Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 49 -50 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.022
Short communication

Formulation and characterization of paracetamol-loaded 3D tablets with co-processed excipients using selective laser sintering

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Introduction

Three-dimensional printing (3DP) has gained sufficient scientific interest in pharmaceutical research for the last eight years. 3DP is a revolutionary technology, which will doubtlessly open a new era through application in pharmaceutical manufacturing science (Charoo et al., 2021). Selective laser sintering (SLS) is a 3D printing technology classified in the Powder bed Fusion category according to the ASTM (American Society of Testing Materials) (Gueche et al., 2021; Basit and Gaisford, 2018). Co-processed excipients are novel structures intended for use in pharmaceutical technology. A co-processed excipient is defined as a combination of two or more compendial or non-compendial excipients designed to physically modify their properties in a manner not achievable by simple physical mixing and without significant chemical change (Carlin et al, 2017). The aim of this work was to investigate the possibility of 3D printing orally disintegrating tablets and prolonged release tablets formulated with StarLac® (85 % (w/w) white native starch and 15 % (w/w) lactose monohydrate) and RetaLac® (50 % (w/w) lactose monohydrate and 50 % (w/w) hypromellose) as co-processed excipients and paracetamol as the active ingredient.

Methods

There were prepared eight different powder mixture formulation with varying the content of drug substance and the co-processed excipient. The indirect and direct flowabillity of each obtained powder mixture was examined. Eight different formulations were successfully printed using the selective laser sintering 3D printing technique (Sintratec central printing device). These formulations contained StarLac® and RetaLac® as diluents in varying amounts (66 %, 61 %, 56 % and 51 % w/w) and varying drug loadings (5 %, 10 %, 15 % and 20 % w/w), on a printing temperatures ranging from 85 °C to 100 °C (chamber temperature) and 95 °C to 110 °C (printing temperature) and laser scanning speed of 180 mm/s. There were measured dimensions of the obtained tablets, mass and hardness. Determination of disintegration time of the obtained tablets was performed in a purified water as a medium, drug assay was determined using UV-VIS spectroscopy, dissolution studies were performed in a purified water as a medium, thermal analysis of the obtained tablets were described using Differential scanning calorimetry (DSC). Fourier transform infrared spectroscopy and X-ray powder diffraction were also performed for examination and characterization of the obtained tablets.

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Results and discussion

Powder formulations with StarLac® exhibited good and passable flowability. Powder formulations with RetaLac® exhibited passable indirect flowability. All obtained tablets had cylindrical shape. Average mass (117.25 mg ± 7.92 to 192.66 mg ± 5.70), diameter (9.05 mm ± 0.68 to 9.59 mm ± 0.34) and thickness (3.32 mm ± 0.31 to 3.64 mm ± 0.29) of the tablets with StarLac® were smaller than tablets with RetaLac® (average mass from 130.77 mg ± 7.56 to 148.59 mg ± 5.97, average diameter from 9.26 mm ± 0.2 to 10.43 mm ± 0.21and average thickness from 3.41 mm ± 0.2 to 3.89 mm ± 0.21). Average hardness of the tablets with StarLac® was greater (20.16 N ± 1.16 to 84.16 N ± 4.75) than tablets with RetaLac® (16 N ± 2.3 to 25.83 N ± 2.7). All the tablets with StarLac® disintegrated faster (18.33 s ± 1.53 to 33.33 s ± 2.08), than tablets with RetaLac® (1620.66 s ± 3.05 to 2036.33 s ± 4.04). The paracetamol content in each formulation ranged from 90.00 % (w/w) to 110.00 % (w/w), in accordance with the requirements set on in the European Pharmacopoeia. Tablets with StarLac® exhibited the characteristic dissolution profile of orally disintegrating tablets, with the total amount of paracetamol being released withn 30 minutes. Tablets with RetaLac® exhibited characteristic dissolution profile of prolonged release tablets with the total amount of paracetamol being released after 250 minutes. According to the DSC thermograph, it was illustrated that paracetamol crystals used in this work had a melting point of 171.33 ºC. As it was noted that paracetamol did not generate melting peak in the DSC thermograph of tablets, it is assumed that the majority of paracetamol in tablets existed in an amorphous form. According to the FT-IR obtained spectrums, it has been shown that there were negligible differences between spectrums in all the obtained tablets, and there were no drug-excipient interactions.

Conclusion

We have shown that the printability an orally disintegrating characteristics and prolonged release characteristics using selective laser sintering as a 3D printing technology, with paracetamol as an active ingredient and StarLac® and RetaLac® as co-processed excipients, was possible and successful within certain process parameters of the printing process. It is obvious that selective laser sintering is an adequate and promising 3D printing technology which will open a new successful era in pharmacy.

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