

Contichrom[®] CUBE

YMC
America

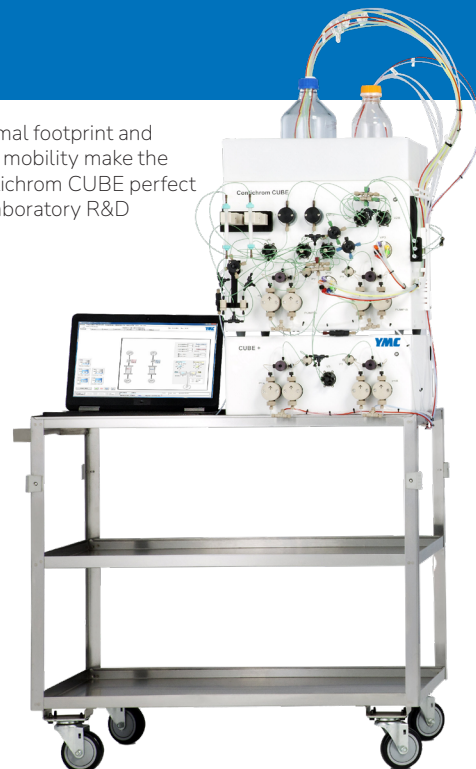
A benchtop chromatography system for batch and continuous processing

Run batch, integrated batch and continuous processes with ChromIQ[®] automation software

Get 50 % more yield with the same target purity and significantly greater throughput

Counter-current processes reduce operating costs significantly, including Protein A resin

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



Twin-Column

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

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. 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.

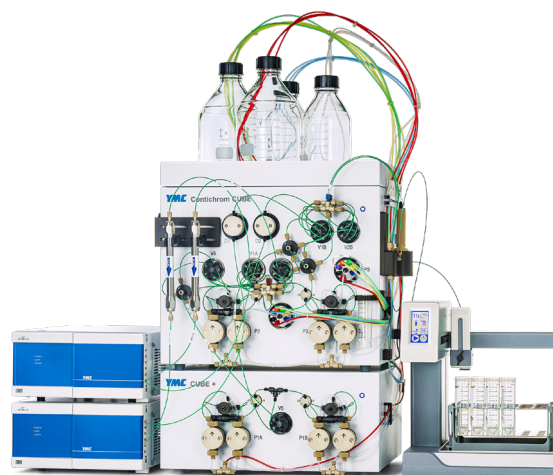
The unique twin-column operational design and software offer several process choices for optimal purification including batch, integrated batch / sequential polishing and continuous counter-current processes.

Contichrom CUBE Platform

The Contichrom CUBE 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, buffer dilutions 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.



Process Capabilities

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

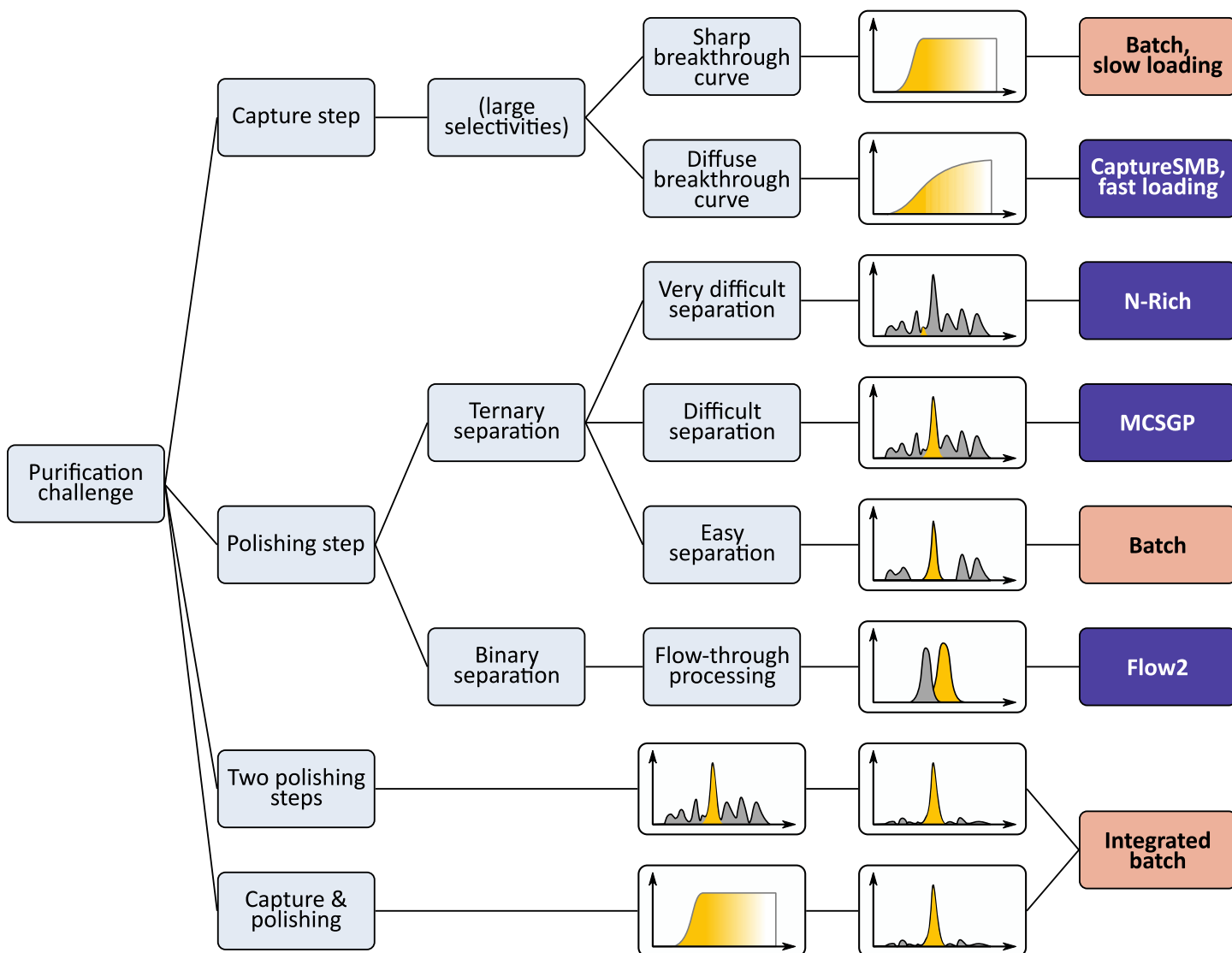
Twin-column capture applications (CaptureSMB) and the dynamic process control function, AutomAb, are useful for automated optimization of the mAb capture process. Twin column capture processes will result in significant cost-of-goods savings at GMP scale-up.

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

MCSGP: Multi-column Counter-current 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 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), feed bottles, and also columns allowing 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 two **external multi-wavelength detectors** (190-500 nm), a **sample loop system** for feed loading, 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**.



Fraction collectors R1 and R2

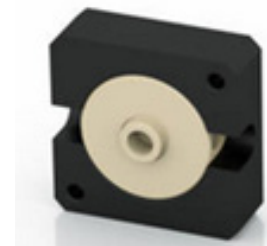
Several rack types are available (listed below).

Additional racks available on request.

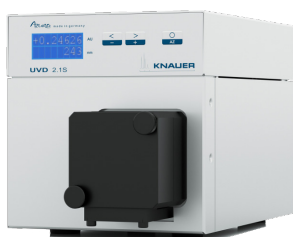
- 50 mL tubes
- 15 mL tubes
- 96-well plates
- 6 mL tube bottles



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



Preparative flow cells in PEEK or steel



External single variable wavelength detector (190-500 nm)

External variable 4-channel multi-wavelength detector (200-600 nm)



Detectors shown may vary from actual supply

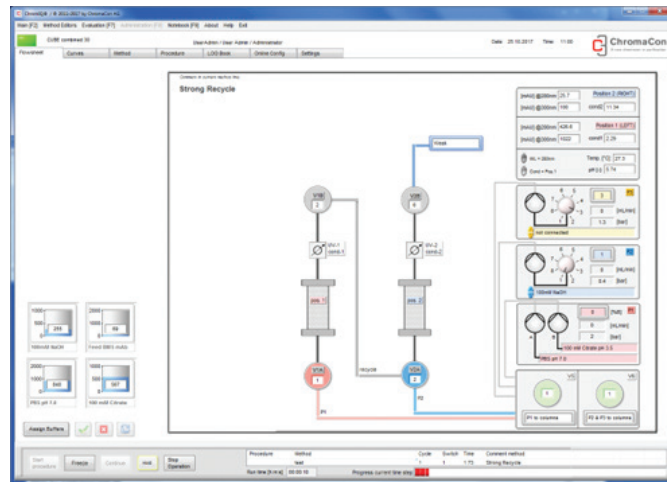
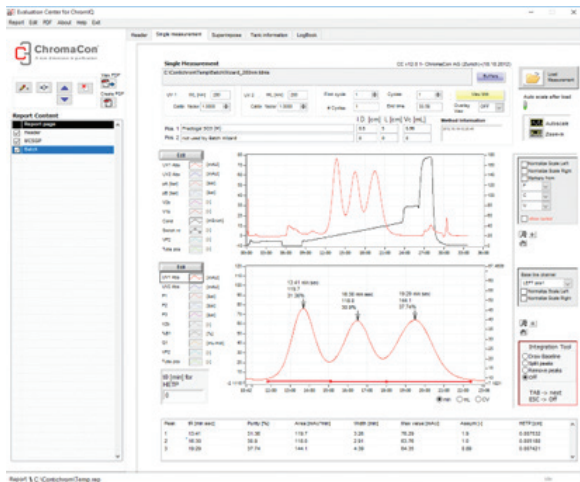
*Cooling Cabinet not suited for chromatography using organic solvents.

ChromIQ® Software

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

ChromIQ has easy step-by-step wizards to help you design batch chromatography runs and to convert them to more efficient Contichrom processes. ChromIQ also includes AutomAB and AutoPeak dynamic process control functions.

ChromIQ includes a number of features that are particularly helpful for continuous processes such as a buffer management system and cycle overlay display options.



- 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 Economics

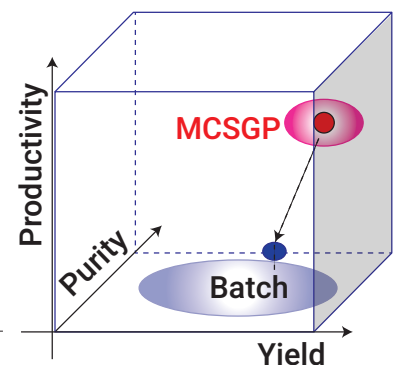
CaptureSMB Technology

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

Saves: 30 % CAPEX, 30-60 % OPEX, 40-60 % Protein A consumption, 40-60 % buffer consumption.

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; 50-90 % more yield and higher purity; up to 10x faster processing than batch.

Saves: Up to 30 % CAPEX, 50 % OPEX overall buffer or solvent consumption

N-Rich Technology

Enables: The enrichment of a minor component while simultaneously depleting 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 needed to isolate sufficient amounts for further characterization. With N-Rich technology processing, this can be achieved overnight.

Process Wizards

Load the process wizards from the ChromIQ software for easy design of 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



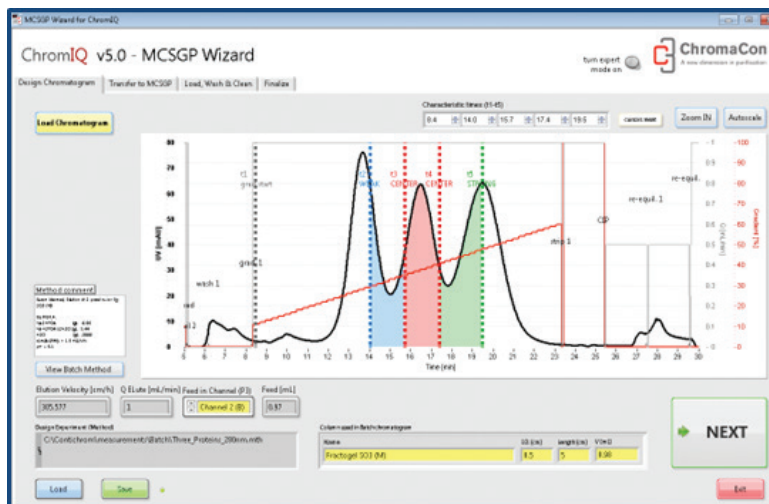
MCSGP

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 Batch AutoPeak, set number of cycles and fractionation



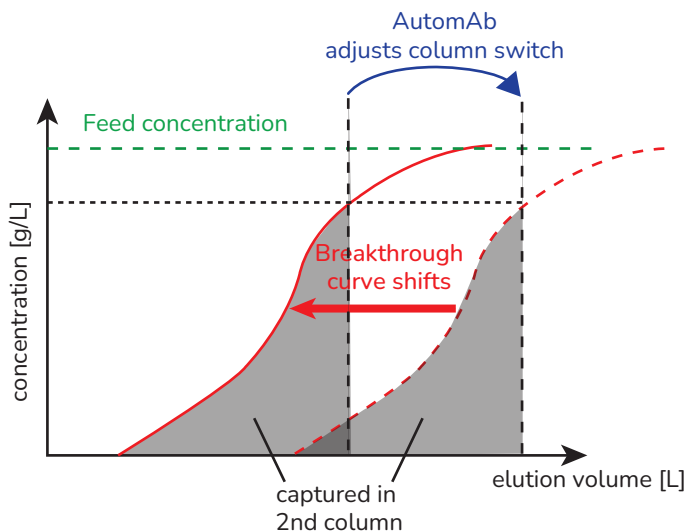
Dynamic Process Control

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

- Works with minimum process knowledge
- Runs fully 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
- Works without detector calibration

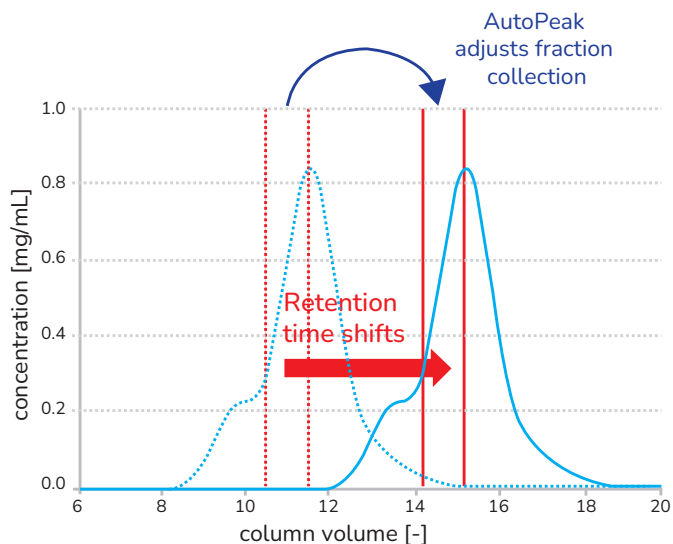


AutoPeak: Dynamic MCSGP Process Control

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

Advantages of AutoPeak

- AutoPeak compensates for peak shifts by adjusting the fractionation start
- Always the same product in same fraction
- Always the same product quality
- Perfect 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 21CFR Part 11 compliance: <ul style="list-style-type: none">• 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:	0.1 - 36 mL/min (Contichrom CUBE 30) 0.5 - 100 mL/min (Contichrom CUBE 100)
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 module: 30 kg (67 lbs) CUBE+ module: 17 kg (38 lbs)
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 capital equipment cost without having to invest in additional (batch) equipment. Our GMP 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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