Title: Evaluation of the stability of 3D-printed paracetamol tablets stored at different relative humidities

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Abstract Body (358)

Introduction: 3D-printing technologies are becoming increasingly available to produce medicines when individualization of the therapy is required (1). Fused deposition modeling (FDM) is a printing technology, which enables the production of tablets with different compositions, shapes and sizes (2). The printer requires the use of a filament prepared in-house by hot melt extrusion (HME). The aim of this work was to assess both extrudability and printability of materials, as well as the impact of environmental humidity on the characteristics of printed tablets.

Methods: Six different mixtures of hydroxypropylcellulose, Soluplus®, magnesium stearate and paracetamol were hot-melt extruded to produce drug-loaded filaments; from these, cylindrical tablets were produced by FDM, according to an AutoCad template exported as a stereolithography (.stl) file into Cura. The processing parameters of the printer were set at: extrusion temperature (200°C), extrusion rate (20mm/s), printing speed (150mm/s), layer height (0.50mm) and a 100% infill. 3D-printed tablets were stored in desiccators, at 24°C and different relative humidities (11%, 53%, 75%, 93%). The tablets were evaluated for thermal properties (DSC), drug content (UV) and dimensions/morphology at 0, 7, 14 and 30 days of storage.

Results: Five out of the six formulations considered (Table 1) could be hot-melt extruded to produce filaments and subsequently 3D-printed by FDM to produce tablets. Heat during printing has produced amorphous solid dispersions of paracetamol in the tablets, as ascertained by the decreased or absent endotherm in DSC thermograms, as compared with pure paracetamol. As anticipated, neither mass nor dimensions varied during the period of study. Noteworthy is that drug content (Table 1) remained constant and amorphous paracetamol was present throughout the stability study.

Conclusion: Tablets with adequate characteristics for oral delivery of paracetamol were successfully printed by FDM and deemed stable upon storage at different humidities, for 30 days.

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Presenter biography: Ana I Fernandes is a Professor and Head of the PharmSci Lab at Instituto Universitário Egas Moniz, Portugal. She holds a degree in Pharmaceutical Sciences (University of Lisbon) and a PhD in Drug Delivery (University of London). Her research is currently related to formulation in pediatrics, drug solubility enhancement and 3D-printing of pharmaceuticals.