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Comparison between a gravity feed extruder and a twin screw extruder

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Summary

Extrusion forces and power consumption were measured for binary mixtures microcrystalline cellulose/water and ternary mixtures microcrystalline cellulose/drug substitute/water on a gravity feed extruder and a twin screw extruder, respectively. Ternary diagrams were constructed for mixtures microcrystalline cellulose/dicalcium phosphate dihydrate/water determining the regions where good quality spheres were obtained. This region was much smaller for the twin screw extruder in comparison with the gravity feed extruder and was correlated with differences in the die design of the extruders. Likewise profiles for the amount of water vs extrusion forces and power consumption were obtained in the case of binary mixtures microcrystalline cellulose/water. In the case of ternary mixtures drug substitute/microcrystalline cellulose/water likewise profiles for the amount of drug substitute vs extrusion forces and power consumption were obtained for dicalcium phosphate dihydrate as drug substitute. In the case of the more soluble drug substitutes (α-lactose monohydrate and anhydric β-lactose) differences in profile of the amount of drug substitute vs extrusion forces or power consumption were obtained and were correlated with differences in the die design of the different extruders.

Introduction

Extrusion is a process that is used for the preparation of pellets containing one or more drugs. The process consists of the blending of a dry powder, then a granulation step using, e.g., water, water-alcohol or a binder solution, and finally the extrusion of the wet powder mass. The extrudate is rounded into pellets using a spheroniser. Fielden and Newton (1992) classified extruders according to the die design and the feed mechanism which transports the material to the die region and mentioned that differences in type of extruders resulted in differences in pellet quality.

Baert et al. (1992b) reported on the differences in pellet quality obtained from extrudates produced with an instrumented gravity feed extruder and an instrumented ram extruder. The present paper compares the quality of pellets produced with an instrumented twin screw extruder and an instrumented gravity feed extruder.

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Materials and Methods

Materials

Two different types of lactose were used: α-lactose monohydrate (Pharmatose 200 M) (DMV, Veghel, The Netherlands) as a substitute for a medium soluble drug and anhydrous β-lactose (DCL 21) as a substitute for a highly soluble drug. Dicalcium phosphate dihydrate (C.N. Schmidt B.V., Amsterdam, The Netherlands) was used as a substitute for an insoluble drug. Microcrystalline cellulose (Avicel PH 101-FMC Wallingstown, Little Island, Cork, Ireland) was used as a filler. Mixtures were granulated using demineralised water.

Composition of the mixtures used for the measurement of the extrusion forces and the power consumption

Microcrystalline cellulose was granulated with water for 2 min in a planetary mixer (Kenwood Chef, Hampshire, U.K.) at 60 rpm using a K-shaped mixing arm. Mixtures of lactose or dicalcium phosphate dihydrate and microcrystalline cellulose were dry blended for 10 min in a planetary mixer (Kenwood Chef, Hampshire, U.K.) at 60 rpm using a K-shaped mixing arm. The mixtures were granulated with water for 2 min at 60 rpm. The composition of the mixtures was (lactose or dicalcium phosphate dihydrate/microcrystalline cellulose/water) (w/w) 0 : 50 : 50, 5 : 47.5 : 47.5, 10 : 45 : 45. Additionally, the following mixtures were used for the two lactose qualities: 15 : 42.5 : 42.5, 20 : 40 : 40, 25 : 37.5 : 37.5, 30 : 35 : 35, 40 : 30 : 30. Moreover, 50 : 25 : 25 and 60 : 20 : 20 mixtures were prepared with β-lactose.

Composition of the mixtures used for the spheronisation experiments

Mixtures consisting of different ratios of dicalcium phosphate dihydrate and microcrystalline cellulose were dry mixed for 10 min in a planetary mixer (Kenwood Chef, Hampshire, U.K.) at 60 rpm. using a K-shaped mixing arm and then were granulated with demineralised water for 2 min at 60 rpm.

Extrusion and spheronisation procedures

Mixtures were extruded with an instrumented gravity feed extruder (Extruder 40, GB Caleva Ltd, Dorset, U.K.) as described by Baert et al. (1991) and on an instrumented twin screw extruder (Fuji Paudal EXD 60, Collette, Wommelgem, Belgium) as described by Elbers et al. (1992). The rotational speed of the axes was 30 rpm in both cases. Spheronisation was performed with 200 g of the extrudate on a spheroniser Model 15 (∅ 38.5 cm) (Caleva Ltd, Dorset, U.K.) in the case of gravity feed extrusion and on a Schlüter spheroniser (∅ 40 cm) (Schlüter, Neustadt, Germany) in the case of twin screw extrusion. The spheronisation time was 10 min and the speed 750 rpm. Spheres were dried in a fluidized bed (Aeromatic AG, Basel, Switzerland) for 20 min at 50°C (inlet temperature).

Evaluation of the spheres

Spheres were evaluated using the criteria described by Baert et al. (1992a). They were considered of acceptable quality if more than 90% showed a particle size between 710 and 1400 μm, the friability was lower than 0.2% and the calculated E value (roundness value) was between 1 and 1.20. Pictures of the different extrudates were taken using a Wild Heerebrugg stereomicroscope (Van Hopplynus, Brussels, Belgium) set at a magnification of 25 ×.

Results and Discussion

In previous work (Baert et al. 1992b) an instrumented gravity feed extruder was compared with an instrumented ram extruder. Differences were found between both systems for the extrusion forces recorded and for the composition of mixtures with which pellets of the preset quality were obtained. In the case of ram extrusion, less water was required in the granulate in order to obtain pellets of a preset quality compared to the gravity feed extruder. Those differences in water content necessary to prepare good pellets could be explained by the water movement that occurred during ram extrusion. The water movement was due to the continuous pressure on the mixture during extrusion. Using the gravity feed extruder, the pressure was discontinuous and almost no water movement occurred.

The purpose of the present work was the comparison of the regions where pellets of a preset quality were obtained for an insoluble model drug from extrudates produced with an instrumented gravity feed extruder and with an instrumented twin screw extruder. In the case of the gravity feed extruder, extrusion forces were measured using load cells which were placed on the rotating axes. In the case of the twin screw extruder the power consumption of the motor was measured. It should be mentioned that due to the difference in instrumentation of both extruders, the results obtained with the gravity feed extruder are expressed in N while the results obtained with the twin screw extruder are expressed in W.

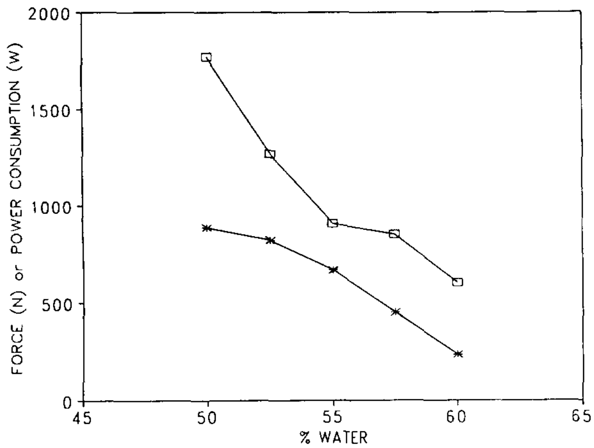

Fig. 1. Influence of the amount of water on the extrusion forces (gravity feed extruder) and power consumption (twin screw extruder) for a mixture Avicel PH 101®/water. Gravity feed extruder (N) (□); twin screw extruder (W) (*).

Fig. 1 shows the extrusion forces and the power consumption as a function of the percentage of water in binary mixtures microcrystalline cellulose/water recorded on the gravity feed extruder and the twin screw extruder, respectively. Similar profiles were obtained for both types of extruders. These results are in accordance with data previously obtained on the ram extruder (Baert et al., 1992b). An increase in the water content of the binary mixture microcrystalline cellulose/water blends resulted in lower extrusion forces in the case of the ram and the gravity feed extruder and in lower power consumption when the twin screw extruder was used. Fig. 2A and B shows the extrusion forces and the power consumption during extrusion of ternary mixtures. In the case of mixtures containing dicalcium phosphate dihydrate comparable profiles were obtained for both extruders. Higher concentrations of dicalcium phosphate dihydrate in the ternary

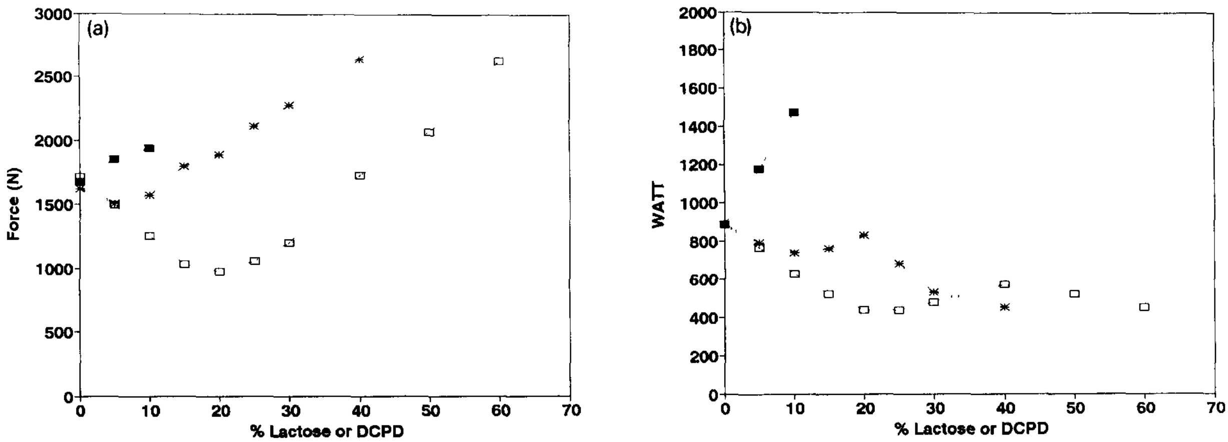

Fig. 2. (a) Influence of the amount of lactose and dicalcium phosphate dihydrate (% of the total weight) on the extrusion forces (N) recorded during extrusion of lactoses and dicalcium phosphate dihydrate/Avicel PH 101®/water mixtures using a gravity feed extruder. (b) Influence of the amount of lactose and dicalcium phosphate dihydrate (% of the total weight) on the power consumption recorded during extrusion of lactoses and dicalcium phosphate dihydrate/Avicel PH 101®/water mixtures using a twin screw extruder. α-Lactose monohydrate 200 mesh (*); anhydrous β-lactose (□); dicalcium phosphate dihydrate (■).

Fig. 3. Extrudate consisting of 40% α-lactose monohydrate, 30% microcrystalline cellulose and 30% water prepared by a twin screw extruder.

Fig. 5. Extrudate consisting of 50% β-lactose, 25% microcrystalline cellulose and 25% water prepared by a twin screw extruder.

mixtures resulted in greater extrusion forces or higher power consumption. In the case of α-lactose monohydrate and anhydrous β-lactose, a decrease in the extrusion forces and power consumption was observed in the first part of the profile between 0 and 10% for α-lactose monohydrate and between 0 and 20% for anhydrous β-lactose. This can be explained on the basis of the increase in the amount of fluid phase, resulting in lower extrusion forces and power consumption.

In contrast, a clear difference in pattern was observed in the second part of the profile when lactose mixtures were extruded. In the case of the twin screw extruder, the power consumption further decreased at concentrations above 20% α-lactose monohydrate and 40% anhydrous β-lactose, respectively. Higher extrusion forces were recorded with the gravity feed extruder at greater concentrations of both lactose qualities. This was due to a lower amount of fluid phase present in the mixtures as was previously reported (Baert et al., 1991). This resulted in the formation of firmly bound extrudate (Figs 4 and 6) whereas with the twin screw extruder, no strongly bound extrudates (Figs 3 and 5) were obtained for mixtures containing more than 20% α-lactose and more than 40% β-lactose.

Fig. 4. Extrudate consisting of 40% α-lactose monohydrate, 30% microcrystalline cellulose and 30% water prepared by a gravity feed extruder.

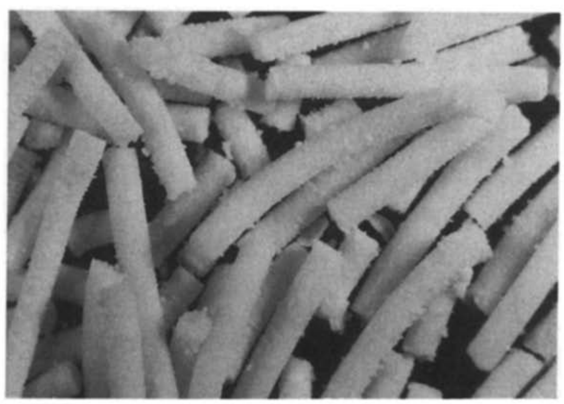

Fig. 6. Extrudate consisting of 50% β-lactose, 25% microcrystalline cellulose and 25% water prepared by a gravity feed extruder.

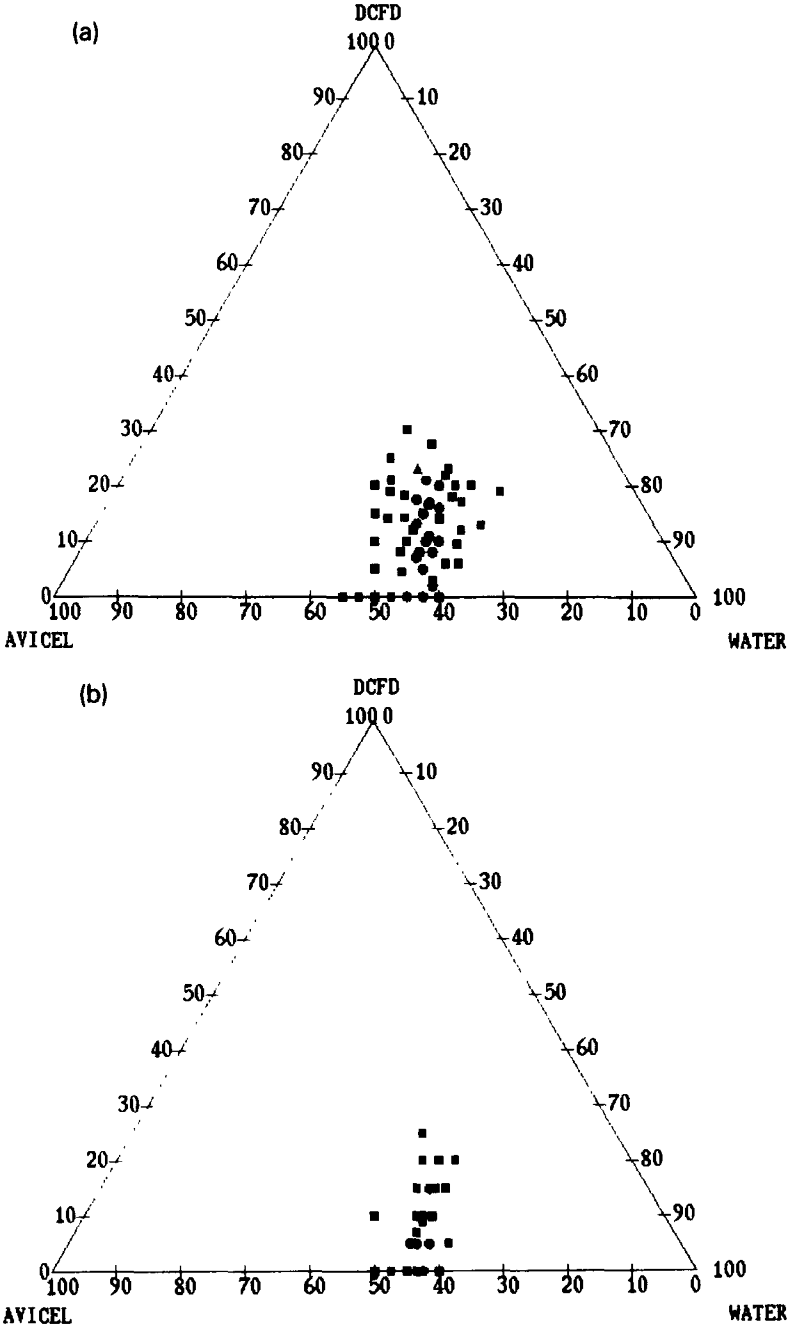

Fig. 7. (a) Phase diagram indicating the quality of spheres made of ternary mixtures consisting of microcrystalline cellulose, dicalcium phosphate dihydrate and water. Extrusion was performed with a gravity feed extruder. (b) Phase diagram indicating the quality of spheres made of ternary mixtures consisting of microcrystalline cellulose, dicalcium phosphate dihydrate and water. Extrusion was performed with a twin screw extruder. Good quality pellets (•); poor quality pellets (■); no pellet production possible (▲).

These differences can be explained by a difference in the geometry of the extrusion screen perforations between both extruders. Both extruder die perforations had a diameter of 1 mm but different lengths: 2 mm in the case of the gravity feed extruder and 0.9 mm in the case of the twin screw extruder. This results in a length-to-radius ratio of 4 and 1.8 for the gravity feed extruder and the twin screw extruder, respectively.

This indicates that during gravity feed extrusion greater densification occurred in comparison to twin screw extrusion.

The compositions for ternary mixtures containing dicalcium phosphate dihydrate as drug substitute yielding spheres of good quality using the two different extrusion processes are compared in Fig. 7A and B. In the case of the twin screw extruder, the region giving good sphere quality was much smaller than for the gravity feed extruder, while no shift in the zone was observed as was reported in the case of the ram extruder (Baert et al. 1992b).

Conclusions

It can be concluded that the results for ternary mixtures microcrystalline cellulose/dicalcium phosphate dihydrate/water obtained on a gravity feed extruder can be extrapolated to a twin screw extruder if one takes into account that the region where spheres of the assumed quality were obtained was smaller in the case of the twin screw extruder. Differences in profiles depicting the amount of drug substitute vs extrusion forces or power consumption were seen for the two extruders in the case of the soluble drug substitutes. No differences in profiles were observed between the two extruders for ternary mixtures with the nearly insoluble drug substitute dicalcium phosphate dihydrate and for binary mixtures microcrystalline cellulose/water.

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