Poster 26

Formulation of variable dose combination drug product exploring effectiveness of SLS 3D printing in pharmaceutical formulations

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Purpose

This study aims to overcome the limitations of conventional pharmaceutical manufacturing techniques by introducing a patient-centric approach through selective laser sintering (SLS) based 3D printing. It focuses on formulation of tablets tailored for patients with type-II diabetes and cardiovascular complications, incorporating variable doses of metformin, sitagliptin, and simvastatin within a single dosage form. The objective is optimizing crucial parameters like laser speed, temperatures, layer thickness, and colored dyes usage and compatibility of common SLS 3D printing excipients through DSC and TGA analysis

Methods

Optimizing 3D printing parameters involved adjusting laser scanning speed (100 – 350 mm/sec), chamber and surface temperatures (60 - 125°C), layer thickness and usage of various colored dyes, including FD&C Red #3, FD&C Red #40, Yellow #5, Yellow #6, and Candurin Gold Sheen in the formulation. An HPLC method was developed and partially validated to combine three drugs in a single tablet. Dissolution testing, conducted using the USP dissolution type-II apparatus, characterized the drug release profiles from the 3D printed constructs

Results

No major incompatibilities were observed between excipients and the drugs employed in the formulation based on DSC and TGA plots. Optimal laser scanning speed was identified at 150 mm/sec, as higher speeds led to poor sintering due to reduced energy transfer to the powder bed. Chamber and surface temperatures were determined to be approximately at 95°C and 120°C respectively. Combination of FD&C red #3 dye and Candurin was chosen for formulation of tablets based on optimal sintering during the optimization process. Average weight of the tablets was 629.7 ± 11.7 mg. Thickness of the tablet was 5.92 ± 0.18 mm and diameter was 15.1 ± 0.3 mm. Dissolution studies indicated approximately 62% release of metformin, ~ 90% release of sitagliptin and ~ 75% release of simvastatin within 45 minutes

Conclusion

Tablets containing multi-drug combinations were successfully prepared via SLS based 3D printing technology. The tablets passed the disintegration test for an immediate release tablet, however dissolution test needs further investigation

Keywords: 3D printing, Selective Laser Sintering,