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A comparison of two methods of instrumenting a small-scale basket extruder

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Abstract

A small-scale basket extruder was instrumented for the simultaneous measurement of extrusion force on the screen and power consumption of the motor during the extrusion process. Binary mixtures of microcrystalline cellulose/water and ternary mixtures of microcrystalline cellulose/lactose or dicalcium phosphate dihydrate/water were tested on this extruder. The results obtained were comparable to those of previous studies using several types of instrumented production-scale extruders. It was also concluded that the results obtained from the two instrumentation systems (extrusion force and power consumption) were identical and that both systems were useful for monitoring and documenting the extrusion process.

Key words: Extrusion; Instrumentation; Basket extruder; Extrusion force; Power consumption

1. Introduction

Several authors have recently reported on the instrumentation of production-scale extruders which allowed them to measure either extrusion force (Baert et al., 1991) or power consumption of the motor (Elbers et al., 1992; Kleinebudde and Lindner, 1993; Vervaet et al., 1994). One major disadvantage of these extruders is that a considerable amount of drug is required in order to perform feasibility studies. A solution to this problem is the use of a small-scale ram extruder as described by Harrisson et al. (1984) and Fielden et al. (1993). One of the shortcomings of this extruder, however, is that movement of water during the extrusion process results in a non-homogeneous extrudate (Baert et al., 1992). Consequently, small-scale basket extruders (capacity < 100 g) were developed. This paper describes the instrumentation of a small-scale basket extruder which allows the measurement of extrusion force and power consumption simultaneously.

2. Materials and methods

2.1. Instrumentation of the extruder

A small-scale basket extruder (Caleva model 10, Caleva Ltd, Dorset, U.K.) has been instrumented to measure extrusion force and power

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consumption during extrusion. In order to measure extrusion force, a single T-rosette foil strain gauge (type FAET-12B-35-S6E, BLH Electronics, Waltham, MA) was bonded to the upper rim of the extruder screen using epoxy glue (Lepage, Brampton, Ontario). This strain gauge was connected to a K50 amplifier (Hottinger Baldwin Messtechnik, Darmstadt, Germany) and a 5113 oscilloscope with 5A26 differential amplifiers (Tektronix, Beaverton, OR). Calibration was performed by hanging weights from the screen, suspended from a cross-bar. The amplifier response was found to be directly proportional to weight over the range used. The extrusion force was expressed as amplifier voltage rather than units of force because it was noted that the force was not uniform across the screen (as demonstrated by some barreling of the lower screen section). The power consumption was determined using a voltmeter (WV-547A, RCA, Deptford, NJ) placed parallel to the extruder DC motor and an ammeter (22-193, Tandy Corp., Barrie, Ontario) in series with the motor. Power consumption was expressed in W, calculated as the product of the average DC voltage and amperage.

2.2. Materials

Two different types of lactose, α-lactose monohydrate 200 mesh (Pharmatose 200M, DMV, Veghel, The Netherlands) and anhydrous β-lactose (Sheffield Products, Norwich, NY), were used as model materials, simulating a moderately soluble and a highly soluble drug, respectively. Dicalcium phosphate dihydrate (Emcompress, Mendell, Carmel, NY) was used as a model material for an insoluble drug. Microcrystalline cellulose (Avicel PH 101, FMC, Philadelphia, PA) with an average particle size of 50 μm was used as filler and deionized water was used as the granulating fluid.

2.3. Composition of the mixtures and granulation procedure

2.3.1. Binary mixtures

Different mixtures of microcrystalline cellulose and water, ranging from 55:45 to 40:60 (w/w), were granulated by mixing for 2 min in a planetary mixer at 50 rpm.

2.3.2. Ternary mixtures

Lactose or dicalcium phosphate dihydrate and microcrystalline cellulose were dry blended for 10 min in a V-blender. The mixtures were then granulated with water for 2 min at 50 rpm in a planetary mixer. The composition of the different lactose/microcrystalline cellulose/water mixtures was 0 : 50 : 50, 10 : 45 : 45, 20 : 40 : 40, 30 : 35 : 35 and 40 : 30 : 30 (w/w). For β-lactose, an additional 60 : 20 : 20 (w/w) mixture was used. The composition of the dicalcium phosphate dihydrate/microcrystalline cellulose/water mixtures was 0 : 50 : 50, 10 : 45 : 45 and 20 : 40 : 40 (w/w).

2.4. Extrusion procedure

After granulation, the mixtures were extruded in the instrumented extruder. The rotational speed was fixed at 12 rpm. Extrusion forces and power consumption readings (i.e., motor voltage and amperage readings) were taken when extrusion reached a steady-state condition.

3. Results and discussion

Table 1 tabulates the power consumption and extrusion force values recorded during extrusion of the granulations studied.

As the amount of water in the binary microcrystalline cellulose/water mixtures increased, there was a proportional decrease in the extrusion force and power consumption. These results are in agreement with previous studies conducted on production-scale gravity-feed (Baert et al., 1991), twin-screw (Baert et al., 1993; Kleinebudde, 1993) and basket (Vervaet et al., 1994) extruders.

The results obtained for the ternary mixtures are also in agreement with a previous study (Baert, 1992) which demonstrated that, with an increasing amount of lactose, a minimum in the extrusion force was observed at a level of 10% α-lactose monohydrate and 20% anhydrous β-lactose. With

Table 1
Comparison of power consumption (PC) and extrusion force values

Mixture	PC (W)	Force (V)	Ratio (PC/force)
Microcrystalline cellulose/water			
55:45	90.7 ± 6.4	2.58 ± 0.19	35.2
50:50	58.3 ± 4.4	1.62 ± 0.13	36.0
45:55	29.7 ± 3.9	0.74 ± 0.22	40.1
40:60	11.5 ± 1.6	0.30 ± 0.07	38.6
Dicalcium phosphate dihydrate/ microcrystalline cellulose/water			
0:50:50	58.3 ± 4.4	1.62 ± 0.13	36.0
10:45:45	92.0 ± 10.4	2.46 ± 0.22	37.4
20:40:40	114.3 ± 7.1	3.30 ± 0.32	34.6
α-Lactose monohydrate/microcrystalline cellulose/water			
0:50:50	58.3 ± 4.4	1.62 ± 0.13	36.0
10:45:45	44.6 ± 3.6	1.40 ± 0.10	31.9
20:40:40	71.8 ± 6.2	2.13 ± 0.19	33.7
30:35:35	84.3 ± 3.9	2.34 ± 0.21	36.1
40:30:30	96.8 ± 4.2	2.80 ± 0.44	34.6
Anhydrous β-lactose/microcrystalline cellulose/water			
0:50:50	58.3 ± 4.4	1.62 ± 0.13	36.0
10:45:45	46.6 ± 4.2	1.27 ± 0.18	36.7
20:40:40	35.5 ± 4.6	0.93 ± 0.16	38.2
30:35:35	60.1 ± 6.1	1.48 ± 0.18	40.6
40:30:30	83.9 ± 6.3	2.14 ± 0.17	39.2
60:20:20	145.2 ± 9.8	3.64 ± 0.49	39.9

Each value is the mean of 12 measurements (± S.D.).

an increasing amount of dicalcium phosphate dihydrate, no minimum in the extrusion force was observed. The differences in the aqueous solubilities of the lactoses and the low solubility of dicalcium phosphate dihydrate could explain this phenomenon. Increasing the amount of α-lactose initially decreased the extrusion forces due to a decrease in the total solid content of the mixture. Once the solubility of lactose had been exceeded in the granulation medium, the extrusion force progressively increased. Since the solubility of β-lactose is higher compared to α-lactose, the point of lowest extrusion force shifted towards 20% total lactose. Dicalcium phosphate dihydrate which is nearly insoluble in water produced an increase in the extrusion force as a function of higher dicalcium phosphate dihydrate concentration.

To illustrate that the two measurement systems give the same results, the ratio of extrusion force and power consumption was calculated. This ratio was found to be a relatively constant value for the different mixtures tested and indicated that measuring either extrusion force on the screen or power consumption on the motor was an equally useful method to follow the extrusion process.

4. Conclusions

It was found to be possible to instrument a small-scale basket extruder in such a way as to measure extrusion force and power consumption simultaneously. Virtually identical responses were obtained from these two instrumentation systems, showing them to be equally useful as monitoring tools, although the determination of power consumption proved to be the simpler and less expensive approach. The extrusion behaviour of several model granulations was found comparable to that reported in previous studies using several types of instrumented production-scale extruders. Thus, an instrumented small-scale basket extruder may be a useful tool in the early stages of formulation development when availability of a new chemical entity may be limited.

References

Baert, L., Formulation and process development of spheres by extrusion spheronisation. Ph.D. Thesis, University of Gent, Belgium (1992).

Baert, L., Fanara, D., De Baets, P. and Remon, J.P., Instrumentation of a gravity feed extruder and the influence of the composition of binary and ternary mixtures on the extrusion forces. *J. Pharm. Pharmacol.*, 43 (1991) 745–749.

Baert, L., Remon, J.P., Elbers, J.A.C. and Van Bommel, E.M.G., Comparison between a gravity feed extruder and a twin screw extruder. *Int. J. Pharm.*, 99 (1993) 7–12.

Baert, L., Remon, J.P., Knight, P. and Newton, J.M., A comparison between the extrusion forces and sphere quality of a gravity feed extruder and a ram extruder. *Int. J. Pharm.*, 86 (1992) 187–192.

Elbers, J.A.C., Bakkenes, H.W. and Fokkens, J.G., Effect of amount and composition of granulation liquid on mixing, extrusion and spheronization. *Drug Dev. Ind. Pharm.*, 18 (1992) 501–517.

Fielden, K.E., Newton, J.M. and Rowe, R.C., The influence of moisture content on spheronization of extrudate processed by a ram extruder. *Int. J. Pharm.*, 97 (1993) 79–92.

Harrison, P.J., Newton, J.M. and Rowe, R.C., Convergent flow analysis in the extrusion of wet powder masses. *J. Pharm. Pharmacol.*, 36 (1984) 796–798.

Kleinebudde, P., Application of low substituted hydroxypropylcellulose (L-HPC) in the production of pellets using extrusion/spheronization. *Int. J. Pharm.*, 96 (1993) 119–128.

Kleinebudde, P. and Lindner, H., Experiments with an instrumented twin-screw extruder using a single-step granulation/extrusion process. *Int. J. Pharm.*, 94 (1993) 49–58.

Vervaet, C., Baert, L., Risha, P.A. and Remon, J.P., The influence of the extrusion screen on pellet quality using an instrumented basket-extruder. *Int. J. Pharm.*, (1994) in press.