THE INFLUENCE OF THE STYLCAM FLOWMATIC® FEED SYSTEM ON TABLET PROPERTIES

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INTRODUCTION

Tablet quality can ultimately be limited by the flow characteristics of the formulation. Failure of a formulation to flow effectively during manufacture can result in tablets of non-uniform weight due to varied volume to mass ratio and particle packing within the die. Whilst uneven flow can produce excess trapped air, leading to tablets of poor mechanical strength, particularly at high machine speeds[1] . Powder flow on single-station tablet presses usually occurs under the influence of gravity whilst rotary tablet presses employ force-feed mechanisms whereby the powder formulation is conveyed into the die cavity either by paddle or screw devices.

Fig. 1. Flowmatic® powder feed system

The Stylcam 100R rotary press simulator is equipped with the Flowmatic® powder feed system (Fig 1). which utilises counter-rotating twin-screws to ensure powder flow during tableting (Fig 2.) The speed of the Flowmatic® screw feed system is adjustable and independent from the machine production speed[2].

Fig. 2. Flowmatic® screw feeders

The aim of the current investigation was to examine the influence of the Flowmatic® feed system and the Stylcam 100R rotary press simulator production speed on the weight uniformity and tensile strength of tablets produced from formulations exhibiting different flow characteristics.

Formulation	Avicel® PH101	Avicel® PH102	Pharmatose® 200M	Tablettose® 80	Magnesium Stearate
A	–	49.75%	–	49.75%	0.5%
B	49.75%	–	–	49.75%	0.5%
C	–	49.75%	49.75%	–	0.5%
D	49.75%	–	49.75%	–	0.5%

Table 1. %w.w composition of formulations A – D.

EXPERIMENTAL

Formulations comprised equal amounts of Lactose (either Pharmatose® 200M (DMV, Netherlands) or Tablettose® 80 (Meggle, Germany)) and Microcrystalline cellulose (either Avicel ® PH101 or PH102, FMC, Ireland)). Each formulation also comprised 0.5 %w/w magnesium stearate (Table 1). Lactose and microcrystalline cellulose were blended in a turbula mixer (Type 2C, WAB, Switzerland) for 5 min, magnesium stearate was then added and blended for a further 2 min.

Angle of repose (θ) and Carr's consolidation index were determined to characterise the flowability of each formulation.

400 mg tablets were produced using the Stylcam 100 R rotary press simulator fitted with 12.7 mm type B flat faced tooling at a compaction force of 15 (±1) kN. Tablets were compacted at production speeds of 5, 15, 25 or 35 tablets min^{-1} and Flowmatic® feed rates of 25, 50 75 or 100%. The weight and tensile strength[3] of 10 tablets from each batch were measured.

Statistical analyses of the data using the Minitab™ software were performed. Three-way ANOVA revealed any significant (P<0.05) effect of the experimental variables (flowability, machine speed or Flowmatic® feed rates) on either tablet weight uniformity or tensile strength.

Formulation	Angle of Repose θ	Carr's Index (%)	Flowability
A	14.8°	14.5	Excellent
B	15.6°	17.6	Good
C	28.1°	22.7	Passable
D	Non Flowing	25.7	Poor

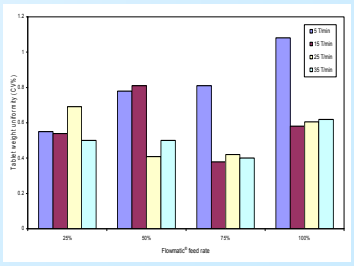
Table 2. Angle of Repose, Carr's Index and corresponding flowability of formulations A - D

RESULTS & DISCUSSION

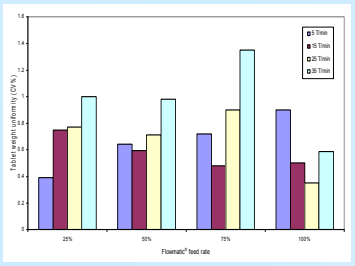
According to the results of both the Angle of Repose and Carr's consolidation index determinations (Table 1), the four formulations exhibited different flow characteristics, with a sequential decrease in powder flowability from formulation A through to formulation D. The influence of the Tablettose® 80 (a direct compression grade of agglomerated α-lactose monohydrate with optimum flow) on the flowability of formulations A and B is clearly evident whilst the milled lactose monohydrate (Pharmatose® 200M) with a smaller particle size reduced the flowability of formulations C and D. The range of flow characteristics were obtained by combining the different lactose grades with either Avicel® PH101, which has a mean particle size of ~ 50 µm, or Avicel® PH102, with a mean particle size of ~90 µm and a corresponding superior flowability.

REFERENCES

1. Staniforth, J., Aulton, M.E. (2007) Powder flow. In: Aulton, M.E. (Ed), Pharmaceutics: The design and manufacture of medicines (3rd Ed) 168-179
2. Fell, J.T., Newton, J.M. (1970) Determination of tablet strength by the diametral compression test. *J. Pharm. Sci.* **59** 688-691
3. Stylcam (www.medelco.fr/medelpharm)
4. Tablettose® 80 (www.meggle-pharma.de/en/products/uebersicht/tablettose80)
5. Pharmatose® 200M (www.dmv-fonterra-excipients.com)
6. Avicel® PH microcrystalline cellulose (www.fmcbiopolymer.com)



Formulation A



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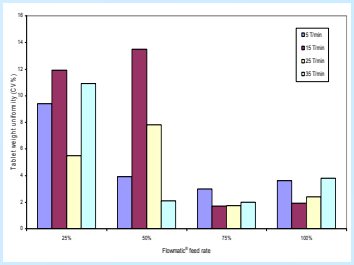
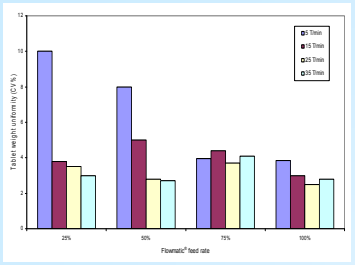


Formulation C



Formulation D

Fig. 3. The effect of Flowmatic® feed rate and Stylcam 100R production speed on the weight uniformity of tablets produced from formulations A – D.

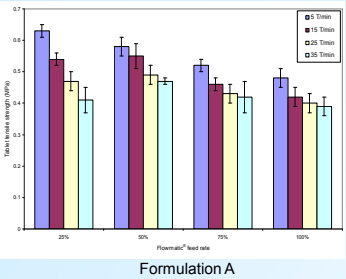
RESULTS & DISCUSSION

The weight uniformity of the formulations varied according to their respective flow characteristics (Fig. 2). Formulations A and B, with excellent and good flow respectively, produced tablets with low weight variation (generally <1%) whereas formulations C and D, with passable and poor flow respectively, generally produced tablets of with far greater weight variation. The effect of powder flow on tablet weight uniformity is well established and a free flowing powder ensures reproducible die filling during production.

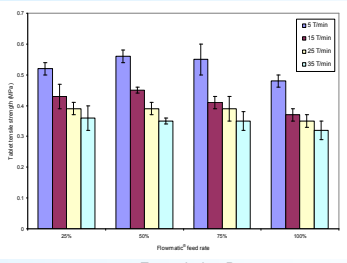
Flowmatic® feed rates had no significant effect on tablet weight uniformity for the formulations with good or excellent flow (P = 0.970). However, increased Flowmatic® feed rates (75% and 100%) reduced the weight variation for the formulations with passable and poor flow (P = 0.09). Consequently, when operated at rates of 75% or above, the Flowmatic® feed system allows tablets to be produced from poorer flowing formulations with comparable weight uniformity to those produced from formulations with good or excellent flow. Tablet production speed had no significant effect on the weight uniformity of tablets produced from either formulations A and B (P = 0.294) nor formulations C and D (P = 0.294).

The flow properties of the formulations had a significant effect on tablet tensile strength (P< 0.05).Tablet tensile strength was generally higher for tablets produced from formulations with good or excellent flow, although some tablets produced from the poorer flowing formulations had higher strengths the overall results were more variable (Fig. 3) and problems occurred during production of tablets from formulations C and D where incomplete tablets or tablets too weak to withstand handling were produced (particularly at the lower Flowmatic ® feed rates of 25 and 50%).

Increased Flowmatic® feed rates had little effect on tablet strength for formulations A and B, however the strength of tablets produced from the poorer flowing formulations (particularly formulation C) was markedly improved at the higher Flowmatic® feed rates of 75% and 100%. Overall, Flowmatic® feed rate had a significant effect on tablet tensile strength (P < 0.05). An increase in tablet production speed generally decreased tablet strength at all Flowamtic® feed rates. An expected trend due to the presence of the plastically deforming microcrystalline cellulose present in each formulation.



Formulation A



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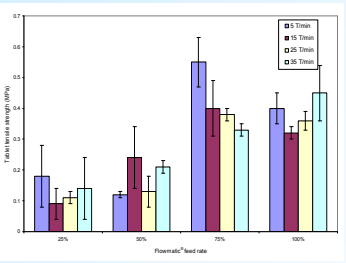

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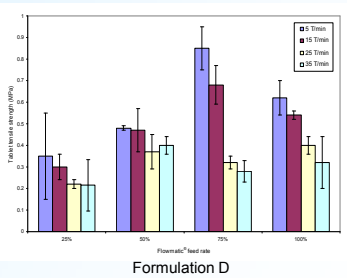

Formulation D

Fig. 4. The effect of Flowmatic® feed rate and Stylcam 100R production speed on the tensile strength of tablets produced from formulations A – D. (mean values ± s.d. n = 10)

CONCLUSIONS

Tablet weight uniformity and strength were dependent on the flow characteristics of the formulations. The Flowmatic® feed system did not influence the properties of tablets produced from formulations with good or excellent flow characteristics but improved both the weight uniformity and strength of tablets produced from formulations with passable or poor flow characteristics when operated at higher rates (≥ 75%).