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Consolidation of ethylcellulose: effect of particle size, press speed, and lubricants

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Abstract

The effect of particle size, press speed, and the presence of lubricants on the tableting properties of ethylcellulose were studied using an instrumented single punch tablet press. Four different data collection and analysis techniques were used: tablet hardness-compression force profiles, ejected tablet Heckel analysis, work calculations from force-displacement data, and force-time profile analysis. Mean yield pressure was derived from the Heckel analysis. Net work and elastic work were derived from force-displacement data and the Area-to-height ratio (A/H ratio) was derived from force-time data. These techniques indicated that plastic deformation is the predominant consolidation mechanism for ethylcellulose under the conditions employed in this study.

Keywords: Ethylcellulose; Particle size; Press speed; Lubricant; Mean yield pressure; Net work; Elastic work; Consolidation

1. Introduction

The consolidation mechanism of a tableting excipient may be classified as either ductile or brittle based on the response to applied stress during tableting. The terms ductile and brittle are descriptions of extreme behavior and excipients may consolidate by both mechanisms to varying degrees.

Several techniques have been used to gain information on the consolidation mechanism, including tableting studies on the effects of particle size and press speed (Fell and Newton, 1971; Rees and Rue, 1978; Ishino et al., 1990), and lubrication (Jarosz and Parrott, 1984). Different particle size fractions of a material will have different initial packing densities. The packing density of a powder is influenced by the particle size distribution, particle shape, and interparticulate forces as in frictional and electrostatic interactions. Generally, smaller particles allow a greater packing density after the particle rear-

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rangement phase of consolidation and a greater number of contact points for interparticulate bonding (Rhines, 1947). With a ductile material, the difference in the packing density will be retained throughout the compression process, and tablet strength and porosity will be dependent on the initial particle size distribution. In contrast, brittle fracture eliminates differences in the initial packing density, and tablet strength and porosity will be independent of the initial size distribution over a particle size range.

The use of press speed to establish the consolidation mechanism is based on the time dependence of ductile deformation and the time independence of brittle fracture (Armstrong and Palfrey, 1989). Slowing the press speed and increasing the dwell time favors more time-dependent deformation producing stronger tablets with ductile materials. For brittle materials, fracture occurs immediately upon application of sufficient stress. Therefore, changes in press speed will not produce significant changes in tablet strength when compressing brittle materials.

Lubricants in tablet formulations may decrease tablet strength. The mechanism of such decrease is thought to be due to the finer lubricant particles coating the larger excipient and drug particles and interrupting interparticulate bonding (Jarosz and Parrott, 1984). Fragmentation of brittle particles results in large areas of new unexposed surfaces reducing the detrimental effect of a lubricant on tablet strength. Ductile deformation does not produce the same extent of new particle surfaces and the tablet strength of ductile materials is typically more sensitive to lubricants. Thus, the sensitivity of tablet strength to the presence of a lubricant can be used to assess the consolidation mechanism.

Knowledge of the consolidation mechanism of a tablet diluent or binder is important to understand the suitability and limitations of the excipient for specific tableting functions. Although tableting theory is not fully developed, it is believed that ductile behavior of a powder system is an important characteristic for success in tableting (Hiestand, 1985). Ductile behavior establishes regions of permanent interparticulate contact and bonding that produce mechanical strength in the resultant tablet (Hiestand, 1985). Formulation efforts are made to confer ductile behavior to drug-excipient powder blends using polymer binders in the wet or dry state. The aim of this report is to quantitatively determine the consolidation mechanism of ethylcellulose under typical direct compression tableting conditions. The interest in direct compression studies on ethylcellulose resulted from the successful use of ethylcellulose as a direct compression controlled release vehicle (Upadrashta et al., 1993). Only limited data are available to support its use in direct compression applications (Nesic, 1987; Upadrashta et al., 1994).

Effects of particle size, press speed, and the presence of lubricants on the tableting properties of ethylcellulose were examined using an instrumented single punch tablet press. Four different data collection and analysis techniques were employed: tablet hardness-compression force profiles, ejected tablet Heckel analysis, work calculations from force-displacement data, and force-time profile analysis. Mean yield pressure was derived from Heckel analysis (Heckel 1961a,b). Net work and elastic work were derived from force-displacement data (DeBlaey and Polderman, 1971; Krycer et al., 1982) and the A/H ratio was derived from force-time data (Chilamkurti et al., 1982, 1983). Since no single method provides a comprehensive analysis of the powder compression process, several supporting data analysis approaches were adopted to overcome the limitations of any one specific approach.

Magnesium stearate is currently the most commonly used tableting lubricant (Shangraw and Demarest, 1993). Glyceryl behenate was studied, in addition to magnesium stearate, because it is relatively new and has been reported to be less prone to tablet strength and dissolution problems associated with traditional lubricants (Shah et al., 1986). The 10 cp grade of ethylcellulose was selected based on its superior direct compression tableting properties (Upadrashta et al., 1994).

2. Materials and methods

Ethylcellulose was a gift from Dow Chemical Co. (Midland, MI) and has an ethoxy content of

48.0–49.5%. The 10 cp viscosity grade of ethylcellulose was studied and five sieve fractions were used in the particle size study (420–840, 250–420, 177–255, 144–177, and 104–144 μm). Sieve fractions were separated on a Ro-Tap Model B sieve shaker (WS Tyler Inc., Mentor, OH) using US Standard sieves. Shaking was continued to achieve constant weight on the smallest sieve. The 250–420 μm fraction was used in the press speed and lubrication studies. Magnesium Stearate, NF (impalpable powder) was obtained from Mallinckrodt Corp. (Chicago, IL) and glyceryl behenate (Compritol 888) was a gift from Gattefosse Corp. (Hawthorne, NY). In the lubricant studies, the lubricants were separately blended with ethylcellulose for 5 min using a 1 l twin-shell blender (Patterson Kelly Co., East Stroudsburg, PA). The concentration of magnesium stearate was varied from 0 to 0.5% w/w and that of glyceryl behenate from 0 to 1.5% w/w. No lubricant was used in the press speed or particle size experiments. An instrumented single punch tablet press (Korsch EK-O, Korsch Tableting Inc., Somerville, NJ) was used for tableting. A 200 mg tablet weight and 5/16 inch standard concave tooling were used. The compression force was varied between 2 and 12 kN in 2 kN increments. A press speed of 20 tablets per min was used in the particle size and lubrication studies. To study the effect of press speed, the press speed was varied between 10 and 50 tablets per min in increments of 10 tablets per min. A Schleuniger hardness tester (Model 2E Vector Corp., Marion, IA) was used to measure tablet hardness and samples of 10 tablets at each set of conditions were analyzed. The true density was measured using a helium pycnometer (Quantachrome Multipyncometer, Quantachrome Corp., Syosset, NY).

The maximum compression force and porosity data were analyzed using the Heckel compressibility model (Heckel, 1961a,b), one form of which is:

$$\ln\left(\frac{1}{1-D}\right) = KP + A$$

where D is the relative density, $(1-D)$ denotes the pore fraction, P is the applied pressure, and K and A represent constants. A plot of $\ln(1/1-D)$ vs P is referred to as a Heckel plot. The constants K and A are the slope and intercept, respectively, calculated from the linear region of the Heckel plot. While the plot is curved at lower pressures, a linear region typically exists at higher pressures. The reciprocal of the slope of the linear region (K) is termed the mean yield pressure. The intercept, A, is related to the initial packing density of the powder. The initial curved region of the Heckel plot is attributed to particle rearrangement and its extent can be quantified using the relationship:

$$D_b = D_a - D_o$$

where D_b is the increase in relative density due to particle rearrangement, $D_a = 1 - e^{-A}$ is the extrapolated relative density from the intercept (A) of the linear portion of the Heckel plot, and D_o is the initial relative density.

Force-displacement data were analyzed using the software supplied by the press manufacturer and the elastic work and the net work were evaluated. Elastic work is the energy delivered by the compact back to the punch during the decompression phase. Net work is the energy permanently imparted to the tabletted material. Deformation of the tablet press components, which arises from the resistance of the powder bed to densification and the elastic recovery of the material, was accounted for. Elastic work was expressed as percentage of total work. The percentage of elastic work was calculated to provide a measure of the relative magnitude of the elastic nature of the materials studied.

Force-time profiles were also analyzed by the software system supplied by the press manufacturer. Five profiles at each compression force were analyzed and averaged. A plot of the area under the force-time profile vs the upper punch force was constructed and its slope yielded the A/H ratio (Chilamkurti et al., 1982).

The ejection force and the lubrication ratio (R) were monitored in the lubrication studies. The lubrication ratio (R) is the ratio of the maximum lower punch force to the maximum upper punch force (Nelson et al., 1954). Five tablet profiles per lubricant were averaged at each lubricant concentration.

3. Results and discussion

3.1. Particle size

Fig. 1 shows the tablet hardness-compression force profiles for the five particle size fractions of ethylcellulose. Approximately parallel curves were observed in all cases with the smaller particle size fractions forming harder tablets. The increase in tablet hardness with a decrease in particle size is consistent with the theory that smaller particles allow a greater packing density and a greater number of contact points for interparticulate bonding (Rhines, 1947). Based on the sensitivity of tablet hardness to the initial particle size, it can be concluded that ethylcellulose consolidates via plastic deformation under the tableting conditions employed. The shape of the tablet hardness-compression force profiles were consistent for all particle sizes studied. The curved shape indicates an approach to a limiting tablet hardness with an increase in compression force.

Fig. 2 shows that the Heckel plots for all particle size fractions of ethylcellulose exhibit type A behavior. This indicates that porosity in the tablet structure is dependent on the initial porosity of the powder bed and that plastic deformation is the primary consolidation mechanism. Type B behavior is exhibited by materials that consolidate by brittle fracture, where a single relationship occurs above a certain pressure irrespective of the initial bed density (Hersey and Rees, 1971).

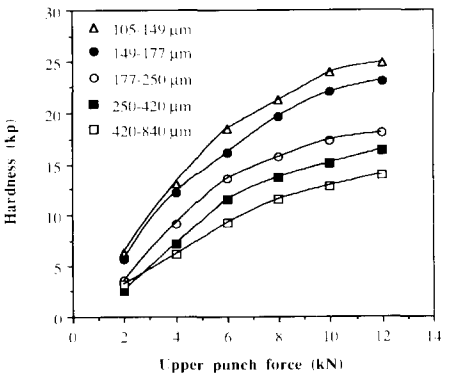

Fig. 1. Compressional force effects on ethylcellulose tablet hardness using different particle size fractions.

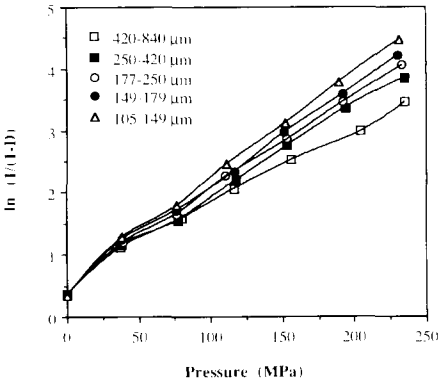

Fig. 2. Heckel plots of different ethylcellulose particle size fractions.

Table 1 lists the initial relative density (D_o), the extrapolated density from the linear portion of the Heckel plot (D_a), the change in the relative density attributed to particle rearrangement (D_b), the mean yield pressure, and the correlation coefficient of the linear region of the Heckel plot for the five particle size fractions. Data in the upper punch pressure range of 80–240 MPa were used to determine the best-fit line. The mean yield pressure decreased significantly (83 to 58 MPa) with decreasing particle size (420–840 to 105–149 μm), indicating more ductile and less brittle behavior with the smaller sized particles. The initial relative density was also found to decrease with decreasing particle size while the change in relative density, attributed to particle rearrangement, increased significantly. Compacts formed from the 105–149 μm fraction had approx. 10% less pore space after the particle rearrangement phase than did those from the 420–840 μm size. A comprehensive study of compaction should also consider the particle shape influence on packing density. In this case, similar yet indistinct particle shapes were present in each size fraction such that no portion of the rearrangement was specifically attributed to differences in shape.

Fig. 3 and 4 graphically present the net work and elastic work, respectively, versus the upper punch compression force. The net work and elastic work for each size fraction increased with increasing compression force. The shape of the net work plots indicated a limit to the net work

Table 1
Constants obtained from Heckel analysis of data for different particle size fractions of ethylcellulose

Particle size range (μm)	D_a	D_o	D_b	Yield pressure (MPa)	r^2
420–840	0.549	0.356	0.193	83	0.981
250–420	0.556	0.306	0.250	66	0.987
177–250	0.568	0.300	0.268	64	0.986
149–177	0.567	0.292	0.275	63	0.993
105–149	0.571	0.282	0.289	58	0.991

Table 2
Effect of particle size on the energy analysis of ethylcellulose tablets at a compaction force of 10 kN

Particle size (μm)	Net work (J)	Elastic work (J)	Percentage of elastic work (%)
420–840	6.30	0.61	8.83
250–420	6.43	0.48	6.94
177–250	6.91	0.46	6.24
149–177	7.16	0.41	5.42
105–149	7.39	0.39	5.01

Table 3
Area/height ratio and intercept values for different particle size fractions of ethylcellulose

Particle size range (μm)	Area/height	
	Ratio (ms)	Intercept (N s)
420–840	146.3	78.3
250–420	141.7	119.1
177–250	139.1	138.3
149–177	137.8	169.4
105–149	136.2	191.5

with an increase in compression force. The elastic work curves were flat at forces up to 6 kN and subsequently increased at forces greater than 8 kN. At each compression force, the smallest particle size produced the largest plastic work and

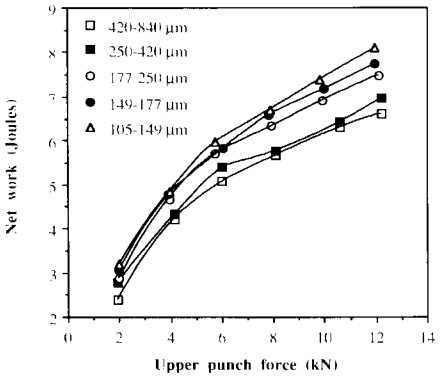

Fig. 3. Upper punch force effects on net work during compression of ethylcellulose tablets using different particle size fractions.

the smallest elastic work. Table 2 lists the net work, elastic work, and percentage elastic work for tablets made at 10 kN force. With a decrease in particle size, net work increased and the percentage of the elastic work decreased, indicating more ductile behavior.

Table 3 shows the results of the force-time analysis including the slope (A/H ratio) and intercept obtained from linear regression of the area under the force-time curve as a function of the peak upper punch force. The A/H ratio decreased slightly with a decrease in particle size

Table 4
Hardness values and Heckel constants obtained from ethylcellulose compression at different press speeds

Press speed (tablets per min)	Hardness [a] (kp)	D_b	Yield pressure (MPa)	r^2
10	15.5	0.247	64	0.985
20	15.2	0.243	66	0.987
30	14.6	0.241	67	0.989
40	14.1	0.238	69	0.991
50	13.9	0.234	70	0.986

[a] Hardness values of tablets compressed at 10 kN.

Table 5
Effect of press speed on the energy analysis of ethylcellulose tablets at a compaction force of 10 kN

Press speed (tablets per min)	Net work (J)	Elastic work (J)	Percentage of elastic work (%)
10	6.59	0.43	6.13
20	6.43	0.48	6.95
30	6.40	0.67	9.48
40	6.35	0.75	10.56
50	6.28	0.79	11.17

Table 6
Area/height ratio and intercept values for ethylcellulose compression at different press speeds

Press speed (tablets per min)	Area/height	
	Ratio (ms)	Intercept (N s)
10	261.9	178.5
20	140.2	117.1
30	90.1	87.1
40	71.8	50.5
50	56.5	36.2

but did not reflect the more significant change in compressibility suggested by the change in the mean yield pressure.

3.2. Press speed

The data in Tables 4 and 5 were obtained from tableting the 250–420 μm sieve fraction of ethylcellulose; the tablet hardness and mechanical energy data were obtained at a compression force of 10 kN. The data in Table 4 describe the effect of press speed on tablet hardness and the results obtained from the ejected tablet Heckel analysis. Table 5 shows the effect of press speed on the net energy, elastic energy, and percentage elastic energy. Increasing the press speed from 10 to 50 tablets per min caused a 10% decrease in the tablet hardness and about a 10% increase in the mean yield pressure; both results suggest ductile behavior. Minor changes were observed in the extent of particle rearrangement (D_b) due to changing the press speed. The sum of the net energy and elastic energy was relatively constant across all five press speeds. The elastic energy nearly doubled on increasing the press speed from 10 to 50 tablets per min but the net energy decreased correspondingly. Table 6 reports the slopes (A/H ratio) and intercepts from linear fits of the area under the force-time curve versus peak upper punch force data for different press speeds. The greater the press speed, the lower the A/H ratio and the lower the intercept. A similar trend of decreasing positive intercepts with increasing press speed was reported with Avicel PH-102, yet the significance of the intercept value is not fully understood (Hoblitzell and Rhodes, 1990). The A/H ratio is dependent on both press type and press speed. Increases in the A/H ratio with decreasing press speed have been reported (Hoblitzell and Rhodes, 1986, 1990).

3.3. Lubricants

Fig. 5 is a plot of tablet hardness as a function of lubricant concentration for magnesium

Table 7
Effect of lubricants on lubrication ratio and ejection force of ethylcellulose tablets

Lubricant concentration (%)	Lubrication ratio		Ejection force (N)	
	Magnesium stearate	Glyceryl behenate	Magnesium stearate	Glyceryl behenate
0.00	0.712	0.712	245	275
0.10	0.735	–	240	–
0.15	0.783	–	215	–
0.20	0.845	–	207	–
0.25	0.863	0.685	181	210
0.35	0.912	–	180	–
0.50	0.932	0.832	174	195
1.00	–	0.865	–	181
1.50	–	0.872	–	175

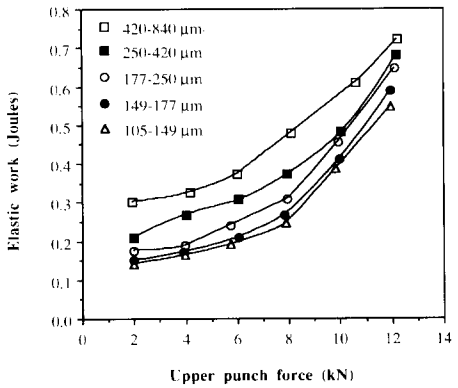

Fig. 4. Upper punch force effects on elastic work during compression of ethylcellulose tablets using different particle size fractions.

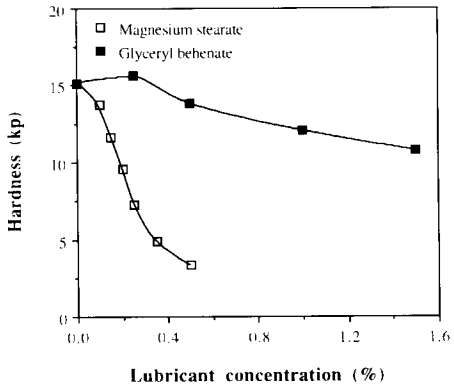

Fig. 5. Lubricant concentration effects on ethylcellulose tablet hardness compressed at 10 kN force.

stearate-ethylcellulose and glyceryl behenate-ethylcellulose powder blends. The tablet strength was more sensitive to the presence of magnesium stearate than glyceryl behenate supporting published data (Shah et al., 1986). Table 7 lists lubrication ratio and ejection force values for ethylcellulose tablets compressed at 10 kN force. Glyceryl behenate was not as effective as magnesium stearate, requiring approx. 3-fold higher concentrations to provide comparable lubrication. The two lubricants had a significantly different impact on the mean yield pressure (Fig. 6). With magnesium stearate, the mean yield pressure was unchanged at the 0.1% level and increased significantly on further increases in lubricant concentration. Mean yield pressure increased by 71% over a range of magnesium stearate concentration from 0.1 to 0.5%. Glyceryl behenate caused only a minor increase in mean yield pressure (7%) over a greater concentration range (0 to 1.5%). Mean yield pressure data are in agreement with tablet strength data, indicating that glyceryl behenate causes less of a perturbation to the ethylcellulose system than magnesium stearate.

Table 8 lists the net work, elastic work, and percentage elastic work for the ethylcellulose-lubricant systems. Both lubricants increased the elastic nature of the powder blends which is consistent with the concept that lubricants disrupt interparticulate bonds. Magnesium stearate caused a greater increase in the elastic nature than glyceryl behenate. Table 9 reports small

Table 8
Effect of lubricants on net work, elastic work and percentage of elastic work of ethylcellulose tablets

Lubricant concentration (%)	Net work (J)			Elastic work (J)			Percentage of elastic work (%)	
	Magnesium stearate	Glyceryl behenate	stearate	Magnesium behenate	Glyceryl stearate	behenate	Magnesium	Glyceryl
0.00	6.43	6.43		0.48	0.48		6.95	6.95
0.10	6.63	–		0.46	–		6.48	–
0.15	6.62	–		0.50	–		7.02	–
0.20	6.32	–		0.52	–		7.60	–
0.25	6.01	6.51		0.68	0.48		10.16	6.86
0.35	5.46	–		1.08	–		16.51	–
0.50	4.85	6.22		1.39	0.56		22.27	8.25
1.00	–	6.01		–	0.66		–	9.89
1.50	–	5.49		–	0.94		–	14.62

Table 9
A/H ratios of ethylcellulose tablets with different levels of lubricants

Lubricant concentration (%)	A/H ratio (ms)	
	Magnesium stearate	Glyceryl behenate
0.00	142	142
0.10	142	–
0.15	139	–
0.20	143	–
0.25	146	141
0.35	146	–
0.50	147	144
1.00	–	145
1.50	–	146

increases in the A/H ratio values in the presence of lubricants. A disparity was observed between the relative changes in the mean yield pressure (Fig. 6) and the A/H ratio for the ethylcellulose-magnesium stearate blends (Table 9). Mean yield pressure derived from the Heckel analysis is a measure of powder compressibility and the 0.5% magnesium stearate level caused a significant increase in mean yield pressure. The change in mean yield pressure indicates a significant difference in compressibility. This was not detected by the A/H ratio technique using the ethylcellulose/lubricant blends in this study.

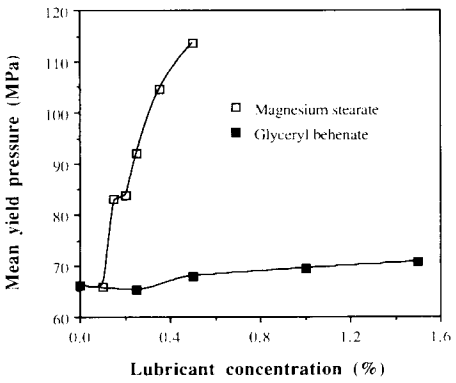

Fig. 6. Lubricant concentration effects on mean yield pressure of ethylcellulose.

4. Conclusions

The sensitivity of ethylcellulose tablet strength to particle size, press speed, and the presence of lubricants indicates that plastic deformation is the predominant consolidation mechanism under the experimental conditions. This conclusion is further supported by the dependence of tablet porosity on the initial particle size (type A Heckel plots) and the range of values obtained for the ejected tablet mean yield pressure under various tableting conditions (130–200 MPa). The elastic mechanical energy data also support the findings and indicate a relatively minor elastic component in ethylcellulose consolidation. The results are consistent with the known compression properties of other celluloses.

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