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Effects of increasing compaction temperature on tablet strength

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SUMMARY

Over time, a standard tablet press heats up during use. This investigation aims to explore heat effects at a small scale in the laboratory. The effects of heat on compression have been studied using a Compaction Simulator fitted with a temperature controlled die. Placebo formulation blends composed of Avicel PH102, Lactose Fast Flo 316, Sodium Starch Glycolate and Magnesium Stearate was compressed using a hydraulic Compaction Simulator. To assess the manufacturability of the formulations a Korsch XL100 profile at 30 rpm was chosen using 10 mm flat faced tooling. A jacketed die was connected to a water-bath, heated to a set temperature. The temperatures assessed were: 20°C, 30°C, 40°C, 50°C and 60°C and any effects on the tabletability of the formulation was assessed. The tensile strength at 100 MPa compaction pressure for each temperature was determined using trend line equations. Increasing temperature changes the tensile strength of the formulation. The highest tensile strength was recorded at 50°C with no further increase for this formulation blend above this temperature.

INTRODUCTION

Over time, a standard tablet press heats up during use. The effects are not often seen at development scale but are experienced during production as run lengths increase. Studies have shown a significant temperature rise during tablet compression can lead to changes in tablet characteristics if physicochemical properties of the materials making up the tablet change.[1] During compression, heat is generated through friction, the deformation and fragmentation of materials and change over the length of time of operation.[2] A study by Bechard and Down, 1992, showed surface temperatures of 50°C being recorded after 19 min running time of a rotary press.[3]

The effects of temperature were assessed on three placebo direct compression formulations. A compaction simulator was used to compress the blends at high speed and a temperature controlled die was used to heat the die to set temperature points to monitor the effects on the formulation. The effect of temperature on tensile strength was determined.

MATERIALS AND METHODS

Three direct compression blends were prepared with varying composition of MCC (Dupont, UK) and Lactose (Kerry, UK) (*Table 1*). Blends also contained a superdisintegrant (JRS Pharma, UK) and lubricant (Mallinckrodt, US). The blends were assessed using a Phoenix Compaction Simulator (Brierley Hill, UK) fitted with a jacketed die connected to a water bath with temperature control. A profile designed to simulate a Korsch XL100 press at a speed of 30 rpm. 10 mm flat faced tooling was used with a target weight of 350 mg. Tablets were made at a range of forces and the diametral crushing strength determined (Ihollands, UK). Temperatures of 20, 30, 40, 50 and 60°C were examined. The compaction simulator was used to accurately record the compact strength.

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The tensile strength against temperature was then plotted at 100 MPa to identify potential differences in the blends with increasing temperature.

Table 1. *Formulation composition.*

Material	Blend 1 MCC: Lactose 1:1	Blend 2 MCC: Lactose 3:1	Blend 3 MCC: Lactose 1:3
Avicel PH102® (MCC)	48.25 %	72.375 %	24.125 %
Fast Flo®316	48.25 %	24.125 %	72.375 %
Explotab®	3 %	3 %	3 %
Magnesium stearate	0.5 %	0.5 %	0.5 %

RESULTS AND DISCUSSION

To explore the differences in tensile strength due to temperature the strength at 100 MPa for all parameters was calculated from the regression lines to compare the strength against compaction temperature (Fig.2)

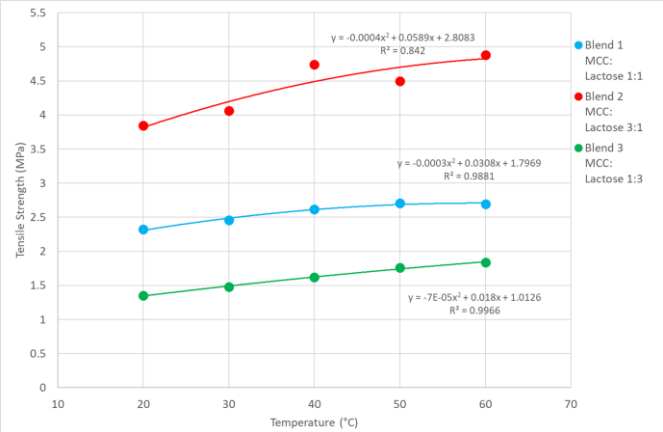

Fig. 2. *Graph showing the effects of temperature on tensile strength at 100 MPa compaction pressure of three direct compression placebo blends.*

Temperature increases the strength of the compacts. From room temperature to 60°C, the increase was 0.4 MPa for Blend 1, 1.0 MPa for Blend 2 and 0.5 MPa for Blend 3. Blend 3 shows a consistent increase of tensile strength with increasing temperature whereas Blend 1 shows a plateau after 50°C and Blend 2 shows an increase in variability after 40°C.

It can be seen from regression values that as a greater concentration of MCC is introduced there is a greater variability of tensile strength whereas increasing the concentration of Lactose reduces this variability. Possibly due to the materials properties of MCC being a soft ductile material and lactose being a brittle material. From the graph it is not easy to see which blend causes the biggest difference with temperature apart from the larger degree of variability seen with Blend 2 after 40°C compared to the other blends which had a higher concentration of lactose. Percentage increases were worked out to magnify this effect. Blend 1 showed a 16% increase in tensile strength, Blend 2 with a 27% increase in strength and Blend 3 with a 36% increase in strength.

CONCLUSIONS

The temperature of the tablet press and die was shown to have a large effect on tablet strength. It increases the strength of tablets. The extent of increase depends upon the formulation composition. As MCC was more affected than Lactose, it suggests that ductile materials appear to be more affected by temperature changes than brittle materials. This suggests differences in the bonding mechanisms that are occurring and both the formulation composition and the temperature play a part in this. Further work would focus on looking at the differences in the particles in the blends as temperature is increasing to observe any changes to identify reasons for increased variability with increased MCC concentration and bigger percentage change in tensile strength with increased Lactose concentration.

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