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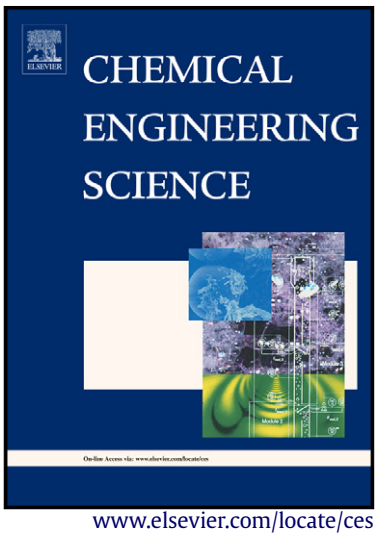

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Continuous purification of active pharmaceutical ingredients using multistage organic solvent nanofiltration membrane cascade

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Abstract

Downstream processing accounts for a large fraction of the production costs in pharmaceutical manufacturing. Organic solvent nanofiltration performed in a membrane cascade offers an interesting possibility for a continuous downstream processing unit operation. This work demonstrates continuous purification of Active Pharmaceutical Ingredient (API) Roxithromycin from potential Genotoxic Impurity (GTI) 4-dimethylaminopyridine (DMAP) in a simple and efficient two stage membrane cascade. Cascade performance is initially evaluated via mathematical simulations, and then validated experimentally. We demonstrated that by careful selection of operating parameters, high purity of the API >99% could be achieved from feed stream purity of 78%. The continuous cascade could be easily coupled with an adsorption column, utilising an inexpensive non-selective adsorbent such as charcoal, as a solvent recovery stage. The combined continuous process generates orders of magnitude less waste than a batch diafiltration which makes it an attractive alternative purification process for pharmaceutical industry.

Key words: Active pharmaceutical ingredients; Continuous purification; Membrane cascade; Organic solvent nanofiltration; Green metrics.

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