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FURTHER STUDIES OF THE POTENTIAL OF RECORDING POWDER FLOW METERS

E. M. Rudnic, R. Chilamkurti and C. T. Rhodes
Department of Pharmacy, University of Rhode Island, Kingston, R. I. 02881

INTRODUCTION

Concerned with the importance of flow factors on pharmaceutical systems, Jordan and Rhodes (1) discussed the obvious potential utility of recording powder flowmeters (R.P.F.'s). They referred to a number of papers of importance in this area, and presented experimental data demonstrating the utility of such devices in the pharmaceutical field.

As an extension of this recently reported study (1), the authors have further investigated the potential use of recording powder flow meters for the evaluation of pharmaceutical formulations. In this study, the flow properties of two grades of AVICEL (microcrystaline cellulose) and two grades of EMCOCEL (alpha cellulose, dicalcium phosphate dihydrate) have been evaluated. Also the effect of lubricant, disintegrant and drug on flow rates have been evaluated. Furthermore, the authors present concepts relevant to the interpretation of recording powder flowmeter results.

EXPERIMENTAL

The recording powder flowmeter (R.P.F.) was set up as follows:

A stainless steel powder hopper taken from a tablet press[1] was suspended over an analogue balance[2] by using ring stands. This height remains constant throughout the study. A glass stop-plate is used to secure the opening of the hopper/funnel. The output of the balance is electrically conveyed to a suitable strip-chart recorder[3]. The recorder is calibrated such that 1 Kilogram of weight on a tared, aluminum pan will cause a pen deflection of 100 units (the entire scale). The 1 Kilogram of powder to be studied is placed in the powder hopper. This weight is kept constant throughout the study. The chart speed is also kept constant throughout the study (20 cm./min.). As the stop-place is removed, the falling weight causes the pen to move, creating a "flowgram" characterizing the system's flow.

This process is then repeated three times. The flowgrams are then analyzed for linearity (based on least squared correlation coefficient; r^2) and mass flow (6 m./sec.) and the three values are averaged.

In this study, two different grades or particle size ranges of a commercially available microcrystalline cellulose products, (Avicel PH 101[4], Avicel PH 102[4], along with two experimental grades of an alpha cellulose/dicalcium phosphate dihydrate mixture /Emcocel "Fine"), Emcocel "Coarse"[5]) were first evaluated for their matrix flow characteristics alone. Then Magnesium Stearate

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[1] Stokes Model F

[2] Sartorius

[3] Linear, Single Channel Model

[4] FMC Corporation

[5] Edward Mendell Co., Inc.

(a poor glidant) was gradually added in concentrations of 0.5% w/w, 1% w/w, and 2% w/w. Here, as in all mixings, the procedure remained constant. A stainless-steel, twin shell blender[6] was used for a time of 5 minutes. The time and speed of the mixer remained constant. The quantity mixed for each run also remained constant at 1 Kilogram. The flow characteristics of these systems was also evaluated. Sodium Starch Glycolate[7] was added to each matrix in a concentration of 4% w/w in addition to 0.5% w/w Magnesium Stearate. The system's flow was then analyzed. Finally 30% w/w Aspirin[8]; 4% w/w Sodium Starch Glycolate and 0.5% Magnesium Stearate was added to each matrix, evaluated for flow and then tabletted using a rotary press[9]. Tablets were then evaluated for weight and hardness.

RESULTS AND DISCUSSION

Fig. 1a, b and c show three replicate powder flow tests for a tablet matrix; they are clearly virtually identical. In all cases, the flow data reported in this paper was similarly reproducable. In Fig. 1 the flowgram is obviously linear but Fig. 2a, b and c shows the results for a more complex system. The flowgram is obviously non-linear. For a flowgram such as that shown in Fig. 1, it is quite possible to characterize the powder flow by determining the slope of the curve, i.e., the mass flow per unit time. However, for those of the type shown in Fig. 2, we must devise some method of quantifying and digitalizing the variation in flow rate. We propose that it may be appropriate to characterize the degree of linearity by use of a FLOW LINEARITY term, FL.

$$FL = (r^2 - 0.8) \times 100$$

where r^2 is the correlation coefficient derived from ten points.

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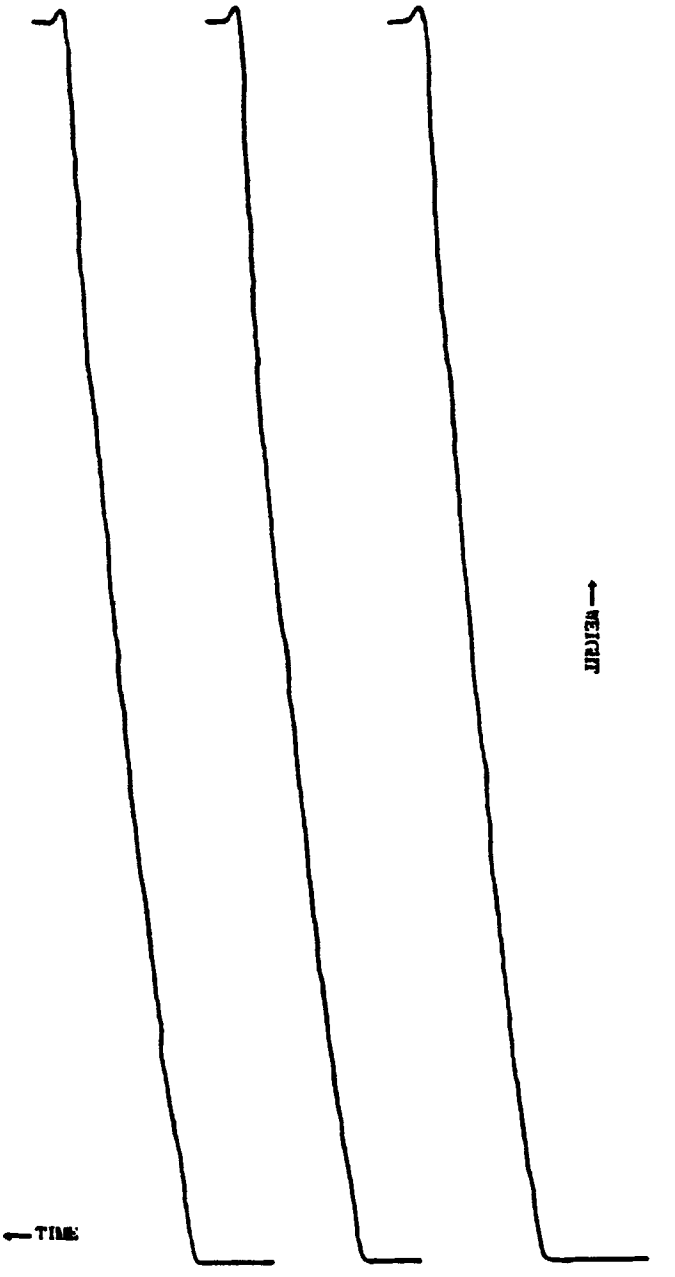
[6] Patterson-Kelley Co.

[7] Explotab, Edward Mendell Co., Inc.

[8] Ruger Chemical Co.

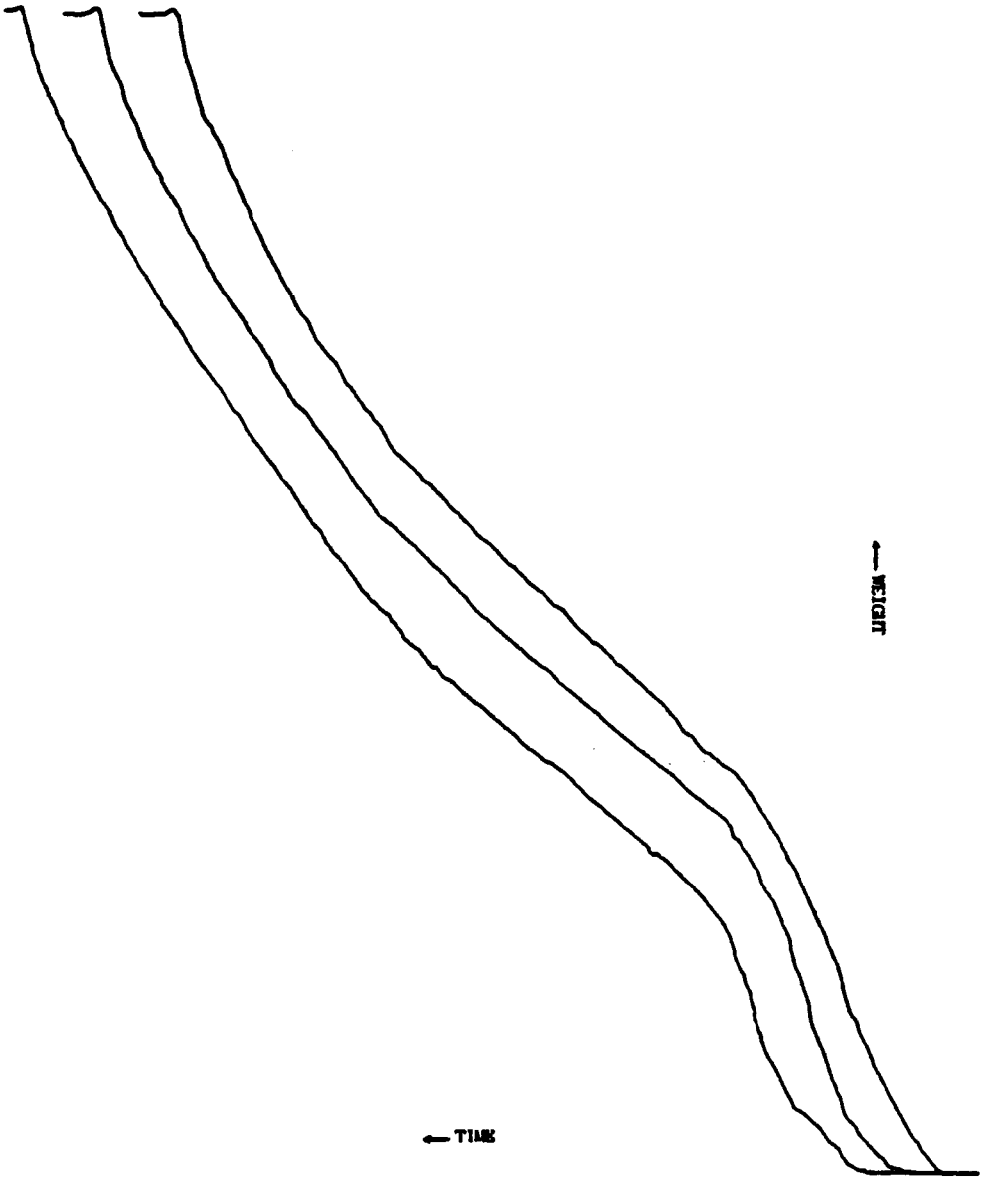
[9] Colton Model 216

[10] Erweka



Figs. 1a, 1b, 1c- Three Replicate Flowgraph Tracings

Run	g/sec	Linearity
A	196	19.5
B	196	18.3
C	196	18.6
Avg.	196	18.8



Figs. 2a, 2b, 2c- Three Replicate Flowgraph Tracings

Run	g/sec	Linearity
A	18.5	13.6
B	19.3	12.4
C	20.0	8.8
Avg.	19.3	11.6

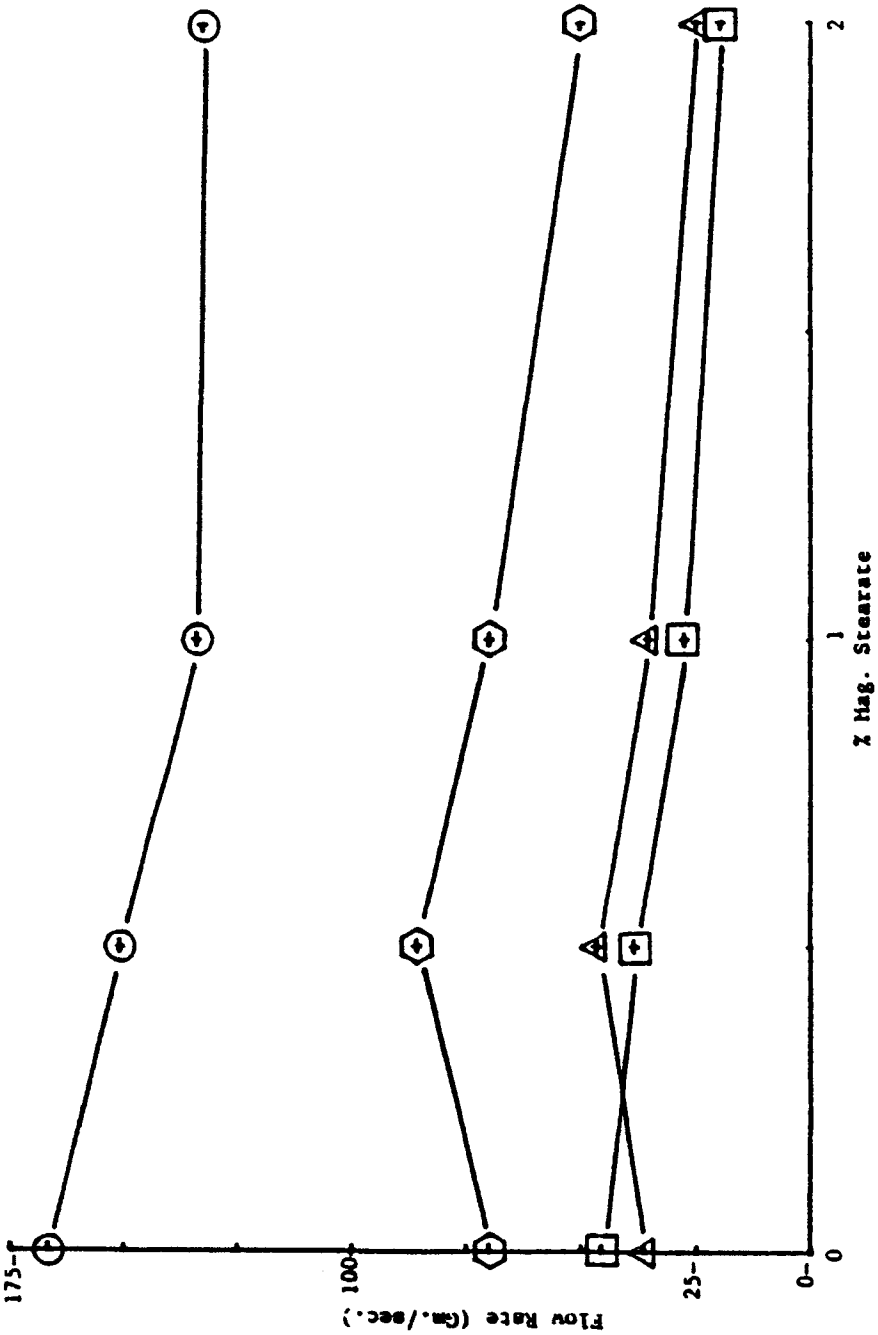


Fig.3a-Change in Flow Rate (Gm./sec.)
○-Emcocel Coarse ⬡-Emcocel Fine △-Avicel PH102 □-Avicel PH102

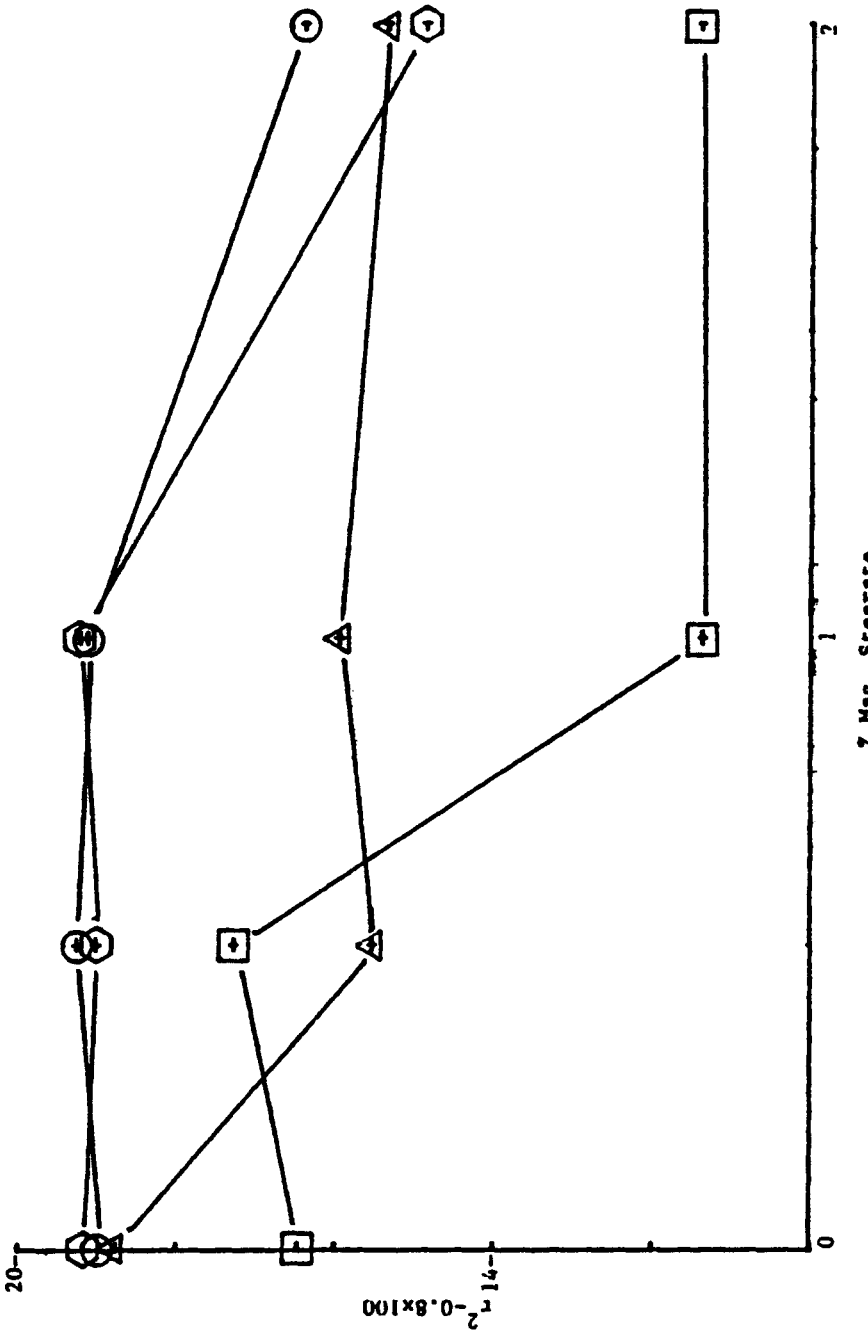


Fig.3b-Change in Linearity (r^2-0.8x100)
(O-Emcocel Coarse ⬡-Emcocel Fine △-Avicel PH101 □-Avicel PH102)

Thus Fl has a range of zero to twenty (with negative values being possible for extremely non-linear flow); twenty represents perfectly linear flow whereas zero indicates a substantial modification in flow rate. At present we cannot definitively identify all the causes of non-linear flow; rat holing, bridging and flow bed weight dependent flow are some factors which may be involved. Obviously the ideal powder system will have both a high mass flow rate and a flow linearity value approaching twenty.

Table I records the mass flow and flow linearity data for two AVICEL and two EMCOCEL tablet matrices. The course particle grades of AVICEL and EMCOCEL show much better mass flow and flow linearity than the finer grades. Also both the EMCOCEL products flow better than the AVICEL's.

Figs. 3a and b show the effect of the addition of magnesium stearate to the flow of the four matrices. For all systems, addition of 2% magnesium stearate significantly reduces both mass flow and flow linearity. The EMCOCEL products, however, appear to be relatively more resistant to the adverse flow affects of the magnesium stearate than the AVICEL's.

Table II characterizes the flow of the four matrices containing 0.5% magnesium stearate and 4% EXPLOTAB (sodium starch glycolate). The mass flow and flow linearity of the two AVICEL products are significantly reduced; the EMCOCEL products were less affected. Table III shows the flow data for systems containing 30% acetylsalicylic acid. Again the EMCOCEL products show the better flow properties.

The aspirin formulations were tabletted and evaluated by a variety of standard tests. Table IV shows the average tablet weight and relative standard deviation of weight calculated from twenty tablets for each formulation. The two EMCOCEL products gave the tablets significantly higher tablet weights than the AVICEL tablets. For all formulations, the weight variations, as indicated by the relative standard deviation of weight, are comparable. Table V shows the hardness data; the EMCOCEL products gave significantly

TABLE I

MATRICES ALONE

	MASS FLOW (GM/SEC)	LINEARITY (r^2 - 0.8) x 100
AVICEL PH-101	46	16.5
EMCOCEL "FINE"*	70	19.2
AVICEL PH-102	36	18.9
EMCOCEL "COARSE"*	167	19.0

*Experimental Grade

TABLE II

MATRICES WITH 0.5% MAGNESIUM STEARATE AND 4% EXPLOTAB

	MASS FLOW (GM/SEC)	LINEARITY (r^2 - 0.8) x 100
AVICEL PH-101	29	13.4
EMCOCEL "FINE"*	60	18.3
AVICEL PH-102	32	14.4
EMCOCEL "COARSE"*	125	19.0

TABLE III

MATRICES WITH 0.5% MAGNESIUM 8% EXPLOTAB AND 30% ASA

	MASS FLOW (GM/SEC)	LINEARITY (r^2 - 0.8) x 100
AVICEL PH-101	25	17.7
EMCOCEL "FINE"*	45	18.6
AVICEL PH-202	28	17.8
EMCOCEL "COARSE"*	63	19.0

*Experimental Grade

TABLE IV

TABLET[1] WEIGHT

	MEAN WEIGHT (MG.)[2]	R. S. D.[2]
AVICEL PH-101	325	1.7
EMCOCEL (FINE)*	422	1.8
AVICEL PH-102	336	1.4
EMCOCEL (COARSE)*	513	1.1

*Experimental Grade

[1] 30% ASA, 4% EXPLOTAB, 0.5% MG. STEARATE (w/w)

[2] n = 20

TABLE V

TABLET[1] HARDNESS

	MEAN HARDNESS (KG)[2,3]	R. S. D.[2]
AVICEL PH-101	2.7	19.2
EMCOCEL (FINE)*	3.6	13.1
AVICEL PH-102	3.2	12.3
EMCOCEL (COARSE)*	5.1	10.8

*Experimental Grade

[1] 30% ASA, 4% EXPLOTAB, 0.5% MG. STEARATE (w/w)

[2] n = 20

[3] Erweka

harder tablets than the AVICEL products. It is noteworthy that all four formulations were compressed on the same press under identical conditions.

CONCLUSIONS

The data presented in this paper indicates that the two experimental EMCOCEL products have better flow properties than the comparable AVICEL's. Also when compacted under identical press settings, the EMCOCEL's give harder tablets. In this preliminary study, no attempt was made to really stress the tablet matrices

by operating at high press speeds or by incorporating high percentages of active ingredient. It is felt that such tests are necessary before the full utility of recording powder flow data can be evaluated. It will also be useful to explore the effect of hopper design and hopper fill levels on powder flow.

REFERENCE

(1) R.P. Jordan and C.T. Rhodes, Drug Devel. and Ind. Pharm., 5, 151 (1979).