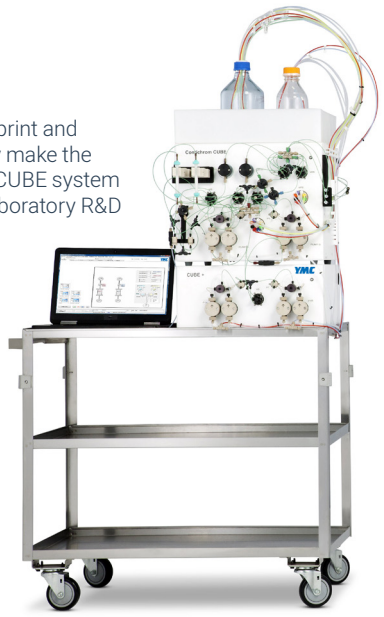
Contichrom® CUBE

A benchtop prep LC system for batch and continuous processing

- Run both automated single column batch chromatography and twin column continuous processes in one system
- Increase yield up to 50 % with the same purity*
- Greatly reduce process time, QC burden, and operating costs

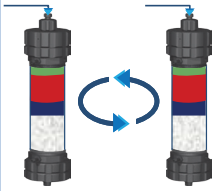
*using MCSGP



Minimal footprint and easy mobility make the Contichrom CUBE system perfect for laboratory R&D

Flexibility - Contichrom Process Portfolio

Traditional Batch

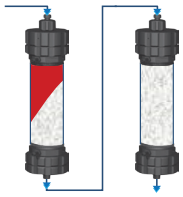


Traditiona Batch or *flip-flop* column chromatography

Integrated Batch

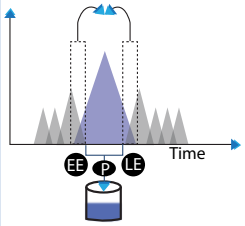
Two sequential batch purification steps without a stop

CaptureSMB®



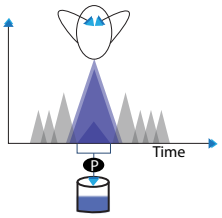
Fast capture process and full capacity utilization of Protein A

MCSGP



Obtain both high yield and purity with difficult separations

N-Rich®



Isolate product-related impurities overnight

All these techniques are possible with the same piece of equipment

Contichrom CUBE Platform

The Contichrom CUBE system has extended process capabilities for difficult purification challenges. The system consists of the CUBE hardware and PC with batch mode capability, CaptureSMB with AutomAb® control, MCSGP with AutoPeak® control, integrated batch / sequential polishing, and N-Rich processing.

AutomAb and AutoPeak dynamic process control functions allow robust operation of the CaptureSMB and MCSGP processes under changing process conditions or feed variations.

Contichrom CUBE systems are delivered ready-to-use with fully mounted tubing and pre-delivery IQ/OQ testing.

Twin-Column Technology

The Contichrom CUBE system is a flexible purification system for process development of (bio)pharmaceuticals such as monoclonal antibodies, peptides, oligonucleotides and small molecules.

It enables single-column batch and twin-column counter-current processes, such as capture (CaptureSMB) for monoclonal antibody (mAb) affinity chromatography and MCSGP for peptide purification. Additionally, the N-Rich process functionality allows the rapid isolation of product-related impurities for CMC development. The systems are offered with pump flow rates of up to 36 mL/min or 100 mL/min and pressure ratings of 100 bar.

Process Capabilities

The Contichrom CUBE system has batch process capabilities like conventional FPLC systems. Additionally, enhanced continuous process capabilities offer performance gains (productivity, yield and throughput).

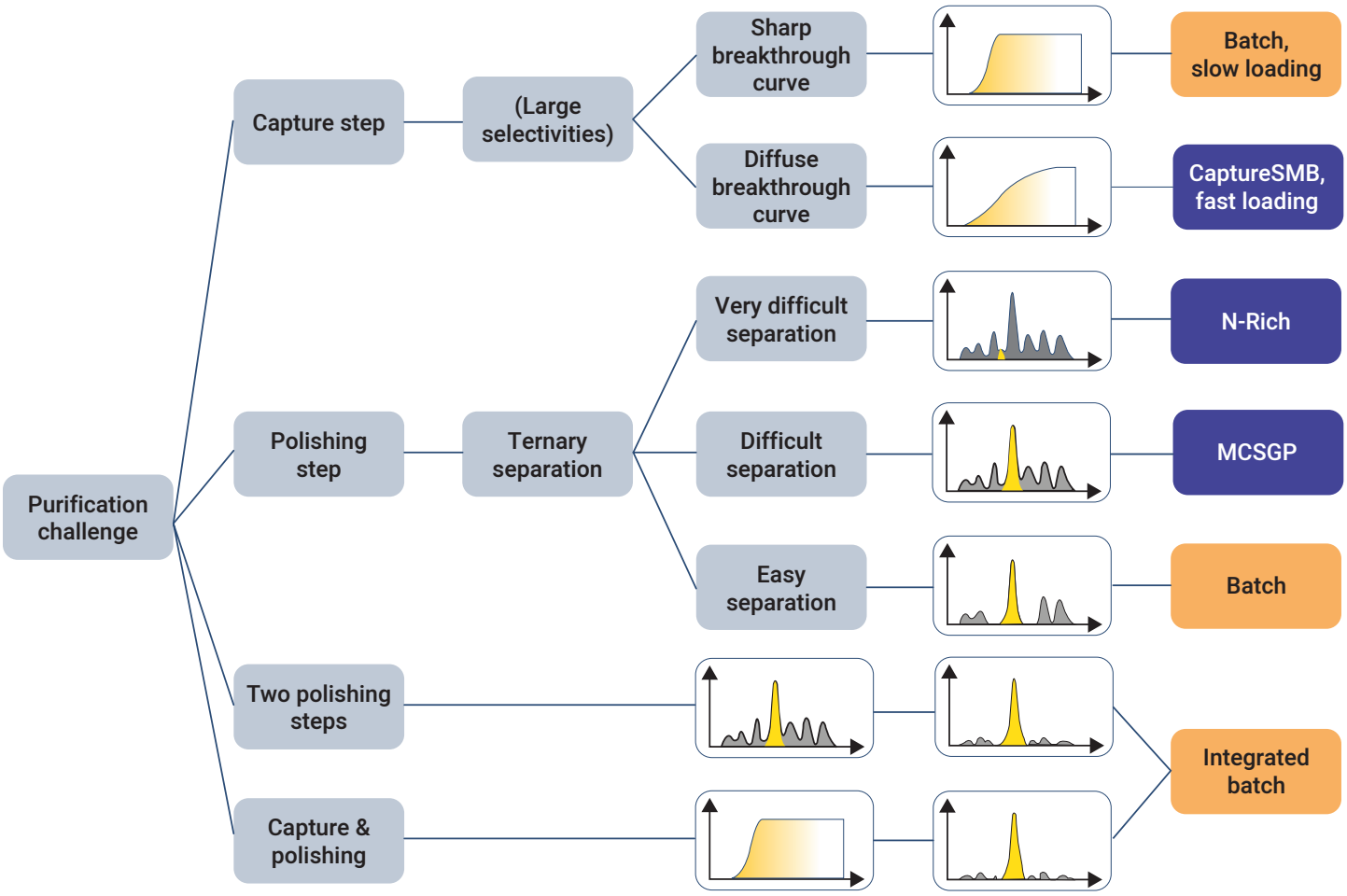
Twin-column capture applications (CaptureSMB) and the dynamic process control function, AutomAb, are useful for automated optimization of the mAb capture process. Twin column capture processes will result in significant cost-of-goods savings at GMP scale-up.

The Contichrom CUBE system adds twin-column / membrane process capabilities for polishing applications.

MCSGP: Multicolumn Countercurrent Solvent Gradient Purification. A powerful gradient elution process that increases yield by up to 80 % while maintaining target purity. AutoPeak, a dynamic process control tool, keeps the MCSGP process at an optimal operating mode.

N-Rich: a process for enriching and isolating minor components from complex mixtures. It is an ideal tool for fast isolation of product-related impurities for characterization pre-clinical testing.

CUBE Separation Matrix



System Accessories

Benchtop Cooling Cabinet preserves product integrity during purification. Cooling of the product feed and of fractions is important for preserving product integrity. We offer a compact cooling chamber that fits on a lab bench and can accommodate a fraction collector (Foxy R1), and feed bottles, for preparative runs under cooled conditions*.

Additional useful accessories include a sample loop system for feed loading, and external valve with an injection loop and a stable, reusable transport box.

Enhancing system performance and convenience with additional accessories, including an optional **external loading valve** with sample injection loops of 500 µL up to 20 mL, a **screening valve** for column screening addressing up to 6 columns, and **reusable transport boxes**.

*Cooling Cabinet not suited for chromatography using organic solvents.

Fraction collectors R1 and R2

Several rack types are available (listed below).

Additional racks available on request.

- 50 mL tubes
- 15 mL tubes
- 96-well plates
- 6 mL tube bottles

Injection valve system with injection loops of 500 µL up to 20µL allowing application of different sample volumes

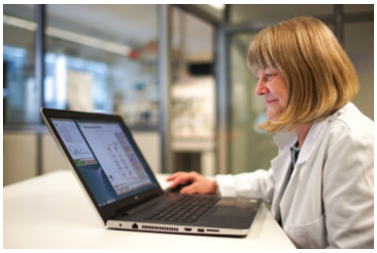
External variable 4-channel multiwavelength detector (200-600 nm)

Column thermostat (5-85 °C, wMax flow rate = 5 mL/min)

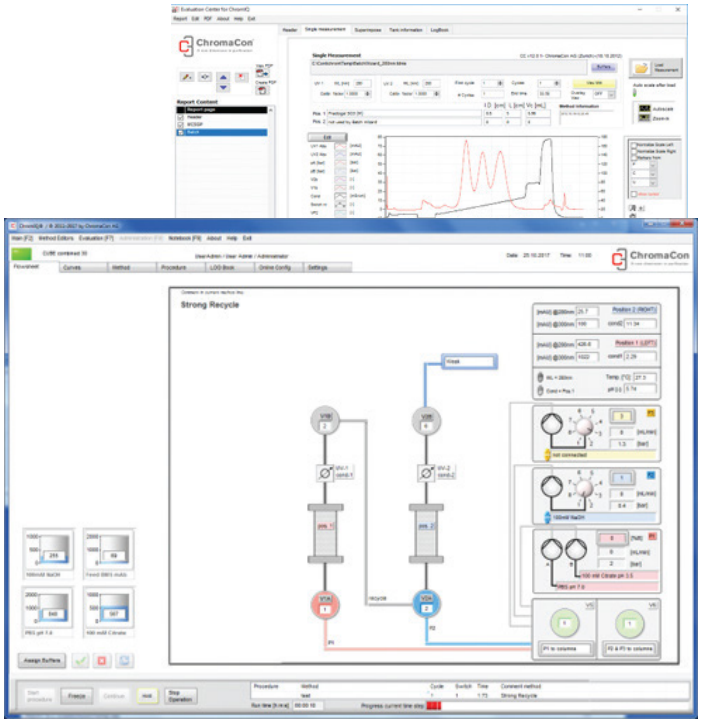
*Cooling Cabinet not suited for chromatography using organic solvents.

ChromIQ® Software

The ChromIQ operating software controls the Contichrom CUBE systems. It supports batch and continuous chromatographic processes with an intuitive, user-friendly interface.



ChromIQ includes several features that are particularly helpful for continuous processes such as a buffer management system, cycle overlay display options, and detector triggered dynamic process controls.



- Drag-and-drop method creation
- Wizards for convenient method creation
- Interactive process picture
- Single-click evaluation

- Easy data export (xlsx, csv, jpg)
- Predefined user groups with individual rights management
- Password protected user accounts
- Logging with time stamp and user name

Process Wizards

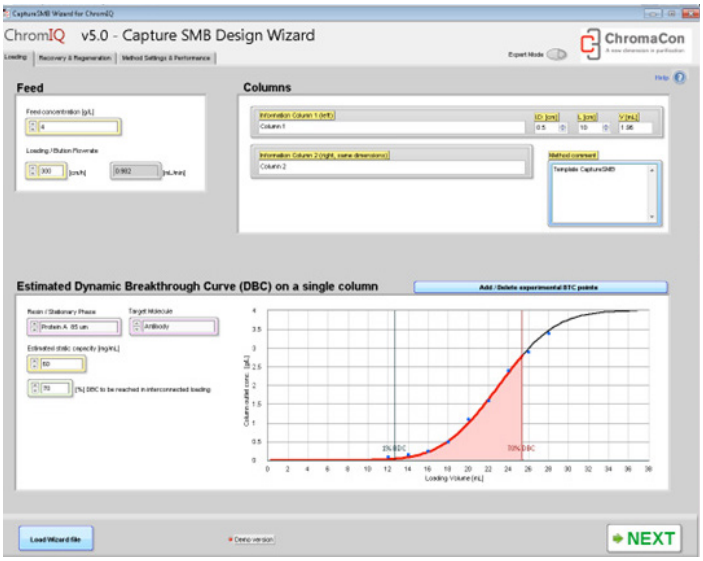
Load the process wizards from the ChromIQ software for rapid design of processes. ChromIQ has easy step-by-step wizards to help you design batch chromatography runs and to convert them to more efficient Twin column processes.

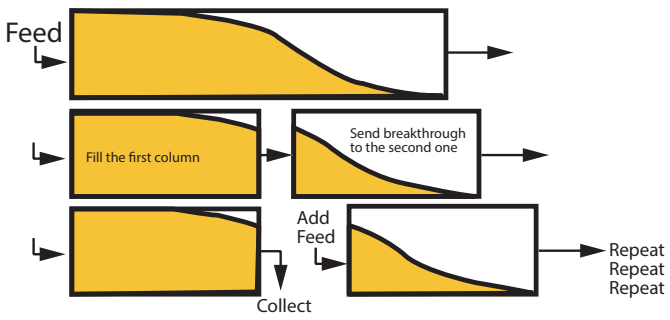
CaptureSMB

Step 1: Enter feed and column parameters and fit experimental breakthrough curve

Step 2: Define wash, elution and regeneration steps

Step 3: Activate AutomAb control, auto-generate method and receive performance prediction





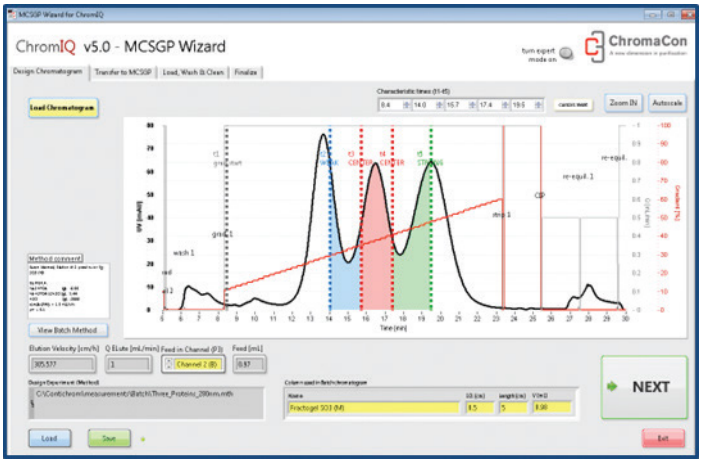
MCSGP

Step 1: Load chromatogram of batch run. Drag & drop to select product range and recycling fractions.

Step 2: Set column size and feed volume

Step 3: Define washing and regeneration steps

Step 4: Activate AutoPeak, set number of cycles and fractionation



Process Economics

CaptureSMB Technology

Enables: Two-fold faster processing of feed streams preserving product integrity; higher project turnover.

Saves: 40%-60% affinity resin costs and eluents while increasing productivity up to 2-3x.

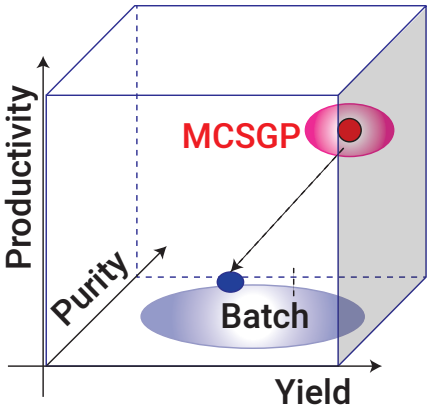
Integrated batch or sequential chromatography

The twin-column setup runs two consecutive process steps in an integrated way, using inline dilution between the first and second process step, eliminating intermediate hold steps.

MCSGP

Enables: Isolation of pure components from complex mixtures, dramatically increasing yield at target purity.

Saves: Up to 70 % solvent/PMI (including upstream) and 90 % of in-process controls (IPCs) while increasing yield to > 90 % and productivity up to 10-fold.



N-Rich Technology

Enables: The on-column enrichment of minor components while simultaneously removing and collecting the large excess of interfering product. It is particularly useful for isolation of product-related impurities.

Saves: Tedious, repetitive analytical separations taking weeks to isolate the compound of interest. With batch processes, up to several hundred analytical injections are often needed to isolate sufficient amounts for further characterization. With N-Rich technology processing, however, this can be achieved overnight.

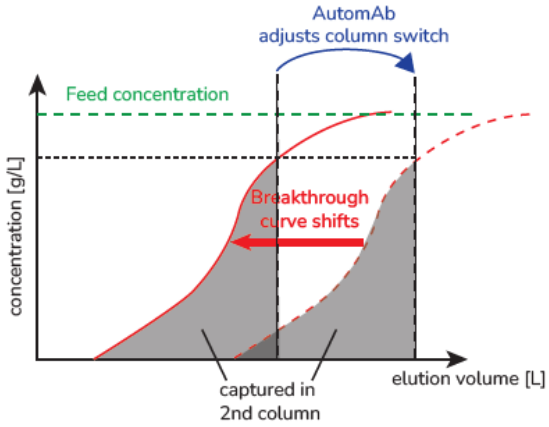
Dynamic Process Control

AutomAb: Dynamic CaptureSMB Process Control

AutomAb is a tool that automatically optimizes the CaptureSMB process in terms of resin capacity utilization, throughput, and ensuring steady product quality. AutomAb controls the process and maintains optimal process performance, effectively offsetting process changes such as feed titer variations and column aging.

Advantages of AutomAb

- Requires minimal process characterization
- Runs automatically without intervention
- Works with low and high feed titers
- Works without feed signal measurement
- Works with dirty feeds with a high impurity signal and low product feed concentrations

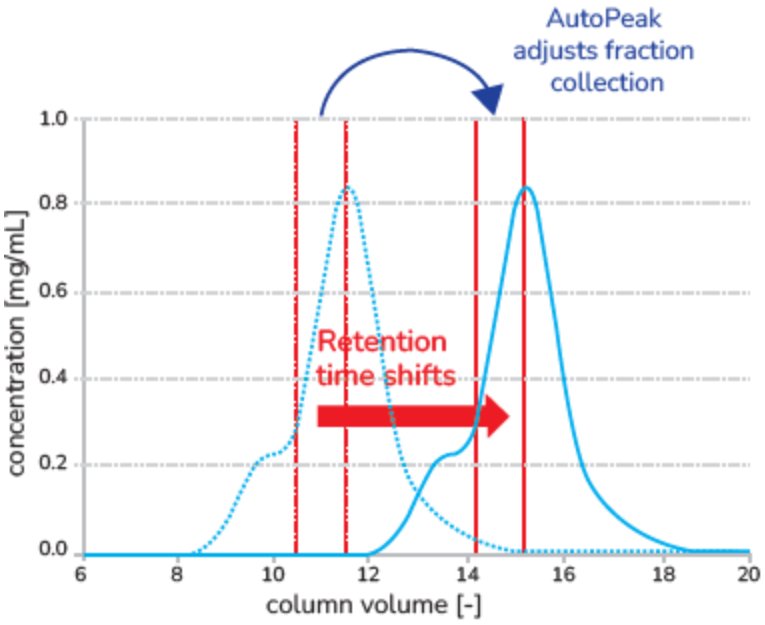


AutoPeak: Dynamic MCSGP Process Control

The chromatographic elution profile can be influenced by various parameters such as temperature, buffer composition, conductivity, pH and quality of the stationary phase (bed height, resin aging, packing variation) leading to variability. To counteract such effects, MCSGP includes a control function which compensates for these variations. The resulting process is very robust and runs continuously without sacrificing productivity.

Advantages of AutoPeak

- AutoPeak compensates for peak shifts by adjusting the start of fractionation
- Consistent product quality of the isolated fraction
- Precise control of cyclic continuous processes



Technical Specifications

Contichrom CUBE Systems

Process Capabilities:	Batch (isocratic, gradient), integrated batch, CaptureSMB, MCSGP, N-Rich
Operating Software:	User-friendly operating software with step-by-step wizards to help you design batch chromatography runs and convert them into more efficient Contichrom technologies, such as MCSGP and N-Rich processes. ChromIQ also includes dynamic process controllers AutomAb and AutoPeak.
Software Compliance:	ChromIQ software with essential elements of 21 CFR Part 11 compliance: • Predefined user groups, administrators, R&D and production users • Rights management for individual user groups • User accounts are password protected • Logging with time stamp and user name (cannot be deleted)
Pressure Rating:	1450 psi (100 bar) [10 MPa]
Flowrate Range:	Contichrom CUBE 30: recommended for columns of inner diameter 4.6 mm - 30 mm Contichrom CUBE 100: recommended for columns of inner diameter 8 mm - 50 mm
Buffer Selection:	16 inlets (2 x 8-fold buffer selection valve) 4 outlets
UV:	2 external UV detectors with 4 variable wavelengths 200-600 nm recorded simultaneously
Conductivity Monitoring:	2 conductivity sensors (1-250 mS/cm)
pH Monitoring:	1-14
Pump Type:	4 high precision double-piston-pumps with active seal wash (2x single inlet gradient pumps, 2x isocratic pumps with 8x inlets each)
Valves:	6 reliable multi-position valves
Computer Hardware:	Stand-alone laptop computer (Windows, 64 bit, full HD resolution, 1920 x 1080 or higher) with ChromIQ software
Other:	Cold room compatible Large buffer tray Portable and compact Runs resins and membrane stationary phases
Dimensions:	CUBE modules are stackable. CUBE module: 20" x 17.7" x 14.6" (509 mm x 450 mm x 370 mm) CUBE+ module: 20" x 17.7" x 8.4" (509 mm x 450 mm x 214 mm) External detector modules are stackable: 11" x 18.2" x 5.3" (280 mm x 463 mm x 135 mm)
Weight:	CUBE (top module): 67 lbs (30 kg) CUBE+ (bottom module): 38 lbs (17 kg)
Materials:	All biocompatible. PEEK high pressure side capillaries. FEP low pressure side tubing. PEEK fittings.

After-Sales Services and Products

GMP Scale-up with Twin Column Processing

The Contichrom CUBE system scales up to the Contichrom TWIN platform for a single-system solution which allows for ultimate flexibility for manufacturing. Save space and money without having to invest in additional (batch) equipment. Our CGMP skid systems are customized to your needs.

Services

We offer Preventive Maintenance, repair, and system validation and qualification support including IQ/OQ and a generic PQ testing scheme. We also offer an annual Software PM package.

We provide onsite and offsite training, webinar-based product support, and annual workshops on continuous chromatographic purification.

HPLC Columns and Resins

YMC is proud to be a trusted developer and manufacturer of high-quality, reliable, and reproducible resins that are used by chromatographers around the world. Our portfolio contains a wide range of product lines in reversed-phase, normal phase, ion exchange, chiral, and SEC chemistries. YMC media is available in prepacked columns as well as bulk quantities of packing material, allowing seamless scaleup to preparative applications.

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