Transactions on Additive Manufacturing Meets Medicine
Trans. AMMM, 2026, Vol. 8, No 1, Suppl. 1, Article ID 2767, 1 Page

Infinite Science Publishing

Abstract

Development of a 3D printed peroral dosage form containing multiple drug-releasing particles

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3D printing provides new strategies to precisely arrange matter in pharmaceutical dosage forms and thus new ways to control drug release. Additionally, it allows for design changes without the need for tooling changes, which offers great potential for individualized medicines. Multiple unit particle systems (MUPS) have been developed as an alternative to peroral coated dosage forms to control drug release. Such MUPS can offer several advantages compared to coated non-disintegrating dosage forms with respect to safety aspects (dose dumping) and emptying from the fed stomach. We have previously introduced the concept of a 3D printed MUPS using commercially available (drug-free) filament [1].

In this work, a fused filament fabrication method using a dual extrusion 3D printer setup (UltiMaker S3) was further developed to print dosage forms consisting of a fast-dissolving shell and non-dissolving drug-releasing particles. The filaments were produced using a twin-screw extruder (ThreeTec ZE 9) and pharmaceutical grade polymers (Kollicoat® IR, Eudragit® RL PO) in combination with the drug metoprolol succinate, which is also clinically used in MUPS. The dosage form was designed to host 196 particles in four layers with a modular design that allows for adaptation of the number of particles according to individual patient needs and potentially also the combination of different drugs in different particles while avoiding direct contact and thus reducing the risk for incompatibilities.

Following printing, dosage forms were characterized concerning mass and dimensions of the entire unit as well as individual particles, solid state (X-ray powder diffraction), disintegration time, drug content, drug release, as well as drug stability under the process conditions. In addition, imaging was performed using scanning electron microscopy as well as X-ray micro-computed tomography. The results of these examinations yielded several technical challenges that remain to be addressed in the future such as drug stability under the printing conditions, processing times and potential for particle agglomeration. Nevertheless, this study was able to show that MUPS can be 3D printed using a dual extrusion printing technique achieving good reproducibility as well as the potential of this technique for manufacturing complex peroral dosage forms which can be adapted to the specific needs of the individual patient.

AUTHOR'S STATEMENT

Authors state no conflict of interest. Authors state no funding involved. This work has been previously published [2] under a CC BY license (http://creativecommons.org/licenses/by/4.0/), the work was paraphrased for this abstract. Acknowledgments: The authors thank S. Köhler (Center for Advanced Imaging, HHU Düsseldorf) and S. Klinken-Uth (Pharmaceutics and Biopharmaceutics, HHU Düsseldorf) for expert assistance with imaging, INVITE GmbH for permission to use their mini vessels, as well as BASF SE and Evonik Industries AG for the generous donation of excipients.

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DOI: 10.18416/AMMM.2026.26062767