ÄKTA process™ chromatography system

PROCESS CHROMATOGRAPHY

ÄKTA process™ is an automated liquid chromatography system built for process scale-up and large-scale biopharmaceutical manufacturing (Fig 1). The system has a flexible design, and it can be easily configured to meet different process demands. It has the accuracy and documentation required for use in GMP-regulated environments.

ÄKTA process systems are a good choice for scaling up and transferring processes developed on smaller ÄKTA™ chromatography systems. The system is also compatible with the AxiChrom™ chromatography platform, ensuring an efficient column packing process.

System benefits

- Highly flexible system design for different process needs with over 1 million possible configurations
- Compatible with AxiChrom chromatography columns for efficient unit operation
- Suitable for GMP-regulated manufacturing with option for various automation solutions for diverse process control requirements

Flexible system design for your manufacturing needs

The ÄKTA process chromatography system is available in three different flowrate ranges from 1 L/h to 2000 L/h, and the system flow path (Fig 2) is available with either electropolished stainless steel or polypropylene (PP) process piping. The system is suitable from process scale up to clinical and full-scale manufacturing.

The ÄKTA process system has a highly flexible system design with over a million possible configurations for meeting different manufacturing requirements. Configurable options include additional inlets, outlets, particle filters, and column connections; the type and quantity of sensors; and isocratic versus gradient and inline dilution (ILD) functionality. All these options are part of the validated and tested hardware design space to ensure compliance and reliability in GMP-regulated environments.



Fig 1. The ÄKTA process automated liquid chromatography system is built for process scale up and large-scale biopharmaceutical manufacturing.

The system has industrial-standard components and control architecture for easy alignment with other equipment in a biomanufacturing facility. The UV-sensor can be calibrated automatically using built-in and certified reference filters, and the pH and conductivity sensors can be calibrated offline with in-built sensor traceability that speeds up calibration.

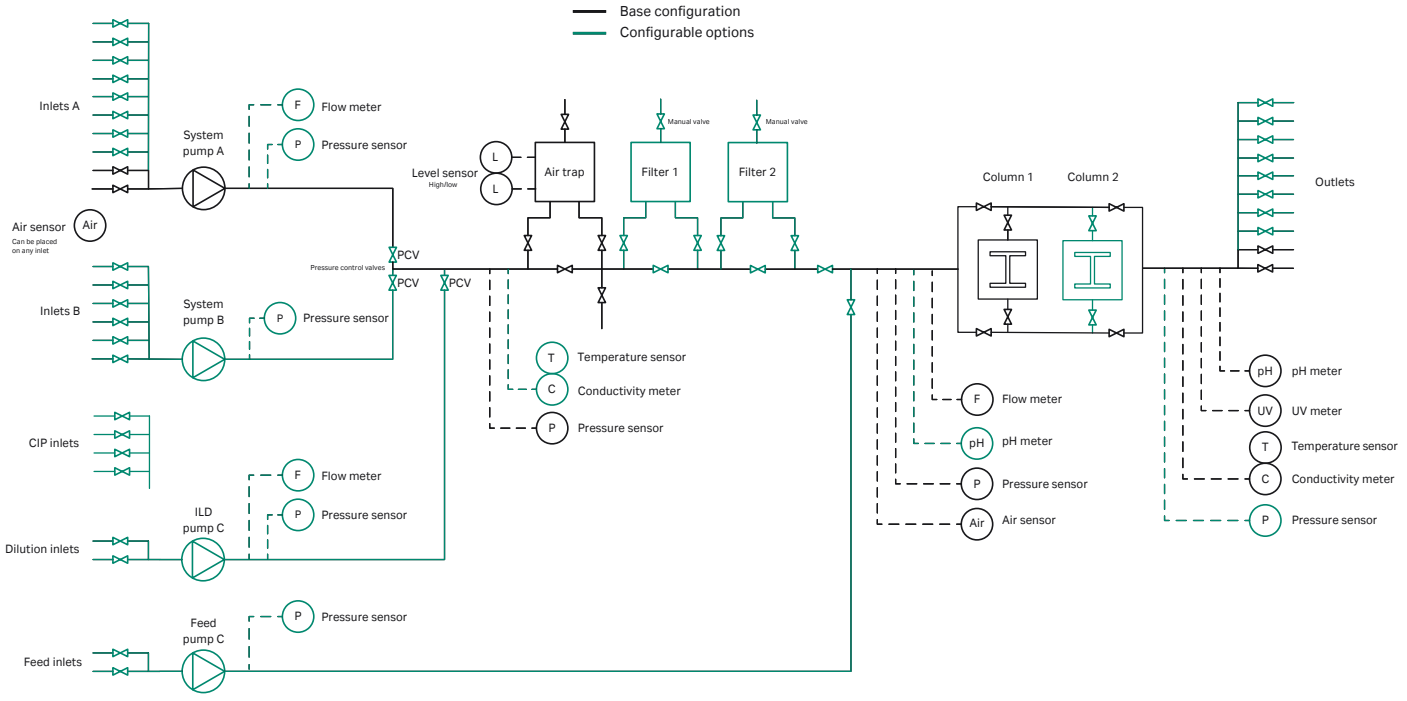


Fig 2. ÄKTA process chromatography system flow path.

The system has a compact design with a built-in computer that allows the system to fit neatly into a plant with minimal floor-space utilization. The dedicated user console has a large 24 in. industrial computer screen and keyboard with industrial mouse to support improved ergonomics and operations in a cleanroom environment. The stack light on top of the system provides real-time visibility of the system status.

ÄKTA process systems can be configured to develop gradients at any flow rate with feedback loop technology. This ensures thorough mixing of different liquids without air bubbles, so even challenging gradients can be created with 1% control accuracy within the marked area using flow feedback (Fig 3).

The ÄKTA process system is delivered with UNICORN™ control software as a turnkey solution. We can also deliver the system with other automation solutions, such as DeltaV, Siemens, or Rockwell PlantPAx as a customized solution.

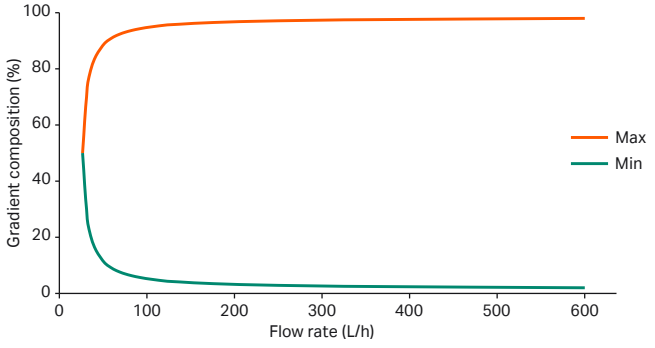


Fig 3. The gradient acceptance range of ÄKTA process system with flowrate 0–600 L/h. The same accuracy can be achieved on systems with other flowrates.

The flexible system design enables post-installation changes such as the addition of valves, filters, and pumps. This allows the system to be reassigned to other process requirements, increasing its usability and flexibility.

Streamlined sanitization

The ÄKTA process system has several features to make sanitization with 1 M sodium hydroxide simple and effective. Sanitization means the use of a chemical agent to reduce a microbial population to a predetermined acceptable level.

In a sanitization study, the system was subjected to a high level of microbial challenge organisms (> 1 × 10^6 colony forming units [CFU]/mL and organism). The results showed excellent efficiency, with at least 6-log reduction in CFU for the organisms.

UNICORN software supports automation of cleaning-in-place (CIP). The air trap design makes CIP more efficient, and the placement of CIP valves together with inlet valves drives automated cleaning.

Robust control with UNICORN software

The standard ÄKTA process system is delivered with UNICORN software pre-installed and configured. The system can be used directly after power-up.

The ÄKTA process system and UNICORN software allow standalone operations or integration into a plant-wide control system. UNICORN software can be integrated with other control systems and manufacturing environments using Open Platform Communications-Unified Architecture (OPC-UA) or EtherNet/IP gateway.

UNICORN software is an interface for both chromatography and membrane separations that provides efficient control of process, flexible method programming, extensive data evaluation, and powerful reporting functionality. Key run data is visible in the interactive Process Picture (Fig 4). Manual instructions and alarm limits for each component can be set and viewed in the Process Picture for easier troubleshooting. The Process Picture also includes guidance for Intelligent Packing.

User activities are logged in audit trails for usage history. The UNICORN software is dedicated to chromatography operations and enables users to set up runs, evaluate and analyze data, generate reports, and more.

UNICORN software is designed according to GAMP 5 guidelines (ISPE) and can be used in a manner that follows 21 CFR Part 11, the US Food and Drug Administration's regulation on electronic records and signatures. The software supports full data integrity and consistency throughout the process, enabling digitized and validated manufacturing. Process data and user administration are stored in a database repository either locally on the system or on external, central server. Secure access is mediated by password-protected user login.

Reliable column packing

Robust column packing is key to achieving a reliable chromatographic process. Reproducibility is essential for moving from process development to full-scale manufacturing. The ÄKTA process system is integrated with AxiChrom columns (Table 1) for Intelligent Packing. In addition to saving time, Intelligent Packing supports reproducibility of results with scalability, whether scaling up or down. Intelligent Packing uses axial compression for packing resins, and even contained filling of production size AxiChrom columns.

UNICORN software has predefined methods with phases for the development of packing, unpacking, priming and column performance test methods for AxiChrom columns. There is support for all AxiChrom column sizes, which makes it easy to create the column type and save relevant parameters for packed columns. Packed AxiChrom columns are traceable in the UNICORN software column list. Feedback is received continuously from the interactive Process Picture during Intelligent Packing.

Chromatography unit operation involves many steps that can each be optimized for a simplified workflow. Aside from being compatible with AxiChrom columns, the ÄKTA process system can also be integrated with the BioProcess™ resin mixer to enable an automated solution for resin transfer and column packing and unpacking to facilitate effective operations.

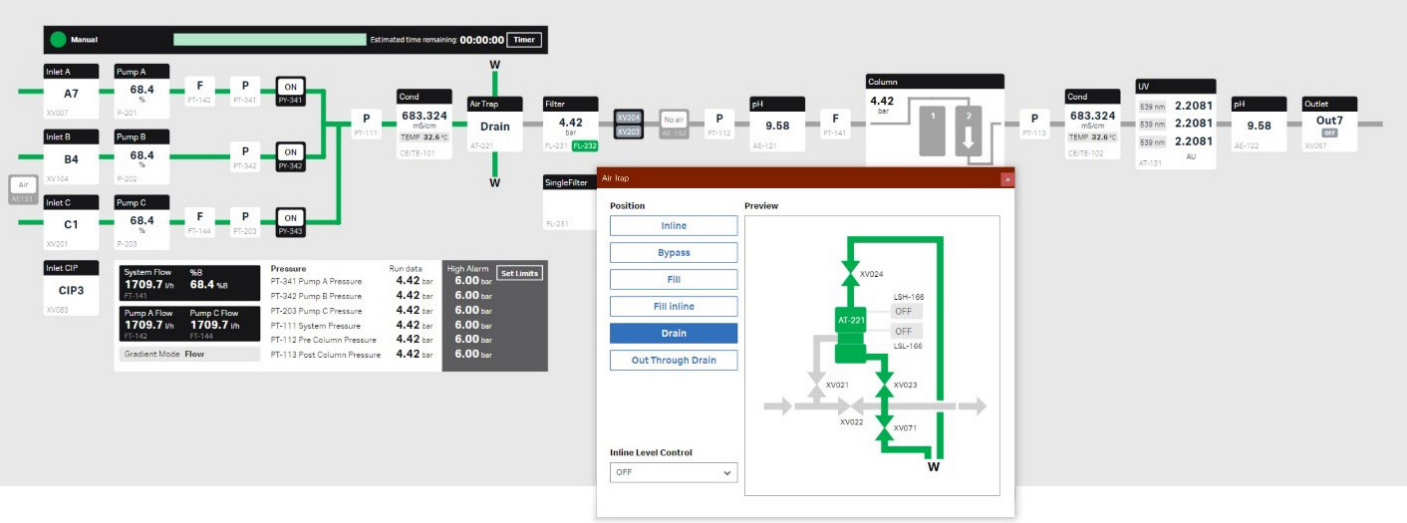


Fig 4. The ÄKTA process™ chromatography system Process Picture is part of UNICORN software. The user can view the most common manual interactions by clicking on the Process Picture to interact with the system.

Table 1. Overview of compatibility for Intelligent packing with AxiChrom columns and BioProcess resin mixer

	ÄKTA process system 6 mm	ÄKTA process system 10 mm	ÄKTA process system ⅜ in.	ÄKTA process system ½ in.	ÄKTA process system 1 in.
Flow rate	1–180 L/h	3–600 L/h	1–180 L/h	3–600 L/h	10–2000 L/h
AxiChrom columns	100, 140, 200, 300, 400, 450	140, 200, 300, 400, 450, 600	100, 140, 200, 300, 400, 450	140, 200, 300, 400, 450, 600	600, 800, 1000, 1200, 1400, 1600
BioProcess resin mixer	500/1250 L	500/1250 L	500/1250 L	500/1250 L	500/1250/2000 L

Inline dilution

ÄKTA process chromatography system has an option for a third pump that supports ILD, automated buffer preparation (Fig 5). With ILD, different buffer concentrates are diluted to create the required buffers. These buffer concentrates can be prepared in-house or outsourced. ILD can bring significant time, labor, and space savings without compromising quality or consistency.

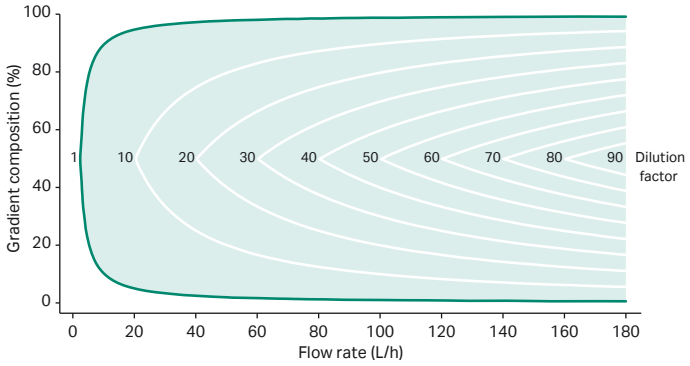


Fig 5. The accuracy of ÄKTA process system with flowrate 1–180 L/h performing inline dilution. The control accuracy of ± 2% is ensured for stated dilution factors within the marked area using flow feedback. The same accuracy can be achieved with systems with higher flowrates.

Full regulatory documentation

Every ÄKTA process system is delivered with comprehensive documentation to support fulfillment of regulatory requirements and compliance. We designed the system with the complete chromatography process in mind using carefully selected materials.

We provide documentation to certify that the system's wetted materials are Animal Origin Free or compliant with EMA 410/01 and meet relevant biocompatibility requirements, such as USP <88> class VI and FDA 21 CFR 177 and fulfill defined chemical composition requirements. This documentation is traceable to original production batches.

The system is also delivered with operating instructions and extensive documentation that includes assembly drawings, piping and instrumentation diagrams, and system specifications.

Equipment service solutions

Regulatory authorities require chromatography systems to be qualified and maintained within specifications during use in process scale-up and GMP-manufacturing. Our equipment service solutions offer a comprehensive range of services (Table 2) throughout the product's life cycle to support your technology, processes, and people.

Table 2. Service solutions for ÄKTA process chromatography systems

Services	Description
Equipment installation	To ensure eligibility for manufacture warranty, an installation performed by Cytiva is required.
Online equipment management	My Equipment keeps track of your instrument service contracts, service records, and your Cytiva installed base.
Preventive maintenance	Replacement of wear and tear parts and functional testing to ensure continuous performance of your instrument.
IQ/OQ* and re-qualification (RQ)	Standard and custom qualification services for Cytiva equipment throughout its lifecycle, including IQ/OQ, RQ, and continuous verification.
Instruments upgrades	Hardware and software upgrades to keep your equipment state-of-the-art during your equipment LifeCycle.
Repairs	Field, remote and mail-in repairs are available depending on your instrument type and environment.
Digital services	A range of digital solutions from remote assistance to network installation and virtual support and trainings.
Spare parts	High quality spare parts for use in GxP environment. Parts security of supply consultancy.
Relocation support	Preparing your equipment for move and re-installing it in its new location.
Training	Standardized and customized operator and maintenance training services and eLearning courses.
Service plans	A range of plans to support your operations and instrument performance.

* IQ/OQ: installation qualification and operational qualification.

System specifications

	ÄKTA process system 6 mm	ÄKTA process system 10 mm	ÄKTA process system ⅜ in.	ÄKTA process system ½ in.	ÄKTA process system 1 in.
Piping material	PP	PP	Stainless steel (SS)	SS	SS and PP
Flow rate Range: Accuracy:	 1–180 L/h ± 1.0% or 0.10 L/h	 3–600 L/h ± 1.0% or 0.10 L/h	 1–180 L/h ± 1.0% or 0.10 L/h	 3–600 L/h ± 1.0% or 0.10 L/h	 10–2000 L/h ± 1.0% or 1.0 L/h
Dimensions (W × H × D)	840 × 1931 × 1340 mm				1041 × 1995 × 2111 mm
Operating max. pressure	6 bar (max 40°C)	6 bar (max 40°C)	10 bar (max 40°C)	10 bar (max 40°C)	6 bar (max 40°C)
Pressure sensor Range: Accuracy:	 0–11 barg ± 0.05 barg between 0–10 barg for SS, and 0–6 barg for PP				
Conductivity sensor (range and accuracy):	0.001 to 0.1 mS/cm, ± 4% 0.1 to 50 mS/cm, ± 2% 50 to 100 mS/cm, ± 2.5% 100 to 500 mS/cm, ± 4%				
Temperature sensor Range: Accuracy:	 0°C–99°C ± 1°C at 2°C–40°C				
pH sensor Range: Acceptance range: Accuracy:	 pH 0–14 pH 2–12 pH ± 0.1				
UV sensor: 3-wavelength Range: Acceptance range: Accuracy:	Present both absorbance units (AU) and optical density (OD) -6 to 6 AU / -12 to 12 OD (5 mm path length) 0 to 2 AU / 0 to 4 OD (5 mm path length) AU linearity 2% / OD 1% (actual path length compensated accuracy)				
Ingress protection	NEMA 250 Type 4X / IP 56 electrical cabinet				
Electrical standards	UL 508A, IEC/EN 60204-1				
Wetted surface finish, metallic materials (welds excluded)	Ra 0.5 µm				
System control	UNICORN 7.9 software or a later version. Other automation solutions can be delivered as customized projects.				

Ordering information

To order the ÄKTA process chromatography system, please contact your local sales representative.

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cytiva.com

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