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3D Bioprinting of an Oral Solid Dosage Form: Preliminary Formulation Study

S. Moutaharrik, A. Foppoli, M. Cerea, M. Cirilli, A. Buscarini, L. Palugan, A. Gazzaniga, A. Maroni

Dipartimento di Scienze Farmaceutiche, Sez. Tecnologia e Legislazione Farmaceutiche "M.E. Sangalli", Università degli Studi di Milano

Bioprinting, which consists in 3D printing of biomaterials (bio-inks), has drawn increasing interest in regenerative medicine and tissue engineering for fabrication of biomimetic constructs. Also, its use may offer unique opportunities in the pharmaceutical field, mainly to manufacture implantable biocompatible systems. In oral delivery, it may profitably be harnessed for viable probiotic administration and targeting to the large bowel. Importantly, the gut microbiota of patients suffering from inflammatory bowel disease (IBD) and other gastrointestinal disorders has been found to exhibit profound differences compared to healthy individuals, suggesting that addressing these microbial imbalances, or dysbiosis, could ameliorate their conditions. However, their viability, ability to adhere to the intestinal mucosa and proliferation rate at the inflammation site are threatened by pharmaceutical processing and exposure to the gut environment during transit. The goal of this research was to develop an immediate-release formulation, suitable for subsequent encasing within a colon-targeting polymer shell, where probiotics could be conveyed without involvement of any harmful procedures or variables. A preliminary setup of the composition and printing process was thus carried out. For this purpose, extrudable pastes that contained a high percentage of solids, enabling successful printing with a 3D Discovery™ Gen. 5 bioprinter (RegenHU, CH), were developed using paracetamol as an analytical tracer. The pastes included insoluble or soluble fillers, *i.e.* Kollidon® SR and Manogem® XL, respectively. The fillers were intended to provide the final product with the desired mass and density while ensuring that viscosity properties suitable for extrusion were retained. Additionally, adjustments in the paste formulations were made to enhance disintegration in aqueous fluids, a crucial feature to allow for release of the probiotics upon arrival in the colon. The units obtained through the printing process were allowed to dry at room temperature, followed by physico-tecnological characterization in terms of mass, dimensions, mechanical resistance, disintegration time and dissolution rate. Mass variation was fairly limited, not exceeding 10% of the mean weight of prototypes (n=10). The units generally underwent minor shrinking upon drying, proving to be slightly smaller than expected based on theoretical dimensions. Albeit variable, the relevant hardness was in all cases sufficient for handling. The disintegration and dissolution performance turned out to be affected by the type of filler used; soluble fillers provided faster disintegration compared to the combination of insoluble fillers with superdisintegrants. Further extensive studies are necessary, particularly for probiotic incorporation into the dosage form and in-depth understanding of the effects of various formulation components, printing parameters and drying methods on bacteria viability. Still, this work could pave the way for using 3D bioprinting to manufacture oral solid dosage forms and for improving delivery and effectiveness of living microorganisms.

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Autore di riferimento da contattare per ulteriori informazioni:

Nome e Cognome: Saliha Moutaharrik

E-mail: saliha.moutaharrik@unimi.it