ÄKTA ready™ 450

SINGLE-USE CHROMATOGRAPHY SYSTEM

ÄKTA ready™ 450 is a single-use liquid chromatography system designed for small-scale manufacturing (Fig 1). To meet the needs of purifying small drug volumes, the system has a low flow range of 5 to 450 mL/min per pump and a low hold-up volume. The single-use flow path minimizes the need for cleaning and cleaning validation, allowing for quick changeover between productions and reducing the risk of carryover. The ÄKTA ready™ 450 chromatography system offers the performance and documentation required for use in a GMP-regulated environment.

Designed for small-scale manufacturing:

- Small hold-up volume and flow rate support efficient purification of small drug volumes.
- Single-use flow path with a fully closed option reduce contamination risk.
- Small benchtop footprint makes efficient use of valuable facility space.

Designed for small-scale GMP manufacturing

We designed the ÄKTA ready™ 450 chromatography system 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.
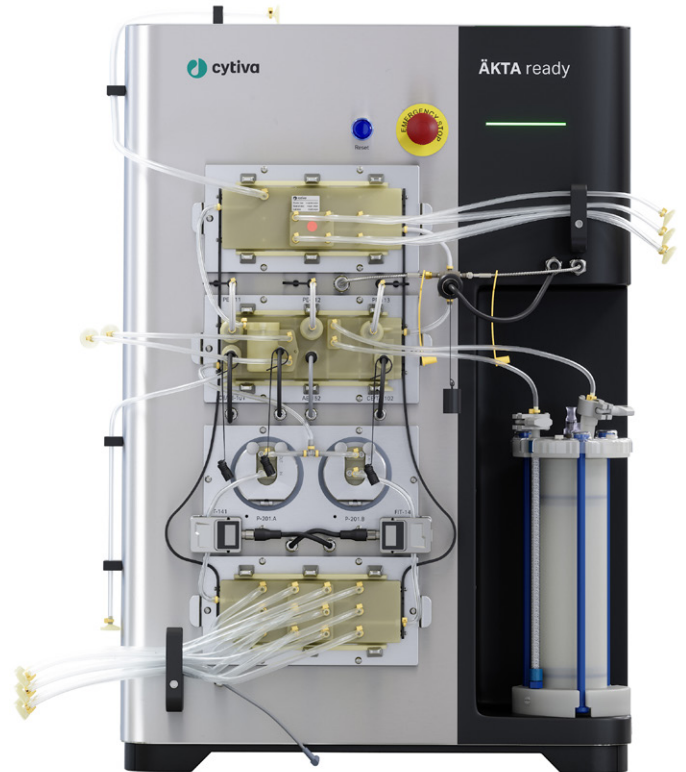

Fig 1. The ÄKTA ready™ 450 chromatography system is single use and has a low flow rate and hold-up volume for efficient purification of small quantities in a GMP environment.

The ÄKTA ready™ 450 chromatography system 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 editing. The system has a standard for open platform communication (OPC), and the interface is compatible with third-party system control software.
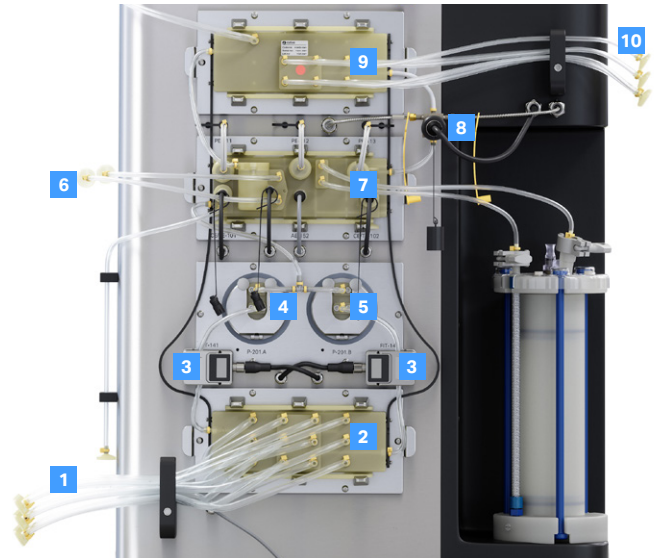
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Flow kit

ÄKTA ready™ 450 chromatography systems can be used for isocratic or gradient elution. Flow kits are available for both types of operation, either with Tri-Clamp™ or AseptiQuik™ connectors. 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. Installation can be done in as few as 10 minutes.

Flow kits (Fig 2) 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.

Flexibility and manufacturing capability

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.

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

Fig 2. Flow kit for ÄKTA ready™ 450 chromatography system. The flow kit includes pump head(s), valve blocks, and sensors.

AS = air sensor
C = conductivity and temperature sensor
F = flow meter
L = level switch
P = pressure sensor
pH = pH sensor
Pu = pump
UV = UV sensor
W = waste
→►◄ = valve
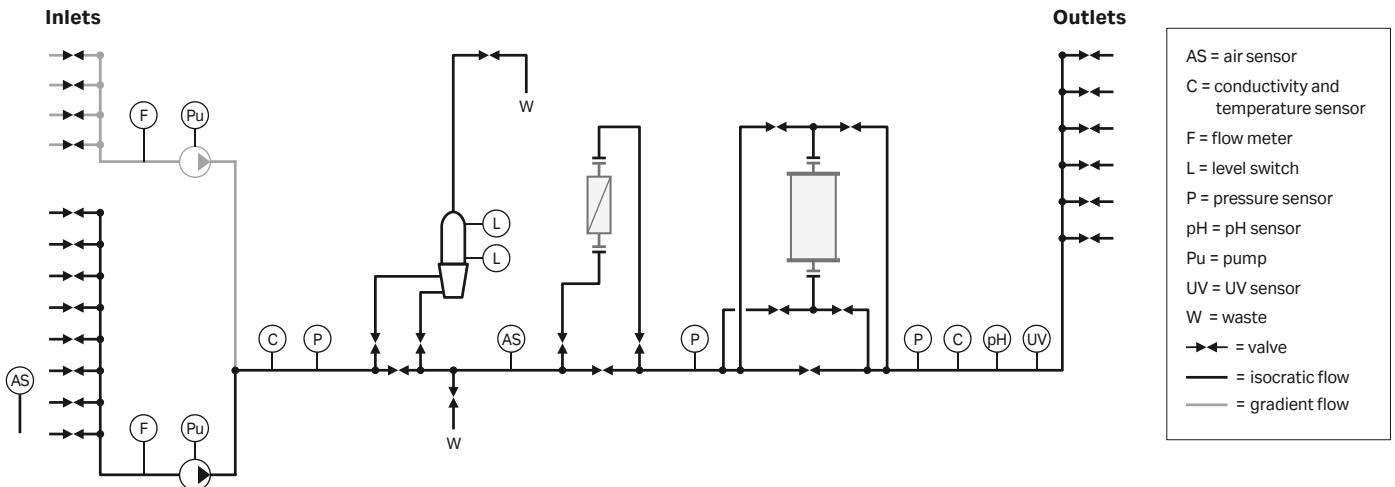— = isocratic flow
— = gradient flow

Fig 3. ÄKTA ready™ 450 flow chart.

Specifications

System specifications are listed in Table 1.

Table 1. ÄKTA ready™ 450 chromatography system specifications

General specifications

Dimensions (W × H × D)	640 × 940 × 558 mm
Dry weight	110 kg
Operating max. pressure	4 bar
Flow rate	5–450 mL/min
Ingression protection	IP55

Sensor specifications

Operating max. pressure	4 bar

Sensor	Acceptance range	Measurement error
Pressure sensor	0.1–4 bar	± 0.1 bar or ± 5% of actual value
Temperature sensor	2°C to 30°C	± 1°C
Conductivity sensor	1–200 mS/cm	± 5% of actual value
UV sensor	0–2 AU*	linearity ± 2%
pH sensor	3–10	± 0.3
Flow rate	5–450 mL/min	± 6% of actual value or ± 12 mL/min whichever is greater

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

Material compliance

USP <88> Class VI Test for biocompatibility
Animal free or complies with the conditions in EMA/410/01

Pretreatment of flow kits (wetted components)

Assembly of cleaned parts in ISO class 7 clean room
The complete flow kit is gamma irradiated.

System control

Software	UNICORN™ 7.0.2 or higher

Ordering information

The ÄKTA ready™ 450 chromatography system and ordering information will be available in 2022.

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