Investigating Processing Window of Affinisol™ and Plasdone™ - S630 polymers during Hot-melt extrusion

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Abstract - **There are numerous polymers that have been used commercially to produce pharmaceutical solid dispersions and solutions from hot melt extrusion. Affinisol™ (HPMC) and Plasdone™ S630 (PVP based co-povidone copolymer) have been used in the present work to determine the viable processing space with regards thermal and work input on a twin screw extruder. Processing viability has been determined by monitoring degradation, initially assessed by physical appearance and colour of the extrudates across the full operating range of a twin screw extruder. It has been found that the Affinisol™ had a relatively narrow viable operating window compared with the Plasdone™.**

INTRODUCTION

Degradation by thermal or mechanical energy of polymers to produce solid dispersion/solutions is a challenge [1]. Within the present work, two polymers. Affinisol™ 15LV and Plasdone™ S630 have been studied across the full operating range of a twin screw extruder in order to identify processing space where degradation is likely to occur and where it can be avoided. This has been carried out as pre-work prior to inclusion of the pharmaceutical ingredient.

MATERIALS AND METHODS

Affinisol™ (Dow Chemical Co.) and Plasdone™; (Ashland) were fed into a Eurolab 16mm co-rotating twin screw extruder (Thermo Scientific, Karlsruhe, Germany) at 1kg/hr through a 3mm die to produce an extrudate strand. Three barrel temperatures (150, 180 and 210°C) were used and the screw speed was adjusted between 100-1000RPM. The physical appearance of the extrudate was monitored for discolouration and clarity.

RESULTS AND DISCUSSION

The physical appearance of the extrudate of both polymers at different processing temperatures and screw speed are shown in Figures 1 and 2. Specific mechanical energy calculated by torque produced during extrusion at different screw speed shown in Figure 3. It can be seen from the physical appearance of Affinisol™ was degraded/discoloured by a combined effect of screw speeds and temperature whereas Plasdone™ doesn't show any immediate discolouration. Degradation of Affinisol™ at low temperature is due to the mechanical energy produced during extrusion whereas thermal energy degrades the polymer at high temperature (Figure 3). However Plasdone™ showed a foaming during extrusion at 210°C.

Further work using screw configurations that introduce less mechanical energy may increase the operating window for polymers such as Affinisol™.

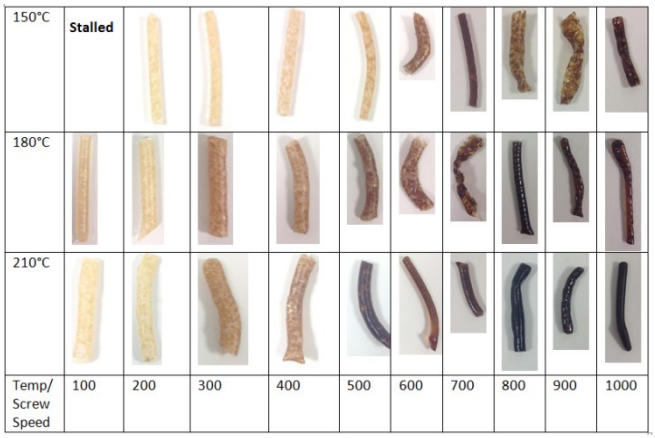

Figure 1: Physical appearance of Affinisol™ HPMC HME 15LV polymer extrudates

Figure 2: Physical appearance of Plasdone™ S630 polymer extrudates

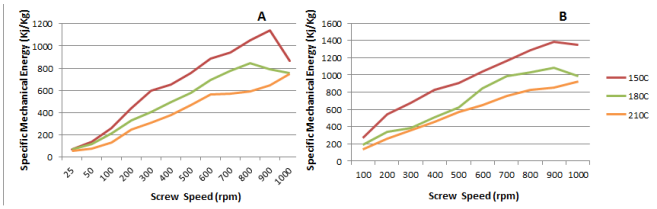

Figure 3: Specific mechanical energy curve for A) Affinisol™ and B) Plasdone™ S630

CONCLUSIONS

From the current work it was concluded that, Plasdone™ appears to have a broad operating window in HME, Affinisol™ readily discolours and likely degrades due to the mechanical energy as well as operating temperature; this in turn may limit its use in extrusion.

REFERENCES

[1] S.S. Gupta, N. Solanki, and A.T.M Serajuddin, Investigation of Thermal and Viscoelastic Properties of Polymers Relevant to Hot Melt Extrusion, IV: Affinisol™ 15LV HPMC HME Polymers, AAPST PharmSciTech, 2015