

The Contichrom[®] CUBE FPLC System

A Twin-Column Protein Purification System for Batch and Continuous Processing



The Contichrom CUBE Platform

Buy what you need

Twin-Column Preparative FPLC System

The Contichrom **CUBE** and **CUBE Combined** are flexible modular purification systems for biopharmaceuticals such as monoclonal antibodies.

- □ The Contichrom **CUBE**, the basic hardware, can be expanded to the **CUBE Combined** system by adding the **CUBE**+ module for additional polishing capabilities to obtain higher efficiency and yield in challenging separations.
- □ You can combine hardware and software modules to obtain an optimal configuration that matches your budget and your needs. You can always upgrade with a hardware or software module for obtaining enhanced process capabilities.

The systems are offered with pump capabilities of up to 36 mL/min or 100 mL/min, respectively.

The CUBE's unique twin column operational design and software offer several process choices for optimal separation and purification of proteins and oligonucleotides, including batch, integrated batch, cyclic and continuous countercurrent processes.



Run batch and cyclic processes with ChromIQ automation software providing automated process optimization and control.





Get 50% more yield with the same target purity and significantly greater throughput. Develop mAb capture processes saving 50% resin costs.

The modular CUBE system allows you to upgrade process capabilities from batch and twin-capture to extended polishing options and to scale up to GMP pilot and process scale.

The CUBE – A Versatile System



The CUBE is a chromatography system for protein purification with ChromIQ software having batch, integrated batch and CaptureSMB (2C-PCC) process capabilities: an ideal tool for optimized mAb purification. The AutomAb dynamic process control function keeps the process at an optimum.



The CUBE Combined is a

chromatography system for protein purification consisting of the CUBE and CUBE+ modules with ChromIQ software having all CUBE functions and in addition extended polishing functions with MCSGP and N-Rich. MCSGP is supported by MControl, a dynamic process control function keeping the MCSGP process always at an optimum.

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

CUBE System Accessories

Benchtop Cooling Cabinet

Preserving Product Integrity During Purification

Cooling of 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 R-1), feed bottles and also columns allowing for preparative runs under cooled conditions.

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



CUBE System Accessories

Enhancing System Performance and Convenience

Additional accessories include 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 μ L up to 20 mL, a screening valve for column screening addressing up to 6 columns and stable, re-usable transport boxes.



Teledyne-Isco fraction collectors Foxy R-1 and R-2



Injection value system with injection loops of 500 μL up to 20 mL allowing to apply different sample volumes



Valve system with 6 different positions for column screening



External variable wavelength detector (190-500nm)





Re-usable transport boxes for system modules



Preparative flow cells in PEEK or Steel

Powerful Functionalities



- compact benchtop design
- large buffer tray
- clear easy-to-access interface
- high visibility tubing inlets and outlets
- flexible tubing connections
- high performance pumps (36 or 100 mL/min)
- easy-mount clip-in column supports

- 2 x long life LED UV detectors each at 280 nm and 300 nm, 260 nm optional
- easy plug-in CUBE and CUBE+ installation
- pH detector
- 2 x conductivity flow cell
- laptop and desktop options

All-In-One Process Capabilities

The Contichrom CUBE has batch process capabilities like any preparative chromatography system. In addition it has enhanced process capabilities for integrated batch: Two batch steps can be executed consecutively with an in-line dilution in between. The CUBE systems also offer cyclic and continuous operating modes using twin column configurations.

Twin column capture applications (**CaptureSMB** / 2C-PCC) and the software tool (AutomAb) are useful for automated optimization of the capture process. Twin column capture processes will result in significant cost-of-goods savings at GMP scale-up.

The Contichrom CUBE+ module adds additional process capabilities for polishing applications in combination with the CUBE module:

- MCSGP: a powerful polishing process that increases yield while maintaining target purity. It comes with MControl, a dynamic process control tool that keeps the MCSGP process at an optimum.
- N-Rich: a process to isolate minor compounds from complex mixtures an ideal tool for fast isolation of low concentrated product-related impurities for pre-clinical testing.



Process Economics

Batch and integrated batch chromatography

The Contichrom equipment contains all hard- and software tools to run normal batch processes such as capture and polishing steps with isocratic, step and gradient elution. The batch software wizard facilitates process design significantly. Due to the twin-column setup you can run two process steps consecutively in an integrated way, even with an in-line dilution between the first and second column steps, eliminating intermediate hold steps.

CaptureSMB (2C-PCC)

ENABLES

Significant economic benefit compared to batch: Two-fold faster processing of feed streams preserving product integrity; higher project turnover.

SAVES

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

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, 70% buffer consumption.

N-Rich

ENABLES

N-Rich enables the enrichment of a minor compound while simultaneously depleting the large excess of interfering compounds. It is particularly useful for isolation of product-related impurities.

SAVES

Tedious repetitive analytical separations to isolate the compound of interest. With batch processes, up to several hundred analytical injections are needed to is

With batch processes, up to several hundred analytical injections are needed to isolate sufficient amounts for further characterizations. With N-Rich, this can be achieved overnight.



ChromIQ Software

The ChromIQ operating software controls the CUBE system. 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 the more efficient Contichrom Processes. ChromIQ also includes the AutomAb toolbox for optimization of the CaptureSMB process.

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



The software contains all essential elements for 21CFR part 11 compliance:

- ✓ Pre-defined 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
- ✓ Electronic signature with checksum of log and measurement files



Process Wizards



Dynamic Process Control

AutomAb: CaptureSMB (2C-PCC) control

AutomAb is a tool that automatically optimizes the CaptureSMB process in terms of resin capacity utilization and throughput. In addition, AutomAb controls the process and maintains optimal process performance. AutomAb lets you develop an efficient powerful process in a short time. AutomAb effectively controls the process even under conditions of changing feed titer and column aging, making it a valuable tool also for



MControl: MCSGP 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 algorithm allowing to keep the MCSGP runs always at an optimum by compensating for variations. The resulting MCSGP process is very robust and will run at an optimum without sacrificing productivity.



Advantages of MControl

MControl 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

Who Uses CUBE Systems?

Bio/Pharmaceutical companies

- Process development for therapeutic proteins
- Biomarker discovery, target identification, assay development
- Isolation of product-related impurities
- Isolation of Biosimilar isoforms
- Stability studies of bulk drug substance and formulated product
- High-throughput purification of mAbs for Protein A capture and SEC polish

CMOs and CROs producing Biologics

- CROs and CMOs producing compounds for small and mid-sized biotech companies can dramatically reduce their project turnaround time. Alternatively they can reduce the Protein A bill.
- Slash the processing time and increase the number of projects that can be undertaken
- Time and labor for process development can be cut with AutomAb automated optimization software
- Fast process development with MCSGP
- Economic clinical trial manufacturing
- Pre-clinical development services with N-Rich. Isolation and characterization of product-related impurities

Research and health institutes

- Identify and isolate difficult fractions with N-Rich's fast, high resolution, automated process
- No more hours and hours of manually injecting small quantities, and products that have degraded before you have a chance to analyze them. N-Rich will do the same task overnight with minimal manual handling
- Biomarker discovery, target identification, assay development
- Production of biological targets

Universities and colleges

- Explore new territory with a range of techniques at your fingertips, all on one easy-to-use system. Isolate difficult product-related impurities, biomarkers, aggregates and defective molecules quickly
- Biomarker discovery, target identification, assay development
- Production of biological targets, using tagged proteins
- Protein purification

GMP Scale-Up

Twin-column pilot-process scale

Ecoprime[®] Twin: Best-in-class GMP skids



Product features

- Integrated Buffer Inline Dilution (BID)
- Ability to run batch, integrated batch, parallel batch and CaptureSMB. MCSGP will be available soon.
- CIP & SIP
- Drain & blow dry
- Custom designed set up
- Scale-up method conversion
- Allan-Bradley Rockwell operating system
- Compliant with GMP, GAMP, ASTM, 21CFR part 11
- Alarm and event logs, access control
- All wetted parts cleanable
- Flow accuracy: better than 0.5% variation.
- Gradient accuracy: better than 0.5% variation
- Pressure rating: 7.5 bar (108 psi)
- Flow path: 316L stainless steel

Туре	Min L/min	Max L/min
Ecoprime 100	0.004	0.6
Ecoprime 250	0.02	2.4
Ecoprime 500	0.06	9

EcoPrime[®] is a trademark of LEWA and LEWA Process Technology Ltd. System quotes can be obtained under www.lewaprocesstechnologies.com

After Sales Services

Training, Maintenance, and Repair

A reliable and cost-effective service network

Purchasing an FPLC System and operating it is only part of a customer's value proposition. After sales support such as Preventive Maintenance (PM) and total life cycle costs are an important consideration in a system's procurement evaluation.

We offer PM, 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 perform on-site and off-site training, webinar-based product support and we organize annual workshops on continuous chromatographic purification.

Our system is designed to have very low maintenance costs: only wear parts from pumps and valves need to be exchanged occasionally in an easy way without disassembling the system. The UV detector operates in pulsed mode, thus the UV lamps have virtually an unlimited lifetime.



We offer comprehensive and cost-effective Preventive Maintenance and Repair Service packages.



Worldwide Preventive Maintenance and Repair Service packages. On-site and off-site service with fast turnaround times.

For details please require a quote at your local ChromaCon representative.

Technical Specifications

Contichrom CUBE (30 / 100) 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 to design batch chromatography runs and to convert them into more efficient Contichrom processes, such as MCSGP and N-Rich. ChromIQ also includes the AutomAb toolbox for CaptureSMB optimization.
Software compliance:	 ChromIQ software with all essential elements of 21CFR Part 11 compliance: Pre-defined 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 (non-deletable) Electronic signature with checksum of log and measurement files
Pressure rating:	50 bar (5 MPa)/ 725 psi
Flow rate range:	 0.1 – 36 mL/min (Contichrom CUBE 30) 0.1 – 100 mL/min (Contichrom CUBE 100)
Buffer selection:	16 Inlets (2 x 8-fold buffer selection valve) 4 Outlets
UV, fixed wavelength:	2 Long lifetime LED UV detectors, each with 280 & 300 nm recorded simultaneously (260 nm optional)
Conductivity monitoring:	2 Conductivity sensors (1-150 mS/cm)
pH monitoring	1-14
Pump type	High precision double-piston-pumps with active seal wash 2 pumps (CUBE), 4 pumps (CUBE Combined)
Valves:	4 Reliable multi-position valves 1 Automated drain valve (CUBE), 2 automated drain valves (CUBE combined)
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 & compact Runs resins and membrane stationary phases
Dimensions:	Contichrom CUBE module: 450 mm x 509 mm x 370 mm CUBE+ module: 450 mm x 509 mm x 214 mm
Weight:	Contichrom CUBE module: 30 kg (67lb) CUBE+ module: 17 kg (38lb)
Materials:	All biocompatible High pressure side capillaries: PEEK Low pressure side tubing: PTFE Fittings: PEEK

Contact



Contact us now to find out how you can solve your separation challenges more easily

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