Contichrom® PILOT 300X

A High-Performance Preparative HPLC System for Continuous Chromatography at Pilot-Scale (MCSGP with AutoPeak®)

Advanced Processes for Oligonucleotide and Peptide Purification

The Contichrom® PILOT 300X is a preparative HPLC system engineered for pilot-scale manufacturing of pharmaceuticals in a GMP environment. It combines our advanced twin-column continuous chromatography process (MCSGP with AutoPeak®) with the robustness required for pilot-scale production.

Designed to handle both aqueous and organic solvents, the system is fully compliant with hazardous location requirements (ATEX Zone 2, Class I Div 2), making it ideal for the purification of peptides, oligonucleotides, and other synthetic molecules. With a maximum operating pressure of 100 bar and a flow rate of up to 300 mL/min, it is perfectly suited for modern, high-performance resins for reversed-phase and ion exchange chromatography, using columns up to 10 cm ID.

The integration of our unique hardware and software provides a scalable, and GMP-ready platform, enabling users to develop and run more efficient and robust purification processes.

Available from 2026.
Contact us to request a quote.

The Contichrom® Platform for MCSGP – Key Benefits

Contichrom systems deliver significant improvements across the purification workflow by addressing the core challenges of manufacturing:

Tech-Transfer & Scalability: Processes developed and optimized on the lab-scale Contichrom CUBE are easily scalable and transferable to the Contichrom PILOT 300X ensuring a predictable, robust, and validated process. Further scale-up from the Contichrom PILOT 300X to the Contichrom TWIN HPLC is also possible.

Enhance Automation for Robust, Unattended Operation: Integrated dynamic process control (AutoPeak®) compensates for process variability, enabling extended, unsupervised 24/7 operation. This high degree of automation reduces the scope for user error, minimizes operator interaction, and makes the process more economical.

Designed for GMP Compliance: The Contichrom PILOT is designed for use in GMP environments, with a comprehensive documentation package, support for 21 CFR Part 11 compliance, and construction using certified materials.

Improve Sustainability and Process Economics: MCSGP decreases eluent consumption and allows for downscaling of upstream synthesis batches due to higher yields. This significantly improves the Process Mass Intensity (PMI), lowers the overall cost of goods, and creates a more sustainable manufacturing operation.

Eliminate Re-Chromatography and Reduce QC Burden: By maximizing yield at target purity, MCSGP eliminates the need for re-chromatography of side-fractions. This simplifies the manufacturing operation by reducing intermediate handling & storage, and the significant analytical QC burden associated with batch processes.

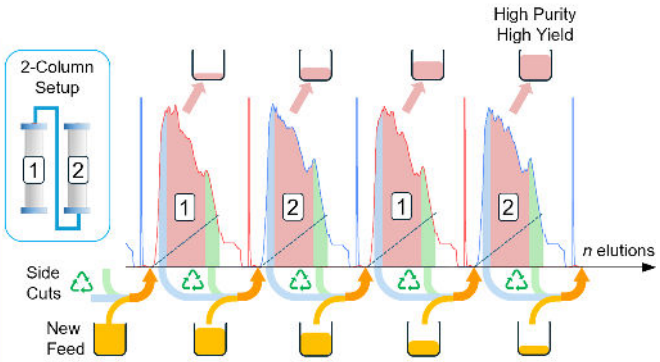
Increase Productivity: Leverage our continuous polishing process (MCSGP) to maximize the output from expensive chromatography resins, significantly increasing overall productivity and reducing the need for oversized columns.

Unlock Efficiency with Twin-Column Continuous Processes

The core innovation of the Contichrom PILOT system lies in its ability to execute patented twin-column continuous processes (MCSGP) with integrated dynamic process control (AutoPeak). This technology moves beyond the limitations of sequential batch chromatography, enabling interconnected, continuous operations that fundamentally improves process economics and efficiency.

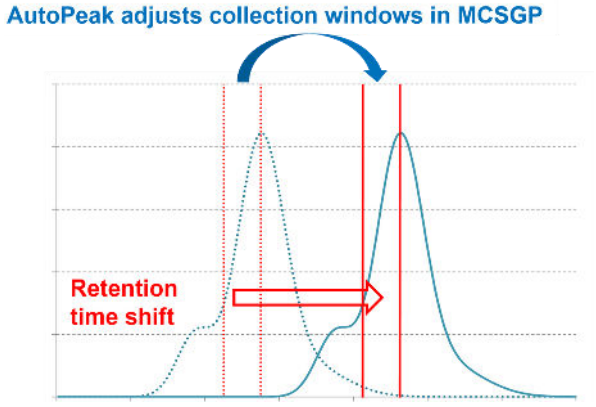
MCSGP: Continuous Polishing for Increased Yield and Automation

In polishing steps, process developers often face a difficult choice: collect a narrow peak to achieve high purity at the cost of yield, or collect a wider peak to maximize yield at the cost of purity. The Multi-column Counter-current Solvent Gradient Purification (MCSGP) process resolves this yield-purity trade-off. MCSGP is a continuous polishing process where impure side-fractions are not discarded or stored for re-chromatography. Instead, the system's software identifies these fractions and automatically recycles them back to the inlet of the second column ready for the next elution. This allows for the near-complete recovery of the target molecule while simultaneously removing impurities, achieving high purity and high yield at the same time in a continuous, automated process.



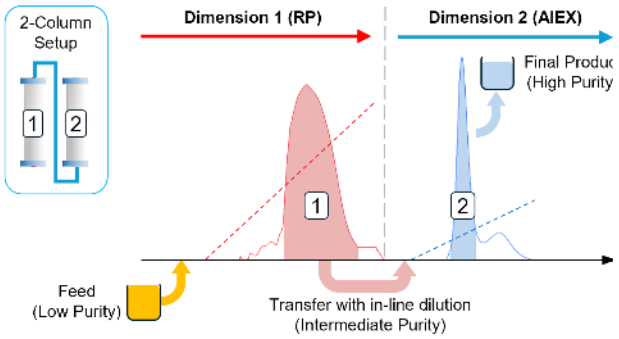
AutoPeak® Control for MCSGP

UV-based, dynamic process control is essential for a robust MCSGP process, ensuring consistent yield and purity in the presence of process drift by dynamically adjusting the collection window based on real-time UV triggers.

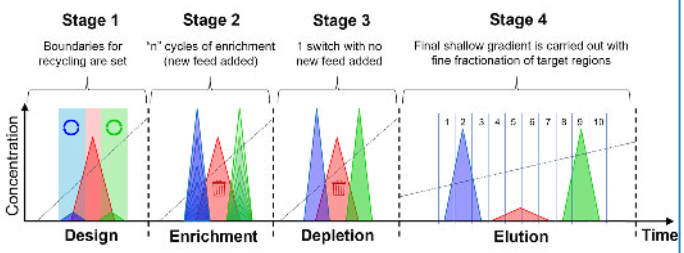


2-Dimensional Integrated Chromatography (2D-LC)

Beyond fully continuous MCSGP process, the twin-column setup is ideal for performing 2D integrated batch chromatography. This powerful capability allows for the direct coupling of two different chromatography steps (e.g., Dimension 1 = Reversed Phase polishing (RP), Dimension 2 = AIEX polishing) into a single, automated process. The product-containing eluate from the first column is directly transferred to the second column (see diagram), with inline dilution to ensure optimal binding conditions. This eliminates the need for intermediate hold tanks, manual handling, and associated quality control, significantly reducing process time and facility footprint.



N-Rich: Automated, On-column Compound Enrichment

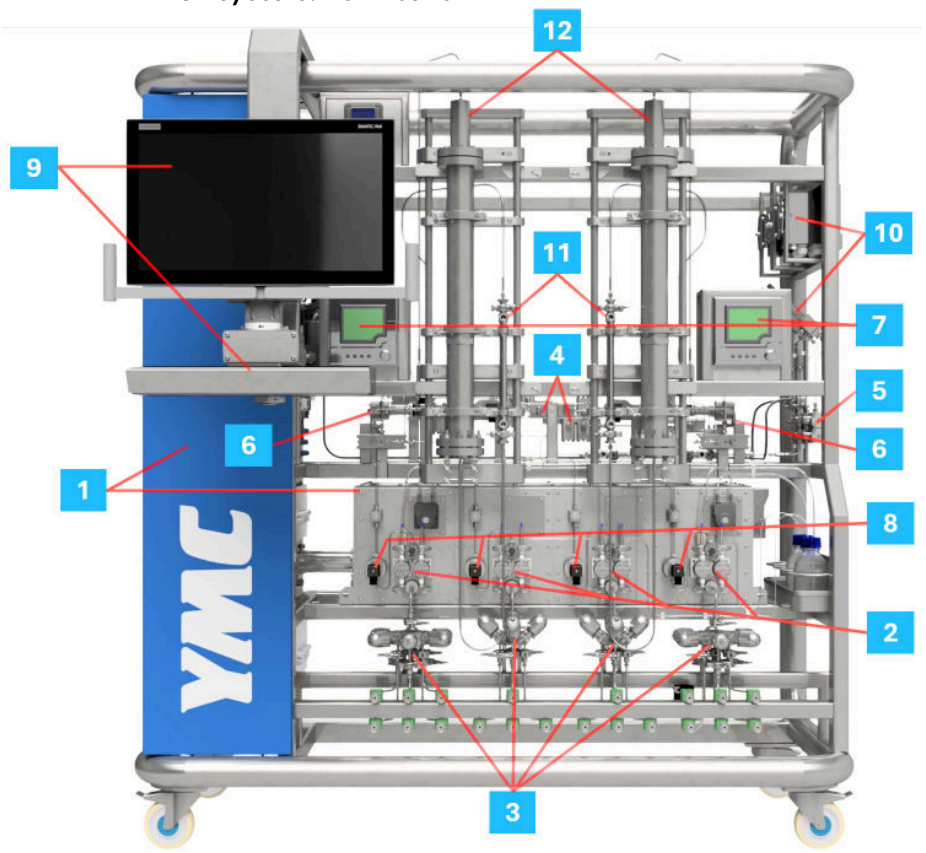


Isolating sufficient quantities of low-abundance compounds with a high purity can require hundreds of repetitive HPLC runs. The N-Rich process provides an automated, on-column solution. Using a two-column cyclic enrichment methodology, N-Rich applies new feed each cycle while depleting undesirable products (red) and continuously recycling purified fractions containing the compound of interest (blue and green). This leads to on-column accumulation of desired compound with a high purity, drastically reducing manual handling and project time.

Contichrom® PILOT 300X System: Hardware Overview

The Contichrom PILOT system is built on a foundation of robust, high-performance hardware components, engineered for reliability, flexibility, and GMP-compliant operation. The system is designed as a stand-alone unit on lockable, clean-room compliant wheels with an IP23-rated enclosure, with the entire fluid path located outside the main chassis for accessibility and serviceability.

HMI & Keyboard: Front Position



HMI & Keyboard: Side Position

1. **Explosion Proof Design (ATEX):** A two-column preparative HPLC system (100 bar) for batch and continuous processes.
2. **High-Precision Piston Pumps (x4):** Designed for the low pulsation and high accuracy (300 mL/min max)
3. **Inlet Valves (x4):** A total of 20 inlets are provided via dedicated valve assemblies
4. **Fast Switching HP Valves (x7):** Valve arrangement provides fluidic control for single column and interconnected flow paths
5. **Fractionation Valves (x2):** Dedicated valves for product and waste collection (4 fractions for each)
6. **UV-Vis Detectors (x2):** External, variable 4-channel multi-wavelength (200-600 nm)
7. **Conductivity Sensors (x2):** Monitoring between 0–250 mS/cm
8. **Pressure Sensors (x8):** Post pump (x4), Pre-column (x2), Post-column (x2)
9. **HMI & Keyboard:** 24" Touchscreen and keyboard on a rotatable arm for front or side facing interaction
10. **pH sensor (x2 Optional):** pH range 1–14
11. **Heat Exchangers (x3 Optional):** Pre-column eluent heating and post-column product cooling
12. **Recommended Column ID:** Contichrom PILOT 300X = 2.7 cm - 10 cm (depending on linear flow rate)

Contichrom® PILOT 300X System: Hardware Components

ATEX-COMPLIANT DESIGN FOR HAZARDOUS LOCATIONS

The system is fully certified for operation in ATEX Zone 2 and Class I, Division 2 environments, making it suitable for use with flammable organic solvents. Safety is ensured through a multi-layered design approach, including the use of intrinsically safe components, an electrical cabinet protected by a continuous air purge system, and an ATEX-compliant keyboard connected via an electronic safety barrier.

PUMP SYSTEM

The system is equipped with four high-precision, dual-head piston pumps designed for the low pulsation and high accuracy required for HPLC. Pumps feature an active seal wash to ensure longevity and reliability during long runs.

- **Configuration:** One binary gradient pump (Pumps 1A/1B) and two isocratic pumps for inline dilution/regeneration (Pump 2) and feed (Pump 3).
- **Flow Rate:** Up to 300 mL/min per pump.
- **Pressure Rating:** Maximum operating pressure of 100 bar (10 MPa, 1450 psi).
- **Wetted Materials:** Key fluid path components are constructed from SS 316L (or Hastelloy), PEEK, Tefzel™ (ETFE), polyethylene (PE), ceramic (pistons), and high-performance seals (PTFE or UHMW-PE).

VALVE AND FLUIDIC CONTROL

A network of fast-acting, pneumatically actuated on/off valves enables the complex, automated switching sequences required for all batch and continuous processes.

- **LP Inlet valves:** A total of 20 inlets are provided via four dedicated valve assemblies for automated buffer and sample selection.
- **Fast Switching HP Valves:** Two multi-way valve arrangements provide full control over flow direction (forward, reverse) and bypass for each column position. Additional valves direct flow between columns for interconnected processes.
- **Fractionation:** Dedicated valves for product and waste allow for the collection of up to 4 fractions for each stream, with an optional interface for a larger fraction collector.
- **Wetted Materials:** To ensure high chemical resistance, valve flow paths are constructed from SS 316L (or Hastelloy), PCTFE (seat), FFKM (seals), PTFE,

DETECTORS AND SENSORS

To provide comprehensive real-time monitoring of the purification process, the Contichrom PILOT 300X system is equipped with a range of detectors and sensors. Of particular note is the unique placement of UV and conductivity detectors at the outlet of each column. This is essential for process monitoring between interconnected columns, which is critical for the robust dynamic control of all twin-column processes during interconnected phases.

Multi-Wavelength UV-Vis Detectors

The standard configuration includes two external, variable 4-channel multi-wavelength UV-Vis detectors, with one detector positioned at the outlet of each column.

- **Technology:** Diode Array Detector (DAD)
- **Wavelength Range:** 200–600 nm
- **Channels:** Up to 4 wavelengths can be monitored simultaneously per detector.
- **Light Source:** Long-life deuterium lamps connected via fiber-optic light guides.
- **Optical Path Length:** A standard 0.5 mm path length flow cell is included. The cells are easily exchangeable for other path lengths (0.1 to 1 mm).
- **Wetted Materials:** PEEK, Quartz, FEP.

Conductivity Sensors

- Two temperature-compensated conductivity sensors are located at the outlet of each column, providing accurate gradient monitoring during interconnected phases, with a measurement range of 0–250 mS/cm.
- **Wetted Materials:** PEEK, Titanium.

Pressure Sensors

- Pressure transducers are placed at all critical points (post-pump, pre- and post-column) for precise system and differential pressure monitoring.
- **Wetted Materials:** SS 316L (or Hastelloy) and FKM (seal).

Air Sensors

An ultrasonic sensor on the feed line protects columns from running dry and allows complete feed consumption. (Optional: Additional air sensors can be added)

FLOW PATH AND MIXERS

- **Tubing:** High-pressure lines are 1/8" OD (1.78 mm ID) SS 316L (or Hastelloy). Low-pressure lines are 1/4" OD (4.8 mm ID) FEP tubing with ESD protection.
- **Inline Filtration:** To protect the columns and system components from particulates, dedicated filter holders are located after each pump, allowing for the installation of optional inline filters (e.g., ≤ 1 µm).
- **Mixers:** High-pressure static mixers are used to ensure homogeneous mixing of gradients. Wetted materials is SS 316L.

HUMAN-MACHINE INTERFACE (HMI)

The system is controlled via an integrated industrial PC running the ChromIQ X software. Operator interaction is managed through a high-resolution ATEX-compliant touchscreen monitor and keyboard with an integrated touchpad, ensuring safe and efficient operation within a GMP environment.

RECOMMENDED COLUMN ID

- The Contichrom PILOT 300X supports columns from 2.7 to 10 cm inner diameter (ID).

OPTIONAL HARDWARE

- **pH Sensors:** In-line pH probes (pH 1-14) can be installed on the product and waste outlet lines. Wetted parts are glass and PEEK (16 bar max pressure).
- **Eluent Tempering:** Pre-column heat exchangers can be added for precise eluent temperature control. Eluent pre-heating up to 60°C is possible. A third heat exchanger can be added at the system outlet. Supply of heating or cooling can be done via utilities or a via standalone solutions recommended by YMC.
- **Fraction Collector:** The system can be integrated with a automatic fraction collector for large-volume collection.

ChromIQ® X Software: Designed for Compliance

The Contichrom PILOT 300X is operated by ChromIQ X software, which is designed for use in regulated GMP environments and supports compliance with relevant regulations including 21 CFR Part 11.

Workflow: Continuous and integrated processes are developed on the laboratory-scale Contichrom CUBE, which features process wizards for streamlined method creation. These methods are then easily transferred to the Contichrom PILOT's method editor for scale-up studies and pilot-scale production.

Scalability: Furthermore, methods validated on the Contichrom PILOT 300X are directly scalable to larger Contichrom TWIN line of production-scale systems.

Dynamic Process Control: To ensure process robustness and optimal performance, ChromIQ X incorporates patented process control (AutoPeak) functionallity that enables reliable, unattended 24/7 operation. AutoPeak adjusts fraction collection windows based on real-time UV triggers, ensuring consistent purity and yield even with process drift.

Data Integrity and Security: The system ensures full traceability and data integrity.

- All data is stored in a secure database (PostgreSQL).
- A comprehensive, time-stamped, and unalterable logbook + comment field allows a complete audit trail of all user actions, system events, and alarms.
- Multi-level user rights management with support for Active Directory integration. Unique username/password combinations and user group memberships control access and permissions.

Connectivity: OPC UA client and server functionality is available for seamless integration with external control systems and data transfer.

Regulatory Compliance and Documentation

The Contichrom PILOT is designed and fabricated to meet the stringent requirements of GMP environments.

Certification and Explosion Proof:

- CE and ATEX Zone 2
- UL and Class I Division 2

Automation: Developed under GAMP 5 framework and complies with FDA CFR 21 part 11 regulations

Standard and norms: The system is designed to enable and facilitate compliance with:

- 21 CFR Part 211 (Subparts C & D)
- EudraLex, Vol. 4, Part II, Chapter 5ICH Q7 (Good Manufacturing Practice for API)
- EC Machine Directive EC, Low Voltage Directive EC, EMC Directive
- RoHS / REACH
- NFPA70 / NFPA79 (for US version)

Materials of Construction: All wetted materials are selected for biocompatibility and chemical resistance, with full traceability. Material certificates (e.g., FDA 21 CFR 177, USP <88> Class VI, EMA 410/01) are provided in the documentation package. Surface roughness of wetted metallic parts is < 0.8 µm.

Turnover Package (TOP): The system is delivered with a comprehensive documentation package conforming to ASME BPE standards, including P&IDs, material certificates, component lists, calibration certificates, and performance reports to support qualification and validation activities.

Contichrom® PILOT 300X Specifications

Category	Parameter	Specification
System	Flow Path Materials	Choose from SS 316L or Hastelloy options
	Control System	ChromIQ® X operating software on an integrated industrial PC
	Maximum System Pressure	100 bar (10 MPa, 1450 psi)
	Processes	Batch, 2D Integrated Batch, MCSGP, N-Rich
	Dimensions (W x H x D)	180 x 197 x 85 cm excluding HMI arm (for transport). HMI arm increases W to 242 cm or D to 150 cm depending on position.
	Weight	650 kg
	Power Supply	100-240 VAC, 50-60 Hz, 2000 W
	Environmental Conditions	+4°C to +30°C.
	Explosion Proof Rating	ATEX Zone 2 and Class I Division 2
	Recommended Column ID	2.7 cm to 10 cm
Pumps	Pump Type	4x Piston pumps (dual head). 2 active seal wash loops are standard, 1 dedicated to the feed pump, 1 shared between the other 3 pumps.
	Configuration	1x Binary gradient pump, 2x Isocratic pumps
	Flow Rate Range	2 - 300 mL/min per pump for isocratic pumps 10 - 300 mL/min for the gradient pump (Sum A + B) and a 10-90 %B gradient
	Flow Rate Accuracy	±2% (above 2.0 mL/min)
	Flow Rate Precision	±0.5% RSD
	Gradient Accuracy	±2% (above 10 mL/min for 10-90 %B of gradient)
Detectors & Sensors	UV-Vis Detectors (x2)	Type: DAD, Wavelength: 200-600 nm, Path length: 0.5 mm (standard, exchangeable)
	Conductivity Sensors (x2)	Range: 0-250 mS/cm
	pH Sensor (x2, optional)	Range: pH 1-14
	Temperature Sensors (x2)	Range: 0-80°C
	Pressure Sensors (x8)	Placed post-pump, pre-column and post-column for precise system and differential pressure monitoring.
	Air Sensor (x1)	Non-contact ultrasonic sensor on feed line (Standard). Additional air sensors (Optional)

Contichrom® PILOT 300X Specifications

Category	Parameter	Specification
Valves	Valve System	Pneumatically actuated on/off valves
	Buffer/Sample Inlets	Gradient Pumps: 8 (2x 4-port valves); Isocratic Pumps: 12 (2x 6-port valves)
	Column Connections	2 column positions with dedicated inlet, outlet, and bypass valves (100 bar)
	Outlets	4 product outlets, 4 waste outlets
Flow Path & Mixer	High-Pressure Tubing	Material: 316L stainless steel or Hastelloy, OD: 1/8" (3.18 mm), ID: 1.78 mm
	Low-Pressure Tubing	Material: FEP (with ESD protection), OD: 1/4" (6.35 mm), ID: 4.8 mm
	Gradient Mixer	Static mixer
	Recycle Line Mixers (x2)	Static mixers
User Interface	HMI	ATEX-compliant Siemens HMI, 24", FullHD
	Keyboard	ATEX-compliant keyboard with integrated touchpad
Optional Modules	Eluent Tempering	Pre-heating range: RT to 60°C. Cooling to RT at system outlet. External water source for heating/cooling is required - Inquire with YMC for suggestions.
	Fraction Collector	Interface for external fraction collector (operation in ATEX zone is user's responsibility)
Operating Software	Software Name	ChromIQ® X Software Suite
	Method Design	Powerful method editor for GMP-compliant execution of batch, integrated, and continuous processes. Methods are transferable from Contichrom CUBE and scalable to the Contichrom TWIN
	Dynamic Process Control	AutoPeak® (for MCSGP & N-Rich)
	Data Integrity	21 CFR Part 11 compliant features, full audit trail, secure database
	Connectivity	OPC UA compatible
Required Utilities	Pressurized gas source	Nitrogen 8-10bar (0.8-1MPa, 118-147psi) for ATEX

Service and Support

To ensure maximum uptime and performance, a full range of service and support options is available.

- **Maintenance & Qualification:** Preventive maintenance protocols, on-site service, and full IQ/OQ support by certified personnel.
- **Spare Parts:** A list of recommended spare parts is provided to ensure operational readiness.
- **Remote Support:** The system is equipped with remote access capability (optional) for efficient troubleshooting and support by ChromaCon specialists.
- **FAT / SAT:** Services and Support are available.

Contact Us

Contact us to request a budgetary quote or to discuss your chromatography challenges with an expert:

Americas:
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Web: www.ymcamerica.com

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