



- Certification - 2D Chromatography - Newest Publications - Event Note -

Dear customers and friends of Chromicent,
we wish you a successful start to the new year.

Chromicent is pleased to inform you that the inspection by the local drug authority in accordance with § 64 of the German Medicinal Products Act was extremely successful at the end of 2022.

Chromicent's GMP compliance confirmation will be issued for a further three years.

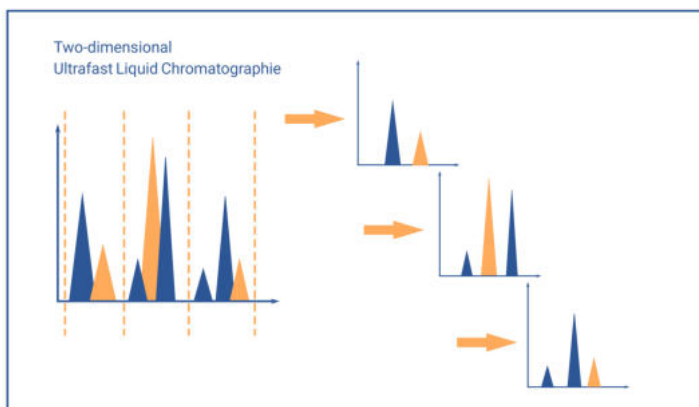
The report from the authority and the associated GMP certificate are expected to be available from February 2023.



Chromicent is now offering **multidimensional chromatography** in its portfolio.

Chromatographic separation methods are always faced with the challenge that the resolution is limited in relation to the peak purity and the peak capacity. This limitation is counteracted with increasingly high-performance and thus cost-intensive detection methods such as mass spectrometry.

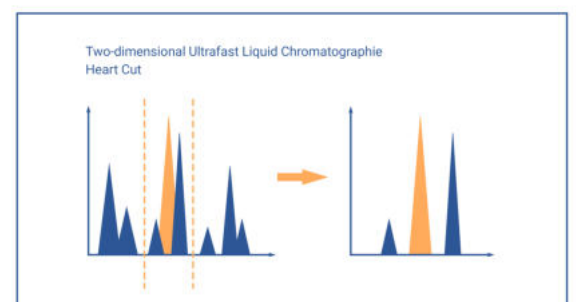
The demands on analytics are growing, especially in the area of complex samples. Another possibility for high-performance analysis is **multidimensional chromatography**, also called 2D-LC or LCxLC, which is **predestined for the separation of complex samples**.



For this purpose, **orthogonal separation techniques** were used. The complete chromatogram of the first separation dimension is fractionally applied to a second orthogonal separation column.

With this method, the separation of highly complex samples is possible in an effective and targeted manner; **peak capacities > 1000** can be achieved.

A second variant is the heart-cut technique (LC-LC) - in this method, fractions are precisely cut out of the first separation dimension and transferred to a second orthogonal column. This method can be used when a higher purity of individual peaks is required.





In principle, all classic detectors for LC are available for detection. This includes mass spectrometry as well as UV and fluorescence detectors.

Chromicent's 2D system consists of: the ACQUITY UPLC H-Class with additional pump, switching valves and PDA and QDa detectors.

For enquiries and further information, please do not hesitate to contact us.

Newest publications of Chromicent (open access)

Prevalence of nitrosamine contaminants in drug samples: Has the crisis been overcome?

Schmidtsdorff S., Neumann J., Schmidt A.H., Parr M.K.
Arch. Pharm., 02 Dec 2022

Application of sub-/supercritical fluid chromatography for the fingerprinting of a complex therapeutic peptide

Jonas Neumann, Sebastian Schmidtsdorff, Alexander H. Schmidt, Maria K. Parr
Arch. Pharm., 06 July 2022

Risk assessment for nitrosated pharmaceuticals: A future perspective in drug development

Sebastian Schmidtsdorff, Jonas Neumann, Alexander H. Schmidt, Maria K. Parr
Arch. Pharm., 27 January 2022

Event note

We are pleased to be able to offer another conference in cooperation with Concept Heidelberg on the topic of **Method LifeCycle Management**.

The ICH Q14 - Development of Analytical Methods will take in presence at the Chromicent site in Adlershof.

Lerninhalte

- Neuere Entwicklungen der Regelwerke, USP <1220>, ICH Q12, ICH Q2, ICH Q14
- Phasenkonzept der Methodenentwicklung/-validierung
- Computergestützte Entwicklung/Optimierung (DoE / QbD, Design Space)
- Management von Entwicklungsarbeiten/ Schnittstellen
- Versuchsplanung in der Entwicklungsanalytik
- PAT / RTRT (Annex 17 EU GMP Leitfaden)
- Post approval Life Cycle Management

LEHRGANG
ENTWICKLUNG

A 2

ICH Q14 – Entwicklung analytischer Methoden

Von QbD zum Life-Cycle-Konzept

In German only

14. – 16. Februar 2023, Berlin

Further information and the possibility to register can be found under

[this link](#).

We look forward to seeing you!