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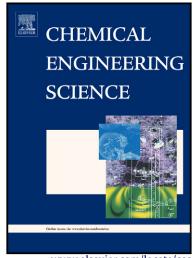
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A model based approach for identifying robust operating conditions for industrial chromatography with process variability

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Abstract

A model based approach has been developed and used to identify robust operating conditions for an industrial hydrophobic interaction chromatography where resin lot variability, combined with feed stream variability, was resulting in serious performance issues during the purification of a multi component therapeutic protein from crude feed material. An equilibrium dispersive model was formulated which successfully predicted the key product critical quality attribute during validation studies. The model was then used to identify operating parameter ranges that assured product quality despite the process variability. Probabilistic design spaces were generated using stochastic simulations that showed the

1