



FAQ's for YMC's MCSGP technology

Q. What does MCSGP stand for?

A. *Multi-column Counter-current Solvent Gradient Purification* – a technology using two or more columns for continuous chromatography when using gradient elution.

Q. How do I test my molecules to see if this technology would benefit me?

A. There are several ways to evaluate MCSGP technology on your molecule. YMC offers feasibility studies in one of our labs, using our equipment and experts on a contract basis. Additionally, YMC offers a rental program for our Contichrom CUBE (typically one to two-month period). YMC offers those who rent a unit on-site training and weekly application support for the duration of the rental period.

Q. Is the MCSGP process proven by companies manufacturing therapies / vaccines?

A. Yes. The MCSGP process has been evaluated in-house by many top-tier CMO's and pharmaceutical companies. Their results confirmed our claims. A number of production scale systems are scheduled to go into production in GMP suites in 2021 in Europe, Asia, and US.

Q. Have end-users presented their work with the MCSGP process?

A. Yes. One such example is Bachem who have presented a webinar on their work with MCSGP on peptides. You can view it on [YouTube here](#). Additionally several end users are publishing papers to be released in the fall of 2021.

Q. Which options do I have to check out the technology if I cannot test it with my own molecule(s) or at my own lab facility?

A. YMC offers Webinars and Workshops. The latter gives the attendees a hands-on opportunity during the lab part. Demonstration at YMC sites can be done using a model system, which we can also recommend during the on-site testing.

Q. Are special resins or column required?

A. No, you can use your column packing / resins. However YMC resins and columns are well understood and can optimize the MCSGP process and should be strongly considered. For the initial process design, you can also use conventional column sizes; however, we recommend YMC columns with shorter length, if possible 10 but not more than 15 cm lengths. These shorter columns will allow you to run at maximal flow rates and, therefore, to reach maximal productivity. In addition YMC can supply resins and corresponding columns with the system as a complete solution package.

Q. What is the lead time for a lab system? GMP scale system?

A. Lab scale (Contichrom CUBE) systems are 12-15 weeks and GMP scale (Contichrom TWIN) are 28 to 36 weeks (depending on options and capacity).

Q. Are these standard systems or custom?

A. The lab systems, Contichrom CUBE are standard with different option packages allowing users to run up to five modes of chromatography on the same bench-top systems, which include traditional batch and sequential chromatography, CaptureSMB, MCSGP, and N-Rich. Two different scales are available, CUBE 30 and 100.

The GMP scale platform, Contichrom Twin MCSGP, offers 3 standard systems as well as custom designs based on the standard platform design. The systems can execute both traditional batch chromatography with gradient elution and the MCSGP process.

Q. Can the system be configured to operate in a hazardous location?

A. Yes, YMC can provide most levels of compliance with regional regulatory requirements such as Class I Div II and ATEX.

Q. Can I transfer my current batch strategy directly to the MCSGP protocol?

A. Yes. With some minor modifications that we advise you on, your batch protocol can be directly transferred into a MCSGP process using the MCSGP Wizard. Further optimizations are possible for enhanced performance using MCSGP.

Q. How do I know this system will scale from the bench top to production?

A. We will provide you with a template that allows the seamless transfer from methods of the Contichrom CUBE to the recipes of the Contichrom Twin MCSGP. This template will contain system related scaling factors that will ensure proper scale up from the bench to production.

The design of GMP scale systems is based on the Contichrom CUBE. A team of dedicated engineers at YMC locations collaborated closely during the development of the system platform. We verified the design by testing multiple external examples on the CUBE and the TWIN. The results of both systems are comparable; thus, it could be shown that CUBE systems can provide predictable process performance. As YMC has both CUBE and TWIN rental systems, users can evaluate at both bench and production scale before purchasing.

Q. Can MCSGP be used for IEX or just for RP applications?

A. The Contichrom CUBE can execute both applications. The standard Contichrom TWIN MCSGP system is designed as an HPLC system, and while it can operate at lower pressure suitable for IEX, components such as pumps and fittings are chosen to meet the high-pressure requirements, which depending upon your criteria may or may not be suitable for low-pressure IEX application due to cleanability limitations. YMC can offer custom designs to meet aseptic design considerations.

Q. Will I need a separate batch system for my legacy product production?

A. No. The standard MCSGP units can execute conventional batch chromatography as well as twin-column continuous (MCSGP) modes. This gives users a great deal of flexibility with a single piece of capital equipment.

Q. There might be variability when my peaks elute due to variability in the solvent/buffer composition or due to temperature fluctuates. Does the system adjust for that?

A. Yes. The patented control strategy “AutoPeak”, as part of the process automation, can react to process variabilities without operator intervention, which enables the user to operate under optimal conditions. A white paper and webinar are available to walk you through how this works.

Q. My product requires to be processed at elevated or reduced temperatures. Can your system maintain these process temperatures?

A. The GMP scale units can maintain elevated or reduced process temperatures. Additionally, YMC design systems to heat or cool the process streams.

Q. Who came up with the acronym “MCSGP”?

A. Scientists who drink a bit.

Q. Do impurities accumulate in MCSGP due to the internal recycling?

A. No accumulated impurities end up in the final product pool. Depending on the selected operating conditions, impurities may initially accumulate in the process to some degree, however without ending up in the product pool after steady state is reached.

Q. Where can I get more information on MCSGP technology?

A. The following links will lead to more detail on these topics:

General MCSGP overview: <https://www.chromacon.com/en/technology/continuous-polishing-processes-mcsgp>

AutoPeak control (MControl):
https://www.chromacon.com/resources/public/lava3/media/kcfinder/files/MControl_dynamic_process_control_MCSGP.pdf

Application Note – Oligo purification:
https://www.chromacon.com/resources/public/lava3/media/kcfinder/files/Oligonucleotide_MCSGP_application_note.pdf

Paper on Peptide purification: <https://ispe.org/pharmaceutical-engineering/march-april-2019/purification-synthetic-peptides>

Contichrom CUBE lab unit: <https://www.chromacon.com/en/products/contichrom-cube-combined-1>

Contichrom TWIN GMP unit:
https://www.ymcpt.com/sites/default/files/YMC%20TWIN%20MCSGP%20HPLC%20YMC%20Cut%20Sheet_D6-030-B-02-21-2020.pdf

Note: This is not a controlled document. Subject to change without notification.

The YMC logo, Contichrom and AutoPeak are registered marks of YMC.

Valid as of July 2021.

Statement herein do not constitute a quote or guarantee of performance.