Quality control test for pharmaceutical feedstock material for FDM 3D printers

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Background

3D printing (3DP) of pharmaceutical formulations via commercially available FDM printers has gained interested in recent years, enabling personalisation of medicines. It also facilitates advanced control of the micro-structure of the tablet core, permitting fine tuning of product release characteristics with a single formulation. In addition, the technology also offers a platform for Dose escalation studies employing a single formulation and single manufacturing step.

Objectives

The objective of this study was to develop a mechanical properties screening tool and quality control test for pharmaceutically relevant feedstock material for FDM.

Methods

Hot-Melt-Extrusion (HME): 10 % (w/w) Paracetamol (PCM), PVA, Parteck MXP Emprove, containing 5, 10 and 15% w/w Sorbitol, Emprove Parteck SI 150, were extruded at 150, 140 and 130C, respectively (75 rpm, powder feed rate 0.5kg/h) on a 16mm Hot-Melt-Extruder (Eurolab 16, Thermofisher, Germany) equipped with a 1.6 mm round die. PVA filament only was also prepared.
Mechanical properties of filaments were tested on a Texture Analyser TA-XT (Stable Micro Systems, UK) equipped with a mini 3-point bend rig and the flexural modulus determined [1].
Printability of filaments was assessed at 190°C using a modified Startt printer [1] equipped with an 0.4 mm diameter nozzle.

Results and Discussion

- **Filament failure** during FDM process: PVA only and PVA containing 5 and 10% (w/w) plasticiser (D-Sorbitol); filaments break in drive gear (Figure 1); high flexural modulus, no ductility (brittle) (Figure 2A).
- **Printable filaments**: PLA and PVA containing 15% (w/w) plasticiser. These filaments showed ductile behaviour (Figure 2A).
- **Stability assessment at 3 months**: in-house prepared filaments (except PVA only) too soft for printing, filament buckles in drive gear (Figure 2B).

  This was most likely due to moisture uptake upon storage with water acting as a secondary plasticiser.

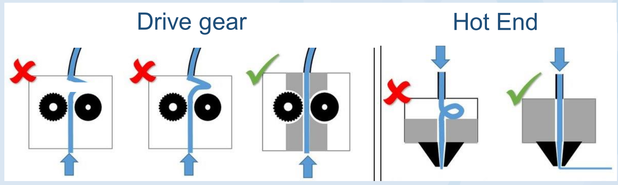

Figure 1: Failure mode of feed stock material in drive gear and hot end of an FDM printer.

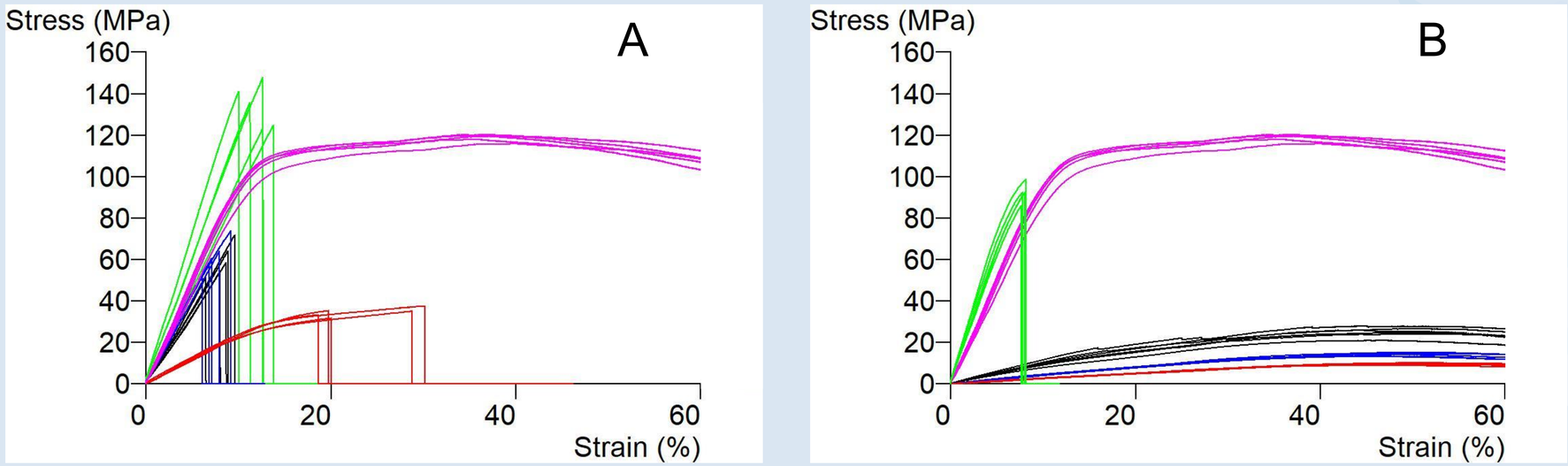

Figure 2: Stress-Strain graph of FDM feed stock material: commercial filament PLA (dutch orange, MAXX) – pink; in house prepared filaments: PVA only – green, 10% w/w PCM - 5% w/w Sorbitol – PVA – black, 10% w/w PCM - 10% w/w Sorbitol – PVA – blue, 10% w/w PCM - 15% w/w Sorbitol – PVA – red. A) 0 months, B) 3 months (n=5).

Conclusion

Mechanical properties of commercial and in house prepared filaments were assessed and aided identification of suitable properties for conveying in a FDM drive gear. The mechanical assessment may also serve as quality control test to assess the stability of feedstock material.

References

1. Prasad E, Islam MT, Goodwin DJ, Megarry AJ, Halbert GW, Florence AJ, Robertson J 2019. Development of a hot-melt extrusion (HME) process to produce drug loaded Affinisol™ 15LV filaments for fused filament fabrication (FFF) 3D printing. Additive Manufacturing 29:100776.