OP-2

DOI: 10.14232/syrptbrs.2021.op2

Personalized Fused Deposition Modeling 3D printed (FDM-3DP) tablets: a Quality by Design (QbD) approach

Andrea-Gabriela Crișan[1*], Sonia Iurian[1], Cătălina Bogdan[2], Lucia Rus[3], Alina Porfire[1], Sebastian Porav[4], Kinga Ilyés[1], Ioan Tomuță[1*]

1. Department of Pharmaceutical Technology and Biopharmacy, Faculty of Pharmacy, University of Medicine and Pharmacy „Iuliu Hațieganu", Cluj-Napoca, Romania
2. Department of Dermopharmacy and Cosmetics, Faculty of Pharmacy, University of Medicine and Pharmacy "Iuliu Hațieganu", Cluj-Napoca, Romania
3. Department of Drug Analysis, Faculty of Pharmacy, University of Medicine and Pharmacy „Iuliu Hațieganu", Cluj-Napoca, Romania
4. National Institute for Research and Development of Isotopic and Molecular Technologies, Cluj-Napoca, Romania

Pharmaceutical manufacturing by three-dimensional printing (3DP) provides unique advantages, including individualization potential by associating customizable doses of various active pharmaceutical ingredients (APIs) with different release profiles in one drug delivery system (DDS). One of the most promising techniques is fused deposition modeling (FDM). The aim of this research was to explore FDM-3DP for the development of personalized immediate release (IR) DDSs with diclofenac sodium (DS) by applying the quality-by-design (QbD) approach.
High drug loaded (50%) FDM 3D printable filaments were prepared by hot melt extrusion. Regarding the printing process, a systematic assessment of the influence of the selected independent variables (design feature, dosage form size and printing resolution) on the quality attributes of the 3D printed DDSs was conducted. By adjusting the dimensions of the digital models, tablets with API content in the range of 32-75 mg were produced. The optimum formulation represented by a concentric ring design tablet with a DS content of 50 mg presented 78% drug release after 5 minutes and 90% drug release after 10 minutes. A correlation between the investigated factors and the dissolution performance of the dosage forms was found as high-resolution printing (0.1 mm) and greater tablet dimensions promoted faster release of the API.
In conclusion, by employing the QbD approach to investigate the influence of the printing parameters and the dimensions of the DDS on the dissolution performance and API content of the dosage forms, preparation of tablets with very rapid dissolution and adjustable doses of API was completed.

Acknowledgements: This project was supported by "Iuliu Hațieganu" University of Medicine and Pharmacy internal doctoral research grant 1680/34/19.01.2018 and by The European Social Found, Human Capital Operational Programme 2014-2020, project no. POCU/380/6/13/125171.

Supervisor: Prof. Ioan Tomuță