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## Compaction studies on pellets: II. Coated pellets

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### Summary

Compaction characteristics of Surelease coated pellets were studied using several techniques including porosity change, Heckel equation, total work of compaction and elastic recovery indices. The reduction in yield strength and an increase in tensile strength of the compacts caused by the addition of a Surelease coating to the pellets is ascribed to the interlocking forces between the substrate and the coating and to the development of additional bonds formed by plastic deformation of the coating during compaction. However, increasing amounts of the coating on the pellets reduced their yield strengths and resulted in compacts with lower tensile strength and higher elastic recovery values. The effect of the rate of load application on the compaction characteristics of Surelease coated pellets was also studied. As the punch velocity increased there was a reduction in the tensile strength values of the compacts and an increase in both yield pressure and elastic recovery values. The change in the magnitude of these values with the rate of load application was greater for the compacts made from pellets coated with increasing amounts of Surelease. A nonlinear optimization technique was also employed to further investigate the effect of rate of load application on the coated pellets. Pellets coated with increasing amounts of coating exhibited relatively more punch velocity dependence. Dissolution studies revealed that coated pellets lost their sustained release characteristics on compaction due to formation of cracks within the coating and to the fragmentary/elastic nature of the pellets.

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### Introduction

The effect that the coating of fine powders has on the tensile strength of the compacts was reported previously by several researchers (York and Pilpel, 1973; Malamataris and Pilpel, 1983). It was shown that yield pressures of loosely packed

pharmaceutical powder beds are affected by the presence of coatings and that the strength of tablets prepared from them depends on the nature and amount of coating, on the plastic deformation of the particles during compression, and on their elastic recovery when the pressure is removed.

Pilpel and Hephner (1977), in a study on tensile strength of fatty acid coated lactose powder, concluded that the tensile strength of the powdered lactose decreased to a minimum value when the coating is monomolecular and then increased as

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the fatty acid forms pendular bonds between the particles. They analyzed the results in terms of the van der Waals and London forces that act between the particles of coated and uncoated lactose.

Ejiofor et al. (1986) evaluated the effects produced on the tensile strength, brittle fracture index, plasto-elasticity ratio and yield pressure of sodium salicylate and calcium carbonate as a result of coating their particles with increasing amounts of silicones and polysorbates. They found that coatings acted as lubricants and also caused a reduction in the tensile strength and yield pressure of the tablets.

Although a good deal of work has been done on the effects of coating on the compaction characteristics of pharmaceutical powders, much less has been reported on the effects produced on compaction behavior of pellets by adding coating to them (Lehmann, 1984).

In the present work, a study was attempted to determine the effects produced on the compaction characteristics of pellets as a result of coating them with increasing amounts of Surelease. The effect of rate of load application on their compaction properties was investigated. Dissolution characteristics of the coated pellets and their compacts were also studied.

## Materials and Methods

The materials employed for the preparation of pellets were the same as in the previous investigation (Maganti and Çelik, 1993). Surelease (Col-orcon, Inc.), an aqueous coating material, was used to coat the pellets.

A 1 kg Glatt rotor granulator was employed to make the pellets from two powder formulations. One formulation consisted of 80% w/w microcrystalline cellulose, 10% w/w propranolol HCl and 10% w/w lactose, while the other contained 80% w/w microcrystalline cellulose, 10% w/w propranolol HCl and 10% w/w dicalcium phosphate dihydrate. Throughout the study, the former formulation was designated as F-I and the latter as F-II. Both F-I and F-II pellets with particle size distribution presented in the earlier

study (Maganti and Çelik, 1992) were then coated with Surelease at three different coating levels (10% w/w, 15% w/w, and 20% w/w) in the same equipment and were dried until their moisture content reached a constant value of  $4.25\% \pm 0.15\%$ .

Compaction of the pellets was carried out using the Integrated Compaction Research System (Çelik and Lordi, 1991) using double ended profiles with constant punch velocities of 1, 100, 200 and 300 mm/s per punch. The details of the experimental procedures and compaction data analysis techniques have been described elsewhere (Maganti and Çelik, 1993). All pre-compaction, compaction and post-compaction tests were performed on at least five replicates.

## Results and Discussion

The pellets were subjected to varying applied pressures at constant punch velocity of 100 mm/s in order to produce compacts at pre-determined in-die porosities of  $3 \pm 0.3\%$ . The percentage porosity changes as a function of compaction pressure for the compacts made from uncoated and Surelease coated F-I pellets are shown in Fig. 1. The uncoated pellets required higher applied pressures to produce compacts of the same in-die porosities as the coated pellets. The data presented in Table 1 indicate that the coated pellets produced compacts of higher tensile strength than the uncoated pellets. The study on the compaction of pellets (Maganti and Çelik, 1993) revealed that the uncoated pellets exhibited elastic deformation and brittle fragmentation to a certain extent. An increase in the tensile strength of the compacts caused by the addition of Surelease coating to the pellets may be attributed to the development of stronger bonds between the substrate and the coating material.

The maximum applied pressure required to compact the coated pellets to the pre-determined in-die porosity decreased as the amount of coating on the pellets increased, indicating that the pellets coated with higher amounts of coating were more easily compressible. However, tensile strength values of their ejected compacts de-

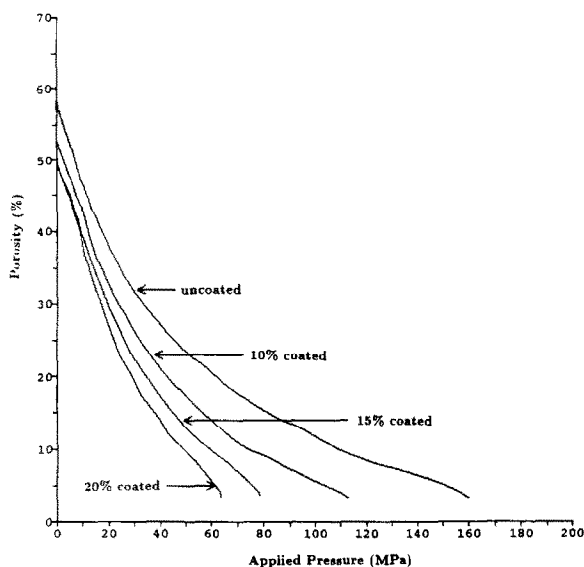


Fig. 1. Porosity vs pressure plots for the compacts made from uncoated and coated F-I pellets.

creased with an increase in coating level (Table 1), suggesting that the increased compressibility of these materials under load does not necessarily result in stronger compacts.

The changes in the volume of the materials with applied pressure were also analyzed using the Heckel equation. The slopes of the linear portion ( $1/\text{yield pressure}$ ) of the Heckel curves in Fig. 2 increased with the coating level. Since the density values 'at pressure' contain both elastic and plastic components, the yield pressure determined from the slope of the linear portion of the Heckel profiles therefore reflects the total ability of the material to deform (Duberg and Nystrom, 1986). The predominant mechanism of compaction cannot be distinguished from these plots. On comparing the Heckel plots at corresponding coating levels, the compacts produced from coated F-I and F-II pellets did not show significant differences in the slopes of their profiles.

As discussed previously (Maganti and Çelik, 1993), the energy involved in compaction of the coated pellets was calculated by the equation proposed by Çelik and Marshall (1989). The total work of compaction (TWC) vs pressure plots for

TABLE 1

*Post-compaction data of the compacts made from Surelease coated pellets*

Compacts	Tensile strength (MPa)	ER (%)	Disintegration time (s)	Friability (%)
<b>F-I</b>				
Uncoated	0.56	7.64	5	100
10% w/w coated	1.71	6.62	64	0.12
15% w/w coated	1.46	8.74	52	0.98
20% w/w coated	0.85	10.04	41	1.78
<b>F-II</b>				
Uncoated	0.54	8.23	5	100
10% w/w coated	1.66	6.95	58	0.32
15% w/w coated	1.41	9.19	49	1.04
20% w/w coated	0.81	10.33	32	1.84

the compacts of coated pellets presented in Fig. 3a and b indicate that on compaction, pellets with increasing amounts of coating exhibited relatively lower TWC values at corresponding pressures. Similar correlation was observed in the tensile strength values of their ejected compacts (Table 1).

The rank order for the tensile strength of the compacts of coated and uncoated pellets is as follows: 10% coated pellets > 15% coated pellets

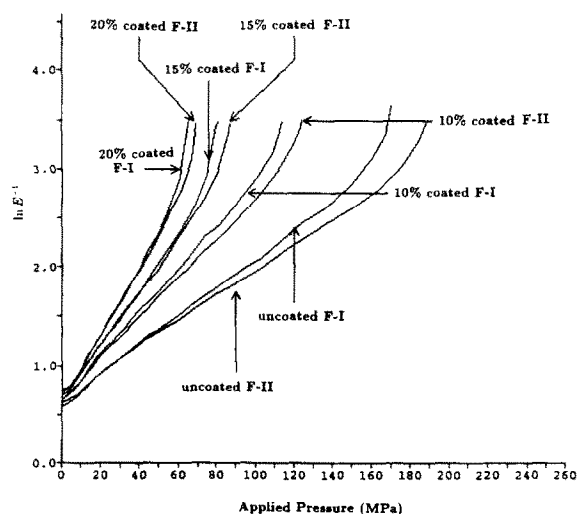


Fig. 2. Comparison of the Heckel plots for the compacts made from Surelease coated F-I and F-II pellets.

> 20% coated pellets > uncoated pellets. A possible explanation for the lower tensile strength of the compacts with increasing amounts of coating on the pellets may be attributed to the binding properties of Surelease. The binder efficiency is influenced by its cohesive and adhesive properties. Like starch and other sugar-like binders, Surelease may be acting as an adhesive. The increase in the tensile strength of the compacts with the addition of 10% of Surelease as a coating to the pellets may be presumed to cause the development of some binder-binder and some binder-substrate bonds, in addition to the substrate-substrate bonds between the fragmented neighboring pellets. However, a further increase in the addition of coating to the pellets caused an increase in overall binder concentration and in the relative ratio of binder-binder bonds to substrate-binder bonds, thereby producing compacts with lower tensile strength values due to lack of its cohesive properties. Further studies covering additional coating levels (between 0 and 10% w/w, and 10 and 15% w/w) on the pellets are needed to determine the critical binder concentration of Surelease under the experimental conditions described in this work.

Although the pellets coated with different amounts of Surelease were compressed to the same in-die porosity (i.e., the same thickness) the ejected compacts exhibited some differences in their diameter and thickness values. This was due to the significant changes in the magnitude of elastic recovery of compacts during decompression and after ejection. The elastic recovery (ER) values presented in Table 1 were calculated according to the equation proposed by Maganti and Çelik (1993).

The compacts of uncoated pellets exhibited higher ER and lower tensile strength values and this was attributed to their elasto-brittle properties (Maganti and Çelik, 1993). The values of tensile strength of the compacts made from 10% coated pellets increased substantially while their ER values decreased as compared to those of uncoated pellets. This can be attributed to an increase in the number of bonds that survived the unloading phase of the compaction process due to the introduction of stronger binder-substrate bonds by Surelease. However, further increase in the amount of coating (15% and 20%) on the pellets diminished the mechanical strength of the resulting compacts. As explained above, this may

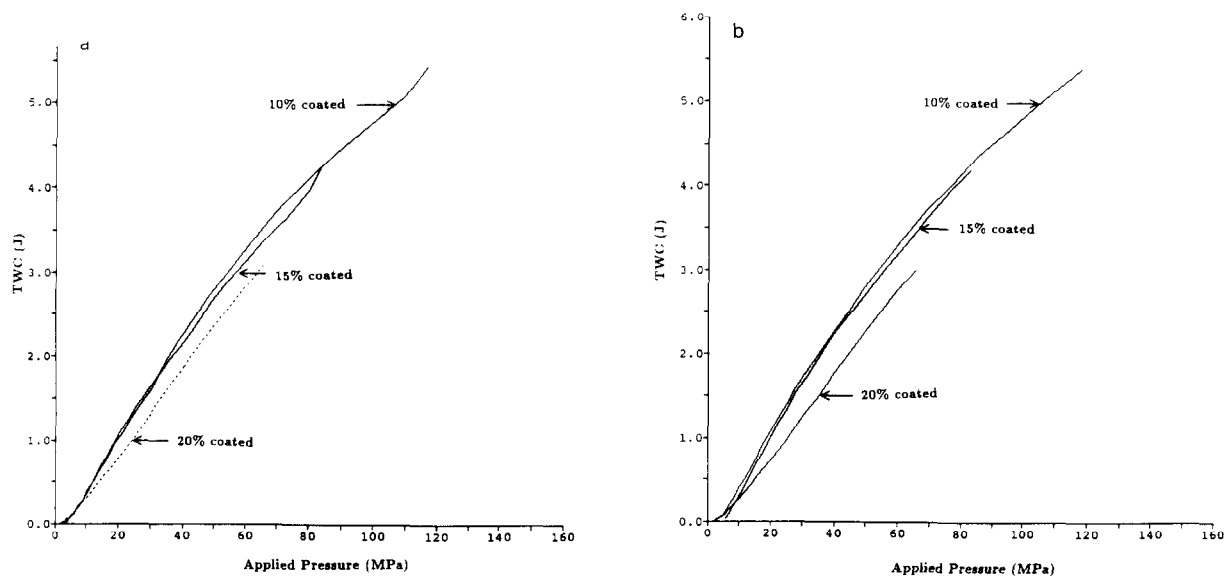


Fig. 3. Total work of compaction (TWC) vs pressure plots for the compacts of Surelease coated (a) F-I pellets and (b) F-II pellets.

be due to lack of cohesive properties of Surelease. The elastic recovery values of the compacts made from 15% and 20% coated pellets were higher than that of those of uncoated pellets, although their tensile strengths were higher. The 'apparent' contrast in the rank order of elastic recovery values and tensile strength values could be attributed to the difference in the elastic properties of the uncoated pellets and the film coating. The latter, while still contributing to the strength of the compacts due to its plastic properties, caused an additional expansion of the compacts by virtue of its elastic characteristics.

On comparing the tensile strength of the compacts of the coated F-I and F-II pellets at corresponding coating levels, it appears that higher elastic recovery of the compacts of F-II pellets may have resulted in slightly lower tensile strength of their compacts.

The post-compaction data for the compacts made from the coated pellets are also presented in the Table 1. Increasing amounts of coating on the pellets caused a reduction in the disintegration times and increased the friability of their compacts. This can be attributed to the lower tensile strength of their compacts.

#### *Effect of punch velocity on coated pellets*

Armstrong and Palfrey (1989) reported that if the rate at which the load is applied exceeds the rate at which a material can react to the force, then resistance to further densification will increase. Hence, at any given applied pressure, the in-die porosity of the compact is higher at greater punch velocities or alternatively, to achieve a given porosity within a die, a higher pressure is needed. When a material is subjected to constant applied load at different punch velocities, it is likely that differences in the tensile strength of the compacts produced at these punch velocities are caused by different in-die porosities achieved during the compaction process. Therefore, in this case, to determine the effect of punch velocity on the tensile strength, it is necessary that the tensile strength values are corrected for in-die porosity differences obtained at different punch velocities.

A different approach was used in the present work, in that F-II pellets coated with different amounts of Surelease, were subjected to a varying applied pressure to produce compacts with constant in-die porosity at different punch velocities. This technique facilitates the comparison of the tensile strength values of compacts made at dif-

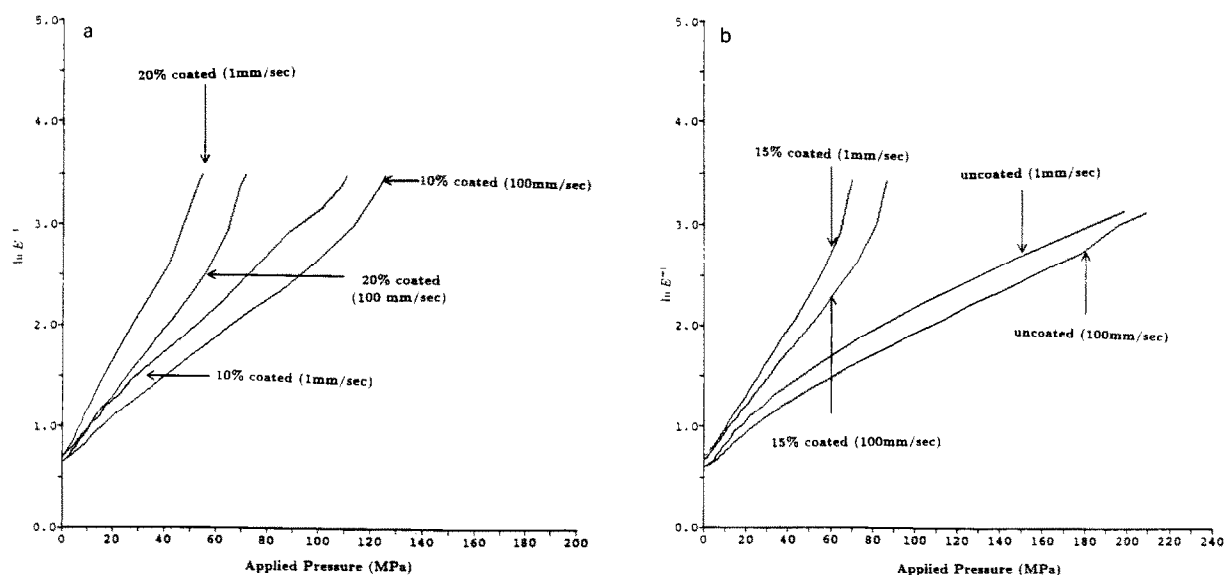


Fig. 4. Heckel plots for (a) the compacts made from 10 and 20% coated F-II pellets at two different punch velocities and (b) compacts made from uncoated and 15% coated F-II pellets at two different punch velocities.

ferent punch velocities without any need for normalization for the difference in the porosities. However, the ejected compacts can exhibit differences in their final porosities since the amount of plastic-elastic deformation during compression, and elastic expansion during decompression and after ejection, may vary at different punch velocities.

On compaction of coated pellets, the difference between the pressures applied to cause a reduction in porosity, to a pre-determined value ( $3 \pm 0.3\%$ ) within the die, increased with the rate of load application. The uncoated pellets, which exhibit elastic deformation and fragmentation to a certain extent on compaction (Maganti and Çelik, 1993) also required slightly higher applied pressures to produce compacts of the same porosities at higher punch velocity. This finding confirms the view expressed by Armstrong and Palfrey (1989) that the materials examined, regardless of their deformation characteristics, did not react sufficiently quickly to the applied load at higher punch velocities.

The Heckel plots for the uncoated and coated pellets at 1 and 100 mm/s punch velocities are presented in Fig. 4a and b. At any given coating level the yield pressure values of the coated pellets increased with the rate of load application and this is possibly due to a reduction in plastic flow. At higher punch velocities, the compaction event is significantly shorter, and plastic deformation of the coating, which is known to be time dependant, appears to be unable to produce ade-

quate inter-particle bonding during compaction. In addition, decompression and ejection phases may have caused high elastic expansion of the compact by breaking the weak bonds formed during compression. A combination of low overall plasticity due to high punch velocities and relatively high elasticity after compression force has been removed, resulted in compacts with lower tensile strength.

Table 2 presents the data on the yield pressure, tensile strength and ER values for the compacts made from coated pellets at two different punch velocities. The *A* values in Table 2 represent the percentage change in the slopes of Heckel curves relative to the slope of the Heckel curve of the compacts made at 1 mm/s punch velocity. The *B* values in Table 2 represent the percentage change in the tensile strength relative to the tensile strength values of the compacts made at 1 mm/s punch velocity. Both *A* and *B* values appear to increase with an increase in the coating level and clearly indicate that higher amounts of the coating on the pellets exhibited more time-dependent deformation characteristics.

The elastic energy, which is not utilized for bonding, is usually stored as deformation energy under stress. The inevitable release of this stored energy during the decompression and ejection phases of the compaction cycle can cause the rupture of weak particle-particle bonds. The ER values of the compacts presented in the Table 2 increased with the punch velocity. The *C* values presented in Table 2 represent the percentage

TABLE 2

*The effect of punch velocity on compaction properties of uncoated, coated F-II pellets and F-II powder*

Compact	<i>K</i> value		Tensile strength (MPa)		ER (%)		<i>A</i> (%)	<i>B</i> (%)	<i>C</i> (%)
	1 (mm/s)	100 (mm/s)	1 (mm/s)	100 (mm/s)	1 (mm/s)	100 (mm/s)			
Powder	0.01182	0.00684	9.910	8.280	3.96	4.32	42.13	16.45	9.09
Pellets									
Uncoated	0.01124	0.01098	0.542	0.540	8.10	8.23	2.31	0.37	1.60
Coated									
10%	0.02299	0.01961	2.090	1.660	5.91	6.95	14.70	20.57	17.60
15%	0.03333	0.02597	1.810	1.410	7.74	9.19	22.08	22.10	18.73
20%	0.04949	0.03333	1.100	0.810	8.33	10.33	32.65	26.36	24.01

See text for the definitions of terms ER, *A*, *B*, and *C*.

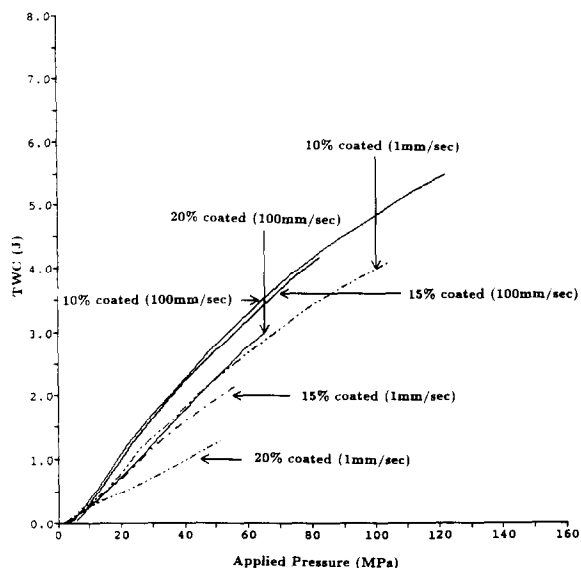


Fig. 5. Comparison of TWC vs pressure plots for the compacts made from coated F-II pellets at different punch velocities.

change in the ER values relative to the ER values of the compacts made at 1 mm/s punch velocity. Within the range of coating levels studied, the  $C$  values gradually increased with the amount of coating applied on the pellets, and this indicates that the pellets coated with higher amounts of Surelease produced compacts which exhibited more elastic expansion as the punch velocity increased.

On examining  $A$ ,  $B$ , and  $C$  values (Table 2), it can be concluded that increasing the amount of coating on the pellets resulted in an increase in both plasticity and elasticity of the coated pellets. It is rather difficult to determine the absolute values for the individual contributions of plastic and elastic deformation to total deformation of the material. However, evaluating the relative changes in the values of yield pressure, tensile strength, and elastic recovery values at different punch velocities and their inter-relationships under constant experimental conditions, as described in the present work, may be helpful in comparing the changes in plasto-elasticity caused by coating pellets with Surelease.

The work of compaction may be defined as the total energy input required for making a compact.

Fig. 5 presents the total work of compaction (TWC) vs pressure plots for the compacts made from the coated pellets at 1 and 100 mm/s punch velocities. At any given coating level the total work of compaction at corresponding pressure was found to increase as the punch velocity increased. This can be attributed to relatively high energy input required for elastic deformation and fragmentation of the pellets.

The tensile strength of the compacts (Table 2) made at 1 mm/s punch velocity were found to be higher than those made at 100 mm/s, but their TWC values at corresponding pressures were lower than those obtained at higher punch velocity. It has been reported in the earlier studies (Çelik and Marshall, 1989) that there is a direct correlation between TWC and tensile strength values of the compacts. However, the results in this study suggest that this method may not be valid if such comparisons are made for the compacts produced at different punch velocities.

#### Nonlinear optimization

A factorial nonlinear design was also employed for assessing the time dependant deformation characteristics of increasing amounts of Surelease coating added to the pellets. A complete factorial experimental design (Box et al., 1978) was used to determine the effect of coating level and punch velocity on the crushing force of their ejected compacts. In this experimental set-up the following factors were varied:

- (1) Coating level ( $C$ );
- (2) Punch velocity ( $V$ );
- (3) Pre-determined in-die porosity at maximum applied pressure ( $E$ ).

Each factor was studied at three levels, resulting in 27 different experiments (Table 3). In

TABLE 3  
3 × 3 factorial design

$E$ (%)	$C$								
	10			15			20		
1	100	200	300	100	200	300	100	200	300
7	100	200	300	100	200	300	100	200	300
13	100	200	300	100	200	300	100	200	300

addition, five replicates were run for the experiments representing the central levels of the factors and all the experiments were run in a random order. Since the theoretical relationship between the response variable, crushing force of the ejected compacts, and the factors was not clear, a multiple regression analysis was applied. The thickness and diameter values of the ejected compacts, which are used to calculate the tensile strength, made at different punch velocities (100, 200, and 300 mm/s) were not significantly different. Therefore, in this optimization technique the crushing force values were utilized instead of tensile strength values. Moreover crushing force values determined in kP units are widely used as a measure of hardness of the tablets in pharmaceutical manufacturing.

The response variable was predicted accurately by the following second-order polynomial equation, because the regression equation was significant with high  $F$  values.

$$Y = a_0 + a_1C + a_2V + a_3E + a_4C^2 + a_5V^2 + a_6E^2 + a_7VE + a_8CE + a_9CV \quad (1)$$

where  $Y$  is the crushing force of the ejected compacts, and  $a$  denotes the regression coefficient.  $C$ ,  $E$ , and  $V$  represent the levels for coating (% w/w), in-die porosity (%), and punch velocity (mm/s), respectively.

The correlation coefficient was used as an index for the selection of optimum combination of the factors. Table 4 presents the regression coefficients and correlation coefficients for the crushing force of the ejected compacts. The coefficients of  $V$ ,  $CV$ ,  $VE$  and  $V^2$ , all of which include the punch velocity term, were found to be insignificant with a low level of confidence coefficient and Eqn 1, if solved for the variable punch velocity, may lead to erroneous results. Hence, the quadratic equation was solved by varying the other two factors at any given punch velocity.

Eqn 1 was solved in steps 1 and 2 for the range of in-die porosities to which the pellets coated with different amounts of Surelease ( $C_i$ ,  $i = 10-20$ ) have to be compacted to produce compacts with crushing force values ranging between  $h_1 \leq h$

TABLE 4

Regression coefficients for hardness

Parameter	$a_i$	Coefficient	Confidence coefficient (%)
Constant	$a_0$	6.859	99.9
$C$	$a_1$	0.4583	99.9
$V$	$a_2$	-0.0053	79.7
$E$	$a_3$	-0.5225	99.9
$C^2$	$a_4$	-0.02869	99.9
$V^2$	$a_5$	-0.000005	41.8
$E^2$	$a_6$	0.006971	99.6
$CE$	$a_7$	0.01131	99.9
$VE$	$a_8$	0.000007	18.2
$CV$	$a_9$	0.000207	87.8

$R^2 = 99.3\%$ ; S.D. = 0.212;  $F = 190.5$

$\leq h_m$ .  $h_1$  and  $h_m$  are the lower and upper limits for the range of crushing force values, respectively.

Step 1: Solving Eqn 1 for the lower limit of crushing force ( $h_1$ ):

$$h_1 \leq b_1E^2 + b_2E + b_3 \quad (2)$$

Constants  $b_1$  and  $b_2$  in Eqn 2 depend on the coating level,  $C_i$ , where  $i$  can take any value between 10 and 20% w/w which are the lower and upper limits of coating level, respectively.

The above equation (Eqn 2) can be written as follows:

$$(E - \alpha_1)(E - \beta_1) \geq 0 \quad (3)$$

where  $\alpha_1$  and  $\beta_1$  are the roots of the equation with equality sign.

The condition which satisfies these requirements is represented in Fig. 6a. In order to satisfy Eqn 2, the value of  $E$  should fall in the shaded region represented in Fig. 6a and not in the area lying between the boundaries of  $\alpha_1$  and  $\beta_1$ .

Step 2: Solving Eqn 1 for the upper limit of crushing force ( $h_m$ ):

$$h_m \geq b_1E^2 + b_2E + b_3 \quad (4)$$

Eqn 4 can be written as:

$$(E - \alpha_m)(E - \beta_m) \geq 0 \quad (5)$$



which implies that  $\alpha_m \leq E \leq \beta_m$ , where  $\alpha_m$  and  $\beta_m$  are roots of Eqn 4 with equality sign.

The condition which satisfies Eqn 4 is represented in Fig. 6b. In order to satisfy Eqn 4, the value of  $E$  should fall in the shaded region of Fig. 6b and not in the area lying beyond the limits  $\alpha_m$  and  $\beta_m$ .

The condition represented in Fig. 6c is obtained by combining the above two conditions presented in Fig. 6a and b. To satisfy both conditions, the value of  $E$  should fall in the shaded regions of Fig. 6c.

The above-described procedure was employed to determine the range of in-die porosities ( $E$ ) at various coating levels ( $C_i$ ,  $i$  in increment steps of 0.5) and at a given punch velocity for the following set of constraints. The constraints used in this study seem to be quite proper and significant, though the restricting values can be altered within the experimental region.

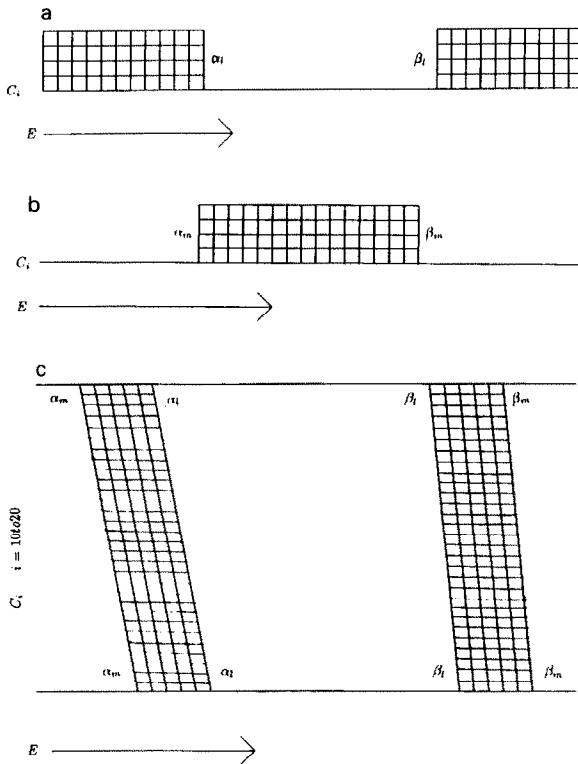


Fig. 6. Conditions satisfying (a) step 1, (b) step 2 and (c) steps 1 and 2.

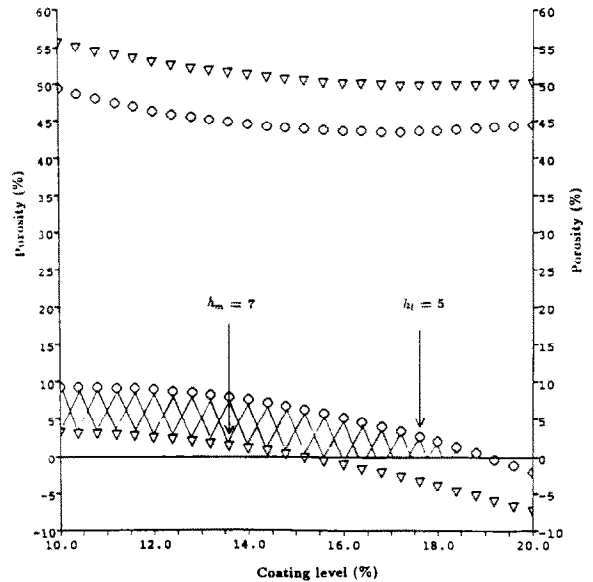


Fig. 7. Porosity range for the hardness ( $h$ ) values with limits of 5 kP ( $h_l$ ) and 7 kP ( $h_m$ ) made at a constant punch velocity of 100 mm/s.

Constraint for coating level ( $C$ ):

$$10 \leq C \leq 20$$

Constraint for response variable, crushing force ( $h$ ), kP:

$$5 \leq h \leq 7$$

A simple program was written in Fortran77 to solve the problem described at two different punch velocities (100 and 300 mm/s). The shaded region in Figs 7 and 8 is of practical importance as it is the state which is physically possible within the experimental limits defined. These figures indicate that as the coating level increased from 10 to 20% w/w, the coated pellets needed to be compacted to lower in-die porosities to produce ejected compacts which satisfy the specifications for the crushing force ( $5 \leq h \leq 7$ ).

On comparing Figs 7 and 8, it is obvious that coated pellets have to be compacted to lower in-die porosities at 300 mm/s punch velocity than at 100 mm/s punch velocity to produce ejected compacts with crushing force values within the specified limits.

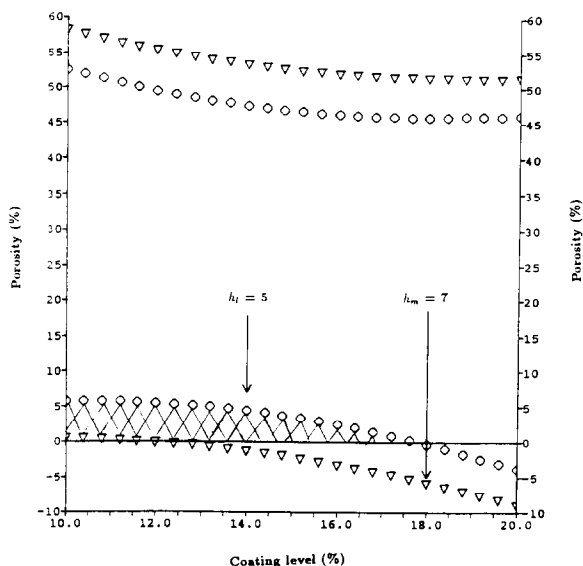


Fig. 8. Porosity range for the hardness ( $h$ ) values with limits of 5 kP ( $h_l$ ) and 7 kP ( $h_m$ ) made at a constant punch velocity of 300 mm/s.

As the punch velocity is increased, the coated pellets consolidated to a reduced extent with a corresponding reduction in the crushing force values of their compacts. Within the range of coating levels examined, pellets with increasing

amounts of coating showed more punch velocity dependence.

#### Dissolution studies

The dissolution profiles of coated and uncoated F-I and F-II pellets in distilled water are presented in Fig. 9a and b. On comparing the cumulative percentage release of propranolol HCl at corresponding coating levels, F-I pellets released higher amounts of drug than F-II pellets at any given time interval (Fig. 10). The osmotic pressure exerted by lactose and its solubility in water facilitated the faster release of the drug from coated F-I pellets.

Regardless of the amount of coating on the pellets, compacts of the coated F-I and F-II pellets released approx. 95% of the drug within 30 min (Fig. 11a and b). The dissolution profiles indicate that compaction forces may have caused cracks (Fig. 12) in the coating and fragmentation of the pellets to a certain extent which resulted in faster release rates of the drug from their compacts.

The compacts made from 20% coated F-I pellets at different in-die porosities (1 and 13%) produced similar dissolution profiles (Fig. 13). The pressure applied to compact 20% coated

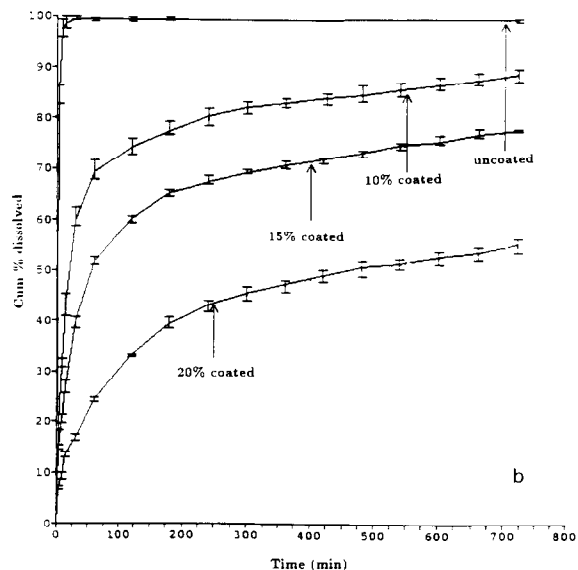
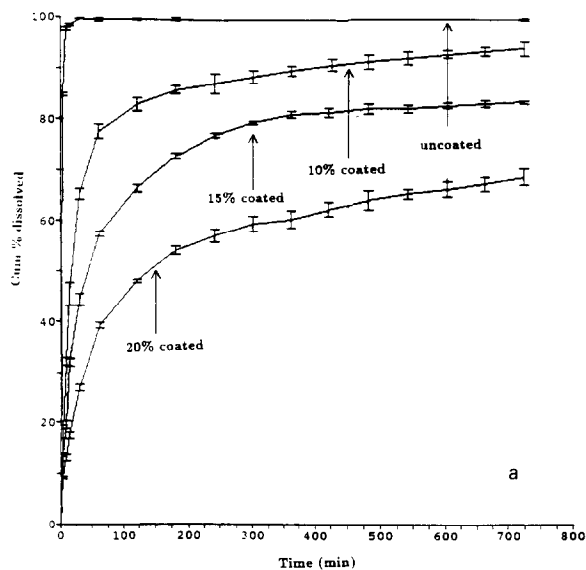


Fig. 9. Dissolution profiles of the uncoated and coated (a) F-I pellets and (b) F-II pellets.

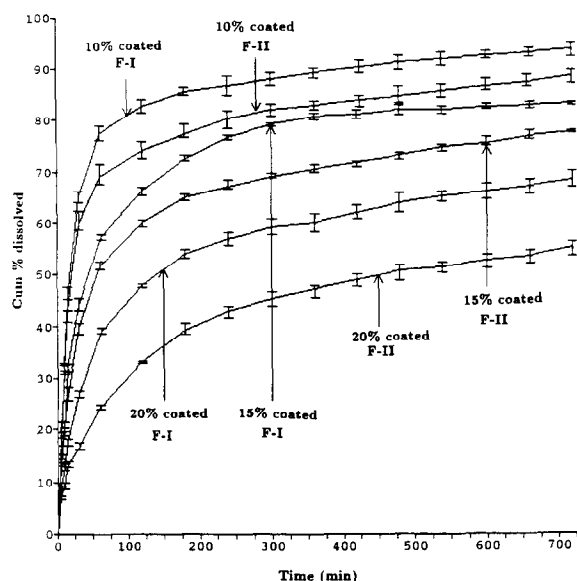


Fig. 10. Comparison of the dissolution profiles of the coated F-I and F-II pellets.

pellets to an in-die porosity of 1% was higher than that required to compact them to an in-die porosity of 13%. Intact compacts were not formed when the pellets were compressed to an in-die

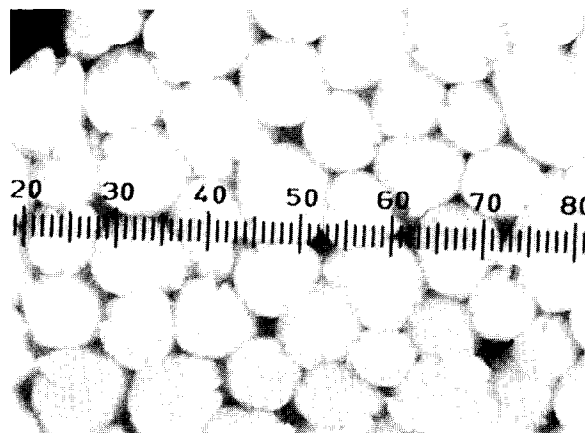


Fig. 12. Microscopic photograph showing cracks in the coating and fragmentary nature of 20% coated F-I pellets.

porosity values of greater than 15%. It would be expected from the dissolution studies that the compacts made at 13% in-die porosity would exhibit some extended release characteristics. However, Fig. 13 reveals that the compacts made at 1 and 13% in-die porosity exhibited similar dissolution characteristics.

The dissolution studies revealed that, regardless of the amount of coating applied, the coated

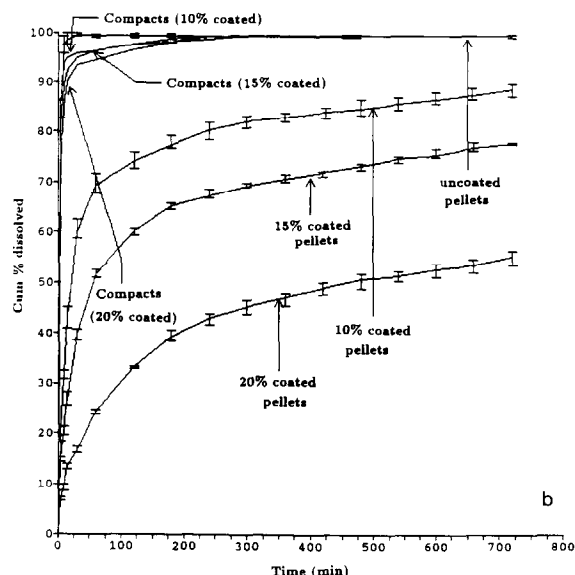
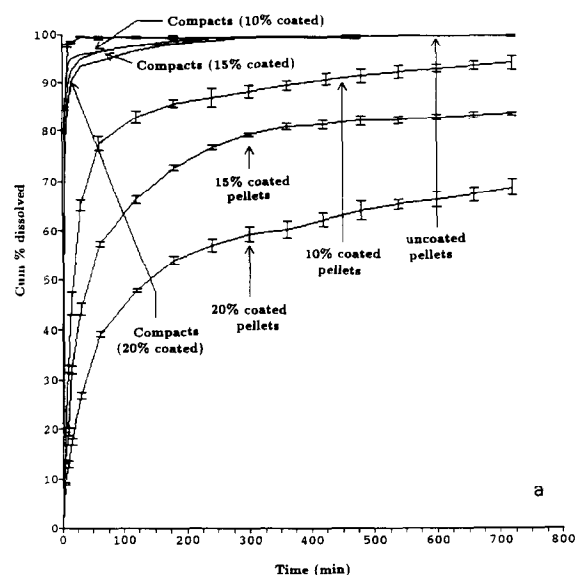


Fig. 11. Comparison of the dissolution profiles of (a) the coated F-I pellets and their compacts and (b) the coated F-II pellets and their compacts.

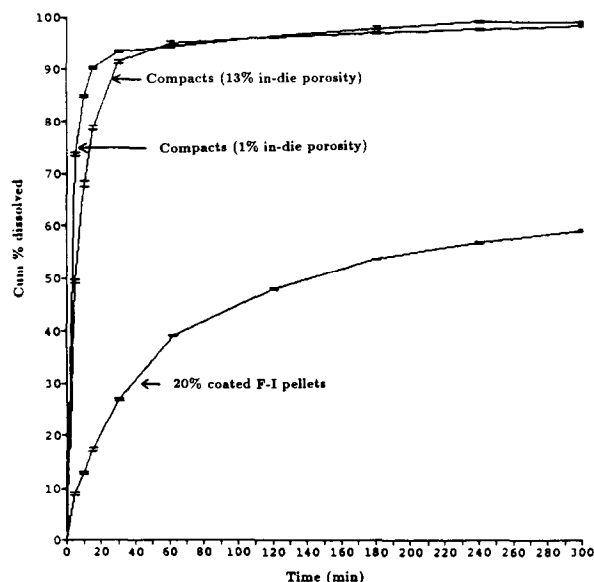


Fig. 13. Comparison of the dissolution profiles of the 20% coated F-I pellets and their compacts made at two different in-die porosities of 13 and 1%.

pellets lost their sustained release characteristics on application of low compaction pressures. This can be attributed mainly to the formation of cracks within the coating and to the fragmentary/elastic nature of the pellets.

## Conclusion

It was found from this study that the addition of Surelease as a coating material altered the deformation characteristics of uncoated pellets by introducing plasto-elastic properties into their previously brittle and elastic nature. An increase in the amount of coating applied caused a reduction in the yield pressure of the pellets, and decreased the tensile strength of the resulting compacts while increasing their elastic recovery on ejection. The total ability of the pellets to deform, both plastically and elastically increased as the coating level increased.

As the rate of load application was increased, and the pellets were coated with increasing amounts of Surelease, they consolidated to a re-

duced extent, thereby producing compacts of lower tensile strength. The total work of compaction was found to increase with speed of compression due to a significant increase in energy input required for elastic deformation and fragmentation of pellets.

The optimization technique provides further evidence that compression velocity dependence is a function of the amount of coating added to the pellets. Pellets with increasing amounts of coating exhibited relatively more punch velocity dependence.

The effect of various parameters on the compaction characteristics of the materials could reasonably be studied by application of the simple optimization technique described in the study.

The dissolution studies revealed that, regardless of the amount of coating applied, the coated pellets lost their sustained release characteristics on application of low compaction pressures. This can be attributed mainly to the formation of cracks within the coating and to the fragmentary/elastic nature of the pellets.

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