Poster 25

Development of a multi-drug combination tablet with variable strengths using innovative 3D Printing technology

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Purpose

Fixed dose combination medications simplify treatment and reduce tablet burden for patients but limit prescription flexibility. With personalized medicine on the rise, there is a growing need for technologies enabling customizable dosage forms and combinations to overcome these limitations. Thus, the purpose of this research is to present a technique for preparing multi-drug tablets with customizable doses using 3D printing.

Methods

Three anti-hypertensive drugs valsartan, hydrochlorothiazide, and amlodipine besylate were formulated into a single tablet with variable doses by using a selective laser sintering (SLS) based 3D printer. Various parameters of the 3D printer like laser scanning speed, surface and chamber temperatures, laser scan spacing were optimized to achieve the desired formulation. Comprehensive drug-excipient compatibility tests utilizing DSC and TGA analysis were conducted to ensure the melting transitions and thermal stability of compounds, contributing to the development of robust formulations. A novel HPLC method was developed and validated to analyze combination of the three drugs and the drug release profiles of the prepared 3D printed tablets were evaluated by performing assay and dissolution studies using USP Dissolution Apparatus II.

Results

The excipients used in the DSC analysis were sodium starch glycolate, croscarmellose sodium, cross povidone, microcrystalline cellulose, hydroxypropyl methyl cellulose, mannitol, polyethylene oxide and Kollidon VA 64. Amongst all the excipients, only mannitol showed incompatibility with valsartan and amlodipine besylate. The 3D printed tablets, with an average weight of 280mg and dimensions of 10mm in diameter and 5mm in height, demonstrated an assay of 96±10% of hydrochlorothiazide, 96±7% of valsartan and 86±3% of Amlodipine besylate. Additionally, the dissolution study showed a cumulative drug release of 70±4% of hydrochlorothiazide, 90±4% of valsartan and 55±6% of Amlodipine besylate within 2 hours.

Conclusion

This research presents an innovative method for producing multi-drug tablets with adjustable doses through the application of SLS 3D printing technology. Through the optimization of printing parameters and extensive assessments of drug-excipient compatibility, robust formulations of anti-hypertensive drugs were successfully developed and thus highlights the promising potential of this methodology in meeting the requirements of personalized medicine.

Keywords: SLS 3D printing, Personalized drug development, Multi-drug combination tablet, Thermal stability, Assay, Dissolution