ÄKTA ready™ chromatography system 450

SINGLE-USE SYSTEM

ÄKTA ready™ chromatography system 450 is a robust single-use system designed to purify advanced therapeutics in small-scale GMP production. With this system, you can streamline purification, minimize product loss, and speed up development – from lab to commercial scale.

The system offers:

- GMP-ready: Gamma-irradiated closed flow path, which eliminates cleaning and the need for cleaning validation.
- Optimized for product recovery: Low hold-up volume (~40 mL*), multi-wavelength UV detection, and low-shear pump.
- Seamless scale-up: UNICORN™ software control from research to GMP manufacturing.
- Space-efficient: Benchtop system for small footprints, well-suited for cleanroom environments.

Designed for small-scale GMP manufacturing

We designed the ÄKTA ready chromatography system 450 for purifying small drug volumes efficiently. All wetted parts of the liquid flow path are single use, minimizing the risk of cross-contamination. Flow kit installation is fast and easy to help minimize risk of error, reduce time spent on non-value-adding activities, and support short turnaround times between batches.

Many products are sensitive to contamination from the surrounding environment. In other cases, the drugs themselves can be very potent or even toxic, so avoiding exposure to the environment is also important. A closed process facilitates preparation and increases safety in both instances.

The system's small footprint enables efficient use of facility cleanroom space. The system has a benchtop design, and all valves, monitors, and tubings are mounted on the forward-facing wet side of the system for easy access. The space in front can hold columns of volumes up to 2.5 L. It can also accommodate a column holder for smaller columns. The system is designed for cleanroom environments and to withstand harsh sanitization.

*Max hold up volume for flowpath from inlet 8 to outlet 6 with filter and column inline and airtrap in by-pass position.



Fig 1. The ÄKTA ready chromatography system 450 is single-use and has a low flow rate and hold-up volume for efficient purification of small quantities of drug substance in a GMP environment.

The standard configuration system (SCS) model of ÄKTA ready chromatography system 450 is controlled by external human-machine interface (HMI) with UNICORN™ control software, which adheres to GAMP 5 practices and is 21 CFR Part 11 compliant. Intuitive method editing enables quick recipe creation. Key run data is visible in the interactive ***Process picture*** (Fig 2). If you need to troubleshoot or interact manually with the system, you can set and view manual instructions and alarm limits for each component in the ***Process picture***. The system has a standard for open platform communication (OPC), and the interface is compatible with third-party system control software.

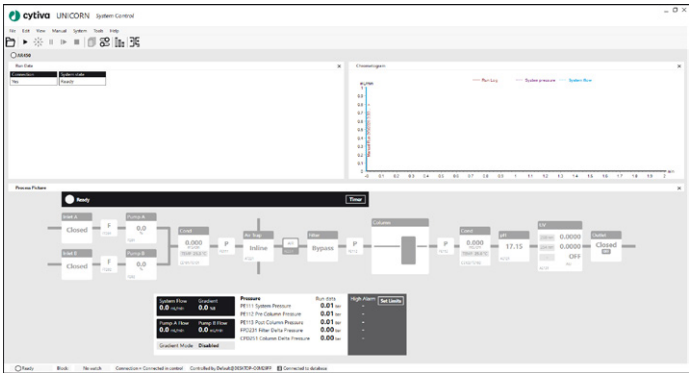


Fig 2. You can control the ÄKTA ready chromatography system 450 with the interactive process picture in the UNICORN control software.

Flow kit

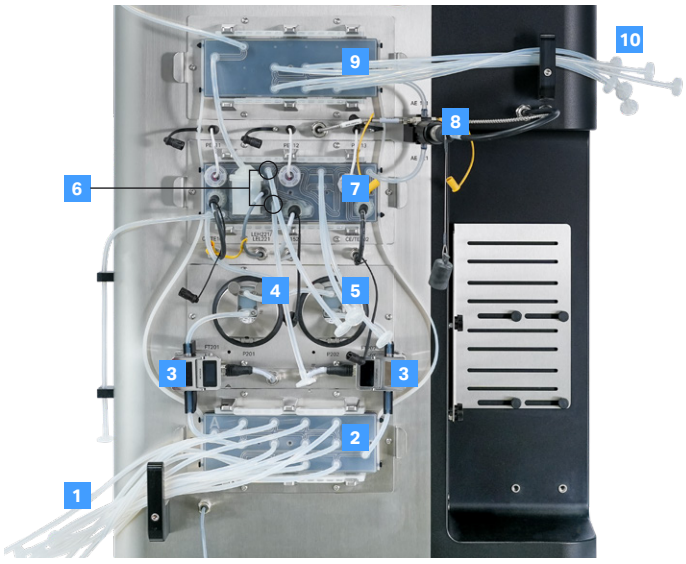
ÄKTA ready chromatography system 450 can be used for isocratic or gradient elution. Flow kits are available for both types of operation, either with sanitary or aseptic connectors. The system has a switch on the left side that allows you to easily install the flow kit. Markers show where to connect the sensors, and the valve blocks snap into place for easy attachment to the system. Sensors do not require calibration. An installation test confirms that the system has been set up correctly. Flow kit installation can be done in as few as 10 minutes.

Flow kits (Fig 3) are produced in an ISO class 7 clean room, double-bagged, and gamma-irradiated before delivery. Upon completion of the run or batch, the single-use flow path is disposed to prevent carryover between production batches or campaigns, facilitating processing in a multiproduct facility.

System overview

The piping and instrumentation diagram for the ÄKTA ready chromatography system 450 is shown in Figure 4. The system flow path has twelve inlets (eight are on pump A and four are on pump B for gradient elution) and six outlets. Flow is measured for each pump. The flow path also features an automated air trap and a location for a pre-filter, and each can be individually bypassed. The air trap automatically detects and prevents introduction of air into the column. An inline air sensor protects the chromatography column from air. The pressure drop over the pre-filter and column can be measured individually.

Post-column sensors monitor pressure, conductivity, temperature, pH, and absorbance (UV sensor). The UV sensor can measure up to three wavelengths between 206 nm and 700 nm simultaneously. The absorbance (A) ratio between two wavelengths (e.g., A_{260}/A_{280}) can be measured and used for pooling criteria. The system can connect to a weight scale with analog in/out to track sample loading or drug substance collected.



1. **Inlets**
2. **Inlet valve block**
3. **Flow meters**
4. **Pump A**
5. **Pump B**
6. **Pre-filter position**
7. **Main valve block with air trap and sensors**
8. **pH and UV sensors**
9. **Outlet valve block**
10. **Outlets**

Fig 3. Flow kit for ÄKTA ready chromatography system 450. The flow kit includes pump head(s), valve blocks, and sensors.

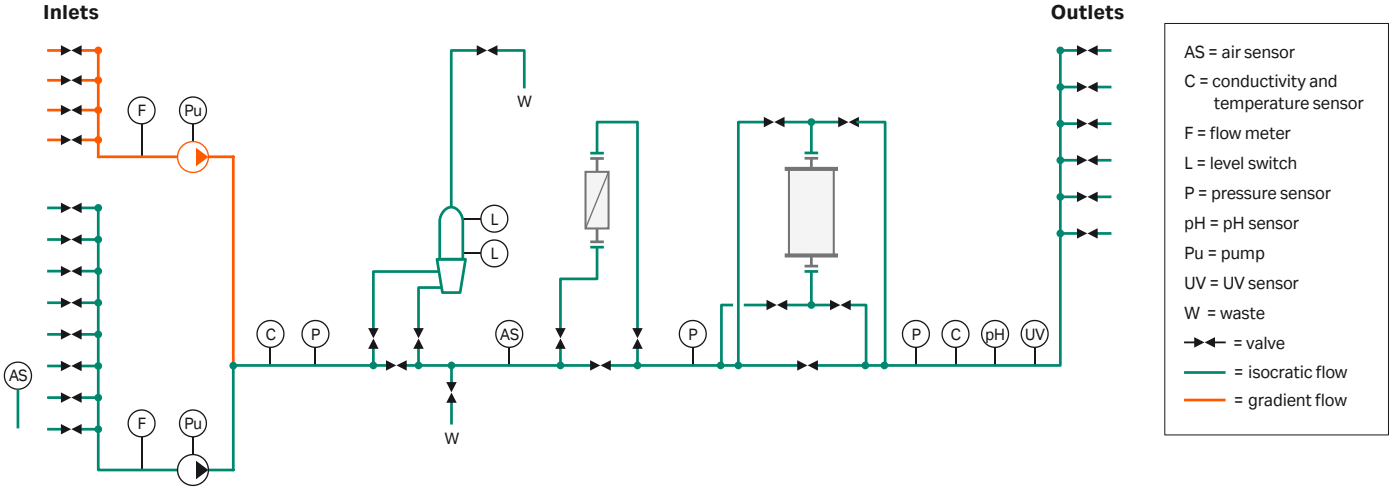


Fig 4. ÄKTA ready chromatography system 450 flow chart. Additional details are provided with the product documentation.

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 comprehensive range of services (Table 1) provide support throughout the product's life cycle to optimize performance and enable smarter equipment ownership.

Table 1. Equipment service solutions for ÄKTA ready chromatography system 450

Services	Description
Equipment installation	We must install your system to ensure it's eligible for manufacture warranty.
Online equipment management	Our online portal My Equipment keeps track of your instrument service contracts and service records for your Cytiva equipment.
Preventive maintenance	Replacement of wear-and-tear parts, and functional testing ensure continuous performance of your instrument.
IQ/OQ and requalification (RQ)	Standard and custom qualification services for Cytiva equipment throughout its life cycle, including IQ/OQ, RQ, and continuous verification.
Repairs	Field, remote, and mail-in repairs are available depending on your instrument type and environment.
Digital services	Comprehensive digital solutions, from remote assistance to network setup and virtual training.
Spare parts	High quality spare parts for use in GxP environment. We can advise on your spare parts strategy.
Relocation support	Preparing your equipment for moving and reinstalling it in its new location.
Training	Tailored and standardized training for operators and maintenance, including eLearning courses.
Service plans	A range of plans to support your operations and instrument performance.

IQ is installation qualification. OQ is operational qualification.

Specifications

General specifications	
Dimensions (W × H × D)	665 × 955 × 562 mm
Dry weight	100 kg
Operating max. pressure	4 bar
Flow rate	5 to 450 mL/min
Gradient flow range	50 to 450 mL/min
Ingression protection	IP55

Sensor specifications		
Operating max. pressure	4 bar	
Sensor	**Acceptance range**	**Measurement error**
Pressure sensor	0.1 to 4 bar	± 0.1 bar or ± 5% of actual value
Temperature sensor	4°C to 30°C	± 1°C
Conductivity sensor	1 to 200 mS/cm	± 5% of actual value
Three-wavelength UV sensor (206–700 nm)	0 to 2 AU*	linearity ± 2%
pH sensor	3 to 10	± 0.3
Flow rate	5 to 450 mL/min	± 12 mL/min or ± 6% of actual value

* Valid for 250 to 700 nm, 2% linearity 0 to 1 AU for 206 to 250 nm.

Pretreatment of flow kits (wetted components)
Details on flow kit wetted materials are in the corresponding product documentation file or the validation guide for each flow kit. We assemble cleaned parts in an ISO Class 7 cleanroom and gamma-irradiate the complete flow kits.

System control	
Software	UNICORN software version 7.10 or higher

Ordering information

System	Product code
ÄKTA ready 450 SCS	31189850

Product	Product code
ÄKTA ready 450 Flow kit Gradient TC	29631244
ÄKTA ready 450 Flow kit Isocratic TC	29631245
ÄKTA ready 450 Gradient AQ	29631246
ÄKTA ready 450 Isocratic AQ	29631247
Air sensor TC	29698478
Air sensor AQ	29698479

Jumpers	Product code
TC Jumper ID 3.2 mm × 200 mm	29698474
TC Jumper ID 3.2 mm × 400 mm	29698475
AQ Jumper ID 3.2 mm × 200 mm	29698476
AQ Jumper ID 3.2 mm × 400 mm	29698477
AQ-TC Jumper ID 3.2 mm × 200 mm	29719942
AQ-TC Jumper ID 3.2 mm × 400 mm	29719943

Qualification	Product code
Binder IQ/OQ AKTA ready 450 SCS	31205242
eIQ/OQ Protocol AKTA ready 450 SCS	31205282
Commissioning and Qualification Performance	28992657
eQualification Performance	30013519

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