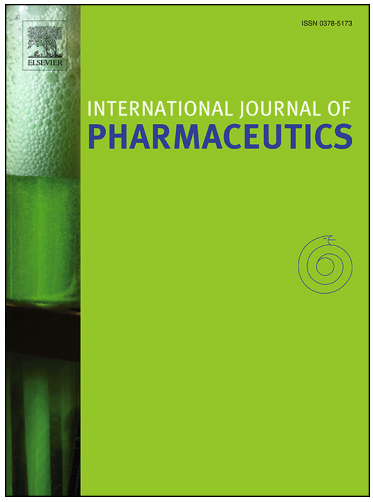

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Mitja Pohlen, Luka Pirker, Matevž Luštrik, Rok Dreu

PII: S0378-5173(18)30548-9
DOI: https://doi.org/10.1016/j.ijpharm.2018.07.064
Reference: IJP 17680

To appear in: *International Journal of Pharmaceutics*

Received Date: 4 May 2018
Revised Date: 10 July 2018
Accepted Date: 27 July 2018

Please cite this article as: M. Pohlen, L. Pirker, M. Luštrik, R. Dreu, A redispersible dry emulsion system with simvastatin prepared via fluid bed layering as a means of dissolution enhancement of a lipophilic drug, *International Journal of Pharmaceutics* (2018), doi: https://doi.org/10.1016/j.ijpharm.2018.07.064

A redispersible dry emulsion system with simvastatin prepared via fluid bed layering as a means of dissolution enhancement of a lipophilic drug

Mitja Pohlen[a], Luka Pirker[b], Matevž Luštrik[a], Rok Dreu[a,*]

a) Faculty of Pharmacy, University of Ljubljana, Aškerčeva cesta 7, 1000 Ljubljana

b) Solid-State Physics Department, Jožef Štefan Institute, Ljubljana, Slovenia

*Corresponding author: Assoc. Prof. Rok Dreu, rok.dreu@ffa.uni-lj.si, Tel.: +386 1 47 69 622, Fax.: +386 1 425 80 31

Keywords:

dry emulsion, fluid bed coating, layering, simvastatin, design of experiments (DoE), redispersibility, droplet size distribution

ABSTRACT

The purpose of the study was to develop a redispersible dry emulsion, containing a lipophilic, poorly water soluble model drug simvastatin, by employing fluid bed coating technology. The presented dry emulsion manufacturing approach produces pellets in a way, where a layer of the dry emulsion is applied to a neutral core. In the preliminary formulation development phase 1-oleoyl-rac-glycerol was chosen as the oily lipid phase, based on the high drug solubility and potential bioavailability enhancement capability. Mannitol, HPMC and Tween 20 were selected as the solid carriers and surfactant, respectively. The design of experiments, specifically the mixture design approach, was used to obtain the optimal formulation composition. The emulsion reconstitution ability and stability were the main responses, used as the decisive parameters for formulation optimisation. Optimised formulations showed narrow droplet size distribution upon reconstitution, high stability, suitable drug loading and enhanced dissolution profile, compared to a non-lipid based tablet and the pure