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Tailored Stationary Phases for Continuous Electro-Chromatographic Separation of APIs

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Highly purified organic materials are essential in various fields, including the fine-chemical, pharmaceutical and food industry. A method widely used to purify, e. g., active pharmaceutical ingredients (APIs), is preparative chromatography. In this context, continuous processing is becoming increasingly important. The development of a novel prototype for continuous annular electrochromatography (CAEC) is the goal of a project which was established by an international consortium of industrial and academic research partners. The CAEC process combines the principles of electrophoresis and chromatography, thus leading to an increase of throughput, whilst maintaining high separation efficiency. An online detection system enables advanced automation and quality control, so that the process accords to the PAT (Process Analytical Technology) guidelines specified by the FDA.

We present the development of stationary phases for this CAEC process. Our approaches include functionalized silica-based monolithic materials [1], which were implemented in different devices, such as capillaries for capillary electrochromatography (CEC) as well as planar test cells that can be continuously operated. The functional groups attached to the monolithic silica backbone can be easily adapted to different separation problems. Alternativly, the functionalization was achieved by implementation of functionalized silica particles in the precursor mixture of the monolithic material. Using these approaches, we succeeded in the preparation of reversed phase as well as amino-, cyano- and thiol-functionalized materials. In addition to these inorganic materials, organic monoliths [2] were successfully implemented in CEC capillaries and planar glass plates. Preliminary results show that the implementation of the stationary phases in the continuous operation set-ups leads to improved feasibility to gain high-value added products.

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