Polyvinyl Alcohol as a Raw Material in Fused-Deposition Modelling 3D Printing of Solid Oral Dosage Forms

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INTRODUCTION

Fused Deposition Modelling (FDM) is an additive manufacture technique used in 3D printing by depositing successive layers of material to create the final product. FDM 3D printing uses a filament of polymeric material such as polyvinyl alcohol (PVA) as the raw material.

PVA is a water-soluble and biodegradable synthetic polymer which is widely used in 3D printing to generate support structures for overhangs, which are unsupported parts or structures of the printed product. PVA is used as a material to make support structures that are easily removed by dissolution after immersing the finished print in water. The property of PVA to dissolve in aqueous solutions allows for the possibility of using it as the raw material in the printing of oral dosage forms (ODFs). DeMerlis and Schoneker noted that PVA is used for the coating of pharmaceutical tablets and dietary supplements and that when administered orally, PVA was found to be harmless and poorly absorbed through the gastrointestinal tract, reducing the incidence of adverse effects or accumulation.[1]

AIMS

- To produce tablets through fused-deposition modelling 3D printing using polyvinyl alcohol as a bulking agent
- To assess impact of amount of PVA infill on dissolution profile

METHOD

- Literature review determined dimensions of tablets: not larger than 8 mm
- Tablet designed using Fusion 360 by Autodesk: cylindrical with 8 mm diameter and 5 mm height
- Slicer software parameters were identified for tablets development (Table 1)
- Five infills selected for printing: 0 %, 25 %, 50 %, 75 %, 100% with 5 replicates each
- Commercially available PVA filament was chosen and tablets were printed
- Tablets were allowed to cool in a desiccator
- Dissolution tests were carried out on 0 % infill tablets as per European Pharmacopoeia[2]
- 1000 mL of water at 37 °C with medium stirring
- Test is repeated with different infills and pH
- Ideal dissolution conditions are determined and HPLC analysis method developed

Parameters	
Printing Temperature	185 °C
Bed Temperature	90 °C
Layer Height	0.1 mm
Wall Thickness	1.05 mm
Top/Bottom Thickness	0.8 mm
Print Speed	50 mm/s
Travel Speed	120 mm/s
Print Cooling	Enabled
Build Plate Adhesion	None

Table 1: Printing parameters in slicing software

RESULTS

- Dissolution time in minutes for 0 % infill PVA tablets are shown in Figure 1 (n=5)
- Dissolution time ranged from 69 to 120 minutes
- Average dissolution time for cylindrical PVA tablets with 0 % infill was 84.2 minutes
- In agreement with Goyanes et al., extrapolating the average dissolution time achieved with a 0 % infill compares with results where solid tablets (100 % infill) had 90 % API release achieved after about 12 hours. Modifications in tablet shape improve dissolution time[3]

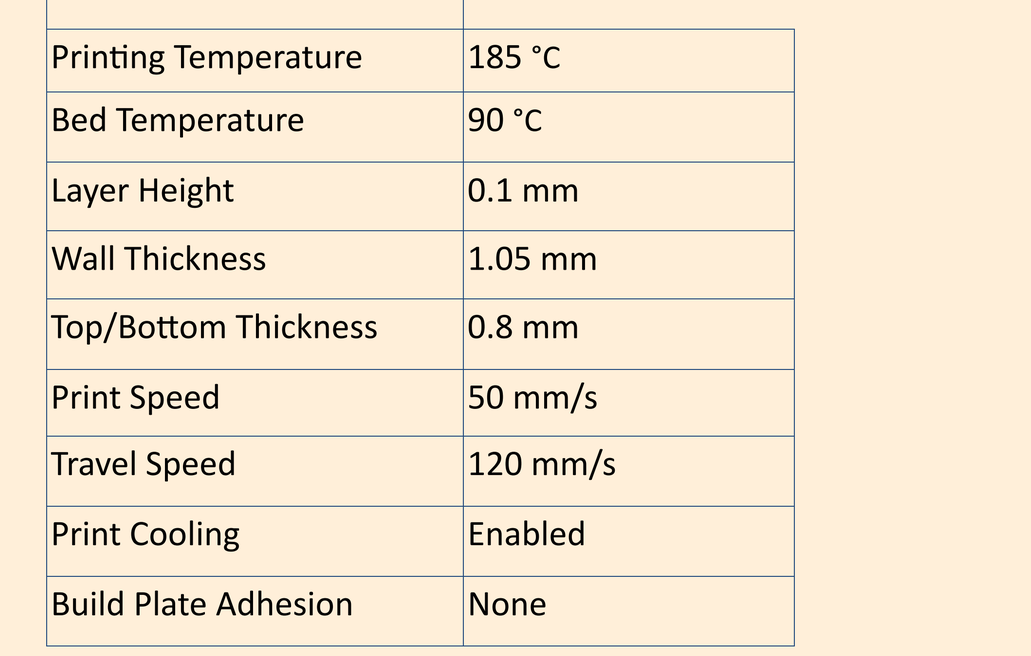

Figure 1: Dissolution time in minutes for 0% infill PVA tablets

CONCLUSION

Results from this study were found to be in line with a study, by Goyanes et al.[3], where a 100 % infill PVA– Paracetamol tablet achieved 90 % API release after about 12 hours. The 0 % infill tablet achieved complete dissolution much quicker due to the fact that there is a drastic increase in surface area available to dissolve once the outer shell of the tablet is breached. A higher infill percentage is expected to affect the dissolution profile of the tablet and increase the time needed for the tablet to completely dissolve.

3D printing can offer the opportunity for patients to obtain medication tailored to suit individual needs. Dose, shape and rate of release can be changed to manufacture a patient-tailored dosage form. Modifications to the 3D printed product are made by changing the 3D model on software, resulting in easier and less expensive means than conventional manufacturing methods. This study will lead to the 3D printing of oral dosage forms having a patient-tailored dose and dissolution profile. 3D printing of ODFs can potentially be used to manufacture small-scale batches of medications used in the management of rare diseases where conventional, large-scale manufacture may not be economically feasible to carry out.

References

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3. Goyanes A, Robles-Martinez P, Buanz A, Basit A, Gaisford S. Effect of Geometry on Drug Release from 3D Printed Tablets. Int. J. Pharm. 2015; 494(2): 657-63.