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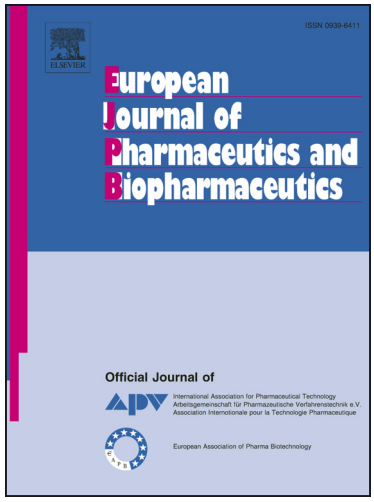

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ACCEPTED MANUSCRIPT

On the exfoliating polymeric cellular dosage forms for immediate drug release

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Abstract

The most prevalent pharmaceutical dosage forms at present—the oral immediate-release tablets and capsules—are granular solids. Though effective in releasing drug rapidly, development and manufacture of such dosage forms are fraught with difficulties inherent to particulate processing. Predictable dosage form manufacture could be achieved by liquid-based processing, but cast solid dosage forms are unsuitable for immediate drug release due to their resistance to fluid percolation. To overcome this limitation, accordingly, we have recently introduced cellular dosage forms that can be readily prepared from polymeric melts. It has been shown that open-cell structures comprising polyethylene glycol 8,000 (PEG 8k) excipient and a drug exfoliate upon immersion in the dissolution medium. The drug is then released rapidly due to the large specific surface area of the exfoliations. In this work, we vary the molecular weight of the PEG excipient and investigate its effect on the drug release kinetics of open-cell structures. We demonstrate that the drug dissolution time increases by more than an order of magnitude if the excipient molecular weight is increased from 12 to 100 kg/mol. A model is then developed to elucidate the exfoliation behavior of cellular structures by considering diverse transport processes: percolation due to capillarity, diffusion of dissolution medium through the cell walls, and viscous flow of the saturated excipient. It is found that the longer dissolution time of dosage forms with higher excipient molecular weight is primarily due to the greater viscosity of the cell walls after fluid penetration.

Keywords: Drug release; Drug manufacture; Cellular dosage forms; Pharmaceutical tablets

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