CE(SDS)-CZE-MS for the analysis of proteins and monoclonal antibodies

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During production and storage of monoclonal antibodies, impurities can be observed and structural modifications may occur. Due to their possible influence on the therapeutic activity and function, a detailed characterization of these modifications and impurities are of outstanding importance [1]. For the purity assessment and quality control, CE(SDS) is a widely used analytical method in pharmaceutical industries. Mass spectrometry (MS) is a powerful tool for the identification of these impurities. A two dimensional CE-system with a mechanical valve as interface and an online SDS removal strategy was developed in our research group.

With the CE(SDS)-CZE-MS system, the MS identification of impurities in stressed intact antibodies is possible. Additionally, a reduced antibody with two different LC structures was analyzed. With the commercial available SDS-buffer, it was not possible to separate these two LCs. After optimization of the SDS separation buffer, a baseline separation was achieved and the MS identification with the 2D-CE-system of the LCs was done.

The importance of the 2D-CE system for the identification of CE(SDS) impurities and the analysis of antibodies with more complex structures will be shown. Additional, further improvements of the 2D-CE-system regarding the efficiency of SDS removal, robustness and sensitivity will be discussed.

1. Moritz B, Schnaible V, Kiessig S, Heyne A, Wild M, Finkler C, et al. Evaluation of capillary zone electrophoresis for charge heterogeneity testing of monoclonal antibodies. J Chromatogr B. 2015;983–984:101–10