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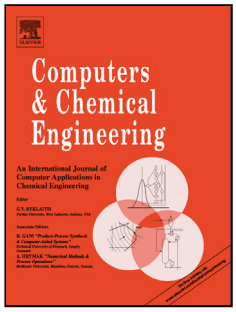

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Optimising Chromatography Strategies of Antibody Purification Processes by Mixed Integer Fractional Programming Techniques

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Abstract

The strategies employed in chromatography steps play a key role in downstream processes for for monoclonal antibody (mAb) manufacture. This work addresses the integrated optimisation of chromatography step sequencing and column sizing in mAb purification processes. Chromatography sequencing decisions include the resin selection at each typical step, while the column sizing decisions include the number of columns, the column diameter and bed height, and number of cycles per batch. A mixed integer nonlinear programming (MINLP) model was developed and then reformulated as a mixed integer linear fractional programming (MILFP) model. A literature approach, the Dinkelbach algorithm, was adopted as the solution method for the MILFP model. Finally, an industrially-relevant case study was investigated for the applicability of the proposed models and approaches.

Keywords: biopharmaceutical manufacturing processes, mAb, chromatography purification, MINLP, MILFP, Dinkelbach algorithm

1. Introduction

The biopharmaceutical industry has been a rapidly growing sector during the past decade. Accounting for 15.6% of the total pharmaceutical market, the global biopharmaceutical market value reached $138 billion in 2011, and is expected to be over $320 billion by 2020 (RBI Research, 2012). Monoclonal antibodies (mAbs) are emerging therapies that have been widely used to treat cancer and autoimmune diseases. Yet mAb manufacturers are faced with increased

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