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Identifying the operating space and repeatability of a novel filament free FDM printer

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PURPOSE

Processing solid dispersion filament feedstock materials by Fused Deposition Modelling (FDM) have shown to facilitate control of drug release profiles through micro-structure design. The mechanical and rheological properties of many feedstock materials, particularly immediate release polymers, are not suitable for processing in a conventional FDM 3D printer. This study shows the operational space and performance of a novel non-filament based FDM printer, overcoming these material-based limitations.

OBJECTIVE(S)

To identify the operational space and repeatability of a novel filament free FDM printer.

METHOD(S)

- Hot melt extrusion – 3D printing was performed on a small-scale twin-screw extruder [1] equipped with a novel, in house produced, custom made die containing a metering device that served as print head;
- Tablets were designed with an elliptical shape with a width of 12 mm, length of 20 mm, height of 5 mm and an infill of 37 % (Figure 1).
- Formulations:
  - 50% w/w PCM-Affinisol™ 15LV,
  - 50% w/w PCM-42.5% w/w PVA-7.5 % w/w D-Sorbitol,
  - 50% w/w Mefenamic acid – 42.5% w/w Soluplus® – 7.5% w/w D-Sorbitol;
- Complex viscosity of formulations was assessed on a Haake Mars rotational rheometer;

RESULT(S)

Processability

Formulation	Processability
50PCM-Plasdone™ S-630	✓
50PCM-42.5PVA-7.5D-Sorbitol	✓
50PCM-Affinisol™ 15LV	✓
50MFA-42.5Soluplus®-7.5D-Sorbitol	✓

Table 1 : Processability of different formulations on filament-free FDM printer.

Operational Space – Complex Viscosity limits

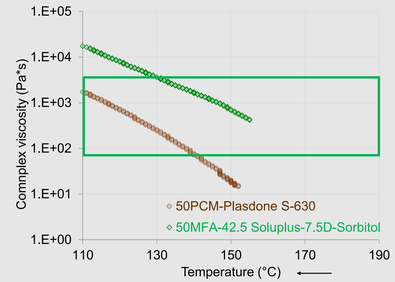

Figure 2 : Complex viscosity versus temperature for different API-polymer formulations: Green diamond – 50% w/w Mefenamic acid – 42.5 % w/w Soluplus® – 7.5 % w/w D-Sorbitol, brown circle – 50 % w/w PCM – Plasdone™ S-630;

Operational space - API solubility in polymer

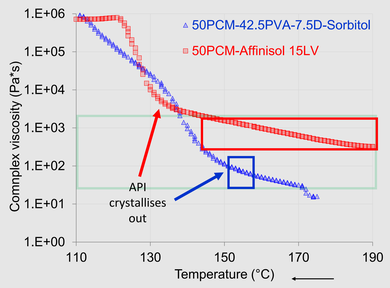

Figure 3 : Complex viscosity versus temperature for different API-polymer formulations. Red square – 50 % w/w PCM-Affinisol™15LV, blue triangle – 50 % w/w PCM – Polyvinylalcohol (PVA):

Impact of print speed on Uniformity and Repeatability

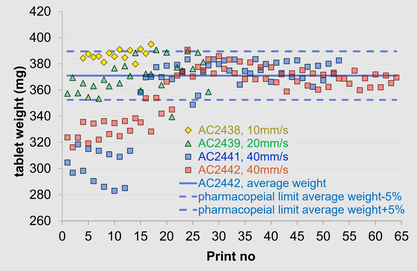

Figure 4: Repeatability of 3D printing 50PCM-Plasdone™ S-630 formulation at printing speeds of 10, 20 and 40 mm/s.

Formulation process window

Formulation	Process window
50PCM-Plasdone™ S-630	broad
50PCM-42.5PVA-7.5D-Sorbitol	very narrow
50PCM-Affinisol™ 15 LV	large
50MFA-42.5Soluplus®-7.5D-Sorbitol	broad

Uniformity of mass

AC2442	
Average weight	371 mg
Max % deviation	5.3
Min % deviation	-7.0

PASS only 1 tablet >5%

Uniformity of dimensions

	Average (mm)	% RSD
Length	19.8	0.9
Width	11.8	0.8
Height	4.7	1.4

CONCLUSION(S)

Operational limits, in terms of rheological properties of formulations, have been identified for this novel non-filament FDM printer. Repeatability of tablet prints showed good uniformity of mass, complying with pharmacopeial specifications for oral solid dose forms.

Figure 1: 3D printed tablet with porous core: elliptical shape with dimensions of 20 mm length, 12 mm width and 5 mm height. Infill percentage 37 %. No top or bottom layer were printed.

FUNDING / GRANTS / ENCORE / REFERENCE OR OTHER USE

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Reference:

1. Prasad E, Robertson J, Halbert GW 2022. Mefenamic acid solid dispersions: Impact of formulation composition on processing parameters, product properties and performance. Int J Pharm 616:121505.