capture/tracking.
- No HESpan required.

*Data provided by New York Blood Center (97.9%. sd 4.9%).

Ordering information

Product	Quantity	Code No.
AXP Startup Kit[1]	1	28-4044-63
AXP Cell Preparation Device[2]	1	28-4044-58
Docking Station, Main	1	28-4044-59
Docking Station, Satellite	1	28-4044-65
AXP Device Stand	1	28-4044-66
Counterweight	1	28-4044-60
Weight Kit	1	28-4044-62
Processing Set	24	28-4044-64
Weight Compensation Cap	1	28-4044-67
ABC Switch Box	1	28-4044-68
Oval Bucket Adapter	2	28-4044-69
Wireless Barcode Scanner	1	28-4044-70

[1] Includes: AXP device with Weight Compensation Cap, Docking Station-Main, XpressTrak Software, Device Stand, Counterweight, Weight Kit, Wireless Barcode Scanner, and Operator Manual.
[2] Includes: Weight Compensation Cap.

New

BioArchive Cryopreservation System

BioArchive Cryopreservation System is a computer-controlled, liquid nitrogen cryopreservation and storage system that freezes and manages up to 3623 twenty-five ml cord blood samples. It integrates controlled-rate freezing, robotic storage and retrieval into a single automated instrument supported with cGMP-compliant data acquisition and tracking software. By integrating and automating these functions, BioArchive ensures precise sample handling by minimizing operator error. Integration also helps maintain sample integrity by eliminating manual transfer from the CRF to storage, which reduces both the frequency and severity of transient warming events (TWEs).

Sample Management System software tracks samples through barcoding and collects sample history information, which is stored in a fully-searchable database.

BioArchive features an uninterruptible power source. The system includes 24-h surveillance of the liquid nitrogen level and controlled access through password protection and documentation of operator ID in the database.

- Precise, controlled-rate freezing and archiving of cord blood.
- 94% post-thaw cell viability when used in conjunction with the AXP AutoXpress Platform*.
- Robotic storage and retrieval.
- Barcode sample tracking, sample history and inventory control.
- Assistance with cGMP and cGTP compliance.
- Built-in thermal tracking, data management and safeguards.

*Data provided by The New York Blood Center.

Ordering information

Product	Quantity	Code No.
BioArchive Cryopreservation System, 200–240 VAC	1	28-4044-43
BioArchive Cryopreservation System, 100–120 VAC	1	28-4044-44
BioArchive Cryopreservation System, 100 VAC	1	28-4044-45
All BioArchive Cryopreservation Systems include BioArchive unit, user interface computer with software, printer, printer stand, two controlled rate freezers, retrieval cartridge, barcode label printer with morpher and labels, hand held barcode scanner, and magnetic retrieval device.		
Canister Opening Tool	100	28-4044-46
Fill/Seal Jig	1	28-4044-47
Controlled Rate Freezer Module (spare)	1	28-4044-48
Manual Retrieval Device	1	28-4044-49
Advanced Overwrap Sealing System, 110 VAC	1	28-4044-50
Advanced Overwrap Sealing System, 220 VAC	1	28-4044-51
AV-1 Auto Expressor	1	28-4044-52
RF (Sebra) Sealer, 90–240 VAC	1	28-4044-53
Barcode Label Set	1000	28-4044-54
Canisters, 25 ml	100	28-4044-55
Canister Sleeves	100	28-4044-56
Overwrap Bags	100	28-4044-57
Needle Positioning Jig	1	28-4044-71

Microcarriers and systems

Microcarrier selection guide

Industrial-scale cell culture using microcarriers has proven to be reliable and cost-effective for the manufacture of both human and animal healthcare products including viral vaccines, interferons, and animal and human growth hormones. Microcarrier technology can reduce culture medium and serum costs by over 50%, decrease labor and lessen the risk of contamination. Interest in microcarrier technology has grown today to include *in vivo* use in a number of therapeutic applications. GE Healthcare supplies microcarriers for a wide range of applications for cell immobilization, particularly in the area of eucaryotic cell culture. Microcarriers can be used to grow a variety of cell types, and with different hardware investments, or production technology.

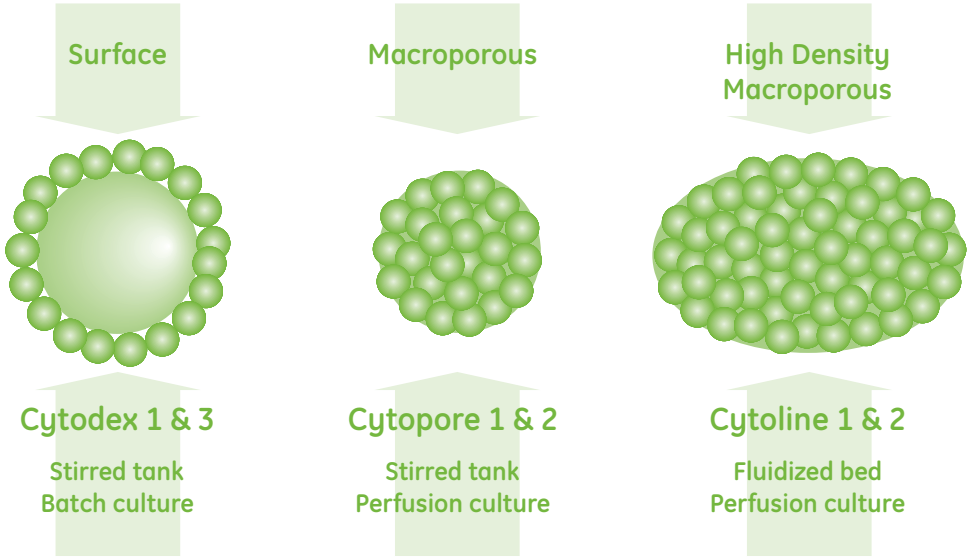
Our range of microcarrier products includes Cytodex, Cytopore, Cytoline and their derivatives.

Quality control

The entire line of microcarriers from GE Healthcare is thoroughly quality controlled, including a function test on all batches with at least one cell type. Certificates of Analysis are available.

Regulatory Support files

Regulatory Support Files have been prepared for Cytodex, Cytopore and Cytoline microcarriers. These files contain information to help industrial scale manufacturers validate their own production processes.



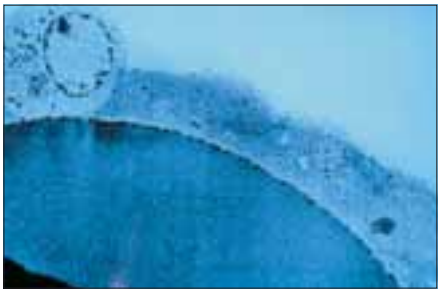
Cytodex 1 and 3

Cytodex microcarriers are based on cross-linked dextran beads. The microporous beads are transparent, spherical and hydrated, and are substituted with positively charged groups. The microcarriers have a mean diameter of 200 µm and a density of 1.04 g/ml. Their small size allows them to be easily transported through tubing. Cytodex has been derivatized to form two types, 1 and 3. Cytodex 3 has been coated with porcine collagen (gelatin).

Cytodex microcarriers are designed for use in stirred tank cultures – homogeneous environments for cell growth in which culture parameters are easily monitored and controlled. Cells grow on the surface of Cytodex, which facilitates inspection, harvesting and infection of the cells. The microporosity of Cytodex enables nutrient supply to all sides of the cells. Cytodex microcarriers are autoclavable at 121°C for 20 minutes.

Application areas

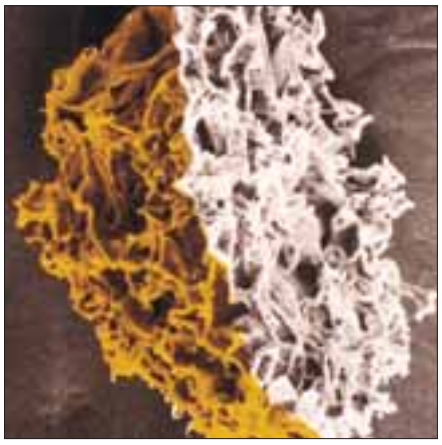
Cytodex is intended for the culture of truly anchorage-dependent cells, a large proportion of which are used in the production of viral vaccines. Another major application for Cytodex is in the production of recombinant proteins. Epithelial and endothelial cells connect through tight junctions and form a cellular layer around the microcarriers.
Cytodex microcarriers are used in batch and perfusion systems, in stirred cultures, and wave bioreactors, as well as to increase the surface area of traditional stationary monolayers and roller cultures.



Transmission electron micrograph of pig kidney cells growing on Cytodex 1.
(Original photograph by B. Meignier and J. Tektoff, IFFA-Mérieux, Lyon, France, reproduced with kind permission.)

Cytopore 1 and 2

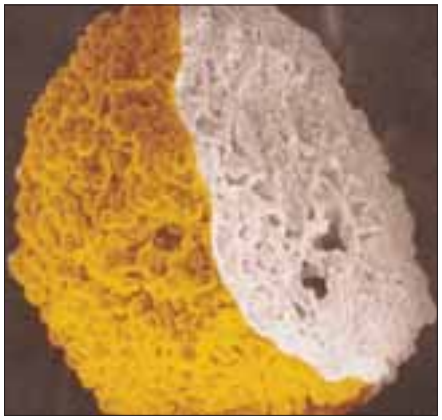
Cytopore microcarriers are hydrophilic DEAE exchangers with a mean diameter of 230 µm and a density of 1.03 g/ml. They are based on a cross-linked cotton cellulose matrix and have an average pore size of 30 µm. The microcarriers are both macroporous and microporous. Cells can enter the interior of the microcarrier where they are protected from shear forces generated by the stirrer, aeration, spin filter or bubbles created through sparging. The microporosity facilitates nutrient supply to all sides of the cells. Cytopore microcarriers are transparent and easily transported through tubing. They can be autoclaved at 121°C for 20 minutes.



The macroporous structure of Cytopore is clearly seen on an "empty" microcarrier.

Application areas

Cytopore 1 has a charge density of 1.0 meq/g and is designed primarily for the production of recombinant CHO cells in stirred tank cultures. Cytopore 2, with a charge density of 1.8 meq/g, is optimized for truly anchorage-dependent cells which require a higher charge capacity for optimal cell growth. Cytopore functions well in the final stages of protein production when anchorage-dependent cells remain on the microcarriers for prolonged periods of time, protected from shear forces. Cytopore is suitable for the culture of other shear-sensitive cells including some hybridomas, insect cells and even some bacteria.



Cytopore 1 filled with CHO cells.

Cytoline 1 and 2

Cytoline microcarriers are based on a matrix of polyethylene and silica. The polyethylene makes the microcarrier hydrophobic while the silica gives it a slightly negative charge. The silica also increases the density of the microcarriers, enabling them to be used in fluidized bed cultures. Cytoline 1 has a density of 1.3 g/ml and Cytoline 2 has a density of 1.03 g/ml. Cytoline microcarriers are macroporous with a pore size between 10 and 400 µm. Cells gain easy access to the interior of Cytoline, where they are protected from shear forces. Since the microcarriers are not microporous, nutrients can only reach the cells through the macroporous structure.

Cytoline microcarriers are lentil-shaped with a length of 2 to 2.5 mm. This size makes their transfer through tubing more difficult, but facilitates their retention in fluidized bed or perfusion cultures.
Weighted Cytoline microcarriers are intended for use in fluidized bed reactors such as Cytopilot Mini, but can also be used in stirred tank, packed bed and suspension cultures. They are autoclavable at 121°C, but melt at higher temperatures.

Application areas

Cytoline 1 is intended for the culture of CHO cells. It can also be used for the culture of other cells that attach well, are less sensitive to shear forces, and require a high circulation rate in the reactor. Cytoline 2 is more suitable for hybridomas and other cells that attach less well. Its lower density requires a lower circulation rate and as a consequence shear forces are less. Cytoline microcarriers can also be used to immobilize insect cells and bacteria.

Cytoline 1 with recombinant CHO attached.

Cytopilot Mini

Cytopilot Mini is a laboratory-scale, fluidized bed reactor designed primarily for cell culture with Cytoline microcarriers. It comprises two chambers divided by a distributor plate. The unique circulation loop runs through both chambers. Oxygen-bearing microbubbles are sparged onto the flow of culture medium that is drawn down through the central circulation loop. During their passage upwards through the fluidized bed, the microbubbles provide a nearly perfect oxygen-buffer function. The microbubbles give the reactor an enormous gas-bearing capacity, preventing gradient formation and creating a homogeneous culture. Cytopilot Mini has a working volume of 2 liters and is well-suited for evaluation studies before scaling up.

Technical data

total volume	2 L
working volume	100–500 ml microcarrier

Magnetic-driven internal recirculation loop. Oxygen supply via microsparger. Standard probe nozzles for electrodes with 25 mm diameter and 70 mm max. length.

Ordering information

Product	Code No.
Cytopilot Mini with motor control	18-1106-35
Cytopilot Mini without motor control	18-1130-37

For large-scale reactors, contact:
Vogelbusch GmbH,
Biopharma
Blechturmgasse 11,
A-1050 Vienna,
Austria.
Tel:+ 43-1-54 661-0
Fax: +43-1-54 661-100

Email: biopharma@vienna.vogelbusch.com
Internet: http://www.vogelbusch.com
Or your nearest GE Healthcare office.

Literature

Data File	Code No.
Cytodex surface microcarriers	18-1060-61
Cytopore macroporous microcarriers	18-1137-68
Cytoline 1 and Cytoline 2, Macroporous microcarriers	18-1060-65
Cytopilot Mini fluidized bed reactor	18-1060-74

Literature

There is a wealth of literature available from GE Healthcare, and most of it is free. These include our product Data Files, Application Notes, well-known chromatography handbooks, and Downstream, our magazine for bioprocessors. Most of these can be found in Acrobat pdf file format on our web site, **www.gehealthcare.com/bioprocess**. In addition, we can help you with reference lists and reprints of articles and scientific posters. Contact us through your local GE Healthcare office or via the web site. We look forward to hearing from you.

Downstream

Downstream is our magazine for customers working in process development and industrial scale separations of biomolecules. Downstream features new technologies, products, applications, and services within both membrane and chromatographic separations technologies, as well as oligonucleotide synthesis and purification.
In addition to our regular magazine, there are a number of special editions of Downstream covering the dedicated conferences sponsored by GE Healthcare.

Ordering information	
	Code No.
Downstream 33	18-1150-32
Downstream 34	18-1159-24
Downstream 35	18-1161-89
Downstream 36	18-1171-05
Downstream 37	11-0008-46
Downstream 38	11-1112-70
Downstream 39	28-4021-59
Downstream 40	28-9022-57

If you are not already on the mailing list and wish to receive Downstream regularly, please contact your nearest GE Healthcare office.

Technique handbooks

These handbooks are designed as an introduction to the principles behind each technique and as a practical guide to the selection and use of the products available from GE Healthcare. They are regularly updated and are frequently used in university education.

Handbooks	Code No.
Gel Filtration: Principles and Methods	18-1022-18
Ion Exchange Chromatography and chromatofocusing: Principles and Methods	11-0004-21
Affinity Chromatography: Principles and Methods	18-1022-29
Hydrophobic Interaction Chromatography & Reversed Phase Chromatography: Principles and Methods	11-0012-69
Protein Purification Handbook	18-1132-29
Microcarrier Cell Culture: Principles and Methods	18-1140-62
Antibody Purification	18-1037-46
The Recombinant Protein Purification Handbook, Principles and Methods	18-1142-75
Percoll (PDF only)	18-1115-69

Data Files, Application Notes and Posters

Data files are available on request for most of our products. These are often complemented with specific technical information or relevant case studies published separately as Application Notes or Posters. You can download many of these in PDF format from our web site. Find them under related literature beside product information.

Books

Preparative Gel Chromatography on Sephadex LH-20.
Henke, H. Hüthig, Heidelburg, 1995, (ISBN 3-7785-2428-3).
This is a comprehensive treatise of how to utilize a "straightforward, universal and powerful" preparative separation technique to separate and purify molecules of a wide variety of low molecular weight organic compounds.

Handbook of Process Chromatography: A Guide to Optimization, Scale-up and Validation 2nd Edition.
Sofer, G., Hagel, L. Academic Press, London, 1997, (ISBN 012654266X).
Over 360 pages of essential reading cover the subject in depth. A chromatography modelling disk is included.

Protein Purification Principles, High Resolution Methods and Applications 2nd Edition.
Edited by J-C. Janson and L. Rydén. Wiley-Liss, New York 1998, (ISBN 0-471-1866260).
Protein Purification provides coverage of chromatographic and electrophoretic protein separation and characterization methods. Balancing theory, procedures and applications, it offers professionals and students in biochemistry, organic chemistry and analytical chemistry quick access to a wide range of important techniques.

Ordering information

Product	Code No.
Preparative Gel Chromatography on Sephadex LH-20	18-1113-89
Handbook of Process Chromatography: A Guide to Optimization, Scale-up and Validation (2nd Edition)	18-1121-56
Protein Purification Principles, High Resolution Methods and Applications (2nd Edition)	18-1128-68

A-Z of media and chemicals

This is an alphabetical listing of our chromatography media and other chemical products for industrial scale applications; it includes technical and ordering information. For laboratory scale media, columns and equipment, and convenience products and kits for research applications, please consult *Products for life sciences 2007 or* web site. Lot number-specific Certificates of Analysis and country-specific Material Safety Data Sheets are available on the internet.

Note: pH stability (operational) = for long term exposure
CIP = Cleaning-in-Place pH for short term exposure
For ion exchangers, the working pH range is dependent on the titration curve. Pressure is given in kPa; conversion as follows (100 kPa = 0.1 MPa = 1 bar = 14.5 psi).

■ = BioProcess Media CDM = Custom Designed Media

CDM 6-AKS Sepharose 4 Fast Flow. See p 40, 53

Pack size	Code No.
1 l	17-3100-04
Regulatory Support File	11-0028-04

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	epoxy
Ligand	carboxylic acid groups on long spacer arm
Ligand density	23–31 µmol carboxylic acid groups/ml drained medium
For coupling to	$-NH_2$
pH stability of medium after coupling	3–13, depending on ligand stability
Pressure/flow spec.	150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

CDM Amino Sepharose 6 Fast Flow. See p 40, 53

Pack size	Code No.
1 l	17-3092-09
Regulatory Support File	11-0028-05

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Coupling chemistry	epoxy
Ligand	amino groups on long spacer arm
Ligand density	~10 µmol primary amino groups/ml drained medium
For coupling to	-COOH, -CHO
Chloride ion capacity	17–22 µmol Cl^-/ml drained medium
pH stability of medium after coupling	3–13, depending on ligand stability
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

■ ANX Sepharose 4 Fast Flow (high sub). See p 53, 96

Pack size	Code No.
25 ml	17-1287-10
500 ml	17-1287-01
5 l	17-1287-04
10 l	17-1287-05
60 l	17-1287-60
Data File	18-1142-25
Regulatory Support File	11-0028-07

Prepacked columns

HiTrap ANX FF (high sub) 5×1 ml	17-5162-01
HiTrap ANX FF (high sub) 5×5 ml	17-5163-01
HiTrap IEX Selection Kit	17-6002-33

Technical data

Composition	highly cross-linked agarose, 4%
Particle size	45–165 µm
Ion capacity	0.13–0.18 mmol Cl^-/ml drained medium
pH stability (operational)	3–13
CIP stability (working)	2–14
Pressure/flow spec.	min 200 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

CDM ANX Sepharose 4 Fast Flow (low sub). See p 53

Pack size	Code No.
500 ml	17-1286-01
5 l	17-1286-04
Regulatory Support File	11-0028-06

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Ion capacity	0.06–0.08 mmol Cl^-/ml drained medium.
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	min 200 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

CDM AVB Sepharose HP. See p 53

Pack size	Code No.
75 ml	28-4112-01
1 l	28-4112-02
Regulatory Support File	11-0029-38

Technical data

Composition	highly cross-linked 6% agarose
Particle size	24–44 µm
Coupling chemistry	NHS
Ligand	protein ligand with affinity for Adeno associated virus

CDM Benzamidine Sepharose 4 Fast Flow (high sub).

See p 40, 53

Pack size	Code No.
25 ml	17-5123-10
100 ml	17-5123-01
500 ml	17-5123-02
5 l	17-5123-03
Regulatory Support File	11-0028-08

Prepacked columns

HiTrap Benzamidine FF (high sub) 5×1 ml	17-5143-01
HiTrap Benzamidine FF (high sub) 2×1 ml	17-5143-02
HiTrap Benzamidine FF (high sub) 1×5 ml	17-5144-01

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	amide linkage (carbodiimide)
Ligand	p-aminobenzamidine
Ligand density	>12 µmol/ml drained medium
Trypsin capacity	>35 mg trypsin/ml packed medium
pH stability (operational)	2–8
CIP stability (short term)	1–9
Pressure/flow spec.	min 150 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

CDM Benzamidine Sepharose 4 Fast Flow (low sub).

See p 53

Pack size	Code No.
100 ml	28-4108-01
5 l	28-4108-03
Regulatory Support File	11-0028-09

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	amide linkage (carbodiimide)
Ligand	p-aminobenzamidine
Ligand density	6–10 µmol/ml drained medium
Trypsin capacity	~25 mg trypsin/ml packed medium
pH stability (operational)	2–8
CIP stability (short term)	1–9
Pressure/flow spec.	min 150 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

Blue Sepharose 6 Fast Flow. See p 38, 40

Pack size	Code No.
50 ml	17-0948-01
500 ml	17-0948-02
1 l	17-0948-03
5 l	17-0948-04
Data File	18-1060-75
Regulatory Support File	11-0028-10

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Ligand	Cibacron Blue F3G-A
Ligand density	~7 µmol Cibacron Blue/ml drained medium
Coupling chemistry	Triazine
Binding capacity	>18 mg HSA/ml drained medium
pH stability (operational)	4–12
CIP stability (short term)	3–13
Pressure/flow spec.	base matrix 200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Butyl Sepharose High Performance. See p 43, 53, 96

Pack size	Code No.
25 ml	17-5432-01
200 ml	17-5432-02
1 l	17-5432-03
5 l	17-5432-04
Regulatory Support File	11-0029-23

Prepacked columns

HiTrap Butyl HP 5×1 ml	28-4110-01
HiTrap Butyl HP 5×5 ml	28-4110-05
HiTrap HIC Selection Kit	28-4110-07

Technical data

Composition	highly cross-linked 6% agarose
Particle size	34 µm average ($d_{50, vol}$)
Ligand	n-butyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	100–200 cm/h, 300 kPa, BioPilot 60/600 column, bed height 30 cm

CDM Butyl Sepharose 6 Fast Flow. See p 43, 53

Pack size	Code No.
1 l	17-5431-03
5 l	17-5431-04

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Coupling chemistry	epoxy
Ligand	n-butyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

Butyl Sepharose 4 Fast Flow. See p 42–43, 96

Pack size	Code No.
25 ml	17-0980-10
200 ml	17-0980-01
500 ml	17-0980-02
5 l	17-0980-04
10 l	17-0980-05
Data File	18-1020-70
Regulatory Support File	11-0028-11

Prepacked columns

HiTrap Butyl FF 5×1 ml	17-1357-01
HiTrap Butyl FF 5×5 ml	17-5197-01
HiTrap HIC Selection Kit	28-4110-07
HiPrep 16/10 Butyl FF 20 ml	17-5096-01

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Ligand	n-butyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	min 150 cm/h, 100 kPa, XK 50/60column, bed height 25 cm.

Butyl-S Sepharose 6 Fast Flow. See p 42–43, 96

Pack size	Code No
25 ml	17-0978-10
200 ml	17-0978-02
1 l	17-0978-03
5 l	17-0978-04
Data file	11-0026-34
Regulatory Support File	11-0028-44

Prepacked columns

HiTrap Butyl-S FF 5×1 ml	17-0978-13
HiTrap Butyl-S FF 5×5 ml	17-0978-14
HiTrap HIC Selection Kit	28-4110-07

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Ligand	butyl-S
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Capto adhere. See p 17–18, 33–36, 92

Pack size	Code No.
25 ml	17-5444-01
100 ml	17-5444-02
1 l	17-5444-03
5 l	17-5444-04
10 l	17-5444-05
60 l	17-5444-06
Regulatory Support File	11-0029-40

Prepacked columns

HiTrap Capto adhere 5×1 ml	28-4058-44
HiTrap Capto adhere 5×5 ml	28-4058-46

Technical data

Ligand type	multimodal strong anion exchanger
Composition	highly cross-linked agarose
Particle size	75 µm ($d_{50v, vol}$)
Ion capacity	0.09–0.12 mmol Cl-/ml medium
pH stability (operational)	3–12
CIP stability	2–14
Pressure/flow spec.	300 kPa at 600 cm/h, 1 m diameter column, 20 cm bed height

Capto MMC. See p 17, 33–36

Pack size	Code No.
25 ml	17-5317-10
100 ml	17-5317-02
1 l	17-5317-03
5 l	17-5317-04
10 l	17-5317-05
60 l	17-5317-60
Data File	11-0035-45
Regulatory Support File	11-0029-30
Prepacked columns	
HiTrap Capto MMC 5×1 ml	11-0032-73
HiTrap Capto MMC 5×5 ml	11-0032-75

Technical data	
Ligand type	multimodal weak cation exchanger
Composition	highly cross-linked agarose
Particle size	75 µm average ($d_{50, vol}$)
Ion capacity	0.07–0.09 mmol H^+/ml medium
pH stability (operational)	3–12
CIP stability	2–14
Pressure/flow spec.	300 kPa at 600 cm/h, 1 m diameter column, 20 cm bed height in water

Capto Q. See p 17, 33–36

Pack size	Code No.
25 ml	17-5316-10
100 ml	17-5316-02
1 l	17-5316-03
10 l	17-5316-05
60 l	17-5316-60
Data File	11-0025-76
Regulatory Support File	11-0028-45
Prepacked columns	
HiTrap Capto Q 5×1 ml	11-0013-02
HiTrap Capto Q 5×5 ml	11-0013-03

Technical data	
Ion exchanger type	Quaternary ammonium strong anion with dextran coating
Composition	highly cross-linked agarose
Particle size	90 µm average ($d_{50, vol}$)
Ion capacity	0.16–0.22 mmol Cl^-/ml medium
pH stability (working)	3–12
CIP stability	2–14
Pressure/flow spec.	300 kPa at 700 cm/h, 1 m diameter column, 20 cm bed height in water

Capto ViralQ. See p 36

Pack size	Code No.
25 ml	28-9032-30
100 ml	28-9032-31
1 l	28-9032-32
Datafile	11-0025-76
Regulatory Support File	11-0028-45
Prepacked columns	
HiTrap Capto ViralQ 5×5 ml	28-9078-09

Technical data	
Ion exchanger type	Quaternary ammonium strong anion with dextran coating
Composition	highly cross-linked agarose
Particle size	90 µm average ($d_{50, vol}$)
Ion capacity	0.16–0.22 mmol Cl^-/ml medium
pH stability (working)	3–12
CIP stability	2–14
Pressure/flow spec.	300 kPa at 700 cm/h, 1 m diameter column, 20 cm bed height in water

Capto S. See p 17–18, 34–36

Pack size	Code No.
25 ml	17-5441-10
100 ml	17-5441-01
1 l	17-5441-03
5 l	17-5441-04
10 l	17-5441-05
60 l	17-5441-60
Datafile	11-0025-76
Regulatory Support File	11-0029-32
Prepacked columns	
HiTrap Capto S 5×1 ml	17-5441-22
HiTrap Capto S 5×5 ml	17-5441-23

Technical data	
Ion exchanger type	Sulfonate, strong cation exchanger with dextran coating
Composition	highly cross-linked agarose
Particle size	90 µm average ($d_{50, vol}$)
Ion capacity	0.10–0.13 mmol Na^+/ml
pH stability (working)	4–12
CIP stability	3–14
Pressure/flow spec.	300 kPa at 700 cm/h, 1 m diameter column, 20 cm bed height in water

CDM Chelating Sepharose Big Beads. See p 53

Pack size	Code No.
1 l	17-5272-03
10 l	17-5272-05
Regulatory Support File	11-0028-12

Technical data

Composition	highly cross-linked 6% agarose
Particle size	100–300 µm
Coupling chemistry	epoxy
Ligand	imino diacetic acid
Metal ion capacity	41–51 µmol copper ion/ml packed medium
pH stability (operational)	3–13
CIP stability (short term)	3–14
Pressure/flow spec.	1200–1800 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Chelating Sepharose Fast Flow. See p 38, 40

Pack size	Code No.
50 ml	17-0575-01
500 ml	17-0575-02
5 l	17-0575-04
Data File	18-1171-41
Regulatory Support File	11-0028-13

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Ligand	iminodiaceticacid groups on spacer
Coupling chemistry	ether
Metal ion capacity	30–37 µmol Cu^{2+}/ml medium
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec	base matrix 200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

CM Sephadex C-25. See p 36

Pack size	Code No.
100 g	17-0210-01
500 g	17-0210-02
5 kg	17-0210-03
Regulatory Support File	11-0028-86

Technical data

Composition	cross-linked dextran
Particle size	wet (in 0.15 M NaCl), 65–235 µm
pH stability (operational)	4–10
CIP stability (short term)	3–13
Pressure/flow spec.	min 120 cm/h, pressure drop cm H_2O/bed height=5, bed height 10 cm, 5 cm i.d.

CM Sephadex C-50. See p 36

Pack size	Code No.
100 g	17-0220-01
500 g	17-0220-02
5 kg	17-0220-03
Regulatory Support File	11-0028-87

Technical data

Composition	cross-linked dextran
Particle size	wet (in 0.15 M NaCl), 110–400 µm
pH stability (operational)	4–10
CIP stability (short term)	3–13
Pressure/flow spec.	min 100 cm/h, pressure drop cm H_2O/bed height=10, bed height 10 cm, 5 cm i.d.

CM Sepharose Fast Flow. See p 37, 96

Pack size	Code No.
25 ml	17-0719-10
500 ml	17-0719-01
10 l	17-0719-05
60 l	17-0719-60
Data File	18-1020-66
Regulatory Support File	11-0028-14

Prepacked columns

HiTrap CM FF 5×1 ml	17-5056-01
HiTrap CM FF 5×5 ml	17-5155-01
HiTrap IEX Selection Kit	17-6002-33
HiPrep 16/10 CM FF 20 ml	17-5091-01

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Binding capacity	50 mg Ribonuclease/ml drained medium
pH stability (operational)	4–13
CIP stability (short term)	2–14
Pressure/flow spec.	300–600 cm/h, 100 kPa, XK 50/30 column, bed height 15 cm

CDM CM Sepharose High Performance. See p 37, 53

Pack size	Code No.
1 l	17-1277-03
5 l	17-1277-04
10 l	17-1277-05
Regulatory Support File	11-0028-15

Technical data

Composition	highly cross-linked 6% agarose
Particle size	24–44 µm
Total capacity H^+	0.06–0.08 mmol/ml medium
pH stability (operational)	4–13
CIP stability (short term)	2–14
Pressure/flow spec.	100–200 cm/h, 300 kPa, BioPilot 60/600 column, bed height 30 cm

CNBr-activated Sepharose 4B.

Pack size	Code No.
15 g	17-0430-01
250 g	17-0430-02
1 kg	17-0430-03
Regulatory Support File	11-0028-16

Technical data

Composition	4% agarose
Particle size	45–165 µm
For coupling to	-NH_2
Activation method	cyanogen bromide (CNBr) activated
Coupling capacity	25–60 mg α-chymotrypsinogen/ml drained medium
pH stability (operational)	3–11, ligand dependent
CIP stability (short term)	3–11, ligand dependent
Pressure/flow spec	base matrix 70–140 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, 5 cm i.d.

CNBr-activated Sepharose 4 Fast Flow. See p 38, 40

Pack size	Code No.
10 g	17-0981-01
250 g	17-0981-03
2 kg	17-0981-05
Data File	18-1113-55
Regulatory Support File	11-0028-16

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
For coupling to	-NH_2
Activation method	cyanogen bromide (CNBr) activated
Coupling capacity	13–26 mg α-chymotrypsinogen/ml drained medium
pH stability (operational)	3–11, ligand dependent
CIP stability (short term)	3–11, ligand dependent
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Con A Sepharose 4B. See p 40

Pack size	Code No.
5 ml	17-0440-03
100 ml	17-0440-01
500 ml	17-0440-02
5 l	17-0440-04

Technical data

Composition	4% agarose
Particle size	45–165 µm
Ligand	Concanavalin A
Ligand density	10–16 mg Con A/ml drained medium
Coupling chemistry	CNBr
pH stability (operational)	4–9
CIP stability (short term)	4–9
Pressure/flow spec	base matrix 70–140 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, 5 cm i.d.

Cytodex 1. See p 154–155

Pack size	Code No.
25 g	17-0448-01
100 g	17-0448-02
500 g	17-0448-03
2.5 kg	17-0448-25
5 kg	17-0448-04
Data File	18-1060-61
Regulatory Support File	11-0028-70

Technical data

Density*	1.03 g/ml in 0.9% NaCl
Particle size*	d_{50} 190 µm
Particle size*	d_{5-95} 147–248 µm
Approx. area*	4 400 cm^2/g dry weight
Approx. no. microcarriers	4.3×10^6 g/dry weight swelling* 20 ml/g dry weight

* In 0.9% NaCl

Cytodex 3. See p 154–155

Pack size	Code No.
10 g	17-0485-01
100 g	17-0485-02
500 g	17-0485-03
2.5 kg	17-0485-25
5 kg	17-0485-04
Data File	18-1060-61
Regulatory Support File	11-0028-72

Technical data

Density*	1.04 g/ml in 0.9% NaCl
Particle size*	175 µm
Particle size*	d_{5-95} 141–211 µm
Approx. area*	2 700 cm^2/g dry weight
Approx. no. microcarriers	3×10^6 g/dry weight swelling* 15 ml/g dry weight

* In 0.9% NaCl

Note: For Cytodex, size is based on diameter at 50% of the volume of a sample of microcarriers (d_{50}), or the range between the diameter at 5% and 95% of the volume of a sample of microcarriers (d_{5-95}). This size is calculated from cumulative volume distributions.

Cytoline 1. See p 154, 156

Pack size	Code No.
50 ml	17-1268-01
500 ml	17-1268-02
5 l	17-1268-03
Data File	18-1060-65
Regulatory Support File	11-0028-74

Technical data

Sedimentation velocity	120–220 cm/min
Length	1.7–2.5 mm
Thickness	0.4–1.1 mm
Density	1.32 g/ml
Pore size	10–400 µm
Surface area	>0.3 m^2/g

Cytoline 2. See p 154, 156

Pack size	Code No.
50 ml	17-1269-01
500 ml	17-1269-02
5 l	17-1269-03
Data File	18-1060-65
Regulatory Support File	11-0028-74

Technical data

Sedimentation velocity	25–75 cm/min
Length	1.7–2.5 mm
Thickness	0.4–1.1 mm
Density	1.03 g/ml
Pore size	10–400 µm
Surface area	>0.1 m^2/g

Cytopore 1. See p 154, 156

Pack size	Code No.
20 g	17-0911-01
100 g	17-0911-02
500 g	17-0911-03
Data File	18-1132-68
Regulatory Support File	11-0028-73

Technical data

Particle diameter	200–280 nm**
Effective surface area	1.1 m^2/g dry weight
Density	1.03 g/ml**
Average diameter of pore openings	30 µm**
Volume	40 ml/g dry weight

* In 0.9% NaCl

** Data from Ashai Chemical Industry Co. Ltd., Japan

Cytopore 2. See p 154, 156

Pack size	Code No.
20 g	17-1271-01
100 g	17-1271-02
500 g	17-1271-03
1 kg	17-1271-04
Data File	18-1132-68
Regulatory Support File	11-0028-73

Technical data

Particle diameter	200–280 nm**
Effective surface area	1.1 m^2/g dry weight
Density	1.03 g/ml**
Average diameter of pore openings	30 µm**
Volume	40 ml/g dry weight

** Data from Ashai Chemical Industry Co. Ltd., Japan

DEAE Sephadex A-25. See p 36

Pack size	Code No.
100 g	17-0170-01
500 g	17-0170-02
5 kg	17-0170-03
40 kg	17-0170-07
Data File	18-1117-58
Regulatory Support File	11-0028-17

Technical data

Composition	cross-linked dextran
Particle size	wet (in 0.15 M NaCl), 45–190 µm
pH stability (operational)	2–10
CIP stability (short term)	2–13
Pressure/flow spec.	min 120 cm/h, pressure drop cm H_2O/bed height=5, bed height 10 cm, 5 cm i.d.

DEAE Sephadex A-50. See p 36

Pack size	Code No.
100 g	17-0180-01
500 g	17-0180-02
5 kg	17-0180-03
Data File	18-1117-58
Regulatory Support File	11-0028-17

Technical data

Composition	cross-linked dextran
Particle size	wet (in 0.15 M NaCl), 100–370 µm
pH stability (operational)	2–10
CIP stability (short term)	2–13
Pressure/flow spec.	min 60 cm/h, pressure drop cm H_2O/bed height=10, bed height 10 cm, 5 cm i.d.

DEAE Sepharose Fast Flow. See p 37, 96

Pack size	Code No.
25 ml	17-0709-10
500 ml	17-0709-01
10 l	17-0709-05
60 l	17-0709-60
IEX Selection Kit	17-0939-01
Data File	18-1020-66
Regulatory Support File	11-0028-18

Prepacked columns

HiTrap DEAE FF 5×1 ml	17-5055-01
HiTrap DEAE FF 5×5 ml	17-5154-01
HiTrap IEX Selection Kit	17-6002-33
HiPrep 16/10 DEAE FF 20 ml	17-5090-01

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Binding capacity	110 mg HSA/ml drained medium
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	300–600 cm/h, 100 kPa, XK 50/30 column, bed height 15 cm

CDM ECH-Lysine Sepharose 4 Fast Flow. See p 40, 53

Pack size	Code No.
500 ml	17-0902-02
5 l	17-0902-04
Regulatory Support File	11-0029-28

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	NHS
Ligand	L-lysine
Ligand density	~16 µmol/ml drained medium
pH stability (operational)	3–12
CIP stability (short term)	2–13
Pressure/flow spec.	150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

Epoxy-activated Sepharose 6B. See p 40

Pack size	Code No.
15 g	17-0480-01
250 g	17-0480-03

Technical data

Composition	6% agarose
Particle size	45–165 µm
For coupling to	-NH_2, -OH, -SH
Active groups	epoxy groups on 12-atom spacer
Amount of active groups	19–40 µmol epoxy groups/ml drained medium
pH stability (operational)	3–13, ligand dependent
CIP stability (short term)	3–13, ligand dependent
Pressure/flow spec	base matrix 100–200 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, 5 cm i.d.

Ficoll PM400. See p 151

Pack size	Code No.
100 g	17-0300-10
500 g	17-0300-50
5 kg	17-0300-05
40 kg	17-0300-08

Technical data

Composition	sucrose polymer
Molecular weight	3×10^5 to 5×10^5
Specific rotation	+50 to +65 degrees
Stokes radius	10 nm

Ficoll-Paque PLUS. See p 151

Pack size	Code No.
6×100 ml	17-1440-02
6×500 ml	17-1440-03

Technical data

Composition	Solution containing Ficoll PM400 and sodium diatrizoate
Density	1.077 ± 0.001 g/ml,

Ficoll-Paque PREMIUM. See p 151

Pack size	Code No.
6×100 ml	17-5442-02
6×500 ml	17-5442-03
Regulatory Support File	11-0029-36

Technical data

Composition	Solution containing Ficoll PM400 and sodium diatrizoate
Density	1.077 ± 0.001 g/ml,

GammaBind G Type 2.

Pack size	Code No.
1 g	17-0884-06
10 g	17-0884-08
50 g	17-0884-99

CDM Gelatin Sepharose 4 Fast Flow. See p 40, 53

Pack size	Code No.
1 l	17-0976-03
5 l	17-0976-04
Regulatory Support File	11-0029-37

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	CNBr
Ligand	bovine gelatin derivative
Ligand density	~5 mg/ml drained medium
Pressure/flow spec.	150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

Glutathione Sepharose 4 Fast Flow. See p 40

Pack size	Code No.
25 ml	17-5132-01
100 ml	17-5132-02
500 ml	17-5132-03
Data File	18-1136-89

Prepacked columns

GSTPrep FF 16/10	17-5234-01
GSTrap FF 5×1 ml	17-5130-01
GSTrap FF 2×1 ml	17-5130-02
GSTrap FF 100×1 ml*	17-5130-05
GSTrap FF 1×5 ml	17-5131-01
GSTrap FF 5×5 ml	17-5131-02
GSTrap FF 100×5 ml*	17-5131-05
GST MultiTrap FF, 96-well prepacked plate, 4 plates	28-4055-01

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Ligand	glutathione
Ligand density	120–320 µmol glutathione/ml drained medium
Coupling chemistry	epoxy
Binding capacity	~10 mg recombinant GST/ml medium, protein dependent
pH stability	3–12
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

*Special pack size delivered on specific customer order.

Heparin Sepharose 6 Fast Flow. See p 40

Pack size	Code No.
50 ml	17-0998-01
250 ml	17-0998-25
1 l	17-0998-03
5 l	17-0998-04
Data File	18-1060-76
Regulatory Support File	11-0028-19

Prepacked columns

HiPrep 16/10 Heparin FF	17-5189-01

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Ligand	heparin
Ligand density	~4 mg heparin/ml drained medium
Coupling chemistry	reductive amination
pH stability (operational)	4–12
CIP stability (short term)	4–13
Pressure/flow spec	base matrix 200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

CDM IgG Sepharose 6 Fast Flow. See p 53

Pack size	Code No.
10 ml	17-0969-01
200 ml	17-0969-02
5 l	17-0969-04

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Coupling chemistry	CNBr
Ligand	human polyclonal IgG
Capacity	~5 mg Protein A/ml drained medium
pH stability (operational)	3–10
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

IMAC Sepharose 6 Fast Flow. See p 40

Pack size	Code No.
25 ml	17-0921-07
100 ml	17-0921-08
1 l	17-0921-09
5 l	17-0921-10
Data File	28-4041-06
Regulatory Support File	11-0029-31

Prepaced columns

HiTrap IMAC FF 5×1 ml	17-0921-02
HiTrap IMAC FF 5×5 ml	17-0921-04
HiPrep IMAC FF 16/10	17-0921-06

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Metal ion capacity	~15 µmol Ni^{2+}/ml drained medium
Dynamic binding capacity	~40 mg histidine-tagged protein/ml medium, protein and metal ion dependent
pH stability (operational)	3–12
pH stability (short term)	2–14
Pressure/flow spec.	base matrix 200-400 cm/h, 100 kPa, XK50/60 column, bed height 25 cm

Lentil Lectin Sepharose 4B. See p 40

Pack size	Code No.
25 ml	17-0444-01
1 l	17-0444-03
Regulatory Support File	11-0028-92

Technical data

Composition	4% agarose
Particle size	45–165 µm
Ligand	lentil lectin
Ligand density	~2 mg lentil lectin/ml drained medium
Coupling chemistry	CNBr
pH stability (operational)	3–10
CIP stability (short term)	3–10
Pressure/flow spec	base matrix 70–140 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm cm, 5 cm i.d.

MabSelect. See p 16, 39–40

Pack size	Code No.
25 ml	17-5199-01
200 ml	17-5199-02
1 l	17-5199-03
5 l	17-5199-04
10 l	17-5199-06
Data File	18-1149-94
Regulatory Support File	11-0028-20
Prepacked columns	
HiTrap MabSelect 5×1 ml	28-4082-53
HiTrap MabSelect 1×5 ml	28-4082-55
HiTrap MabSelect 5×5 ml	28-4082-56

Technical data

Composition	highly cross-linked agarose
Particle size	d_{50v} ~85 µm
Ligand	recombinant Protein A (*E. coli*)
Coupling chemistry	epoxy
Dynamic binding capacity	min 30 mg human IgG/ml medium at 2.4 min residence time
pH stability (operational)	3–10
CIP stability (short term)	2–12
Pressure/flow spec	up to 500 cm/h, < 200 kPa, BPG 300, bed height 20 cm

MabSelect SuRe. See p 13, 16, 39–40

Pack size	Code No.
25 ml	17-5438-01
200 ml	17-5438-02
1 l	17-5438-03
5 l	17-5438-04
10 l	17-5438-05
Data File	11-0011-65
Regulatory Support File	11-0029-18
Prepacked columns	
HiTrap MabSelect SuRe 5×1 ml	11-0034-93
HiTrap MabSelect SuRe 1×5 ml	11-0034-94
HiTrap MabSelect SuRe 5×5 ml	11-0034-95
Prepacked Tricorn 10/100 GL MabSelect SuRe	Inquire

Technical data

Composition	highly cross-linked agarose
Particle size	d_{50v} ~85 µm
Ligand	alkali-stabilized Protein A-derived (*E.coli*)
Coupling chemistry	epoxy
Dynamic binding capacity	min 30 mg human IgG/ml medium at 2.4 min residence time
pH stability (operational)	3–12
CIP stability (short term)	0.1–0.5 M NaOH
Pressure/flow spec	up to 500 cm/h, < 200 kPa, BPG 300, bed height 20 cm

MabSelect Xtra. See p 16, 39–40, 169

Pack size	Code No.
25 ml	17-5269-07
200 ml	17-5269-02
1 l	17-5269-03
5 l	17-5269-04
10 l	17-5269-05
60 l	17-5269-06
Data File	11-0011-57
Regulatory Support File	11-0029-17
Prepacked columns	
HiTrap MabSelect Xtra 5×1 ml	28-4082-58
HiTrap MabSelect Xtra 1×5 ml	28-4082-60
HiTrap MabSelect Xtra 5×5 ml	28-4082-61
Prepacked Tricorn 10/100 GL MabSelect Xtra	Inquire

Technical data

Composition	highly cross-linked agarose
Particle size	d_{50v} ~75 µm
Ligand	recombinant Protein A (*E.coli*)
Coupling chemistry	epoxy
Dynamic binding capacity	approx. 40 mg human IgG/ml medium at 2.4 min residence time
pH stability (operational)	3–10
CIP stability (short term)	2–12
Pressure/flow spec	up to 300 cm/h, < 200 kPa, BPG 300, bed height 20 cm

MacroCap SP. See p 13, 34, 36

Pack size	Code No.
25 ml	17-5440-10
100 ml	17-5440-01
1 l	17-5440-02
5 l	17-5440-03
10 l	17-5440-05
60 l	17-5440-60
Data File	28-4005-84
Regulatory Support File	11-0029-33

Technical data

Composition	Cross-linked co-polymer of allyl dextran and N,N-methylene bisacrylamide
Particle size	50 µm (d_{50v})
Ion exchanger type	Strong cation
Charged group	SO_3^-
Total ionic capacity	0.10–0.13 mmol H^+/ml medium
Recommended separation range	a) proteins in excess of 150 kDa b) functionalized Dextrans or PEGs ≥ 20 000 MW c) PEG-proteins containing ≥ 10000 PEG (total) per conjugate
pH stability (operational)	3–12
pH stability (short term)	2–13
pH stability (long term)	4–11
CIP stability	2–13
Chemical stability	all commonly used aqueous buffers, 0.1 M citric acid, 0.5 M NaOH, 25% ethanol, 30% propanol, 30% methanol, 50% ethylene glycol, 1% Tween 20, 1% SDS.
Flow velocity	120 cm/h in BPG 300 columns with 20 cm bed height at 20°C using process buffers with the same viscosity as water at < 300 kPa.

NHS-activated Sepharose 4 Fast Flow. See p 38, 40

Pack size	Code No.
25 ml	17-0906-01
500 ml	17-0906-02
5 l	17-0906-04
Data File	18-1113-53
Regulatory Support File	11-0028-21

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
For coupling to	$-NH_2$
Active groups	NHS ester on 14-atom spacer
Amount of active groups	~18 µmol NHS/ml drained medium
pH stability (operational)	3–13, ligand dependent
CIP stability (short term)	3–13, ligand dependent
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Ni Sepharose 6 Fast Flow. See p 38, 40

Pack size	Code No.
5 ml	17-5318-06
25 ml	17-5318-01
100 ml	17-5318-02
500 ml	17-5318-03
1 l	17-5318-04
5 l	17-5318-05
Data File	11-0008-86
Regulatory Support File	11-0028-43

Prepacked columns

HisTrap FF 5×1 ml	17-5319-01
HisTrap FF 100×1 ml*	17-5319-02
HisTrap FF 5×5 ml	17-5255-01
HisTrap FF 100×5 ml*	17-5255-02
HisPrep FF 16/10	17-5256-01
His GraviTrap 10×1 ml	11-0033-99
His GraviTrap Kit (20×1 ml + buffers)	28-4013-51
His MultiTrap FF, 96-well prepacked plate, 4 plates	28-4009-90

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Metal ion capacity	~15 µmol Ni^{2+}/ml medium
Dynamic binding capacity	~40 mg histidine-tagged protein/ml medium, protein dependent
pH stability (operational)	3–12
CIP stability (short term)	2–14
Pressure/flow spec	base matrix 200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

*Special pack size delivered on specific customer order.

Octyl Sepharose 4 Fast Flow. See p 42–43, 96

Pack size	Code No.
25 ml	17-0946-10
200 ml	17-0946-02
1 l	17-0946-03
5 l	17-0946-04
Data File	18-1060-38
Regulatory Support File	11-0028-22

Prepacked columns

HiTrap HIC Selection Kit	28-4110-07
HiTrap Octyl FF 5×1 ml	17-1359-01
HiTrap Octyl FF 5×5 ml	17-5196-01
HiPrep 16/10 Octyl FF 20 ml	17-5097-01

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Ligand	n-octyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Oligosynt.

See Solid supports for oligonucleotide synthesis

Percoll. See p 152

Pack size	Code No.
250 ml	17-0891-02
1 l	17-0891-01
6×1 l	17-0891-09

Technical data

Composition	Silica coated with polyvinylpyrrolidone (PVP)
Particle diameter	15–30 nm
Density	1.13 ±0.005 g/ml
Conductivity, max.	100 mS/m
Osmolality, max.	25 mOsm/kg
Viscosity	10 ±5 cP at 20°C
pH	9.0 ±0.5 at 20°C

Percoll PLUS. See p 27, 152

Pack size	Code No.
250 ml	17-5445-02
1 l	17-5445-01
Regulatory Support File	11-0029-39

Technical data

Composition	Silica with covalently linked silane
Particle diameter	15–30 nm
Density	1.13–0.005 g/ml
Osmolality, max.	30 mOsm/kg
Viscosity, max.	15 cP

CDM Phenyl Sepharose Big Beads. See p 43, 53

Pack size	Code No.
1 l	17-5098-03
10 l	17-5089-05
Regulatory Support File	11-0028-25

Technical data

Composition	highly cross-linked 6% agarose
Particle size	100–300 µm
Ligand	phenyl
Coupling chemistry	epoxy
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	1 200–1 800 cm/h 100 kPa, XK 50/60 column, bed height 25 cm.

Phenyl Sepharose 6 Fast Flow (high sub). See p 42–43

Pack size	Code No.
25 ml	17-0973-10
200 ml	17-0973-05
1 l	17-0973-03
5 l	17-0973-04
10 l	17-0973-06
60 l	17-0973-60
Data File	18-1020-53
Regulatory Support File	11-0028-23

Prepacked columns

HiTrap HIC Selection Kit	28-4110-07
HiTrap Phenyl FF (high sub) 5×1 ml	17-1355-01
HiTrap Phenyl FF (high sub) 5×5 ml	17-5193-01
HiPrep 16/10 Phenyl FF (high sub)	17-5095-01

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Ligand	phenyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Phenyl Sepharose 6 Fast Flow (low sub). See p 42–43

Pack size	Code No.
25 ml	17-0965-10
200 ml	17-0965-05
1 l	17-0965-03
5 l	17-0965-04
Data File	18-1020-53
Regulatory Support File	11-0028-23

Prepacked columns

HiTrap HIC Selection Kit	28-4110-07
HiTrap Phenyl FF (low sub) 5×1 ml	17-1353-01
HiTrap Phenyl FF (low sub) 5×5 ml	17-5194-01
HiPrep 16/10 Phenyl FF (low sub) 20 ml	17-5094-01

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Ligand	phenyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Phenyl Sepharose High Performance. See p 43

Pack size	Code No.
75 ml	17-1082-01
1 l	17-1082-03
5 l	17-1082-04
Data File	18-1020-56
Regulatory Support File	11-0028-24

Prepacked columns

HiLoad 16/10 Phenyl Sepharose HP	17-1085-01
HiLoad 26/10 Phenyl Sepharose HP	17-1086-01
HiTrap HIC Selection Kit	28-4110-07
HiTrap Phenyl HP 5×1 ml	17-1351-01
HiTrap Phenyl HP 5×5 ml	17-5195-01

Technical data

Composition	highly cross-linked 6% agarose
Particle size	34 µm average ($d_{50, vol}$)
Ligand	phenyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Max pressure	300 kPa

PlasmidSelect Xtra. See p 19, 45, 92, 96

Pack size	Code No.
PlasmidSelect Xtra Screening Kit	28-4052-69
PlasmdiSelect Xtra Starter Kit	28-4052-68
25 ml	28-4024-02
1 l	28-4024-03
5 l	28-4024-04
Data File	28-4094-87
Regulatory Support File	11-0029-34

Technical data

Composition	highly cross-linked 6% agarose
Particle size	24–44 µm
Ligand	2-mercaptopyridine
Ligand concentration	3.5 mg/ml
Capacity for supercoiled pDNA (6125 bp)	>2 mg/ml
pH stability (operational)	3–11
CIP stability (short term)	2–13
Cleaning-in-place	0.5 M NaOH
Flow velocity for supercoiled plasmid purification	<120 cm/h, XK 16/20 column, bed height 15 cm

CDM Plasminogen Removal Gel. See p 53

Pack size	Code No.
1 l	28-4109-03
Regulatory Support File	11-0029-29

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	epoxy
Ligand	Tranexamic acid
Ligand density	9–13 µmol/ml drained medium
pH stability (operational)	3–12
CIP stability (short term)	2–14
Pressure/flow spec.	150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

Primer Support 200. See p 150

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Protein A. See p 39

Pack size	Code No.
50 mg	17-0872-50
1 g	17-0872-01
10 g	17-0872-02

CDM Procainamide Sepharose 4 Fast Flow. See p 53

Pack size	Code No.
1 l	28-4111-03
5 l	28-4111-04

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	amide linkage (carbodiimide)
Ligand	procainamide
Ligand density	approx. 23 µmol/ml drained medium
Pressure/flow spec	min 150 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

nProtein A Sepharose 4 Fast Flow. See p 40

Pack size	Code No.
5 ml	17-5280-01
25 ml	17-5280-04
200 ml	17-5280-02
1 l	17-5280-03
5 l	17-5280-05
10 l	17-5280-06
Data File	18-1125-19
Regulatory Support File	11-0029-19

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Ligand	Protein A from *Staphylococcus aureus*
Coupling chemistry	CNBr
pH stability (operational)	3–9
CIP stability (short term)	2–10
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

rProtein A Sepharose 4 Fast Flow. See p 40

Pack size	Code No.
5 ml	17-1279-01
25 ml	17-1279-02
200 ml	17-1279-03
1 l	17-1279-04
5 l	17-1279-05
10 l	17-1279-06
Data File	18-1113-94
Regulatory Support File	11-0028-35

Prepacked columns

HiTrap rProtein A FF 5×1 ml	17-5079-01
HiTrap rProtein A FF 2×1 ml	17-5079-02
HiTrap rProtein A FF 1×5 ml	17-5080-01
HiTrap rProtein A FF 5×5 ml	17-5080-02

Technical data

Composition	highly cross-linked 4% agarose
Particle size	60–165 µm
Ligand	recombinant Protein A from *E. coli*
Coupling chemistry	epoxy
Dynamic binding capacity	min 27 mg human IgG/ml medium at 3 min residence time
pH stability (operational)	3–10
CIP stability (short term)	2–11
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

rmp Protein A Sepharose Fast Flow. See p 40

Pack size	Code No.
5 ml	17-5138-01
25 ml	17-5138-02
200 ml	17-5138-03
1 l	17-5138-04
5 l	17-5138-05
Data File	18-1141-34
Regulatory Support File	11-0029-25

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Ligand	recombinant Protein A from *E. coli*
Coupling chemistry	reductive amination
Dynamic binding capacity	min 22 mg human IgG/ml medium at 3 min residence time
pH stability (operational)	3–10
CIP stability (short term)	2–11
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Protein G.

Pack size	Code No.
5 mg	17-0619-01
1 g	17-0619-09
10 g	17-0619-10

Protein G Sepharose 4 Fast Flow. See p 40

Pack size	Code No.
5 ml	17-0618-01
25 ml	17-0618-02
200 ml	17-0618-05
1 l	17-0618-06
5 l	17-0618-04
Data File	18-1012-91
Regulatory Support File	11-0028-29

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Ligand	recombinant Protein G from *E. coli*
Ligand density	~2 mg protein G/ml drained medium
Coupling chemistry	CNBr
pH stability (operational)	3–9
CIP stability (short term)	2–10
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Q Sepharose Big Beads. See p 36, 96

Pack size	Code No.
1 l	17-0989-03
10 l	17-0989-05
60 l	17-0989-60
IEX Selection Kit	17-0939-01
Data File	18-1104-91
Regulatory Support File	11-0028-32

Technical data

Composition	highly cross-linked 6% agarose
Particle size	100–300 µm
Ion capacity	0.18–0.25 mmol Cl^-/ml medium
pH stability (operational)	2–12
CIP stability (short term)	2–14
Pressure/flow spec.	1 200–1 800 cm/h, 100 kPa, XK50/60 column, bed height 25 cm

Q Sepharose Fast Flow. See p 37, 96

Pack size	Code No.
25 ml	17-0510-10
300 ml	17-0510-01
5 l	17-0510-04
10 l	17-0510-05
60 l	17-0510-60
IEX Selection Kit	17-0939-01
Data File	18-1020-66
Regulatory Support File	11-0028-30

Prepacked columns

HiTrap Q FF 5×1 ml	17-5053-01
HiTrap Q FF 5×5 ml	17-5156-01
HiPrep 16/10 Q FF	17-5190-01
HiTrap IEX Selection Kit	17-6002-33

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Binding capacity	120 mg HSA/ml drained medium
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	400–700 cm/h, 100 kPa, XK 50/30 column, bed height 15 cm.

Q Sepharose High Performance. See p 37, 96

Pack size	Code No.
75 ml	17-1014-01
1 l	17-1014-03
5 l	17-1014-04
10 l	17-1014-05
Data File	18-1020-69
Regulatory Support File	11-0028-31

Prepacked columns

HiLoad 16/10 Q Sepharose High Performance	17-1064-01
HiLoad 26/10 Q Sepharose High Performance	17-1066-01
HiTrap Q HP 5×1 ml	17-1153-01
HiTrap Q HP 5×5 ml	17-1154-01
HiTrap IEX Selection Kit	17-6002-33

Technical data

Composition	cross-linked agarose
Particle size	34 µm average ($d_{50, vol}$)
Binding capacity	120 mg HSA/ml drained medium
pH stability (operational)	3–12
CIP stability (short term)	2–14
Pressure/flow spec.	min 75 cm/h, 250 kPa, BioPilot 60/100 column, bed height 30 cm

Q Sepharose XL. See p 37, 96

Pack size	Code No.
300 ml	17-5072-01
5 l	17-5072-04
10 l	17-5072-05
60 l	17-5072-60
Data File	18-1123-82
Regulatory Support File	11-0028-33

Prepacked columns

HiPrep 16/10 Q XL	17-5092-01
HiTrap Q XL 5×1 ml	17-5158-01
HiTrap Q XL 5×5 ml	17-5159-01
HiTrap IEX Selection Kit	17-6002-33

Technical data

Composition	cross-linked 6% agarose with dextran coating
Particle size	45–165 µm
Binding capacity	>130 mg bovine serum albumin/ml medium
pH stability (operational)	2–12
CIP stability (working)	2–14
Flow rate	300–500 cm/h

Q Sepharose XL virus licensed. See p 37

Pack size	Code No.
25 ml	17-5437-10
300 ml	17-5437-01
1 l	17-5437-03
5 l	17-5437-04
Regulatory Support File	11-0028-33

Technical data

Composition	cross-linked 6% agarose with dextran coating
Particle size	45–165 µm
Binding capacity	>130 mg bovine serum albumin/ml medium
pH stability (operational)	2–12
CIP stability (working)	2–14
Flow rate	300–500 cm/h

QAE Sephadex A-25. See p 36

Pack size	Code No.
100 g	17-0190-01
500 g	17-0190-02
5 kg	17-0190-03
Data File	18-1117-58
Regulatory Support File	11-0028-96

Technical data

Composition	cross-linked dextran
Particle size	dry 40–125 µm
pH stability (operational)	2–10
CIP stability (short term)	2–13
Pressure/flow spec.	min 100 cm/h, pressure drop cm H_2O/bed height=5, bed height 10 cm, 5 cm i.d.

QAE Sephadex A-50. See p 36

Pack size	Code No.
100 g	17-0200-01
5 kg	17-0200-03
Data File	18-1117-58
Regulatory Support File	11-0028-97

Technical data

Composition	cross-linked dextran
Particle size	dry 40–125 µm
pH stability (operational)	2–10
CIP stability (short term)	2–13
Pressure/flow spec.	min 60 cm/h, pressure drop cm H_2O/bed height=10, bed height 10 cm, 5 cm i.d.

Sephacryl S-100 High Resolution. See p 50–51, 94

Pack size	Code No.
150 ml	17-0612-10
750 ml	17-0612-01
10 l	17-0612-05
Data File	18-1009-28
Regulatory Support File	11-0028-36

Prepacked columns

HiPrep 16/60 Sephacryl S-100 HR	17-1165-01
HiPrep 26/60 Sephacryl S-100 HR	17-1194-01

Technical data

Composition	allyl dextran and N,N´-methylene bisacrylamide
Particle size	50 µm
Fractionation range, globular proteins	1×10^3–1×10^5
pH stability (operational)	3–11
CIP stability (short term)	2–13
Pressure/flow spec.	flow at 100 kPa >125 cm/h, XK 50/30 column, bed height 15 cm

Sephacryl S-200 High Resolution. See p 50–51, 94

Pack size	Code No.
150 ml	17-0584-10
750 ml	17-0584-01
10 l	17-0584-05
60 l	17-0584-60
Data File	18-1009-28
Regulatory Support File	11-0028-36

Prepacked columns

HiPrep 16/60 Sephacryl S-200 HR	17-1166-01
HiPrep 26/60 Sephacryl S-200 HR	17-1195-01

Technical data

Composition	allyl dextran and N,N´-methylene bisacrylamide
Particle size	50 µm
Fractionation range, globular proteins	5×10^3–2.5×10^5
pH stability (operational)	3–11
CIP stability (short term)	2–13
Pressure/flow spec.	flow at 100 kPa >150 cm/h, XK 50/30 column, bed height 15 cm

Sephacryl S-300 High Resolution. See p 50–51, 94

Pack size	Code No.
150 ml	17-0599-10
750 ml	17-0599-01
10 l	17-0599-05
Data File	18-1009-28
Regulatory Support File	11-0028-36

Prepacked columns

HiPrep 16/60 Sephacryl S-300 HR	17-1167-01
HiPrep 26/60 Sephacryl S-300 HR	17-1196-01

Technical data

Composition	allyl dextran and N,N´-methylene bisacrylamide
Particle size	50 µm
Fractionation range, globular proteins	1×10^4–1.5×10^6
pH stability (operational)	3–11
CIP stability (short term)	2–13
Pressure/flow spec.	flow at 100 kPa >150 cm/h, XK 50/30 column, bed height 15 cm

Sephacryl S-400 High Resolution. See p 50–51

Pack size	Code No.
150 ml	17-0609-10
750 ml	17-0609-01
10 l	17-0609-05
Data File	18-1009-28
Regulatory Support File	11-0028-36

Technical data

Composition	allyl dextran and N,N´-methylene bisacrylamide
Particle size	50 µm
Fractionation range, globular proteins	2×10^4–8×10^6
pH stability (operational)	3–11
CIP stability (short term)	2–13
Pressure/flow spec.	flow at 100 kPa >150 cm/h, XK 50/30 column, bed height 15 cm

Sephacryl S-500 High Resolution. See p 50–51

Pack size	Code No.
150 ml	17-0613-10
750 ml	17-0613-01
10 l	17-0613-05
Data File	18-1009-28
Regulatory Support File	11-0028-36

Technical data

Composition	allyl dextran and N,N´-methylene bisacrylamide
Particle size	50 µm
Fractionation range, globular proteins	not determined
pH stability (operational)	3–11
CIP stability (short term)	2–13
Pressure/flow spec.	flow at 100 kPa >125 cm/h, XK 50/30 column, bed height 15 cm

Sephadex G-25 Coarse. See p 50–51

Pack size	Code No.
100 g	17-0034-01
500 g	17-0034-02
5 kg	17-0034-03
40 kg	17-0034-07
Data File	18-1115-79
Regulatory Support File	11-0028-38

Technical data

Composition	cross-linked dextran
Particle size	dry, min 90% volume share between 100–300 µm; wet (in 0.15 M NaCl), 75–510 µm
Fractionation range, globular proteins	1×10^3–5×10^3
pH stability (operational)	2–13
CIP stability (short term)	2–13
Pressure/flow spec.	480–660 cm/h, pressure drop cm H_2O/bed height=2, bed height 30 cm, 2.6 cm i.d.

Sephadex G-25 Medium. See p 50–51

Pack size	Code No.
25 g	17-0033-10
100 g	17-0033-01
500 g	17-0033-02
5 kg	17-0033-03
Data File	18-1115-79
Regulatory Support File	11-0028-38

Prepacked columns

Prepacked Disposable Columns PD-10 30×9.1 ml	17-0851-01

Technical data

Composition	cross-linked dextran
Particle size	dry, min 90% volume share between 50–150 µm; wet (in 0.15 M NaCl), 40–250 µm
Typical flow rate	200 cm/h
Fractionation range, globular proteins	1×10^3–5×10^3
pH stability (operational)	2–13
CIP stability (short term)	2–13
Pressure/flow spec.	100–150 cm/h, pressure drop cm H_2O/bed height=2, bed height 30 cm, 2.6 cm i.d.

Sephadex G-25 Fine. See p 50–51

Pack size	Code No.
100 g	17-0032-01
500 g	17-0032-02
5 kg	17-0032-03
Data File	18-1115-79
Regulatory Support File	11-0028-38

Prepacked columns

HiPrep 26/10 Desalting 53 ml	17-5087-01
HiPrep 26/10 Desalting 4×53 ml	17-5087-02

Technical data

Composition	cross-linked dextran
Particle size	dry, min 80% volume share between 20–80 µm; wet (in 0.15 M NaCl), 20–130 µm
Typical flow rate	150 cm/h
Fractionation range, globular proteins	1×10^3–5×10^3
pH stability (operational)	2–13
CIP stability (short term)	2–13
Pressure/flow spec.	47–68 cm/h, pressure drop cm H_2O/bed height=2, bed height 30 cm, 2.6 cm i.d.

Sephadex G-25 Superfine. See p 50–51

Pack size	Code No.
100 g	17-0031-01
500 g	17-0031-02
5 kg	17-0031-03
Data File	18-1115-79
Regulatory Support File	11-0028-38

Prepacked columns

HiTrap Desalting 5×5 ml	17-1408-01
HiTrap Desalting 100×5 ml*	11-0003-29

Technical data

Composition	cross-linked dextran
Particle size	dry, min 80% volume share between 20–50 µm; wet (in 0.15 M NaCl), 15–100 µm.
Typical flow rate	100 cm/h
Fractionation range, globular proteins	1×10^3–5×10^3
pH stability (operational)	2–13
CIP stability (short term)	2–13
Pressure/flow spec.	11–26 cm/h, pressure drop cm H_2O/bed height=2, bed height 30 cm, 2.6 cm i.d.

*Special pack size delivered on specific customer order.

Sephadex LH-20. See p 50

Pack size	Code No.
25 g	17-0090-10
100 g	17-0090-01
500 g	17-0090-02
5 kg	17-0090-03
Data File	18-1107-22
Regulatory Support File	11-0029-00

Technical data

Composition	hydroxypropylated, cross-linked dextran (based on Sephadex G-25)
Particle size	dry, min 85% volume share between 30–100 µm, wet (in methanol) 25–165 µm
pH stability (operational)	2–13
CIP stability (short term)	2–13
Pressure/flow spec.	25–45 cm/h, pressure drop cm H_2O/bed height=2, bed height 30 cm, 2.6 cm i.d.

Sepharose 4B.

Pack size	Code No.
1 l	17-0120-01
10 l	17-0120-05
Regulatory Support File	11-0028-39

Technical data

Composition	4% agarose
Particle size	45–165 µm
Fractionation range, globular proteins	6×10^4–2×10^7
pH stability (operational)	4–9
CIP stability (short term)	4–9
Pressure/flow spec.	70–140 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, column 5 cm i.d.

Sepharose 6B.

Pack size	Code No.
1 l	17-0110-01
10 l	17-0110-05
Regulatory Support File	11-0028-39

Technical data

Composition	6% agarose
Particle size	45–165 µm
Fractionation range, globular proteins	1×10^4–4×10^6
pH stability (operational)	4–9
CIP stability (short term)	4–9
Pressure/flow spec.	100–200 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, 5 cm i.d.

Sepharose CL-2B. See p 51

Pack size	Code No.
1 l	17-0140-01
10 l	17-0140-05
Regulatory Support File	11-0028-40

Technical data

Composition	cross-linked 2% agarose
Particle size	45–165 µm
Fractionation range, globular proteins	7×10^4–4×10^7
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	60–120 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, 5 cm i.d.

Sepharose CL-4B.

Pack size	Code No.
1 l	17-0150-01
10 l	17-0150-05
Regulatory Support File	11-0028-40

Technical data

Composition	cross-linked 4% agarose
Particle size	45–165 µm
Fractionation range, globular proteins	6×10^4–2×10^7
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	80–150 cm/h, pressure drop m H_2O/bed height=15, bed height 10 cm, column 5 cm i.d.

Sepharose CL-6B.

Pack size	Code No.
1 l	17-0160-01
10 l	17-0160-05
Regulatory Support File	11-0028-40

Technical data

Composition	cross-linked 6% agarose
Particle size	45–165 µm
Fractionation range, globular proteins	1×10^4–4×10^6
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	100–200 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, column 5 cm i.d.

Sepharose 4 Fast Flow. See p 50–51

Pack size	Code No.
1 l	17-0149-01
10 l	17-0149-05
Data File	18-1020-52
Regulatory Support File	11-0028-41

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Sepharose 6 Fast Flow. See p 50–51

Pack size	Code No.
1 l	17-0159-01
10 l	17-0159-05
Data File	18-1020-52
Regulatory Support File	11-0028-42

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

SOURCE 15ETH. See p 44

Pack size	Code No.
50 ml	17-0146-01
200 ml	17-0146-02
1 l	17-0146-04
Data File	18-1128-86
Regulatory Support File	11-0028-46

Prepacked columns

RESOURCE ETH 1 ml	17-1184-01
RESOURCE HIC Test kit	17-1187-01

Technical data

Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Typical flow rate	150–900 cm/h
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 15ISO. See p 44

Pack size	Code No.
50 ml	17-0148-01
200 ml	17-0148-02
1 l	17-0148-04
Data File	18-1128-86
Regulatory Support File	11-0028-47

Prepacked columns

RESOURCE ISO 1 ml	17-1185-01
RESOURCE HIC Test kit	17-1187-01

Technical data

Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Typical flow rate	150–900 cm/h
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 15PHE. See p 44

Pack size	Code No.
50 ml	17-0147-01
200 ml	17-0147-02
1 l	17-0147-04
5 l	17-0147-05
Data File	18-1128-86
Regulatory Support File	11-0028-48

Prepacked columns

RESOURCE PHE 1 ml	17-1186-01
RESOURCE HIC Test kit	17-1187-01
SOURCE 15PHE PE 4.6/100	17-5071-01

Technical data

Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Typical flow rate	150–900 cm/h
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 15Q. See p 37

Pack size	Code No.
10 ml	17-0947-20
50 ml	17-0947-01
200 ml	17-0947-05
500 ml	17-0947-02
1 l	17-0947-03
Data File	18-1123-65
Regulatory Support File	11-0028-51

Prepacked columns

RESOURCE Q 1 ml	17-1177-01
RESOURCE Q 6 ml	17-1179-01
SOURCE 15Q 4.6/100 PE	17-5181-01
Data File	18-1123-65

Technical data

Ion exchanger type	Quaternary ammonium strong anion exchanger
Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Binding capacity	45 mg BSA/ml drained medium
Typical flow rate	150–900 cm/h
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 30Q. See p 37, 45

Pack size	Code No.
50 ml	17-1275-01
200 ml	17-1275-02
1 l	17-1275-03
5 l	17-1275-04
Data File	18-1107-12
Regulatory Support File	11-0028-52

Technical data

Ion exchanger type	Quaternary ammonium strong anion exchanger
Composition	polystyrene/divinylbenzene
Particle size	30 µm monosized
Binding capacity	40 mg BSA/ml drained medium
Typical flow rate	300–1 000 cm/h
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	2 000 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 15RPC. See p 47

Pack size	Code No.
10 ml	17-0727-20
200 ml	17-0727-02
500 ml	17-0727-03
1 l	17-0727-04
5 l	17-0727-05
Data File	18-1123-50
Regulatory Support File	11-0028-49

Prepacked columns

RESOURCE RPC 1 ml	17-1181-01
RESOURCE RPC 3 ml	17-1182-01
SOURCE 15 RPC ST 4.6/100	17-5068-01
Data File	18-1123-50

Technical data

Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Binding capacity	~10 mg BSA/ml medium at 300 cm/h ~30 mg bacitracin/ml medium at 300 cm/h ~50 mg insulin/ml medium at 300 cm/h
Typical flow rate	150–900 cm/h
pH stability (operational)	1–12
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 30RPC. See p 47

Pack size	Code No.
10 ml	17-5120-20
200 ml	17-5120-02
500 ml	17-5120-03
1 l	17-5120-04
5 l	17-5120-05
Data File	18-1129-73
Regulatory Support File	11-0028-53

Technical data

Composition	polystyrene/divinylbenzene
Particle size	30 µm monosized
Binding capacity	~14 mg BSA/ml medium at 300 cm/h ~23 mg bacitracin/ml medium at 300 cm/h ~72 mg insulin/ml medium at 300 cm/h
Typical flow rate	100–1000 cm/h
pH stability (operational)	1–12
CIP stability (short term)	1–14
Pressure/flow spec.	2 000 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 15S. See p 35, 37

Pack size	Code No.
10 ml	17-0944-10
50 ml	17-0944-01
200 ml	17-0944-05
500 ml	17-0944-02
1 l	17-0944-03
Data File	18-1123-65
Regulatory Support File	11-0028-50

Prepacked columns

RESOURCE S 1 ml	17-1178-01
RESOURCE S 6 ml	17-1180-01
SOURCE 15S 4.6/100 PE	17-5182-01
Data File	18-1123-65

Technical data

Ion exchanger type	Sulfonate strong cation exhanger
Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Binding capacity	75 mg lysozyme/ml drained medium
Typical flow rate	150–900 cm/h
pH stability (operational)	2–13
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 30S. See p 37

Pack size	Code No.
50 ml	17-1273-01
200 ml	17-1273-02
1 l	17-1273-03
5 l	17-1273-04
Data File	18-1107-12
Regulatory Support File	11-0028-54

Technical data

Ion exchanger type	Sulfonate strong cation exhanger
Composition	polystyrene/divinylbenzene
Particle size	30 µm monosized
Binding capacity	80 mg lysozyme/ml drained medium
Typical flow rate	300–1 000 cm/h
pH stability (operational)	2–13
CIP stability (short term)	1–14
Pressure/flow spec.	2 000 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SP Sepharose Big Beads. See p 36

Pack size	Code No.
1 l	17-0657-03
10 l	17-0657-05
60 l	17-0657-60
IEX Selection Kit	17-0939-01
Data File	18-1104-91
Regulatory Support File	11-0028-57

Technical data

Composition	highly cross-linked 6% agarose
Particle size	100–300 µm
Ion capacity	0.18–0.25 mmol H^+/ml medium
pH stability (operational)	4–13
CIP stability (short term)	3–14
Pressure/flow spec.	1 200–1 800 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

SP Sepharose Fast Flow. See p 37

Pack size	Code No.
25 ml	17-0729-10
300 ml	17-0729-01
5 l	17-0729-04
10 l	17-0729-05
60 l	17-0729-60
IEX Selection Kit	17-0939-01
Data File	18-1020-66
Regulatory Support File	11-0028-55

Prepacked columns

HiPrep 16/10 SP FF	17-5192-01
HiTrap SP FF 5×1 ml	17-5054-01
HiTrap SP FF 5×5 ml	17-5157-01
HiTrap IEX Selection Kit	17-6002-33

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Binding capacity	120 mg BSA/ml drained medium
pH stability (operational)	4–13
CIP stability (short term)	3–14
Pressure/flow spec.	400–700 cm/h, 100 kPa, XK 50/30 column, bed height 15 cm.

SP Sepharose High Performance. See p 37

Pack size	Code No.
75 ml	17-1087-01
1 l	17-1087-03
5 l	17-1087-04
10 l	17-1087-05
60 l	17-1087-08
Data File	18-1020-69
Regulatory Support File	11-0028-56

Prepacked columns

HiLoad 16/10 SP Sepharose High Performance	17-1137-01
HiLoad 26/10 SP Sepharose High Performance	17-1138-01
HiTrap SP HP 5×1 ml	17-1151-01
HiTrap SP HP 5×5 ml	17-1152-01
HiTrap IEX Selection Kit	17-6002-33

Technical data

Composition	highly cross-linked 6% agarose
Particle size	34 µm average ($d_{50, vol}$)
Binding capacity	55 mg Ribonuclease/ml drained medium
pH stability (operational)	4–12
CIP stability (short term)	3–14
Pressure/flow spec.	min 100 cm/h, 250 kPa, BioPilot 60/100 column, bed height 30 cm

SP Sepharose XL. See p 37

Pack size	Code No.
300 ml	17-5073-01
5 l	17-5073-04
60 l	17-5073-60
Data File	18-1123-82
Regulatory Support File	11-0028-58

Prepacked columns

HiPrep 16/10 SP XL 20 ml	17-5093-01
HiTrap SP XL 5×1 ml	17-5160-01
HiTrap SP XL 5×5 ml	17-5161-01
HiTrap IEX Selection Kit	17-6002-33

Technical data

Composition	cross-linked 6% agarose with dextran coating
Particle size	45–165 µm
Binding capacity	>160 mg lysozyme/ml medium
pH stability (operational)	3–13
CIP stability (working)	3–14
Flow rate	300–500 cm/h

Superdex 30 prep grade. See p 50

Pack size	Code No.
25 ml	17-0905-10
150 ml	17-0905-01
1 l	17-0905-03
5 l	17-0905-04
Data File	18-1020-92
Regulatory Support File	11-0028-67

Prepacked columns

HiLoad 16/60 Superdex 30 prep grade	17-1139-01
HiLoad 26/60 Superdex 30 prep grade	17-1140-01

Technical data

Composition	composite of cross-linked agarose and dextran
Particle size	34 µm
Fractionation range, globular proteins	up to 1×10^4
pH stability (operational)	3–12
CIP stability (short term)	1–14
Max pressure	300 kPa

Superdex 75 prep grade. See p 50

Pack size	Code No.
25 ml	17-1044-10
150 ml	17-1044-01
1 l	17-1044-02
5 l	17-1044-04
Data File	18-1020-92
Regulatory Support File	11-0028-66

Prepacked columns

HiLoad 16/60 Superdex 75 prep grade	17-1068-01
HiLoad 26/60 Superdex 75 prep grade	17-1070-01

Technical data

Composition	composite of cross-linked agarose and dextran
Particle size	34 µm
Fractionation range, globular proteins	3×10^3–7×10^4
pH stability (operational)	3–12
CIP stability (short term)	1–14
Max pressure	300 kPa

Superdex 200 prep grade. See p 50

Pack size	Code No.
25 ml	17-1043-10
150 ml	17-1043-01
1 l	17-1043-02
5 l	17-1043-04
10 l	17-1043-05
60 l	17-1043-06
Data File	18-1020-92
Regulatory Support File	11-0028-66

Prepacked columns

HiLoad 16/60 Superdex 200 prep grade	17-1069-01
HiLoad 26/60 Superdex 200 prep grade	17-1071-01

Technical data

Composition	composite of cross-linked agarose and dextran
Particle size	34 µm
Fractionation range, globular proteins	1×10^4–6×10^5
Flow rate	30–60 cm/h
pH stability (operational)	3–12
CIP stability (short term)	1–14
Max pressure	300 kPa

Solid supports for oligonucleotide synthesis. See p 149

Oligosynt, prepacked disposable columns. See p 150

Product*	Code No.
Oligosynt dA	
15 µmol	17-5210-01
30 µmol	17-5210-02
120 µmol	17-5210-03
Oligosynt dC	
15 µmol	17-5211-01
30 µmol	17-5211-02
120 µmol	17-5211-03
Oligosynt dG	
15 µmol	17-5212-01
30 µmol	17-5212-02
120 µmol	17-5212-03
Oligosynt T	
15 µmol	17-5213-01
30 µmol	17-5213-02
120 µmol	17-5213-03

Technical data

Composition	Cross-linked polystyrene
Particle size	30 µm

* The 15 µmol columns are sold in packs of 10, the 30 µmol columns in packs of 5, and the 120 µmol columns in packs of 2.

Primer Support 200. See p 150

Product	Code No.
Primer Support 200 dA Synth	
1 mmol	17-5288-01
10 mmol	17-5288-02
50 mmol	17-5288-03
100 mmol	17-5288-04
Primer Support 200 dC Synth	
1 mmol	17-5289-01
10 mmol	17-5289-02
50 mmol	17-5289-03
100 mmol	17-5289-04
Primer Support 200 dG Synth	
1 mmol	17-5290-01
10 mmol	17-5290-02
50 mmol	17-5290-03
100 mmol	17-5290-04
Primer Support 200 T Synth	
1 mmol	17-5292-01
10 mmol	17-5292-02
50 mmol	17-5292-03
100 mmol	17-5292-04
Regulatory Support File	11-0029-20

Technical data

Composition	Cross-linked polystyrene
Particle size	30 µm
Matrix	Cross-linked polystyrene/ divinylbenzene
Bead size (in acetonitrile)	30 µm, retains size in all oligonucleotide in all synthesis reagents
Bead form	Spherical, porous, monodispersed
Particle size distribution	Max 5% CV
Storage	4 to 30°C
Degree of nucleoside substitution	200 ±10 µmol/g
Max recommended bed height	10 cm

Custom Primer Support 200. See p 150

Product*	Code No.
Primer Support dA 40s	
1 g	17-5214-37
10 g	17-5214-31
100 g	17-5214-11
Primer Support dC 40s	
1 g	17-5214-38
10 g	17-5214-32
100 g	17-5214-12
Primer Support dG 40s	
1 g	17-5214-39
10 g	17-5214-33
100 g	17-5214-13
Primer Support T 40s	
1 g	17-5214-40
10 g	17-5214-34
100g	17-5214-14
Primer Support dA 80s	
1 g	17-5250-83
10g	17-5250-82
100g	17-5250-80
Primer Support dC 80s	
1 g	17-5251-83
10g	17-5251-82
100g	17-5251-80
Primer Support dG 80s	
1 g	17-5252-83
10 g	17-5252-82
100g	17-5252-80
Primer Support T 80s	
1 g	17-5253-83
10 g	17-5253-82
100g	17-5253-80
Primer Support riboA 40	
1 g	17-5225-17
10 g	17-5214-85
Primer Support riboC 40	
1 g	17-5225-18
10 g	17-5214-86
Primer Support riboG 40	
1 g	17-5225-19
10 g	17-5214-87
Primer Support riboU 40	
1 g	17-5225-20
10 g	17-5214-88
Primer Support riboA 80	
1 g	17-5225-13
10 g	17-5214-50
Primer Support riboC 80	
1 g	17-5225-14
10 g	17-5214-51
Primer Support riboG 80	
1 g	17-5225-15
10 g	17-5214-52
Primer Support riboU 80	
1 g	17-5225-06
10 g	17-5214-53

Technical data

Composition	Cross-linked polystyrene
Particle size	30 µm

Base protection is ABz, CBz, Gibu, and T for DNA oligonucleotides.

Base protection is ABz, CBz, Gibu, and U for RNA oligonucleotides.

* The number indicated in the product name refers to loading in µmol/g. The "s" in the product name indicates "spacer". Alternative pack sizes are available.

Glossary of terms

BioProcess Media
This label designates our media that have been specifically designed to meet the demands of industrial biotechnology:
- **Scalable** from lab to production.
- With comprehensive **documentation.**
- Meeting **productivity** requirements.
- Having **validated** manufacturing procedures.
- With developed **CIP** and sanitization-in-place procedures.
- Offering **security** of supply.

Fast Trak
is a range of consulting, process development, validation and training services, available to companies working with downstream processing of biopharmaceuticals and diagnostics.

ISO 9001
This International Standard is one of a series of three quality management standards that ensure consistent and reliable quality. ISO-9001 has the widest scope and covers design/development, production, installation and servicing. ISO-9001 is accepted as a basic qualification for any company supplying the biotechnology industry.

Validation
is the process of establishing documentary evidence that provides a high degree of assurance that any product, process, activity, procedure, system, equipment or software used in the control and manufacture consistently performs to or meets its predetermined specifications.

Sanitization-in-Place
The use of chemical reagents to reduce microbial populations to very low levels in packed columns, equipment and systems.

CIP
Cleaning-in-place is the *in-situ* removal of tightly bound substances or particulate matter from media and equipment used in downstream purification.

Regulatory Support File
This document contains information about our products, in particular our media to support process validation, writing of SOPs, quality control and applications submitted to regulatory authorities. The contents include technical specifications, examples of Certificates of Analysis, instructions for use, and leakage and toxicity data.

Hardware Product Documentation
This documentation contains column information to support process validation. Contents include product descriptions, column wetted components and certificates and statements of materials.

Terms & conditions of sale / trademarks / licensing information

Unless otherwise agreed in writing all goods and services are sold subject to the following terms and conditions.

Any use of commercially available software is subject to GE Healthcare Standard Software End-User License Agreement for Life Sciences Software Products.

In no event shall the products be used for *in vivo* applications. Any warranty granted by GE Healthcare shall be deemed void if any goods covered by such warranty are used for any purpose not permitted hereunder.

For the latest information on our trademarks, patent and licensing please go to our website **www.gehealthcare.com/protein_purification**

GE Healthcare Bio-Sciences AB.

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English

Translations of the following terms and conditions are available at **www.gehealthcare.com/protein_purification**. In same territories, local variations to these terms and conditions may apply, If so, such variations are available at **www.gehealthcare.com/protein_purification** and at the local sales office, The local variations shall take precedent in the event of any inconsistency with these conditions.

Dansk

Oversættelser af efterfølgende Almindelige forretningsbetingelser findes under **www.gehealthcare.com/protein_purification**. I nogle lande kan der forekomme lokale varianter af de Almindelige forretningsbetingelser. Hvis det er tilfældet, findes disse under **www.gehealthcare.com/protein_purification** eller på de lokale salgskontorer. Hvis de lokale varianter afviger fra de Almindelige forretningsbetingelser, er det altid førstnævnte, der gælder.

Deutsch

Übersetzungen der nachfolgenden Allgemeinen Geschäftsbedingungen können eingesehen werden unter **www.gehealthcare.com/protein_purification**. In einigen Ländern können örtliche Varianten zu den Allgemeinen Geschäftsbedingungen gelten. Wenn dies der Fall ist, so können die örtlich geltenden Varianten unter **www.gehealthcare.com/protein_purification** oder in dem jeweiligen Vertriebsbüro vor Ort eingesehen werden. Falls die örtlich geltenden Varianten von den Allgemeinen Geschäftsbedingungen abweichen, sind die örtlichen geltenden Varianten als maßgebend anzusehen.

Español

Traducciones de las siguientes Condiciones Comerciales Generales pueden verse en **www.gehealthcare.com/protein_purification**. En algunos países pueden tener validez variantes locales de estas Condiciones Comerciales Generales. Si es así, las variantes localmente válidas pueden verse en **www.gehealthcare.com/protein_purification** o en "in situ" en la respectiva oficina distribuidora. Si las variantes de validez local difieren de las Condiciones Comerciales Generales, estas variantes deberán considerarse normativas.

Français

Les traductions des Conditions Générales de Vente suivantes pourront être consultées sous **www.gehealthcare.com/protein_purification**. Des variantes locales des Conditions Générales de Vente peuvent être applicables dans certains pays. Si cela est le cas, les variantes en vigueur localement peuvent être consultées sous **www.gehealthcare.com/protein_purification** ou dans les bureaux de distribution sur place. Si les variantes en vigueur localement divergent des Conditions Générales de Vente, les variantes en vigueur localement devront être considérées comme déterminantes.

Italiano

Le traduzioni delle seguenti condizioni generali di contratto possono essere visionate sotto **www.gehealthcare.com/protein_purification**. In alcuni paesi possono trovare applicazione alcune varianti locali. In questo caso, le eventuali varianti vigenti in loco possono essere visionate sotto **www.gehealthcare.com/protein_purification** o negli uffici di vendita in loco. Se queste varianti differiscono dalle condizioni generali di contratto, sono da considerarsi determinanti le varianti locali.

Nederlands

Vertalingen van de navolgende algemene handelsvoorwaarden kunnen ingezien worden onder **www.gehealthcare.com/protein_purification**. In enkele landen kunnen plaatselijke varianten voor de algemene handelsvoorwaarden gelden. Indien dit het geval is, kunnen de plaatselijk geldende varianten onder **www.gehealthcare.com/protein_purification** of in het betreffende verkoopkantoor ter plaatse ingezien worden. Indien de plaatselijk geldende varianten van de algemene handelsvoorwaarden afwijken, dienen de plaatselijk geldende varianten als doorslaggevend te worden aanzien.

Norsk

Oversettelser av de etterfølgende generelle forretningsvilkår finnes på **www.gehealthcare.com/protein_purification**. For enkelte land gjelder lokale tilpasninger av forretningsvilkårene. Der hvor dette er tilfelle, gir **www.gehealthcare.com/protein_purification** eller det lokale salgskontor innsikt i de vilkår som gjelder. Dersom det ikke er samstemmighet mellom lokale og generelle forretningsvikår vil de lokale vilkårene gjelde.

Portugês

As traduções das seguintes regras gerais do comércio podem ser visualizadas em **www.gehealthcare.com/protein_purification**. Em alguns países podem ser válidas variantes locais destas regras gerais de comércio. Se este for o caso, as variantes locais válidas podem ser visualizadas em **www.gehealthcare.com/protein_purification** ou no respectivo escritório de vendas no local. Caso as variantes locais válidas desviem das regras gerais do comércio, as variantes locais válidas devem ser tomadas como determinantes.

Suomi

Seuraavien yleisten kauppaehtojen käännökset voi lukea sivulta **www.gehealthcare.com/protein_purification**. Joissakin maissa näistä yleisistä kauppaehdoista voi olla voimassa paikallisia muunnelmia. Jos näin on, voit lukea paikallisesti voimassa olevat muunnelmat sivulta **www.gehealthcare.com/protein_purification** tai paikallisessa myyntikonttorissa. Jos paikalliset muunnelmat poikkeavat yleisistä kauppaehdoista, paikallisia muunnelmia on pidettävä ratkaisevina.

Svenska

Översättning av nedanstående villkor är tillgängliga under **www.gehealthcare.com/protein_purification**. I några länder tillämpas lokala varianter av dessa bestämmelser och villkor. Dessa varianter är då tillgängliga under **www.gehealthcare.com/protein_purification** och i de lokala försäljningslokalerna. De lokala varianterna har företräde i fall av oförenlighet med dessa villkor.

Terms and conditions of sale

1. General

1.1 In these Terms and Conditions:
The *Buyer* means the person, firm, company or other organization who or which has ordered Products and/or Services from GEHC; *GEHC* means the GE Healthcare group company referred to in the final written offer, quotation or order acknowledgement or, if none, the GE Healthcare company making the supply;

The *Contract* means the contract for the sale and purchase of Products and/or Services between GEHC and the Buyer as may be further evidenced by GEHC's final written offer, quotation or order acknowledgement and no prior proposals, statements, representations or conditions will be binding on either party;

The *Equipment* means all electronic equipment, hardware and other electronic or mechanical items agreed to be supplied by GEHC, excluding any consumables and spare parts sold separately; The *Goods* means all items agreed to be supplied by GEHC other than the Equipment and Software; The *Products* means any Goods, Equipment or Software agreed to be supplied by GEHC; and The *Services* means all advice given and services performed by GEHC; and

The *Software* means any firmware, software or data compilations (i) identified in the Contract or (ii) provided to Buyer by GEHC in connection with installation or operation of the Equipment. For the avoidance of doubt, *Software* shall not include any "open source" firmware, software or data compilations, as any such "open source" firmware, software or data compilations will be subject to the terms and conditions set out in the relevant "open source" license.

1.2 These Terms and Conditions shall be incorporated into the Contract and shall apply to the exclusion of any conditions of the Buyer. These Terms and Conditions may not be varied or waived except with the express written agreement of GEHC. The failure of GEHC to enforce its rights under the Contract at any time, for any period of time, shall not be construed as a waiver of any such rights.

2. Prices and Quotations

The price of the Products and/or Services will be GEHC's quoted price, inclusive of any duties, but exclusive of value added or other taxes. All quotations issued by GEHC for the supply of Products and/or Services shall remain open for acceptance for the period stated in the quotation or, if none is stated, for sixty (60) days. In all other cases, prices payable are those currently in effect in GEHC´s then current pricelist.

3. Payment

3.1 Unless otherwise agreed in writing, payment in full shall be made to GEHC in the currency invoiced, no later than thirty (30) days from the date of invoice.

3.2 In the event of late payment, GEHC reserves the right:
(i) to suspend deliveries and/or cancel any of its outstanding obligations; and
(ii) to charge interest at the lower of (a) an annual rate equal to twelve (12) % and (b) any applicable maximum statutory rate on all unpaid amounts calculated on a day to day basis until the actual date of payment.

4. Changes and Returns

4.1 GEHC reserves the right, subject to prior written notice, to make any change in the specification of the Products, which does not materially affect the installation, performance or price thereof.

4.2 Products may only be returned with prior authorization from GEHC.

5. Delivery/Installation/Acceptance

5.1 Any term of delivery shall be construed according the latest edition of Incoterms. If no other term of delivery has been specified in the Contract the Products will be delivered CIP to Buyer's premises or to the agreed destination.

5.2 Partial deliveries shall be permitted. If the Buyer fails to accept delivery of the Products within a reasonable period after receiving notice from GEHC that they are ready for delivery, GEHC may dispose of or store the Products at the Buyer's expense.

5.3 GEHC will use all reasonable endeavours to avoid delay in delivery on the notified delivery dates. Failure to deliver by the specified date will not be a sufficient cause for cancellation, nor will GEHC be liable for any loss or damage due to delay in delivery.

5.4 The Buyer shall notify GEHC in writing within five (5) working days of delivery of any short delivery or defects reasonably discoverable on careful examination. GEHC's sole obligation shall be, at its option, to replace or repair any defective Products or refund the purchase price of any undelivered Products.

5.5 Where delivery of any Product requires an export license or other authorization before shipment, GEHC shall not be responsible for any delay in delivery due to delay in, or refusal of, such license or authorization.

5.6 Where the Equipment requires installation, the Buyer shall be responsible at its own cost for making the place where the Equipment will be located ready for installation in accordance with GEHC's instructions. Installation will not begin unless such responsibilities are completed.

5.7 Following installation, where applicable, GEHC will proceed with final testing using GEHC's published performance specifications and using its standard instruments and procedures. Upon the satisfactory completion of such final testing demonstrating compliance with the above specifications (with any permitted variations/tolerances) GEHC may issue a Test Certificate which shall be conclusive evidence of such compliance and thereupon installation of the Equipment shall be deemed to be complete and in compliance with GEHC's obligations under the Contract. Buyer agrees that the Equipment is accepted (i) seven (7) days after the date on which GEHC notifies Buyer that final testing was successfully completed, or issues the Test Certificate or (ii) on the date Buyer first uses the Product for operational use, whichever is earlier.

5.8 Buyer, at its reasonable request, shall be entitled to be present at and to witness the testing and shall not be entitled to raise any objection to testing carried out, or to the results thereof, if Buyer failed to attend when advised that testing was to take place.

5.9 Where Products are supplied by GEHC in returnable containers, these must be returned at the Buyer's expense and in good condition, if requested by GEHC. Title to these containers shall remain with GEHC at all times, but they shall be held at the risk of the Buyer until returned to GEHC. Failure by the Buyer to comply with the above provision shall entitle GEHC to invoice the Buyer for the full replacement value of the containers.

6. Risk and Title

6.1 The Buyer shall bear all the risks of loss of and damage to the Products on delivery. Full title to the Goods and Equipment shall pass to the Buyer on full payment. The Buyer agrees not to dispose of or resell the Equipment, until it has been paid for in full.

6.2 In relation to any Equipment used for clinical or diagnostic purposes, the Buyer shall keep adequate written records of the identity of any person or entity to whom the Equipment is transferred and of the location of such Equipment and shall procure that any purchaser of such Equipment is subject to the same requirement in respect of any onward sales.

7. Services

Where GEHC is to provide Services, the Buyer shall ensure that adequate and safe facilities exist at its premises and that GEHC is properly notified of any relevant regulations.

8. Restricted Use

With respect to certain Products, use restrictions are a condition of the purchase which Buyer must satisfy by strictly abiding by the restriction as set forth in GEHC's catalogue and/or on the Product and/or accompanying documentation. Buyer is solely liable to ensure compliance with any regulatory requirements related to the Buyer's use of the Products. Any warranty granted by GEHC to the Buyer shall be deemed void if any Products covered by such warranty are used for any purpose not permitted hereunder. In addition, the Buyer shall indemnify GEHC and hold GEHC harmless from and against any and all claims, damages, losses, costs, expenses and other liability of whatever nature that GEHC suffers or incurs by reason of any such unintended use.

9. General Warranty

9.1 Section 9.2–9.5 shall apply in the event no other specific warranty has been agreed in the Contract.

9.2 Goods – GEHC warrants that its Goods meet GEHC's specifications at the time of delivery. All warranty claims on Goods must be made in writing within ninety (90) days of receipt of the Goods. GEHC's sole liability and Buyer's exclusive remedy for a breach of this warranty is limited to repair, replacement or refund at the sole option of GEHC.

9.3 Equipment – GEHC's Equipment of its own manufacture is warranted from date of delivery or completion of installation, if later, to be free of defects in workmanship or materials under normal usage for a period of one (1) year and any claim shall be submitted in writing within such period. GEHC's sole liability and Buyer's exclusive remedy for a breach of this warranty is limited to repair, replacement or refund at the sole option of GEHC. Such repairs or replacement will not extend the warranty period.

9.4 Software – GEHC warrants, for a period of ninety (90) days from the date of receipt, that the Software substantially conforms to its published specifications and the media on which the Software resides will be free from defects in materials and workmanship under normal use. GEHC does not warrant that the Software is error free or that Buyer will be able to operate the Software without problems or interruptions. GEHC´s sole liability and Buyer's exclusive remedy in the event of breach of this warranty is limited to repair, replacement or refund, at the sole option of GEHC.

9.5 Services – GEHC warrants that all Services will be carried out with reasonable care and skill. GEHC's sole liability for breach of this warranty shall be at its option to give credit for or reperform the Services in question. This warranty shall only extend for a period of ninety (90) days after the completion of the Services.

9.6 To the maximum extent permitted by applicable law GEHC hereby expressly disclaims, and Buyer hereby expressly waives, any warranty regarding results obtained through the use of the Products, including without limitation any claim of inaccurate, invalid, or incomplete results. All other warranties, representations, terms and conditions (statutory, express, implied or otherwise) as to quality, condition, description, merchantability, fitness for purpose or non-infringement (except for the implied warranty of title) are hereby expressly excluded.

9.7 Unless expressly agreed, GEHC is not obliged to carry out dismantling or re-installation of any Product in connection with any warranty claims.

10. Limitation of Liability

10.1 GEHC shall have no liability under the warranties contained in Section 9 in respect of any defect in the Products arising from: specifications or materials supplied by the Buyer; fair wear and tear; wilful damage or negligence of the Buyer or its employees or agents; abnormal working conditions at the Buyer's premises; failure to follow GEHC's use restrictions or instructions (whether oral or in writing); misuse or alteration or repair of the Products without GEHC's approval; or if the Buyer is in breach of its payment obligations under this Contract.

10.2 Subject to any express obligation to indemnify, neither party shall be liable for any indirect or consequential, or punitive damages of any kind from any cause arising out of the sale, installation, use or inability to use any Product or Service, including without limitation, loss of profits, goodwill or business interruption.

10.3 The total liability of GEHC arising under or in connection with the Contract, including for any breach of contractual obligations and/or any misrepresentation, misstatement or tortious act or omission (including without limitation, negligence and liability for infringement of any third party intellectual property rights) shall be limited to damages in an amount equal to the amount paid to GEHC under the Contract.

10.4 The exclusion of liability in these Terms and Conditions shall not apply in respect of death or personal injury caused by GEHC's negligence.

11. Intellectual Property Rights

11.1 Where the Buyer supplies designs, drawings, and specifications to GEHC to enable it to manufacture non-standard or custom made Products, the Buyer warrants that such manufacture will not infringe the intellectual property rights of any third party.

11.2 All intellectual property rights in the Products and/or Services shall at all times remain vested in GEHC or its licensors.

12. Health, Safety and Waste

The Buyer shall ensure that:

(i) the Products (provided such Products comply with its specifications) are suitable and safe for the Buyer´s intended use;
(ii) the Products are handled in a safe manner.
(iii) containers, packaging, labelling, equipment and vehicles, where provided by the Buyer, comply with all relevant national and international safety regulations.

13. Indemnities

Except where a claim arises as a direct result of the negligence or breach of contract of GEHC, the Buyer shall indemnify GEHC in respect of any claim which may be made against GEHC:

(i) arising in connection with the Buyer's use of the Products;
(ii) alleging that the Buyer´s use of the Products infringes the intellectual property rights of any third party.

14. Insolvency

In the event that the Buyer becomes insolvent or applies for bankruptcy or, being a company, goes into liquidation (other than for the purposes of reconstruction or amalgamation), GEHC shall be entitled immediately to terminate the Contract without notice and without prejudice to any other rights of GEHC hereunder.

15. Force Majeure

15.1 GEHC shall not be liable in respect of the non-performance of any of its obligations to the extent such performance is prevented by any circumstances beyond its reasonable control including but not limited to, strikes, lock outs or labour disputes of any kind (whether relating to its own employees or others), fire, flood, explosion, natural catastrophe, military operations, blockade, sabotage, revolution, riot, civil commotion, war or civil war, acts or threats of terrorism, plant breakdown, computer or other equipment failure and inability to obtain equipment.

15.2 If an event of force majeure exceeds one (1) month GEHC may cancel the Contract without liability.

16. Software License

Unless a separate software license agreement has been concluded concerning the Software, the Buyer is hereby granted a non-exclusive license to use the Software solely in object code format and solely for its own internal business purposes subject to the terms contained herein. The Buyer shall not (i) use the Software for purposes other than those for which it was designed; (ii) use the Software in connection with other manufacturers' products unless such connectivity is authorized in the Product documentation; (iii) grant, assign, transfer, or otherwise make available to third parties any right whatsoever in the Software; (iv) disclose to third parties any information contained in the Software; (v) copy or reproduce the Software (except for one copy for back-up purposes or as may otherwise be permitted by applicable law); (vi) alter or modify the Software; or (vii) reverse engineer, decompile, disassemble or create any derivative works based upon the Software except as expressly permitted by law.

17. Export control

The Buyer undertakes not to re-export the Products without the requisite export license from the relevant body of the United Nations or other similar international organization, the United States Government, the country of origin or the original country of export. The requirement to obtain a license may vary depending on the country of destination, the end user, the end use and other factors. Upon request from GEHC the Buyer shall furnish GEHC with copies of all documents relating to such re-export.

18. Waste Electrical and Electronic Equipment (WEEE)

18.1 Where the Buyer sells, disposes of or otherwise transfers the Equipment to any third party and where this would unreasonably increase the cost of the collection, treatment or recycling of the Equipment for GEHC under applicable WEEE legislation, Buyer shall be liable to GEHC and indemnify GEHC for such increased costs.

18.2 Should the Equipment that Buyer acquires from GEHC be Equipment, which is intended to replace on a 'like for like'-basis, any item of Buyer's existing equipment (e.g., the new Equipment is fulfilling the same function as Buyer's existing equipment) Buyer must have clearly indicated to GEHC the following: the brand, type, age, condition, current use and the exact location and all other relevant information. In the event Buyer has not complied with such obligations, GEHC may charge Buyer such reasonable additional fees to reflect any related obligations it may have under national legislation regarding the recycling, reuse and/or disposal of such existing equipment and related costs it may incur.

18.3 Unless the relevant mandatory national legislation provides otherwise, or unless otherwise agreed in writing, GEHC´s obligation does not include without limitation, creation of physical access to the equipment; de-installation; decoupling; disinfecting; craning/lifting; transportation to a ground level loading area or -ramp; packing; or any related similar activities; and Buyer agrees to perform such activities at its own cost as and when required.

19. Governing Law

This Contract shall be governed by and construed in accordance with the substantive laws of the country or state where the GE Healthcare group company (or relevant branch) office referred to in the Contract is situated and the parties hereby submit to the non-exclusive jurisdiction of the courts of that country or state.

20. Product-Specific Terms and Conditions

Additional terms and conditions govern the sale of certain Products and Services. These additional terms and conditions are available from the sales offices of GEHC and shall take precedence in the event of any inconsistency with these Terms and Conditions.

21. Translations and Local Variations

Translations of these terms and conditions are available from the sales offices of GEHC. In some territories, local variations to these Terms and Conditions may apply. If so, such variations shall take precedence in the event of any inconsistency with these Terms and Conditions.

Trademarks

GE Healthcare trademarks

ÄKTA, ÄKTAbasic, ÄKTAcrossflow, ÄKTAdesign, ÄKTAexplorer, ÄKTAFPLC, ÄKTApilot, ÄKTAprime, ÄKTAprocess, BioPilot, BioProcess, BPG, Chromaflow, Capto, Cytodex, Cytoline, Cytopore, Downstream, Drop Design, Fast Trak Design, Fast Trak Validation, Ficoll, Ficoll-Paque, FineLINE, Flexstand, GammaBind, Grandstand, GSTrap, GSTPrep, GraviTrap, HiLoad, HiPrep, HisPrep, HisTrap, HiTrap, INdEX, Kvick, Labcrew, MacroCap, MabSelect, MabSelect Xtra, MabSelect SuRe, MAbTrap, MidGee, MidJet, MultiTrap, OligoPilot, OligoProcess, Oligosynt, Percoll, Primer Support, Quixstand, RESOURCE, Sephacel, Sephacryl, Sephadex, Sepharose, SOURCE, Superdex, Superose, Tricorn, ULTA, UNICORN, Uniflux, and XL Extreme Load are trademarks of GE Healthcare Ltd. GE, imagination at work, and the GE monogram are trademarks of General Electric Company.

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Separating Miraculin with this product is subject to US patent number 5,886,155. Licenses are available from BioResources International, Inc., of Somerset, N.J., U.S.A.

Capto ViralQ
Separating viral particles with Capto Q products may require a license under United States patent number 6,537,793 B2 and equivalent patents and patent applications in other countries owned by Centelion SAS. Such a license is not included with the purchase of Capto Q but is included with the purchase of Capto ViralQ products.

With the purchase of Capto ViralQ the customer is granted a free limited license under US patent 6,537,793 B2 and equivalent patents and patent applications in other countries owned by Centelion SAS to separate viral particles solely through use of the product purchased.

Chelating Sepharose Fast Flow and Ni Sepharose 6 Fast Flow
US patent numbers 5,284,933 and 5,310,663, and equivalent patents and patent applications in other countries (assignee: Hoffman La Roche, Inc) relate to the purification and preparation of fusion proteins and affinity peptides comprising at least two adjacent histidine residues (commonly known as the histidine-tag technology).

Any customer that wishes to use Chelating Sepharose Fast Flow, Ni Sepharose 6 Fast Flow or IMAC Sepharose 6 Fast Flow for non-research/commercial applications under these patents is requested to contact Hoffman-La Roche AG, Corporate licensing, attention Dr Andreas Maurer, CH-4070 Basel, Switzerland, telephone +41 61 687 2548, fax +41 61 687 2113, for the purpose of obtaining a license.

Chromaflow
Chromaflow nozzle is covered by U.S. patent numbers 5,213,683 and 5,282,973 and equivalent patents and patent applications in other countries.

GST Gene Fusion Vectors
A license for commercial use of GST Gene Fusion Vectors must be obtained from Chemicon International Inc., 28820 Single Oak Drive, Temecula California 92590, USA.

Histidine-tagged protein purification
Purification and preparation of fusion proteins and affinity peptides comprising at least two adjacent histidine residues may require a license under US patent numbers 5,284,933 and 5,310,663 and equivalent patents and patent applications in other countries (assignee: Hoffman La Roche, Inc).

OligoPilot (columns)
Use of these supports for the synthesis of polynucleotides is licensed under the following patents when the synthesis is performed on an instrument provided by a licensed supplier: US patent numbers 4,458,066; 4,973,679; 5,047,524 and 5,262,530, and equivalent patents and patent applications in other countries. No other license is granted to the purchaser either directly or by implication, estoppel or otherwise. Patented reagents suitable for use with this instrument are available from licensed sources.

OligoPilot II
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Percoll PLUS
Percoll PLUS is protected by the following patents and equivalent patents and patent applications in other countries, which are licensed to GE Healthcare from Dendreon Corporation: US patent number 4,927,749, US patent number 4,927,750, Canadian patent number 1,338,492, Japanese patent number 2,628,509, US patent number 5,789,148, US patent number 6,015,843 and European patent number 1,047,635. A free, non-transferable license to use this product for density gradient separation purposes under the above mentioned patent rights accompanies the purchase of the product from a GE Healthcare company and its licensed distributors, but any use of Percoll PLUS or any other organosilanized colloidal silica particle-based separation media to enrich, purge or isolate cells for active immunotherapy for oncology applications shall be excluded from such license.

Plasminogen Removal Gel
The Plasminogen Removal Gel is subject to pending patent application (WO 02/095019) and other intellectual property rights owned by OMRIX BIOPHARMACEUTICALS S.A, Belgium ("OMRIX"). Any customer wishing to use Plasminogen Removal Gel for any purpose falling under any valid claims of the said patent rights other than for research purposes, needs prior to such use to (a) contact OMRIX directly and (b) sign a license agreement with OMRIX.

Q Sepharose XL
Separating viral particles with Q Sepharose XL products may require a license under US patent 6,537,793 B2 and equivalent patents and patent applications in other countries owned by Centelion SAS. Such a license is not included with the purchase of Q Sepharose XL but is included with the purchase of "Q Sepharose XL virus licensed" products. With the purchase of "Q Sepharose XL virus licensed" the customer is granted a free limited license under US patent 6,537,793 B2 and equivalent patents and patent applications in other countries owned by Centelion SAS to separate viral particles solely through use of the product purchased.

Support for oligonucleotide synthesis
Use of support for the synthesis of polynucleotides is licensed under the following patents when the synthesis is performed on an instrument provided by a licensed supplier: US patent numbers 4,458,066; 4,973,679; 5,047,524 and 5,262,530; and corresponding patents issued in other countries. No other license is granted to the purchaser either directly or by implication, estoppel or otherwise. Patented reagents suitable for use with this instrument are available from licensed sources.

Tricorn Columns
The Tricorn column and components are protected by US design patents USD500856, USD506261, USD500555, USD495060 and their equivalents in other countries.

Alphabetical index

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