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Combinatorial model of chromatography applied on optimizing operational conditions in SEC

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Abstract

The shape of the elution curves is greatly influenced by experimental circumstances, particularly polymer molecular weight, concentration, and flow rate. Up to the concentrations of overloading, the effect of concentration on polymers in theta solvents is negligible. The concentration impact, on the other hand, is significant in excellent solvents. With increasing concentration, the effective hydrodynamic volume of dissolved macromolecules decreases. With increasing concentration, the hydrodynamic volume of solvated molecules decreases, which is a known experimental factor with a theoretical explanation. The binomial distribution can be used to express the spatial distribution of the analyte with respect to the longitudinal axis of the separation system as it develops over time. Further treatments for this physical condition, on the other hand, were just approximative. The exact solution to the problem is achieved as the observation of this binomial distribution evolving in time after reaching the exclusion limit at a given point (the detector). This is something that can be done mathematically. On the basis of the displacement- equilibrium model, the concentration influence on SEC elution curves may be described. This is based on the idea of a theoretical plate on which an equilibrium is achieved between analyte molecules moving together with the mobile phase (MP) and those anchored to or pierced into the pores of the stationary phase (SP). With the partition coefficient estimated numerically for each plate at each displacement, the concentration impact may be simulated.

Size exclusion chromatography (SEC) is a well-established technology for the thorough analysis of therapeutic proteins that can be used as a reference and powerful tool for evaluating aggregates qualitatively and quantitatively. The fundamental benefit of this method is the mild mobile phase conditions, which allow for protein characterization with minimum impact on conformational structure and the surrounding environment. Despite the fact that chromatographic behaviour and peak form in SEC are difficult to predict, several generic rules for SEC technique development can be applied, as outlined in this paper. During recent years, some improvements were introduced to conventional SEC that will also be discussed. Of these new SEC characteristics, we discuss (i) the commercialization of shorter and narrower columns packed with reduced particle sizes allowing an improvement in the resolution and throughput; (ii) the possibility of combining SEC with various detectors, including refractive index (RI), ultraviolet (UV), multi-angle laser light scattering (MALLS) and viscometer (IV), for extensive characterization of protein samples and (iii) the possibility of hyphenating SEC with mass spectrometry (MS) detectors using an adapted mobile phase containing a small proportion of organic modifiers and ion-pairing reagents.

The biopharmaceutical sector is at a crossroads, with more personalised and patient-centered therapy on the horizon (precision medicine). Simple procedures, such as the antibody platform process, are expanded to include production processes for a new chemical portfolioAs a result, specific and customised productions necessitate general ways for the construction of a quick and devoted purification process. Different efficient tactics in biopharmaceutical purification process development are reviewed in this article, which can be applied to the development of the next generation of antibodies. Modern technologies such as multivariate calibration and mechanistic modelling tools are reviewed and compared to traditional approaches based on heuristics and high-throughput process development. Such approaches are an excellent foundation for developing new goods and

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processes quickly and effectively, but their full potential is realised when they are combined. As a result, many combinatorial techniques are given, some of which may become future biopharmaceutical business directions.

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